An Overview of the DOD/DOE/TNI/State Assessments-Accreditation Requirements and Common Findings

Presented by:
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Tuesday, June 14, 2022
10:00 am-11:00 AM EDT

PJLA

Presentation Overview

PJLA

- Discuss Accreditation Criteria and Expectations
- Overview of Field Assessment Common Findings
- Questions & Answers

Webinar Housekeeping

- This webinar will be recorded
- All PJLA webinars are made available on our website & YouTube channel
  - https://www.pjlabs.com/training/pjla-webinars/past-webinars
- All attendees are muted
- Please utilize the question tool bar to submit questions
  - To be answered at the end of presentation

PJLA Environmental Programs

- DOD ELAP and DOECAP
  - QSM Version 5.4
- TNI EL NGAB-Non governmental – TNI EL 2016 Standard
- TNI NEFAP –TNI FSMO Volume 1 – Field Sampling and Measurement
- FL DOH–TNI EL – TPA Assessor Only
- CA ELAP-TNI EL, TNI EL Minus 2 or CA Regs – TPA Assessor
- MNLEAP-TNI EL –TPA
- ISO/IEC 17025
- EPA NLLAP-Lead Program

Accreditation Criteria -Schedules

- All programs require slightly different criteria in regard to assessment schedules
- Note all program criteria must be met
- Lab may have to go earlier for certain programs to accommodate them all
- Most programs follow ISO/IEC 17011 requiring a full system assessment to be completed every 2 years
- Extensions of accreditation are not allowed for DOE or DOD programs unless extreme circumstances arise
  - Labs are encouraged to review due dates, coordinate with PJLA on a time period that will allow enough time to complete the assessment; Corrective action process and certificate issuance

Accreditation Criteria -Pre-Documentation

- All labs are required to have a documentation review 30 days in advance of the on site assessment
- If you are accredited with a state program; PTs are important to be completed; fees; application criteria etc.
- Failure to provide PT prior to an assessment may cause tests to be eliminated from the assessments, NCRS or overall delay and issues with the state's decision
- DOD/DOE PTS are also required to be submitted to pt@pjlabs.com to ensure the frequency requirements are met; PT failures will cause tests or particular analytes to be removed off of the scope or an NCR to be written requiring passing results
- Provide LODs/LOQs, Data Package, PTs, Technical SOPS, Internal Audits, past assessments/CA Results etc. competed readiness checklist 30 days in advance to PJLA

Accreditation Criteria- Assessment Reporting

- Depending on the assessment i.e. single program or multiple standard, laboratories may receive multiple reports
- DOD/DOE/TNI EL NGAB - Combined report; may have specific NCRS to DOD or DOE only, TNI
- State programs - TNI EL, State Regulations, Separate Report based on state requirements
- PJLA has all reports reviewed by program management after the assessment
  - DOD/DOE TNI NGAB - Final report issued at the end of the assessment
  - CA ELAP or FL DOH - Final report reviewed by PJLA HQ and issued to the lab after noting that is the final report and corrective action timelines and submittal instructions are provided

Accreditation Criteria- Corrective Action Criteria

- PJLA accreditation program (PJLA issues the certificate)- requires corrective action to be provided within 60 days –includes cause and evidence of implementation on the lab's internal corrective action form
- FL DOH-PJLA utilizes FL's Corrective action form; Labs should provide a plan 30 days from the release of the final report. The report is usually released about 7 days after the assessment.
- Once corrective action is approved a recommendation letter is provided to the state which includes the date and type of assessment, when corrective action was provided by the lab, when PJLA approves it and our recommendation for renewal, initial accreditation, scope expansion, scope reduction etc.
- CA ELAP -PJLA has internal corrective action forms; labs should provide a corrective action plan 30 days from the release of the final report. The report is usually released about 7 days after the assessment.
- Once corrective action is approved a recommendation letter will be provided with a copy of the checklist utilized. The recommendation letter will include the date and type of assessment, when corrective action was provided by the lab, when PJLA approved it and our recommendation for renewal, initial accreditation, scope expansion, scope reduction, etc.

Common Findings
(TNI and DoD/DOE QSM)

Findings Detected on Environmental Lab Assessments

Common Findings
(TNI and DoD/DOE QSM)

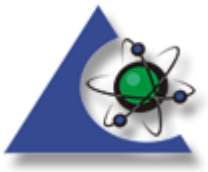
Findings Detected on Environmental Lab Assessments

Course Mechanics:

