California State Water Resources Control Board Environmental Laboratory Accreditation Program (State Water Board CA-ELAP)

An Overview of the CA ELAP Regulations* Versus the TNI EL 2016 Standard

Third-Party Assessments (TPAs)

The NELAC Institute (TNI) Non-Governmental Accreditation Body (NGAB)

*__Title 22__ Social Security __Division 4__ Environmental Health
__Chapter 19__ Certification of Environmental Laboratories __Articles 1-16__ (sections: 6000 series)

CA-ELAP Assessments (CCRs vs. TNI)

CA-ELAP Assessments (CCRs vs. TNI)

National Environmental Laboratory Accreditation Program (NELAP)

- **TNI** - The NELAC* Institute

Volume 1
Management and Technical Requirement for Laboratories Preforming Environmental Analysis
(EL-V1-2016)

TNI 2016
ISO/IEC 17025:2005
(≠ ISO/IEC 17025:2017)

*NELAC - National Environmental Laboratories Accreditation Conference

CA-ELAP Assessments (CCRs vs. TNI)

Third-Party Assessments (TPAs)

The NELAC Institute (TNI) Non-Governmental Accreditation Body (NGAB)

By 2023, all laboratories, regardless of technology, must meet TNI* Minus 2.

- Assessment scope types:
  - **TNI Minus 2** (plus CA Reg): TNI 2016 minus two exceptions*
    ***Exceptions:** CCR Article 2 section 64802.05(a)(1) and 62802.15(b)(1)

  - **TNI Full** (plus CA Reg): TNI 2016

CA-ELAP Assessments (CCRs vs. TNI)

This webinar is not a substitute for reviewing and understanding the applicable standards or obtaining training for implementation of a Quality Management System (QMS) in compliance with the TNI Standard.

The information in this webinar does not cover all requirements. It is only intended to communicate a sampling of requirements to provide participants a foundation of understanding in preparation for compliance to the TNI standard.

Requirements discussed in this training were chosen for various reasons, including:

- Common findings
- Higher potential of gaps in current processes compared to CA Regulations

CA-ELAP Assessments (CCRs vs. TNI)

[illegible]inar is not a substitute for reviewing and understanding the applicable [illegible]s or obtaining training for implementation of a Quality Management System (Q[illegible]pliance with the TNI Standard.

"Define"

"Policy"

"Documented"

"Written"

"Contain sufficient information"

T[illegible] webinar does not cov[illegible]r all req[illegible]on[illegible] s[illegible]ping of requirements to p[illegible]nts a foundation of a[illegible]ers[illegible] compliance to the TNI [illegible]

"Instructions"

Requirements di[illegible]ss[illegible]d in this training were chose[illegible], including:

- Common "Recorded"
- Higher po[illegible]rent processes

"Procedure"

"Retained"

"Clearly described"

CA-ELAP Assessments (CCRs vs. TNI)

Volume 1

Management and Technical Requirements for Laboratories Performing Environmental Analysis

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

TNI Minus 2
(Exceptions to M1 and M2)

CCRs ≥2020:

Article 1. Definitions
Article 2. Accreditation Requirements
Article 3. Types of Accreditation
Article 4. Types of Laboratories
Article 5. Laboratory Personnel, Facilities and Equipment
Article 6. Notification, Reporting, Records Retention, Change of Technical Manager or Ownership, and Trade Secrets
Article 7. Reasons for Denial, Citation, Suspension, or Revocation

CA-ELAP Assessments (CCRs vs. TNI)

Volume 1
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TNI Minus 2
(Exceptions to M1 and M2)

CA-ELAP Assessments (CCRs vs. TNI)

Volume 1

Management and Technical Requirements for Laboratories Performing Environmental Analysis

Module 1: Proficiency Testing

4.0: Requirements for Accreditation
- 4.1 General Requirements
- 4.2 Sample Handling, Preparation, and Analysis Requirements
- 4.3 Reporting Requirements
- 4.4 Record Retention

5.0: PT Study Frequency Requirements for Accreditation
6.0: Requirements for Corrective Action
7.0: Requirements for Complaint Resolution
8.0: Requirements for Reinstatement of Accreditation after Suspension or Revocation

CA-ELAP Assessments (CCRs vs. TNI)

Module 1: Proficiency Testing

Module 1: Proficiency Testing
4.1: General Requirements ➢ Use a TNI approved Proficiency Testing Provider 4.2: Sample Handling, Preparation, and Analysis Requirements ➢ Evaluate results to Proficiency Testing Reporting Limit (PTRL) (PTRLs are specified in the TNI FoPT tables) ➢ Analyze PT samples in same manner (e.g., prep/testing procedures, QC, acceptance criteria) 4.3: Reporting Requirements ➢ Evaluate and report to the PTRL

c) If the analytical result is a "non-detect", the laboratory shall report one of the following:

i. <PTRL, or

ii. <LOQ**

NOTE: In the case where the laboratory LOQ is greater than the PTRL: If the laboratory chooses to report a value of <LOQ and the analyte is present above the PTRL, the result will be scored as "Not Acceptable" by the PT Provider.

CA-ELAP Assessments (CCRs vs. TNI)

Module 1: Proficiency Testing

Module 1: Proficiency Testing TNI Minus 2	**Module 1: Proficiency Testing** TNI Full
Exception CCR Article 2 section 62802.15(b)(1) Comply with 2016 TNI Standard with the following exceptions: (A) Volume 1, Module 1, Section 5.0 - Proficiency Testing Study Frequency Requirements for Accreditation (B) Volume 1, Module 1, Section 8.0 - Proficiency Testing Requirements for Reinstatement of Accreditation after Suspension or Revocation To maintain accreditation, a CAB shall achieve Acceptable Scores in a Proficiency Testing study at least once per year for each Field of Accreditation for which the CAB holds/seeks accreditation. Acceptable Scores in Proficiency Testing studies shall be achieved. ***See CCR Article 2 62802.15 Proficiency Testing for additional requirements***	5.0 Proficiency Testing Study Frequency Requirements for Accreditation 5.1: Initial Accreditation ➢ 2 passing results out of the most recent 3 attempts ➢ Timelines (>7 days apart, ≤18 prior to accreditation, etc.) 5.2: Continued Accreditation ➢ 2 passing results out of the most recent 3 attempts ➢ Timelines (biannually, (>7 days apart, ≤7 months apart, etc.) *Whole Effluent Toxicity (WET) = different requirements* *pay attention to closing date vs analysis date requirements* 8.0: Requirements for Reinstatement of Accreditation after Suspension or Revocation (*points to 5.1 & 5.2*)

CA-ELAP Assessments (CCRs vs. TNI)

Module 1: Proficiency Testing

Module 1: Proficiency Testing
4.4: Record Retention 6.0: Requirements for Corrective Action 7.0: Requirements for Complaint Resolution 8.0: Requirements for Reinstatement of Accreditation after Suspension or Revocation

TNI Full Accreditation = PJLA Policies
➢ PL-1 Proficiency Testing Requirements for Applicant and Accredited Laboratories ➢ LF-81 Proficiency Testing Plan

CA-ELAP Assessments (CCRs vs. TNI)

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TNI Minus 2
(Exceptions to M1 and M2)

CA-ELAP Assessments (CCRs vs. TNI)

Volume 1
Management and Technical Requirements for Laboratories Performing Environmental Analysis

Module 2: Quality Systems General Requirements	**Module 2: Quality Systems General Requirements**
4.0 Management Requirements	5.0 Technical Requirements
4.1 Organization	5.1 General
4.2 Management	5.2 Personnel
4.3 Document Control	5.3 Accommodation and Environmental Conditions
4.4 Review of Request, Tenders and Contracts	5.4 Environmental Methods and Method Validation
4.5 Subcontracting of Environmental Tests	5.5 Calibration Requirements *(ISO/IEC 17025:2005 = "Equipment")*
4.6 Purchasing Services and Supplies	5.6 Measurement Traceability
4.7 Service to the Client	5.7 Collection of Samples
4.8 Complaints	5.8 Handling Samples and Test Items
4.9 Control of Nonconforming Environmental Testing Work	5.9 Quality Assurance for Environmental Testing
4.10 Improvement	5.10 Reporting the Results
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 *(≠ ISO/IEC 17025:2005)*	

Module 3: Quality Systems for Asbestos Testing
Module 4: Quality Systems for Chemical Testing
Module 5: Quality Systems for Microbiological Testing
Module 6: Quality Systems for Radiochemical Testing
Module 7: Quality Systems for Toxicity Testing

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

Update

Policies/Procedures

4.0 Management Requirements

4.1 Organization

4.1.5: The laboratory shall:
c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

Confidentiality

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

Update

Policies/Procedures

4.0 Management Requirements

4.1 Organization

4.1.5: The laboratory shall:
c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

- Access restrictions/privileges (guest accounts)? 4.13.1.1
- Usernames/passwords (frequency of password changes)
- Software updates 5.5..5 a), 5.5.12
- Protection from viruses, malware, etc. 5.4.7
- Securing workstations (locking unattended terminals/workstations)
- Outsourced security/IT (evaluation of service provider and frequency of evaluations)
- Monitoring System events (e.g., log-on failures or break-in attempts)
- Physical access/security to/of servers
- Backup: 4.13.1.4, 4.13.3 f) xv)
  - schedule (including instrument data files from terminals/workstations not on network) and testing of backups (e.g., all applicable networks/folders backed up, backups retrievable)
  - recorded to demonstrate that the backup systems contain all required data and backups were successful
  - backup isolated from server
- Instrument software audit functions enabled 4.13.2.1
- Electronic signatures policy (e.g., protected from unauthorized use) 4.2.8.4
- Data integrity training (improper clock setting, unwarranted manipulation of information).
- How changes are made and controlled. 4.3.3.4, 4.13.3 f) xv)

5.10.7

4.5.1, 4.6.1

4.14

5.2.7

Electronic Data Management

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

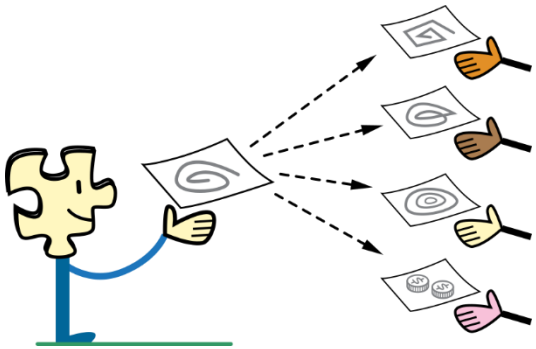
Update

Policies/Procedures

4.0 Management Requirements

4.1 Organization

4.1.5: The laboratory shall:
c) have policies and procedures to ensure the protection of its customers' confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results;

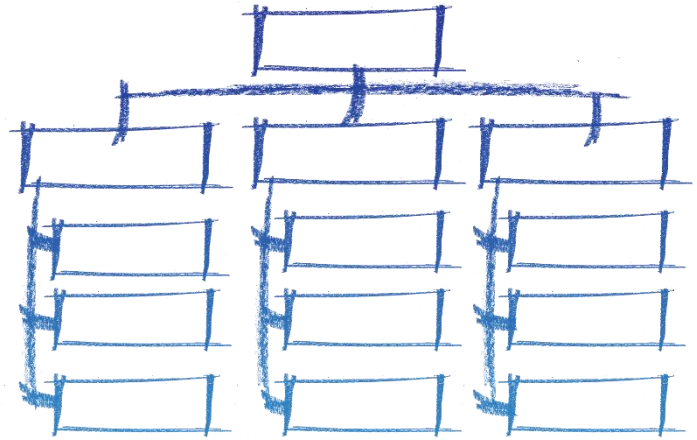


Transmission

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.1 Organization 4.1.5: The laboratory shall: e) define the organization and management structure of the laboratory, its place in any parent organization, and the relationships between quality management, technical operations and support services;



Management (Laboratory Director, Technical Manager, Quality Manager)
Support (LIMS, Purchasing, Project Manager, Waste Management)
Testing Activities (Sample receipt, preparation, analysis)

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.1 Organization

4.1.5: The laboratory shall:
j) appoint deputies for key managerial personnel

Key Personnel	Primary Deputy
Laboratory Director	Technical Manager
Technical Manager	Quality Manager
Quality Manager	Technical Manager
LIMS Manager	Quality Manager
Project Manager	Technical Manager
Purchasing Manager	Quality Manager
Environmental Compliance Officer	Technical Manager

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.1 Organization **4.1.7 Additional Requirements for Laboratories** 4.1.7.2 The laboratory's technical manager(s), however named, and/or his/her designee(s) shall: e) if absent for a period of time exceeding fifteen (15) consecutive calendar days shall designate another staff member meeting the qualifications of the technical manager(s) to temporarily perform this function. If this absence exceeds thirty-five (35) consecutive calendar days, the primary accreditation body shall be notified in writing.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.2 Management **4.2.8 Additional Management System Requirements** 4.2.8.1 ➢ The laboratory shall establish and maintain a documented data integrity system. ➢ The data integrity procedures shall be signed and dated by top management. ➢ Management shall annually review data integrity procedures and update as needed.

Example Finding:
V1M2 4.2.8.1
There was no evidence Management reviewed the data integrity procedures annually (and updated as needed). The last revision was 2011.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.2 Management

4.2.8 Additional Management System Requirements

4.2.8.3 The quality manual shall contain: a-i

b) laboratory's full name and address;
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;
h) the laboratory's official quality policy statement, ……
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-r

a) all maintenance, calibration and verification procedures used by the laboratory in conducting tests;
g) job descriptions of key staff and reference to the job descriptions of other laboratory staff;
i) a list of all methods under which the laboratory performs its accredited testing;
o) procedures for protecting confidentiality (including national security concerns), and proprietary rights;
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.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.2 Management **4.2.8 Additional Management System Requirements** 4.2.8.5 Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods.

Inadequate SOP reviews and/or internal audits?

Example Finding:
V1M2 4.2.8.5
Laboratory procedures did not always accurately reflect current practices. For example:……

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.2 Management **4.2.8 Additional Management System Requirements** 4.2.8.5 Laboratories shall maintain SOPs that accurately reflect all phases of current laboratory activities, such as assessing data integrity, corrective actions, handling customer complaints, and all methods. f) In cases where modifications to the published method have been made by the laboratory or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described. Each method shall include or reference the following topics where applicable: i-xxiii vii. interferences; xv. data analysis and calculations; xix. corrective actions for out-of-control data; xx. contingencies for handling out-of-control or unacceptable data.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.3 Document Control

TNI Standard, PJLA policies/procedures

4.3.1 The laboratory shall establish and maintain procedures to contr… …its that form part of its management system (internally generated or from external sources), su… …regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

External documents would require periodic review to, at a minimum to verify the revision has not changed.

Example Finding:

4.3.1 – The laboratory's document control program did not include external sources. For example:

- SOP LAB-567 referenced the ICP/MS instrument manual; however, that manual was not included in the controlled document program or master list.
- PJLA policies and the TNI standard were not identified on the master list of documents.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.3 Document Control 4.3.2.1 All documents issued to personnel in the laboratory as part of the management system shall be reviewed and approved for use by authorized personnel prior to issue. A master list or an equivalent document control procedure identifying the current revision status and distribution of documents in the management system shall be established and shall be readily available to preclude the use of invalid and/or obsolete documents.

Example Finding:
4.3.2.1 – The master list was not current or accurate *(missing procedures and identified obsolete revisions*).

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.3 Document Control

4.3.2.2 The procedure(s) adopted shall ensure that:

a) authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the laboratory are performed;

b) documents are periodically reviewed and, where necessary, revised to ensure continuing suitability and compliance with applicable requirements;

c) invalid or obsolete documents are promptly removed from all points of issue or use, or otherwise assured against unintended use;

d) obsolete documents retained for either legal or knowledge preservation purposes are suitably marked.

Example Finding:
4.3.2.2 b) – Not all procedures had evidence of annual reviews, in accordance with Laboratory procedure ADM-009 Rev. 2.

Example Finding:
4.3.2.2 c) – Obsolete versions of procedures were observed in laboratory areas.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.3 Document Control

4.3.2.3 Management system documents generated by the laboratory shall be uniquely identified. Such identification shall include the date of issue and/or revision identification, page numbering, and the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

4.3.3.2 Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

Example Finding:
4.3.2.3 – Not all procedures included page numbering or issuing authorities.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.4 Review of Requests, Tenders, and Contracts 4.4.2 Records of reviews, including any significant changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract. **4.5 Subcontracting of Environmental Tests** 4.5.2 The laboratory shall advise the customer of the arrangement in writing and, when appropriate, gain the approval of the customer, preferably in writing. 4.5.4 The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with this International Standard for the work in question. 4.5.5 When a laboratory subcontracts work, this work shall be placed with a laboratory accredited to this Standard for the tests to be performed or with a laboratory that meets applicable statutory and regulatory requirements for performing the tests and submitting the results of tests performed.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.6 Purchasing Services and Supplies

4.6.3 Purchasing documents for items affecting the quality of laboratory output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

Reference Material:

The report (e.g., Certificate of Analysis (COA)) shall contain:

(1) Identification that results are traceable to the International System of Units (SI) through a nationally or internationally recognized metrology institute (e.g., National Institute for Standards and Technology [NIST]) or by reference to a natural constant.
(2) Uncertainty of the results.
(3) Certification date and shelf life/expiration date
(4) Traceability between the item and the report via the use of a unique identification (e.g., serial, lot, batch, heat, or mill number).