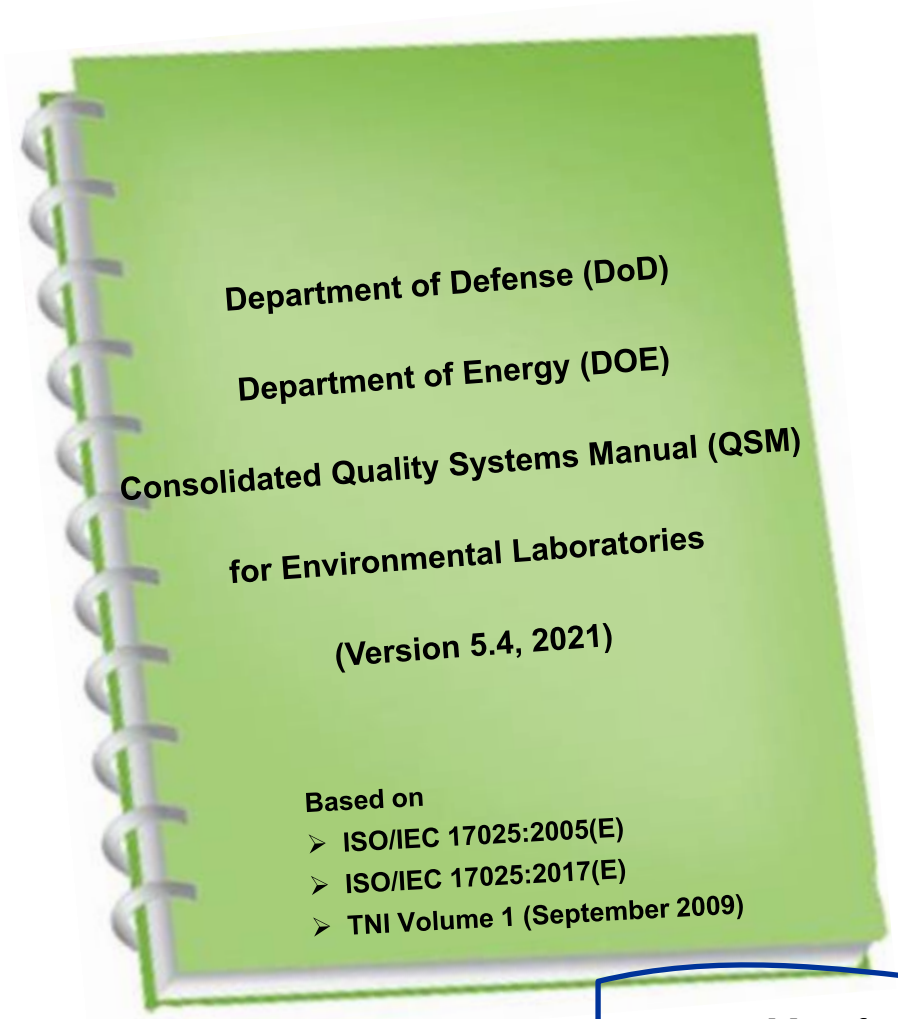
(1) Phone lines and computers are muted. Use **Question** tab in Control Panel
- identify slide # if appliable

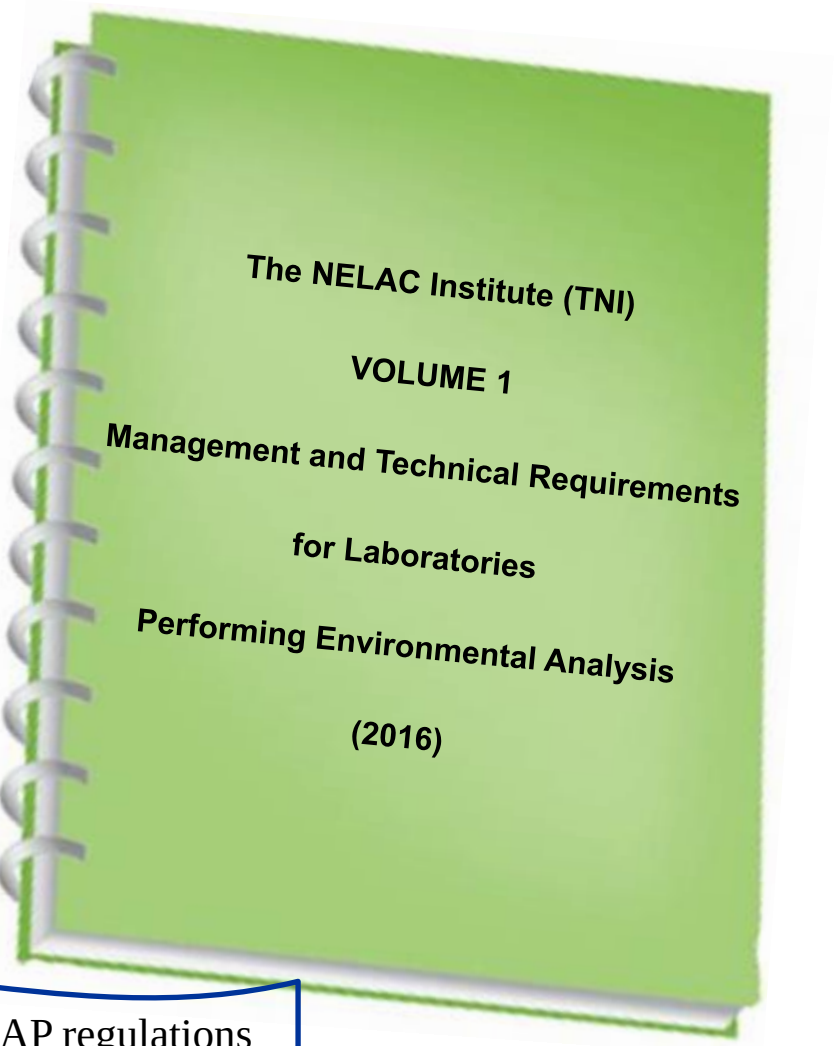
(2) This is being recorded (slides and webinar will be available on PJLA website)