Calibration:

Reference material requirements, plus…

(1) The Contractor's accreditation symbol to provide traceability that the service was performed under the scope of accreditation.
(2) Calibration Range
(3) Tolerance/Acceptance Limits
(4) As-Found data and condition (pass/fail)
(5) As-Left data and condition (pass/fail)
(4) Calibration frequency

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.6 Purchasing Services and Supplies

4.6.2 The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

Reference Material:

The report (e.g., Certificate of Analysis (COA)) shall contain:

(1) Identification that results are traceable to the International System of Units (SI) through a nationally or internationally recognized metrology institute (e.g., National Institute for Standards and Technology [NIST]) or by reference to a natural constant.
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CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Mana

4.6 Purchasing Services and Supplies

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reference to a natural constant.

(2) Uncertainty of the results.

(3) Certification date and shelf life/expiration
date

(4) Traceability between the item and the rep
via the use of a unique identification (e.g.
serial, lot, batch, heat, or mill number).

[redacted]

Reference Materials Producer [redacted]

Chemical Testing [redacted]

Catalog Number: [redacted] Lot No. EN170807006

Description: Nitrosamines Mix

Matrix: Methylene Chloride

Ship Date:

Expiration Date:

This [redacted] Certified Reference Material, CRM, is intended primarily for use as a calibration standard or quality control standard for organic chromatography instrumentation such as GC, GC-MS, LC, and LC-MS. It can be employed in USEPA, ASTM and other methods relevant to the certified properties listed below.

Certified Compounds:

Compound	CAS #	Labeled	Purity	Certified†	Uncertainty
N-Nitrosodiphenylamine	86-30-6	2000 µg/mL	97%	1967 µg/mL	± 51 µg/mL
N-Nitrosodi-n-butylamine	924-16-3	2000 µg/mL	99.9%	2018 µg/mL	± 52 µg/mL
N-Nitrosodiethylamine	55-18-5	2000 µg/mL	99.5%	2034 µg/mL	± 53 µg/mL
N-Nitrosodimethylamine	62-75-9	2000 µg/mL	99.5%	2010 µg/mL	± 52 µg/mL
N-Nitrosodi-n-propylamine	621-64-7	2000 µg/mL	98%	1984 µg/mL	± 52 µg/mL
N-Nitrosomethylethylamine	10595-95-6	2000 µg/mL	99.5%	2006 µg/mL	± 52 µg/mL
N-Nitrosomorpholine	59-89-2	2000 µg/mL	99.5%	2010 µg/mL	± 52 µg/mL
N-Nitrosopiperidine	100-75-4	2000 µg/mL	99.8%	2020 µg/mL	± 53 µg/mL
1-Nitrosopyrrolidine	930-55-2	2000 µg/mL	99%	1988 µg/mL	± 52 µg/mL

Final Solution Verification:

Final solution integrity verified by Gas Chromatography/Mass Spectrometry. The mass spectrum of each compound was confirmed against the NIST mass spectral database.

† Certified concentration based on gravimetric weights and corrected for the purity of the compound(s) used to prepare the standard. Analytical balance calibration is verified daily with C1 weight set #23-190006 which is registered with Atlantic Scale, and traceable to NIST and NJ Division of Weights and Measures.

This CRM is guaranteed stable and accurate to within the uncertainty listed for the certified value. This includes uncertainty components due to preparation, homogeneity, short term and long term stability. During the stated period of validity, the purchaser will be notified if this product is recalled due to any significant changes in the stability of the solution. For further information, contact the Sales Support Department at crmsales@spexcsp.com.

Date of Certification: [redacted] Certifying Officer: [redacted]

(CCRs vs. TNI)

ents

ments

s and consumable materials that affect the
pected or otherwise verified as complying with
tests and/or calibrations concerned. These
Records of actions taken to check compliance

ion:
material requirements, plus…
ntractor's accreditation symbol to
ceability that the service was performed
scope of accreditation.
tion Range
ce/Acceptance Limits
nd data and condition (pass/fail)

[redacted]

Certificate of Analysis

Date Issued 9/23/2014

Lot: N09A

40 NTU Turbidity Standard

Exp 9.30.2015

PRODUCT NUMBER:	R-4094/966-51
QUANTITY:	30ml
APPLICATION:	Used for calibration to turbidity meter 966

	SPECIFICATIONS:	VALUES:
Concentration	40 NTU +/-0.4	Conforms

Quality Control Notes

Test	Pass/Fail	Tolerance Range	Results
40	Pass	± 0.4	40 NTU
Abs 455 (50 mm pathlength)	Pass		0.2332
Lot Base line Material	Pass		C467460

QUALITY CONTROL:

This document is issued without signature.Warranty: The details given here are merely intended for information purposes and are in no way legally binding. Consequently, we do not accept responsibility in the broadest sense of the word for damage that may result from application based upon this information.

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CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

Calibrations by [redacted] are performed in accordance with the principles of ISO 9001:2008. [redacted] maintains a Quality Management System accredited to ISO/IEC 17025:2005. The use of the Accrediting Body's logo is exclusive to calibrations where the contractual obligations meet the minimum requirements as specified by ISO/IEC 17025:2005 and the Accrediting Body. For additional information regarding [redacted] accredited status visit the A2LA website and view scope 2039.01.

The Measurement Standards used during this calibration are traceable to the International System of Units through NIST, other Nationally and/or Internationally recognized standards.

Reference Material:

The report (e.g., Certificate of Analysis (COA)) shall contain:

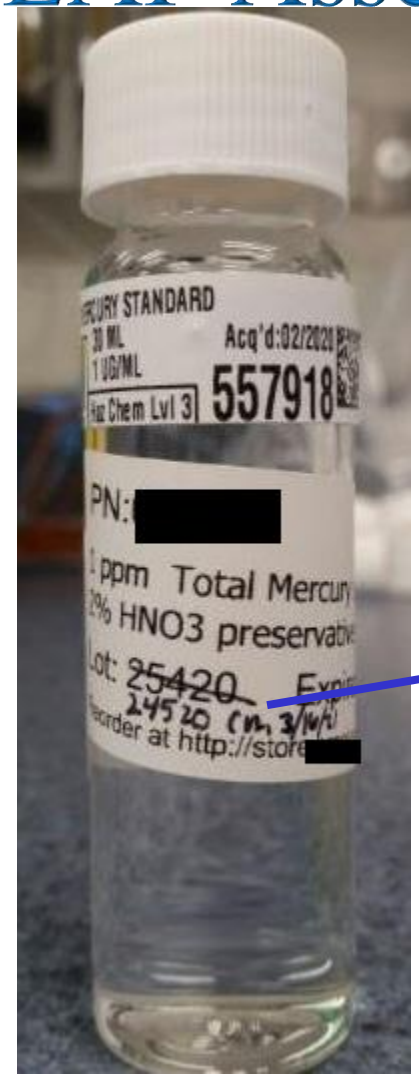
(1) Identification that results are traceable to the International System of Units (SI) through a nationally or internationally recognized metrology institute (e.g., National Institute for Standards and Technology [NIST]) or by reference to a natural constant.
(2) Uncertainty of the results.
(3) Certification date and shelf life/expiration date
(4) Traceability between the item and the report via the use of a unique identification (e.g., serial, lot, batch, heat, or mill number).

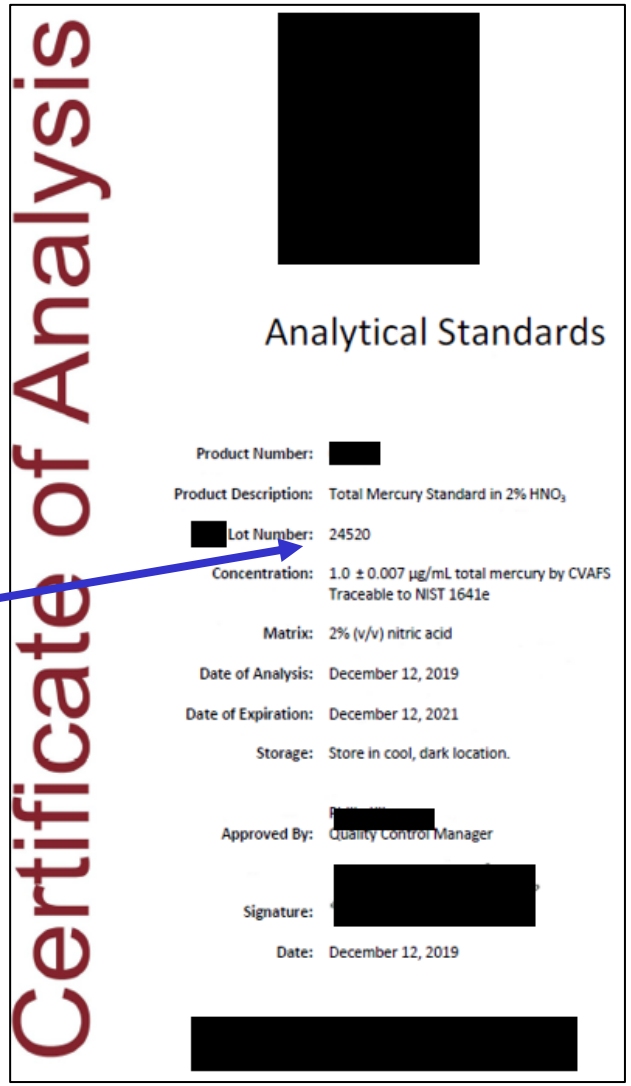
Calibration:

Reference material requirements, plus…

(1) The Contractor's accreditation symbol to provide traceability that the service was performed under the scope of accreditation.
(2) Calibration Range
(3) Tolerance/Acceptance Limits
(4) As-Found data and condition (pass/fail)
(5) As-Left data and condition (pass/fail)
(4) Calibration frequency

CA-ELAP Assessments (CCRs vs. TNI)





fisher scientific
part of Thermo Fisher Scientific

Fisherbrand™ Traceable™ Sentry™ Thermometer

Catalog No. S541112

$54.00 / Each

Qty

Shows current, high and low temperatures simultaneously. Fisherbrand™ Traceable™ Sentry™ Thermometer instantly shows if water bath, freezer or incubator is within temperature specifications and monitors temperature of any experiment, even when you are not there.

Description

- Sensor and 10 ft. (3m) cable may be placed under water, in a refrigerator or in a freezer
- Small cable diameter (1.5mm) allows refrigerator doors to close on it
- Simple one-button operation resets high/low memories
- A probe wire mounting bracket permits easy sensor placement
- Unit's high-impact ABS plastic case has a flip-open stand, plastic hanging hook, magnet and Velcro™ mounting tape

Specifications

- Range: -50° to +70°C (-58° to +158°F)
- Resolution: 1°
- Accuracy: ±1°C
- Dimensions: 2.68 x 2.68 x 0.76 in. (67 x 67 x 19mm)
- Weight: 0.1 oz. (4g)

Specifications

Temperature Range (Metric)	−50° to 70°C
Min. Temperature (Metric)	−50°C
Max. Temperature (Metric)	70°C
Certifications/Compliance	ISO 17025, A2LA, NIST
Dimensions (L x W x H)	2.5 x 2.6 in. (6.3 x 6.6cm)

Accredited

ilac-MRA ACCREDITED Calibration Certificate No. 1750.01

Calibration complies with ISO/IEC 17025, ANSI/NCSL Z540-1, and 9001

Cert. No.: 4121-6923164

Traceable® Certificate of Calibration for Sentry Thermometer °C

Manufactured for and distributed by: Fisher Scientific, P.O. Box 1768, Pittsburgh, PA 15230

Instrument Identification: [redacted]

Model: S54111-2 S/N: 150547310 ✓ Manufacturer: Control Company

Standards/Equipment:

Description	Serial Number	Due Date	NIST Traceable Reference
Temperature Calibration Bath TC-256	B01375		
Temperature Probe	128	4/02/16	15-A0P2S-40-1
Thermistor Module	A17118	3/03/16	1000371058
Temperature Calibration Bath TC-179	A45240		
Thermistor Module	A17118	3/03/16	1000371058
Temperature Probe	3039	4/02/16	15--A0P2S-20-1

Certificate Information:

Technician: 68 Procedure: CAL-03 Cal Date: 7/21/15 ✓ Due Date: 7/21/17 ✓

Test Conditions: 23.0°C 48.0 %RH 1014 mBar

Calibration Data: (New Instrument)

Unit(s)	Nominal	As Found	In Tol	Nominal	As Left	In Tol	Min	Max	±U	TUR
°C		N.A.		0.000	-1	Y	-1	1	0.60	1.7:1
°C		N.A.		50.000	50	Y	49	51	0.60	1.7:1

This Instrument was calibrated using Instruments Traceable to National Institute of Standards and Technology.

A Test Uncertainty Ratio of at least 4:1 is maintained unless otherwise stated and is calculated using the expanded measurement uncertainty. Uncertainty evaluation includes the instrument under test and is calculated in accordance with the ISO "Guide to the Expression of Uncertainty in Measurement" (GUM). The uncertainty represents an expanded uncertainty using a coverage factor k=2 to provide a 95% confidence level. In tolerance conditions are based on test results falling within specified limits with no regulation by the uncertainty of the measurement. The results contained herein relate only to the item(s) calibrated. This certificate shall not be reproduced except in full, without written approval of Control Company.

Nominal=Standard's Reading As Left=Instrument's Reading In Tol=In Tolerance Min/Max=Acceptance Range ±U=Expanded Measurement Uncertainty TUR=Test Uncertainty Ratio
Accuracy=(±U+|Min|+|Max|)/2 Min = As Left Nominal(Rounded) - Tolerance Max = As Left Nominal(Rounded) + Tolerance Date=MM/DD/YY

Noel Rodriguez, Quality Manager

Aaron Justice, Technical Manager

Maintaining Accuracy:

In our opinion once calibrated your Sentry Thermometer °C should maintain its accuracy. There is no exact way to determine how long calibration will be maintained. Sentry Thermometer °Cs change little, if any at all, but can be affected by aging, temperature, shock, and contamination.

Recalibration:

For factory calibration and re-certification traceable to National Institute of Standards and Technology contact Control Company.

[redacted]

CONTROL COMPANY 4455 Rex Road Friendswood, TX 77546 USA
Phone 281 482-1714 Fax 281 482-9448 service@control3.com www.control3.com

Control Company is an ISO 17025:2005 Calibration Laboratory Accredited by (A2LA) American Association for Laboratory Accreditation, Certificate No. 1750.01.
Control Company is ISO 9001:2008 Quality Certified by (DNV) Det Norske Veritas, Certificate No. CERT-01805-2009-AQ-HOU-RvA.
International Laboratory Accreditation Cooperation (ILAC) - Mutual Recognition Arrangement (MRA).

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CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.6 Purchasing Services and Supplies

4.6.4 The laboratory shall evaluate suppliers of critical consumables, supplies and services which affect the quality of testing and calibration, and shall maintain records of these evaluations and list those approved.

Name	Address	Commodity	Approval Base*	Exp. Date
Calibrations R Us	123 Main St. Anywhere, US 12345	Balance, Weight, Thermometer calibrations	ISO/IEC 17025	09/30/2021
PTs for You	777 Lucky Ave. Over There, MN 77777	PTs	ISO/IEC 17043	10/30/2021
Data Custodians, Inc.	555 5th St. Anywhere, US 12345	LIMS and IT services	Audit of QMS	07/21/2022
Reference Material Providers, Inc.	753 Freedom Somewhere, CA 99883	Traceable reference material	Performance via verifications and COAs	04/15/2022

Example Finding:
4.6.4– Not all suppliers of items/services that affect quality were included on the approved list of suppliers or had evidence of evaluation/approval.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.7 Service to the Client

The laboratory shall seek feedback, both positive and negative, from its customers.

Example Finding:
4.7– There was no evidence of the laboratory seeking feedback from customers.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.8 Complaints

The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties. Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory (see also 4.11).

Example Finding:
4.8– Review of amended report 20200216a identified the amendment resulted from a customer complaint. Also, personnel interviews indicated other customer complaints; however, there was no policy/procedure for handling customer complaints and no records of customer complaints.