(3) Tracy Szerszen (PJLA President) is also joining the Webinar
- will be monitoring questions in the **Question** tab



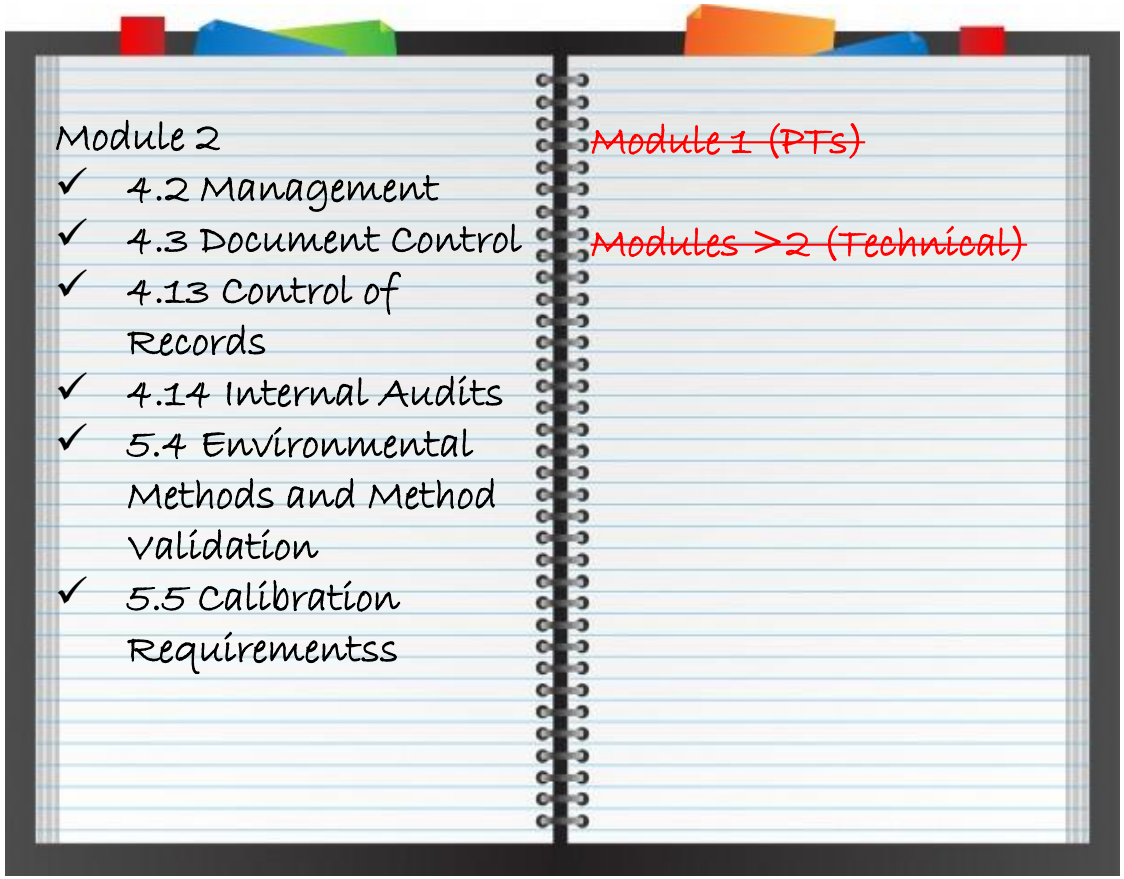
Common Findings (TNI and DoD/DOE QSM)





A sprinkle of CA-ELAP regulations

Common Findings (TNI and DoD/DOE QSM)



Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.2 Management
4.2.8 Additional Management System Requirements
4.2.8.4 The quality manual shall contain or reference procedures for audits and data review;

DoD/DOE Requirement

Data reviews shall consist of a tiered or sequential system of verification, consisting of at least three tiers, 100% review by the analyst, 100% verification review by a technically qualified supervisor or data review specialist, and a final administrative review.

The quality manager or designee shall review a minimum of 10% of all data packages for technical completeness and accuracy on a quarterly basis.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.2 Management
4.2.8 Additional Management System Requirements
4.2.8.4 The quality manual shall contain or reference procedures for audits and data review;

DoD/DOE Requirement

If electronic audit trail functions are available, they must be in use at all times, and associated data must be accessible.

If the instrument does not have an audit trail, the laboratory must have procedures to record the integrity of the data.

Common Findings
(TNI and DoD/DOE QSM)

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.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.2 Management
4.2.8 Additional Management System Requirements

CA ELAP Regulations

(64812.00)
Quality Manager Requirements (TNI 2016 V1M2 4.1.5(i), 4.1.7.1, 4.2.6, 4.2.8.2 and 4.14.1)

(64812.05, 64812.15 & 64814.00)
Various Quality Manual requirements

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.3 Document Control

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

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Standards (TNI, DoD/DOE QSM, ISO/IEC 17025)
PJLA Policies/Procedures
Test Methods
Equipment manuals

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

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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:

The document control program was not current or accurate.