CA-ELAP Assessments (CCRs vs. TNI)

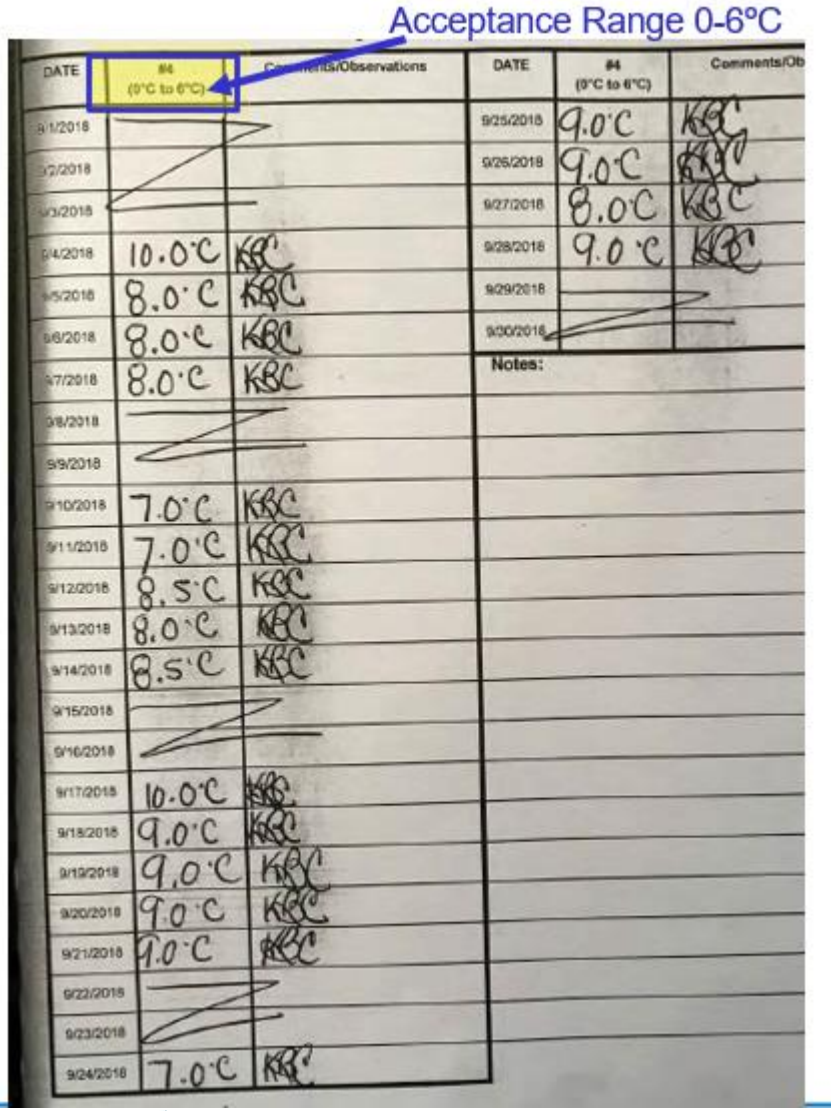
Module 2: Quality Systems General Requirements

4.0 Management I

4.9 Control of Nonconforming Environmental Testing Wo

4.9.1 The laboratory shall have a policy and procedures that s
and/or calibration work, or the results of this work, do not con
of the customer. The policy and procedures shall ensure that:

b) an evaluation of the significance of the nonconformi



CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

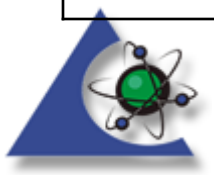
4.11 Corrective Action

4.11.2 Cause Analysis
The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

5) Root Cause of Problem: Insufficient training

6) Corrective Action: Retrain analyst

Investigation Finding / Root Cause
Lack of knowledge.



CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.11 Corrective Action

4.11.4 Monitoring of Corrective Actions
The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.

Example Finding:
V1M2 4.11.4
The laboratory had not monitored the corrective actions taken in response to the 2019 assessment to ensure that the corrective actions taken had been effectively implemented.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.11 Corrective Action

4.11.5 Additional Audits
The laboratory shall ensure that the appropriate areas of activity are audited.

Extent of condition

Finding:
Not all logbooks were reviewed quarterly in compliance with laboratory procedure ABC-123 Rev. 02. For example:

- balance logbook BAL-2008 did not have any evidence of review (start date 02/15/2008)
- maintenance logbook ICP/MS-2012 did not have any evidence of review (start date 03/19/2012)
- the archived records access logbook ARCH-2018 was last reviewed March 2019 (>2 years since last review)

Additional Audits:
Reviewed logbooks in all other laboratory areas and identified three other logbooks that were not included in the quarterly review.

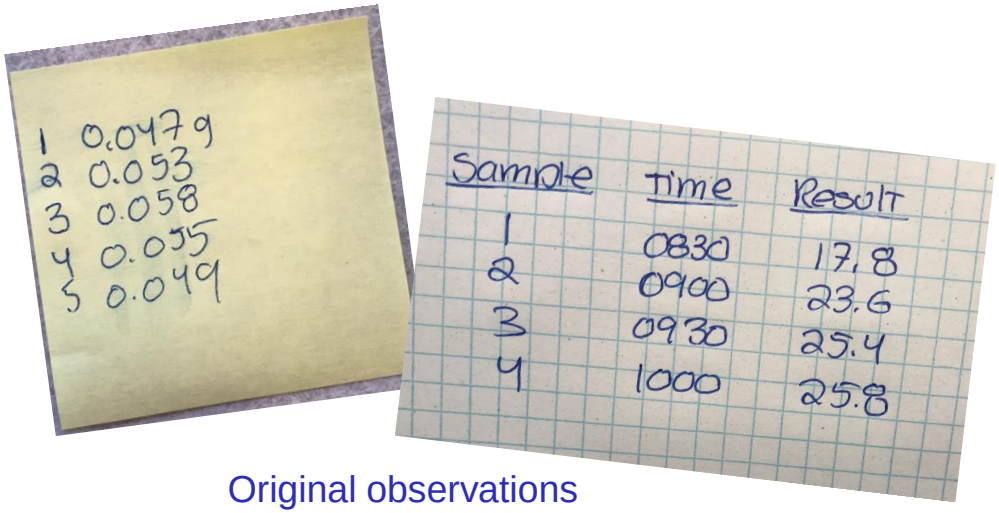
CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.13 Control of Records

4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail.



Original observations

Observed Temp. **and** Corrected Temp.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.13 Control of Records

4.13.2.1 The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail….. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.

Example Finding:
V1M2 4.13.2.1
Laboratory records did not always provide sufficient evidence to establish an audit trail or to facilitate identification of factors affecting the uncertainty. For example,

- *Weight set IDs not on balance verification records*
- *Thermometer IDs not on temperature monitoring records*
- *Lot #s not on test records*
- *Identification of person performing the activity not identified on test records*
- *Use of model #s vs unique IDs (e.g., SNs, Asset ID)*

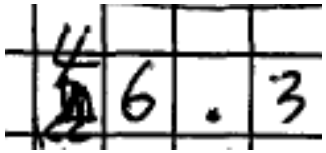
CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

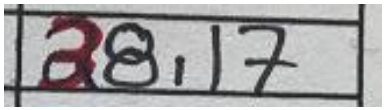
4.13 Control of Records

4.13.2.3 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be signed or initialed by the person making the correction.

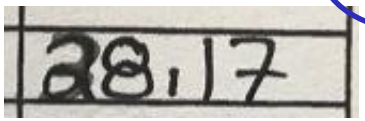


Lost original observation

Also needs to be reproducible (scans/copies)



Original



Duplication

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.13 Control of Records

4.13.3 Additional Requirements

b) The laboratory shall retain all records for a minimum of five (5) years from generation of the last entry in the records.

e) Access to archived information shall be documented with an access log.

f) All information necessary for the historical reconstruction of data shall be maintained by the laboratory…..i-xix

xix. a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.

Name	Initial	Signature
Tom Hanks	TH	Tom Hanks

Example Finding:
V1M2 4.13.3 f) xix)
Initials on records were not always traceable on the signature/initial log to identify personnel performing activities.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.13 Control of Records

4.13.3 Additional Requirements

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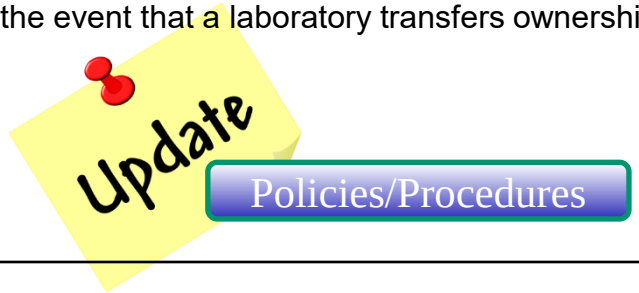
xix. a record of names, initials, and signatures for all individuals who are responsible for signing or initialing any laboratory record.