- 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.
- Documents in use (e.g., SOP AB-77 Rev. 7) did not have evidence of approval for use.
- The master list of documents was missing procedures.
- The master list of documents identified obsolete procedure revisions.

Common Findings
(TNI and DoD/DOE QSM)

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.

DoD/DOE Requirements

4.3.2.2

g) any documents providing instructions to laboratory personnel (e.g., operator aids) are considered part of the management system and are subject to document control procedures.

Example Findings:

SOP LAB-567 referenced the ICP/MS instrument manual; however, that manual was not included in the controlled document program or master list.

Operator aids observed in the laboratory were not controlled (e.g., not identified in document control program, not authorized for use, no revision information, no ID)

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

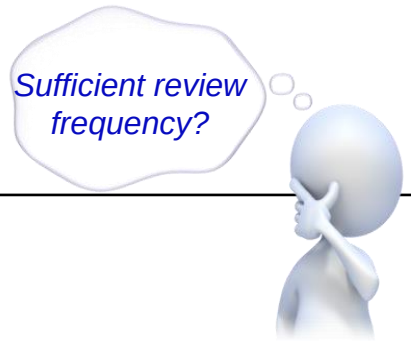
4.3 Document Control

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.

TNI 2016	DoD/DOE QSM 5.4
4.3.2.2 Periodically reviewed	4.2.8.5 g) All technical SOPs (e.g., sample preparation, analytical procedures, sample storage, or sample receipt) shall be reviewed for accuracy and adequacy at least annually and updated if necessary.



Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.3 Document Control

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

DoD/DOE Requirement

4.3.2.2 f) reviews (internal or external) of management system documentation shall be maintained

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

Example Findings:

Not all procedures had evidence of biannual reviews in accordance with procedure ADM-009 Rev. 2.

There was no evidence of periodic review of external management system documentation.

Common Findings
(TNI and DoD/DOE QSM)

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 availabl… …ssential to the effective functioning of the laboratory are perf…

b) documents are periodically review… …ility and compliance with applicab…

DoD/D…

4.3.2.…

Comments/Notes	Recommended Action
	Acceptable As Is ☐
	Revision Required* ☐
	Cancel/Retire Procedure ☐
	Review Upon Use ☐

…d evidence of biannual reviews in accordance with procedure ADM-…

There was no evidence of periodic review of external management system documentation.

Common Findings
(TNI and DoD/DOE QSM)

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:
Obsolete versions of procedures were observed in laboratory areas.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.3 Document Control

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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.

Various requirements for documented information

5.8.6 Additional Requirements – Sample Acceptance Policy

The laboratory shall have a written sample acceptance policy that includes the following (a-g)

5.8.8 Additional Requirements – Legal Chain of Custody Protocols

Legal chain of custody procedures are used for evidentiary or legal purposes. If a client specifies that a sample is to be used for evidentiary purposes, then a laboratory shall have a written SOP for how that laboratory will carry out legal chain of custody.

DoD/DOQ QSM 5.4 4.2.8.1 c) The laboratory shall have a documented program to detect and deter improper or unethical actions.

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Common Findings
(TNI and DoD/DOE QSM)

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.

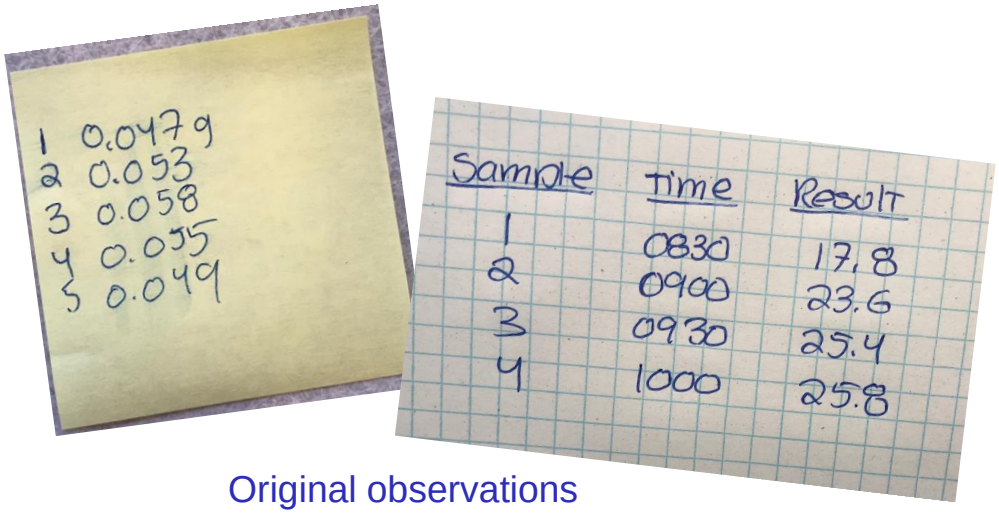
Example Finding:
Not all procedures included page numbering or issuing authorities.

Common Findings
(TNI and DoD/DOE QSM)

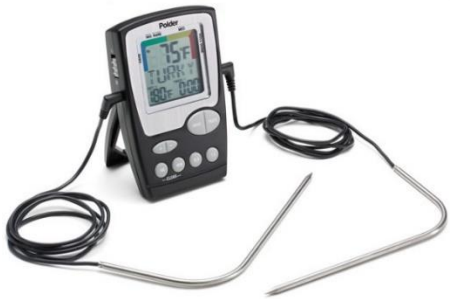
Module 2: Quality Systems General Requirements
4.0 Management Requirements

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.

Common Findings
(TNI and DoD/DOE QSM)

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:

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

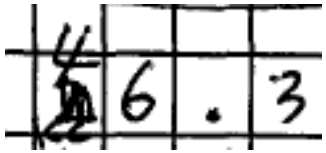
- *Weight set IDs not on balance verification records*
- *Thermometer IDs not on temperature monitoring records*
- *Lot #s not on test records*
- *Identification of person performing the activity not identified on test records*

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

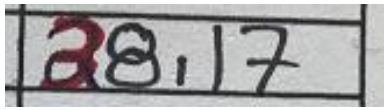
4.13 Control of Records

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.

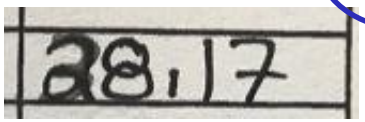


Lost original observation

Also needs to be reproducible (scans/copies)



Original



Duplication

Common Findings
(TNI and DoD/DOE QSM)

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:
Initials on records were not always traceable on the signature/initial log to identify personnel performing activities.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.13 Control of Records

4.13.3 Additional Requirements

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.

Policies/Procedures

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
4.0 Management Requirements

4.13 Control of Records

DoD/DOE Requirements

4.13.4 Permanent, bound laboratory notebooks (logbooks) or notebooks with measures in place to prevent the removal or addition of pages are required if utilized. Electronic logbooks are acceptable. For permanent, bound logbooks the following applies:

a) laboratory notebook pages shall be pre-numbered, all entries shall be signed or initialed and dated by the person responsible for performing the activity at the time the activity is performed, and all entries shall be recorded in chronological order;
b) all notebook pages must be closed when the activities recorded are completed or carried over to another page. The person responsible for performing the closure shall be the one who performed the last activity recorded. Closure shall occur at the end of the last activity recorded on a page, as soon as practicable, thereafter. Satisfactory records of closure include analyst initials and date; and
c) each laboratory notebook shall have a unique serial number clearly displayed.

Example Findings:
Not all logbooks prevented removal or addition of pages (3-ring binder).

Logbooks were not paginated or identified the total number of pages (or mark to signify the end of the document).

Not all logbooks had a unique ID

Common Findings
(TNI and DoD/DOE QSM)

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 to verify that its operations continue to comply with the requirements of the management system and this International Standard. The internal audit programme shall address all elements of the management system, including the testing and/or calibration activities.

DoD/DOE Requirements

4.14.6 The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year. The review shall include both technical and quality systems areas. The review shall also include raw electronic data files derived from test reports.

4.15.1 Management reviews and internal audits are separate activities.
5.4.7.1 f) periodic inspections (at least annually) of the LIMS shall be performed…

Various requirements applicable to audits

Example Finding:
The laboratory's internal audit plan and audit program/records did not address or include all testing activities.

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.4 Environmental Methods and Method Validation

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.

4.2.8.5 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.

DoD/DOE Requirements

- Various Modules section 1.5 Method Validation
- 5.4 Grey box 24 (ISO/IEC 17025:2017 7.2.2.2 and 7.2.2.4)

Example Finding:
Method modifications were not validated or documented in the SOP.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

Acting Attorney General Hoffman Announces $2 Million Settlement of False Claims Act Litigation with Environmental Testing Firm

According to the Settlement Agreement with the DOJ, the United States alleged that [redacted] violated the False Claims Act by submitting, under contract with various federal agencies, results of analytical testing which were not performed in accordance with U.S. EPA guidelines. The allegations were disputed by [redacted], and it has not admitted any wrongdoing. More specifically, the allegations involved analyses performed during 2011 through 2013 involving semi-volatile organic compounds. The DOJ alleged that, in some cases, the lab did not strictly follow the applicable method by:

1. "not performing the required number of 'shakes' and/or not waiting the required period of time between 'shakes' of waste water samples, potentially resulting in the inability to fully extract all of the SVOA compounds in the samples;"
2. not 'spiking' a soil or waste water sample with a known compound in the correct sequence or manner, potentially affecting the quality control process that ensured all SVOA compounds in a sample were likely to be fully extracted;" and
3. "altering the settings on GC/MS instruments or disregarding calibration protocols."

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.4 Environmental Methods and Method Validation

DoD/DOE Requirements

5.4.7.2 h) spreadsheets used for calculations shall be verified before initial use and after any changes to equations or formulas, including software revision upgrades, and records shall be available for review. Formula cells must be write-protected to minimize inadvertent changes to the formulas. Printouts from any spreadsheets shall include all information used to calculate the data;

Example Findings:
Verification records were not available for spreadsheets used for calculations.