Name	Initial	Signature
Tom Hanks	TH	Tom Hanks

h) The laboratory shall have a plan to ensure that the records are maintained or transferred according to the clients' instructions in the event that a laboratory transfers ownership or goes out of business.



CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

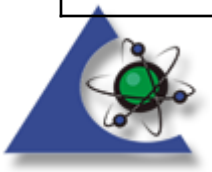
4.0 Management Requirements

4.14 Internal Audits

4.14.1 The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, conduct internal audits of its activities**….**The internal audit programme shall address all elements of the management system….

Electronic Data Management
Training
Activities vs Procedures
Reporting
Sample Receipt
Purchasing
Records
Contract Review
Data Review
Document Control
Corrective Action
QMS vs Requirements
Other….

Example Finding:
V1M2 4.14.1
Internal audit records did not provide evidence that all elements (e.g., LIMS, contract review, control of records, sample receipt, purchasing, training) were addressed.



CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements

4.14 Internal Audits

4.14.1 Such audits shall be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

4.14.5 Additional Items
c) The internal audit schedule shall be completed annually.

Example Finding:
V1M2 4.14.1 (and TNI V1M2 5.2.2 & 5.2.5)
The laboratory had not formulated goals with respect to the education, training and skills for the laboratory personnel performing internal audits and there were no available record of training and authorization for the internal auditors.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

4.0 Management Requirements
4.15 Management Reviews 4.15.1 The review shall take account of: ➢ 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 ts; ➢ changes in the volume and ➢ customer feedback; ➢ complaints; ➢ recommendations for improv ent; ➢ other relevant factors, such as quality control activities, resources, and staff training. 4.15.2 Findings from management reviews and the actions that arise from them shall be recorded. Note: ISO/IEC 17025:2017 *Management Review* has additional inputs/outputs

4.7 Service to Client vs 4.8 Complaints

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements
5.2 Personnel 5.2.4 The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations. 5.2.5 The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment. The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence is confirmed.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements TNI Minus 2	**5.0 Technical Requirements** TNI Full
Exception CCR Article 2 64802.05(a)(1) ▪ (A) Module 2, Section 4.1.7.2(f) - Technical Manager Qualifications ▪ (B) Module 2, Section 5.2.6 - Technical Manager Requirements CCR Article 5 64812.00 ➢ Minimum education and experience ➢ Laboratory Analyst Certificate from CWEA or Laboratory Quality Analyst Certificate from CA-NV/AWWA. **see CCR Article 2 62802.05 *Quality Systems* and Article 5 64812.00 *Laboratory Personnel* for additional requirements**	4.7.2.1f) meet qualification requirements as specified in Section 5.2.6.1. 5.2.6.1 Technical Manager Qualifications a-f Various educational and laboratory experience for different types of laboratories (e.g., inorganic, microbiological, radiological, asbestos)

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

5.2 Personnel

5.2.7 Data Integrity Training
Data integrity training shall be provided as a formal part of new employee orientation and shall also be provided on an annual basis for all current employees.

The initial data integrity training and the annual refresher training shall have a signature attendance sheet or other form of documentation that demonstrates all staff have participated and understand their obligations related to data integrity.

At a minimum, the following topics and activities shall be included: a-e

e) specific examples of breaches of ethical behavior such as improper data manipulations, adjustments of instrument time-clocks, and inappropriate changes in concentrations of standards.

Example Finding:
V1M2 5.2.7
Evidence of annual data integrity training was not available for all personnel (e.g., ICP/MS analyst (last record = 2019), project managers and LIMS manager (no records)).

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

5.3 Accommodation and Environmental Conditions

5.3.2 The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results.

5.3.3 There shall be effective separation between neighbouring areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

5.3.4 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled.

5.3.5 Measures shall be taken to ensure good housekeeping in the laboratory.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements
5.4 Environmental Methods and Method Validation 5.4.2 Selection of Methods 5.4.3 Laboratory-Developed Methods 5.4.4 Non-Standard Methods 5.4.5 Validation of Methods 5.4.5.2 The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use. 5.4.6 Estimation of Analytical Uncertainty 5.4.6.2 ….the laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty..

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requi

5.0 Technical Requ

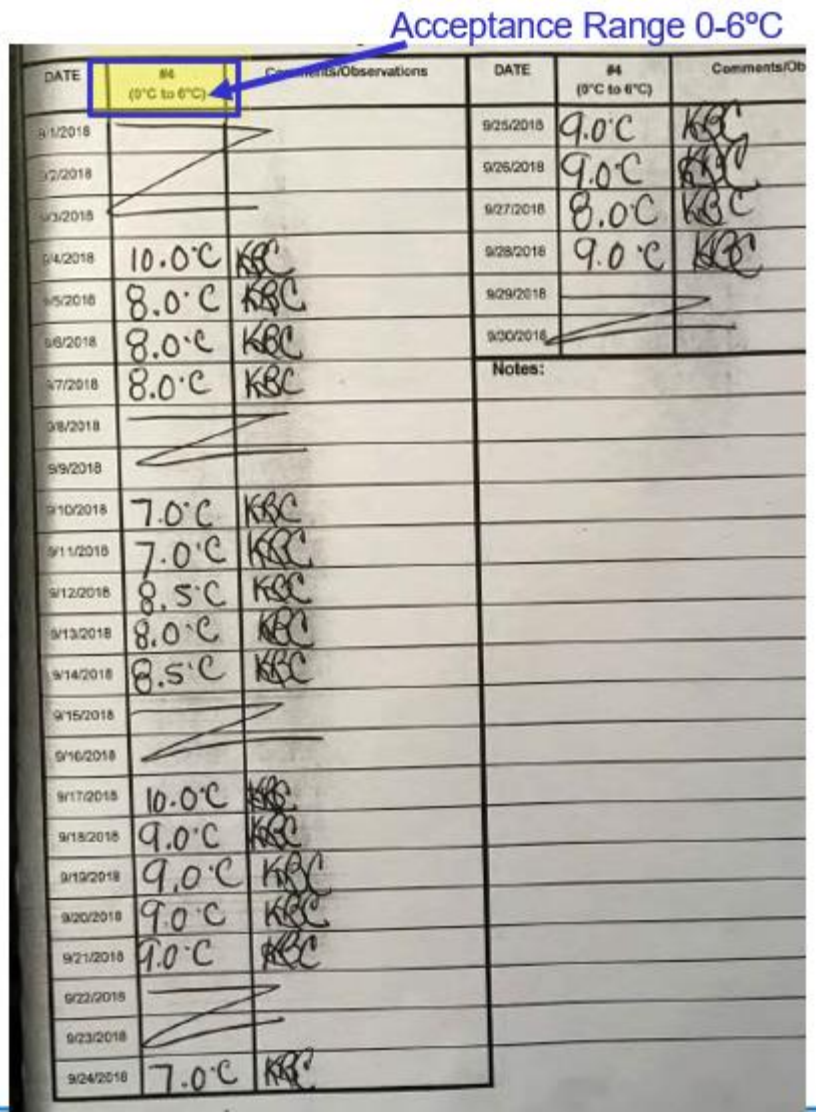
5.5 Calibration Requirements

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy require and shall comply with specifications relevant to the tests and/or calibrations concerned.

5.5.7 Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside specified limits, shall be taken out of service

It shall be isolated to prevent its use or clearly labelled or marked as being out of service until it has been repaired and shown by calibration or test to perform correctly.

The laboratory shall examine the effect of the defect or departure from specified limits on previous tests and/or calibrations and shall institute the "Control of nonconforming work" procedure.



CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

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CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

5.5 Calibration Requirements

5.5.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the accuracy required and shall comply with specifications relevant to the tests and/or calibrations concerned.

5.5.4 Each item of equipment and its software used for testing and calibration and significant to the result shall, when practicable, be uniquely identified.

5.5.5 Records shall be maintained of each item of equipment and its software significant to the tests and/or calibrations performed. The records shall include at least the following: a-h

a) the identity of the item of equipment and its software;
b) the manufacturer's name, type identification, and serial number or other unique identification;
f) dates, results and copies of reports and certificates of all calibrations, adjustments, acceptance criteria, and the due date of next calibration;
g) the maintenance plan, where appropriate, and maintenance carried out to date;
h) any damage, malfunction, modification or repair to the equipment.