Formula cells were not write-protected in spreadsheet used for calculations.

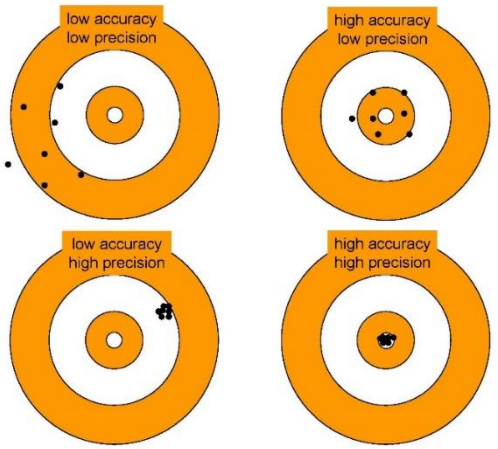
Common Findings
(TNI and DoD/DOE QSM)

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.

5.5.13.1 f) …shall be calibrated or verified...bracketing the range of use.



DoD/DOE Requirements

5.5.13.1 d) These checks must be performed in the expected use range

Example Finding:

No all equipment had evidence of capability to achieve accuracy

- Thermometer accuracy (±1°C) was not sufficient for test specifications (e.g., incubator = 35±0.5°C, water bath = 44.5 ±0.2°C).
- Thermometers were not calibrated covering the range of use.

Common Findings

fisher scientific
part of Thermo Fisher Scientific

Fisherbrand™ Traceable™ Sentry™ Thermometer SCIED

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)

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 approximate a 95% confidence level. In tolerance conditions are based on test results falling within specified limits with no regard for 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)/2; Min = As Left Nominal(Rounded) - Tolerance; Max = As Left Nominal(Rounded) + Tolerance; Date=MM/DD/YY

Nicol 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) - Mutilateral Recognition Arrangement (MRA).

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Common Findings (TNI and DoD/DOE QSM)

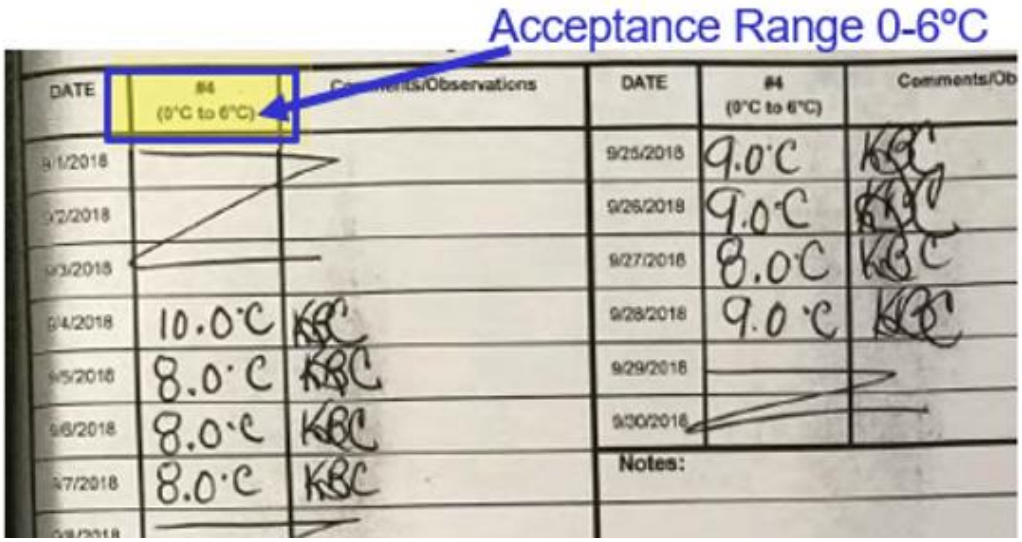
Module 2: Quality Systems General Requirements
5.0 Technical Requirements

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.

5.5.13.1 Support Equipment

a) The results of any calibration or verification shall be within the specifications required of the application for which this equipment is used.



Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements

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

4.9.1 The laboratory shall have a policy and procedures that shall be implemented when any aspect of its testing and/or calibration work, or the results of this work, do not conform to its own procedures or the agreed requirements of the customer. The policy and procedures shall ensure that

b) an evaluation of the significance of the nonconforming work is made

ISO/IEC 17025:2017

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laboratory activities or results of this work do not conform to its own procedures. The procedure shall ensure that:

d) a decision is taken on the acceptability of the nonconforming work.