5.5.6 The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

5.5 Calibration Requirements

5.5.8 Whenever practicable, all equipment under the control of the laboratory and requiring calibration shall be labelled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

Indication Only

Not for quality purposes

Limited Cal
(approved range = 35-85°C)

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements
5.5 Calibration Requirements 5.5.13.1 Support Equipment c) On each day the equipment is used, balances, ovens, refrigerators, freezers, incubators, and water baths shall be checked and documented. d) Temperature measuring devices shall be calibrated or verified at least annually. i. If the temperature measuring device is used over a range of 10°C or less, then a single point verification within the range of use is acceptable. ii. If the temperature measuring device is used over a range of greater than 10°C, then the verification must bracket the range of use. e) If quantitative results are dependent on their accuracy, such as in standard preparation or dispensing or dilution into a specified volume, the laboratory shall verify volumetric measuring devices as follows: i-iv ii. disposable or single-use volumetric equipment shall be verified once per lot, prior to or in conjunction with its first use; iii. mechanical devices shall be verified prior to first use and on a quarterly basis; mechanical devices used at more than one volume shall be verified at volumes bracketing the range of use, and at the mid-point of the volumes used by the device. f) All other support equipment shall be calibrated or verified at least annually…. bracketing the range of use.

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

5.6 Measurement Traceability

5.6.3 Reference Standards and Reference Materials

- traceable to SI units of measurement
- have procedures for safe handling, transport, storage

5.6.4.2 Documentation and Labeling of Standards, Reagents, and Reference Materials a-f

a) The laboratory shall retain records for all standards, reagents, reference materials, and media, including the manufacturer/vendor, the manufacturer's Certificate of Analysis or purity (if available), the date of receipt, and recommended storage conditions.

d) All containers of prepared standards, reference materials, and reagents shall bear a unique identifier and expiration date.

Vend

PJLA

- PL-2 Policy On Measurement Traceability
-
- PL-3 Policy on Measurement Uncertainty for Calibration and Testing Laboratories
- LF-123 Traceability Acceptance Criteria Form

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements
5.7 Collection of Samples Note: Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole.   

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements
5.8 Handling Samples and Test Items 5.8.2 The laboratory shall have a system for identifying test and/or calibration items. The identification shall be retained throughout the life of the item in the laboratory. The system shall be designed and operated so as to ensure that items cannot be confused physically or when referred to in records or other documents. The system shall, if appropriate, accommodate a sub-division of groups of items and the transfer of items within and from the laboratory. 5.8.5 a) The laboratory shall have a documented system for uniquely identifying the sample containers that hold samples to be tested, to ensure that there can be no confusion regarding the identity of such samples at any time. This system shall include identification for all samples, sub-samples, preservations, sample containers, tests, and subsequent extracts and/or digestates. 5.8.6 The laboratory shall have a written sample acceptance policy that includes the following: a-g f) procedures to be used when samples show signs of damage, contamination or inadequate preservation; 5.8.9 The laboratory shall have SOPs for the disposal of samples, digestates, leachates and extracts or other sample preparation products.

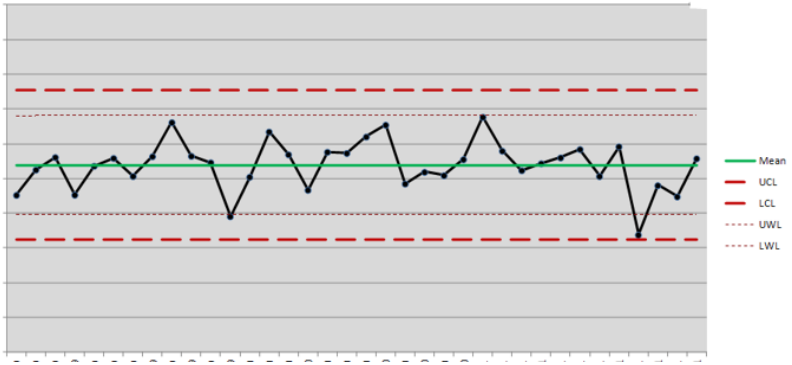
CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

5.0 Technical Requirements

5.9 Quality Assurance for Environmental Testing

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.



Eight or more points on one side of the centerline without crossing
Six points or more in a row steadily increasing or decreasing
14 points in a row alternating up and down
Any other noticeable/predictable pattern, cycle, or trend

Note: Many control chart trend rules (e.g., Shewhart control chart rules).

CA-ELAP Assessments (CCRs vs. TNI)

Module 2: Quality Systems General Requirements

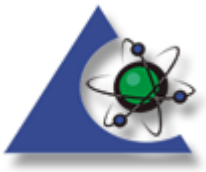
5.0 Technical Requirements
5.10 Reporting the Results 5.10.2 Each test report or calibration certificate shall include at least the following information, unless the laboratory has valid reasons for not doing so: a-k c) unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate; 5.10.9 Amendments to test reports and calibration certificates Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report [or Calibration Certificate], serial number... [or as otherwise identified]", or an equivalent form of wording. Such amendments shall meet all the requirements of this International Standard. 5.10.11 c) Any non-accredited tests shall be clearly identified as such to the client when claims of accreditation to this Standard are made in the analytical report or in the supporting electronic or hardcopy deliverables.

CA-ELAP Assessments (CCRs vs. TNI)

Volume 1
Management and Technical Requirements for Laboratories Performing Environmental Analysis

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

TNI Minus 2
(Exceptions to M1 and M2)



CA-ELAP Assessments (CCRs vs. TNI)

Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements
1.4 Method Selection 1.5 Method Validation 1.5.1 Validation of Methods 1.5.2 Limit of Detection and Limit of Quantitation (However Named) 1.5.2.1 Detection Limit (DL) 1.5.2.1.1 Initial determination of the DL 1.5.2.1.2 Ongoing verification of the DL 1.5.2.2 Limit of Quantitation (LOQ) 1.5.2.2.1 Initial verification of the LOQ 1.5.2.2.2 Ongoing verification of the LOQ 1.5.2.3 Verification of DL/LOQ 1.5.2.4 Documentation 1.5.3 Evaluation of Precision and Bias 1.5.4 Evaluation of Selectivity 1.6 Demonstration of Capability (DOC) 1.6.1 General 1.6.2 Initial DOC 1.6.3 Ongoing DOC

CA-ELAP Assessments (CCRs vs. TNI)

Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements

1.4 Method Selection

1.5 Method Validation
- 1.5.1 Validation of Methods
- 1.5.2 Limit of Detection and Limit of Quantitation (However Named)
  - 1.5.2.1 Detection Limit (DL)
    - 1.5.2.1.1 Initial determination of the DL
    - 1.5.2.1.2 Ongoing verification of the DL
  - 1.5.2.2 Limit of Quantitation (LOQ)
    - 1.5.2.2.1 Initial verification of the LOQ
    - 1.5.2.2.2 Ongoing verification of the LOQ
  - 1.5.2.3 Verification of DL/LOQ
  - 1.5.2.4 Documentation
- 1.5.3 Evaluation of Precision and Bias
- 1.5.4 Evaluation of Selectivity

Initial and ongoing

Precision & Bias

1.6 Demonstration of Capability (DOC)
- 1.6.1 General
- 1.6.2 Initial DOC
- 1.6.3 Ongoing DOC

CA-ELAP Assessments (CCRs vs. TNI)

Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements

1.4 Method Selection

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  - 1.5.2.3 Verification of DL/LOQ
  - 1.5.2.4 Documentation
- 1.5.3 Evaluation of Precision and Bias
- 1.5.4 Evaluation of Selectivity

1.6 Demonstration of Capability (DOC)
- 1.6.1 General
- 1.6.2 Initial DOC
- 1.6.3 Ongoing DOC

Initial and ongoing (annual)
(Precision and Accuracy)

CA-ELAP Assessments (CCRs vs. TNI)

Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements
1.7 Technical Requirements 1.7.1 Calibration 1.7.1.1 Initial Calibration 1.7.1.2 Continuing Calibration Verification (CCV) 1.7.2 Quality Control (QC) 1.7.2.1 Negative Control – Method Performance: Method Blank 1.7.2.2 Positive Control – Method Performance: Laboratory Control Sample (LCS) 1.7.2.3 Sample Specific Controls 1.7.2.3.1 Matrix spike; matrix spike duplicates 1.7.2.3.2 Matrix duplicates 1.7.2.3.3 Surrogate spikes 1.7.2.4 Data Reduction 1.7.2.5 Reagent Quality, Water Quality, and Checks 1.7.2.6 Selectivity 1.7.3 Data Acceptance/Rejection Criteria 1.7.3.1 Negative Control – Method Performance: Method Blank 1.7.3.2 Positive Control – Method Performance: Laboratory Control Sample (LCS) 1.7.3.3 Sample Specific Controls 1.7.4 Sample Handling

CA-ELAP Assessments (CCRs vs. TNI)

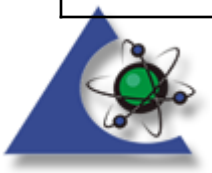
Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements

1.7 Technical Requirements
- 1.7.1 Calibration
  - 1.7.1.1 Initial Calibration
  - 1.7.1.2 Continuing Calibration Verification (CCV)
- 1.7.2 Quality Control (QC)
  - 1.7.2.1 Negative Contr… …d Performance: Method Blank
  - 1.7.2.2 Positive Co… …erformance: Laboratory Control Sample (LCS)
  - 1.7.2.3 Sample Specific…
- 1.7.4 Sample Handling

- Shall have a written procedure addressing removal and replacement of calibration standards.
- Minimum number of non-zero calibration standards.
- Use and document a measure of relative error in the calibration.

…ol Sample (LCS)



CA-ELAP Assessments (CCRs vs. TNI)

Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements

1.7 Technical Requirements
- 1.7.1 Calibration
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  - 1.7.2.2 Positive Control…od Performance: Laboratory Control Sample (LCS)
  - 1.…
  - 1.…
  - 1.…
  - 1.7.2.6 Selectivity
- 1.7.3 Data Acceptance/Rejection Criteria
  - 1.7.3.1 Negative Control – Method Performance: Method Blank
  - 1.7.3.2 Positive Control – Method Performance: Laboratory Control Sample (LCS)
  - 1.7.3.3 Sample Specific Controls
- 1.7.4 Sample Handling

- ≤1/2 Highest level in calibration.
- Beginning and end of analytical batch.

CA-ELAP Assessments (CCRs vs. TNI)

Module 4: Quality Systems for Chemical Testing

5.0 Technical Requirements

1.7 Technical Requirements
- 1.7.1 Calibration
  - 1.7.1.1 Initial Calibration
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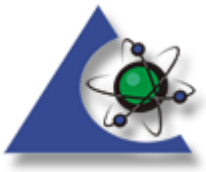
  - 1.7.2.2 Positive Control – Method Performance: Laboratory Control Sample (LCS)
  - 1.7.2.3 Sample Specific Co
    - 1.7.2.3.1 Matrix spike trix spike duplicates
  - 1.7.2
  - 1.7.2
  - 1.7.2.6 Selectivity
- 1.7.3 Data Acceptance/Rejection Criteria
  - 1.7.3.1 Negative Control – Method Performance: Method Blank
  - 1.7.3.2 Positive Control – Method Performance: Laboratory Control Sample (LCS)
  - 1.7.3.3 Sample Specific Controls
- 1.7.4 Sample Handling

Shall consist of a quality system matrix that is similar to the associated Samples.

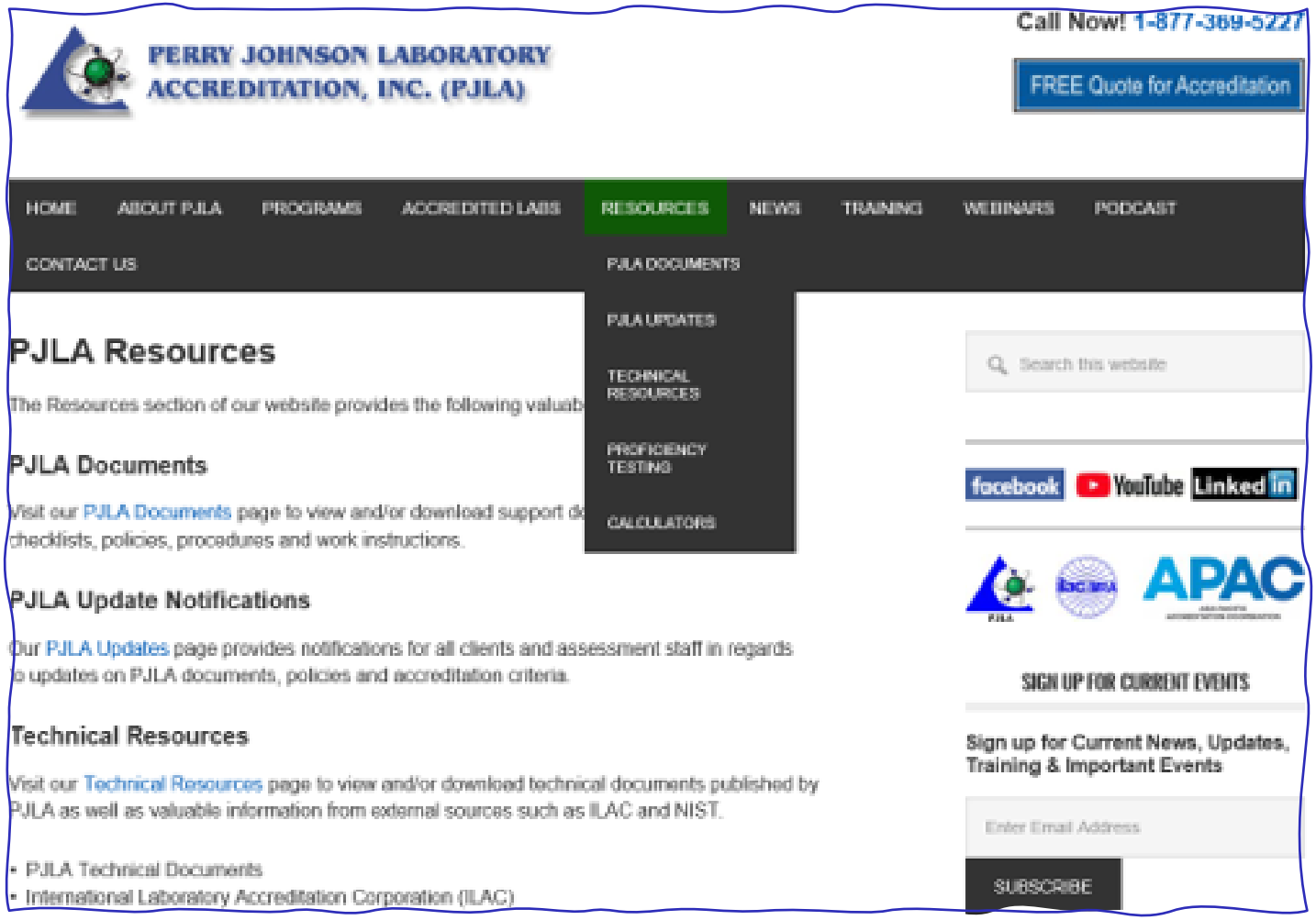
TNI Resources

- Implementation Resources
- Guidance Documents
- TNI FoPT tables
  https://nelac-institute.org/content/NEPTP/fopt.php
- Standard Interpretation Requests (SIRs)
  http://www.nelac-institute.org/content/NELAP/interpret.php
- Training
  http://nelac-institute.org/content/eds-home.php



PJLA Resources

www.PJLA.com



PJLA Resources

Forms

- PJLA Proficiency Testing Plan LF-81
- Traceability Acceptance Criteria Form LF-123

Policies

- Proficiency Testing Requirements for Applicant and Accredited Laboratories PL-1
- Policy On Measurement Traceability PL-2
- Policy on Measurement Uncertainty for Calibration and Testing Laboratories PL-3
- Policy on Calibration Scopes of Accreditation PL-4

Procedures

- Accreditation Procedure – General – SOP-1 General
- Accreditation Procedure – DoD ELAP – SOP-1 DoD ELAP
- Accreditation Procedure – EPA NLLAP – SOP-1 EPA NLLAP
- Accreditation Procedure – FCC – SOP-1 FCC
- Accreditation Procedure – Inspection Bodies – SOP-1 Inspection Bodies
- Accreditation Procedure – Medical – SOP-1 Medical
- Accreditation Procedure – MP – SOP-1 MP
- Accreditation Procedure – TNI EL – SOP-1 TNI EL
- Accreditation Procedure – TNI NEFAP – SOP-1 TNI NEFAP
- The FDA Accreditation Scheme for Conformity Assessment Program (ASCA) – SOP-1 FDA ASCA
- Proficiency Test Provider (PTP) Accreditation Procedure – SOP-1-PTP
- Appeal Procedure SOP-10
- Complaint Procedure SOP-9
- Use of Accreditation Claims and Symbols SOP-3
- Suspension, Withdrawl or Reduction of Accreditation SOP-11

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Upcoming Webinars

Thursday, May 27 – 1:00pm EST
A Look at the Requirements Specified in PJLA Policy on Proficiency Testing Requirements “PL-1”

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- more….

Questions