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements

Conventional Mass Value - Mass in Atmosphere

Nominal Value	As Found Value (g)	As Found Correction* (mg)	As Left Value (g)	As Left Correction* (mg)	Uncertainty (mg)	Tolerance (mg)
100 g	100.000097	0.097	100.000097	0.097	0.029	0.25
50 g	50.000314	0.314	50.000030	0.030	0.016	0.12
20 g 1-dot	20.000058	0.058	20.000058	0.058	0.012	0.074
20 g 2-dot	20.000025	0.025	20.000025	0.025	0.012	0.074
10 g	9.999997	-0.003	9.999997	-0.003	0.011	0.074
5 g	5.0000587	0.0587	5.0000312	0.0312	0.0048	0.054
2 g	1.9999984	-0.0016	1.9999984	-0.0016	0.0021	0.054
2 g 1-dot	2.0000096	0.0096	2.0000096	0.0096	0.0021	0.054
1 g	1.0000166	0.0166	1.0000166	0.0166	0.0024	0.054

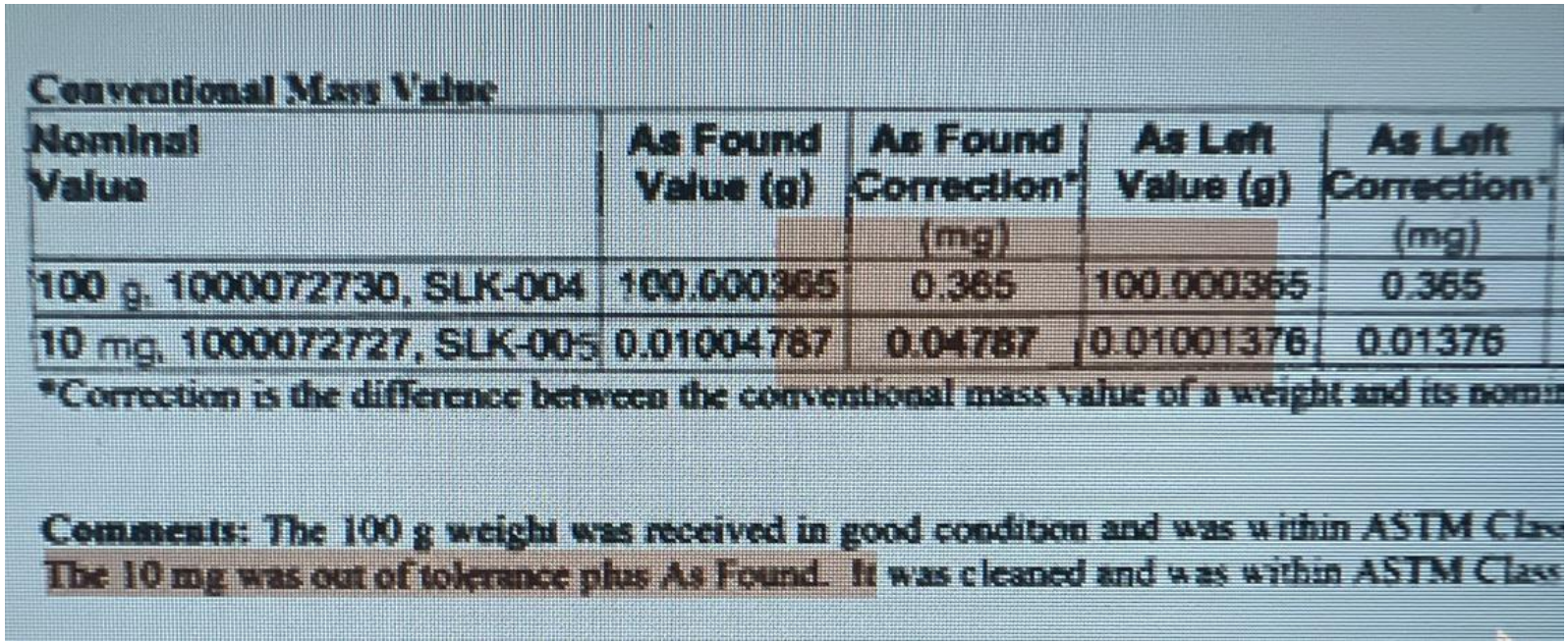
*Correction is the difference between the conventional mass value of a weight and its nominal value.

Comments:
The 50 g & 5 g weights were out of tolerance plus As Found. They were cleaned and were within NBS Class S tolerances As Left. All other weights listed above were received in good condition and were within NBS Class S tolerances As Found.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements



Conventional Mass Value

Nominal Value	As Found Value (g)	As Found Correction* (mg)	As Left Value (g)	As Left Correction* (mg)
100 g, 100072730, SLK-004	100.000365	0.365	100.000365	0.365
10 mg, 100072727, SLK-005	0.01004787	0.04787	0.01001376	0.01376

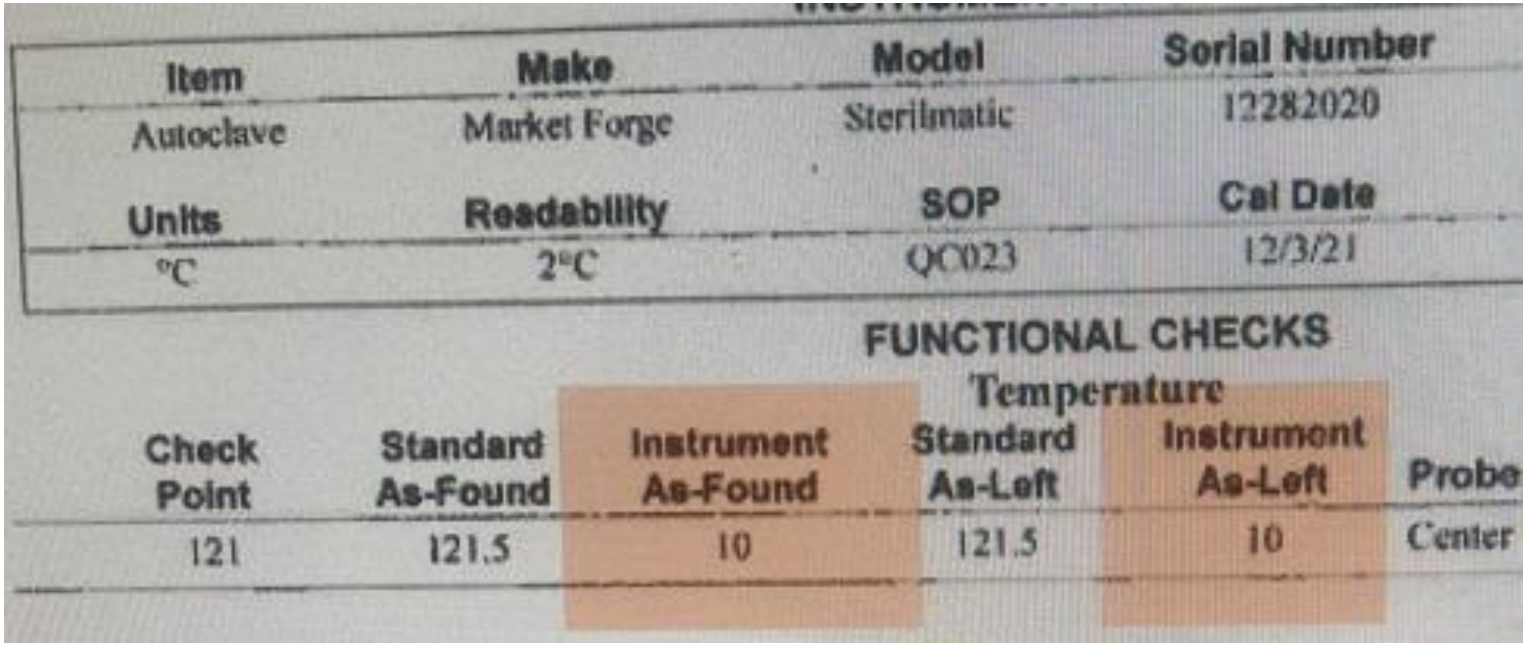
*Correction is the difference between the conventional mass value of a weight and its nomi

Comments: The 100 g weight was received in good condition and was within ASTM Clas
The 10 mg was out of tolerance plus As Found. It was cleaned and was within ASTM Clas

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements



Item	Make	Model	Serial Number
Autoclave	Market Forge	Sterilmatic	12282020
Units	**Readability**	**SOP**	**Cal Date**
°C	2°C	QC023	12/3/21

FUNCTIONAL CHECKS

			Temperature		
Check Point	Standard As-Found	Instrument As-Found	Standard As-Left	Instrument As-Left	Probe
121	121.5	10	121.5	10	Center

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements

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 wo

Met lab tolerance?
Not used at that range?
Equipment = indication only?

4.9.1 The laboratory shall have a policy and procedures that sh spect of it and/or calibration work, or the results of this work, do not confo agreed of the customer. The policy and procedures shall ensure that
b) an evaluation of the significance of the nonconforming work is made

ISO/IEC 17025:2017

7.10.1 The laboratory shall have a procedure that shall be implemented when any aspect of its laborato ivities or results of this work do not conform to its own procedures. The procedure shall ensure that:
d) a decision is taken on the acceptability of the nonconforming work.

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements

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) 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.

Example Finding:

The equipment inventory list was not current or accurate

- SW versions identified were not current
- Missing balance B06 and Thermometers T12 & T13
- Model numbers used instead of a unique ID (e.g., serial number, asset ID)

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements

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.

5.6.3.4 The laboratory shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

ISO/IEC 17025:2017

6.4.7 The laboratory shall establish a calibration program, which shall be reviewed and adjusted as necessary in order to maintain confidence in the status of calibration.

Example Finding:

Calibration reports identified various weights were out of tolerance and/or dirty. As a result of the unfavorable trend, there were no records for evaluation of suitability of the five-year calibration interval and/or adequacy of the handling, transport, storage and use of the weights.

The 07/2021, 07/2017 and 08/2013 Calibration reports for flow unit (SN 114036) identified flow rate out of tolerance conditions. As a result of the unfavorable trend, there were no records for evaluation of suitability of the four-year calibration interval and/or adequacy of the handling, transport, storage and use of the flow unit.

Common Findings
(TNI and DoD/DOE QSM)

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)

Example Finding:
A thermometer was observed without a label identifying its calibration status. Although interview with the quality manager indicated it was not used for quality purposes, it was not labeled to prevent inadvertent use.

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements

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.

Supplier's website does **not** = record retention

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

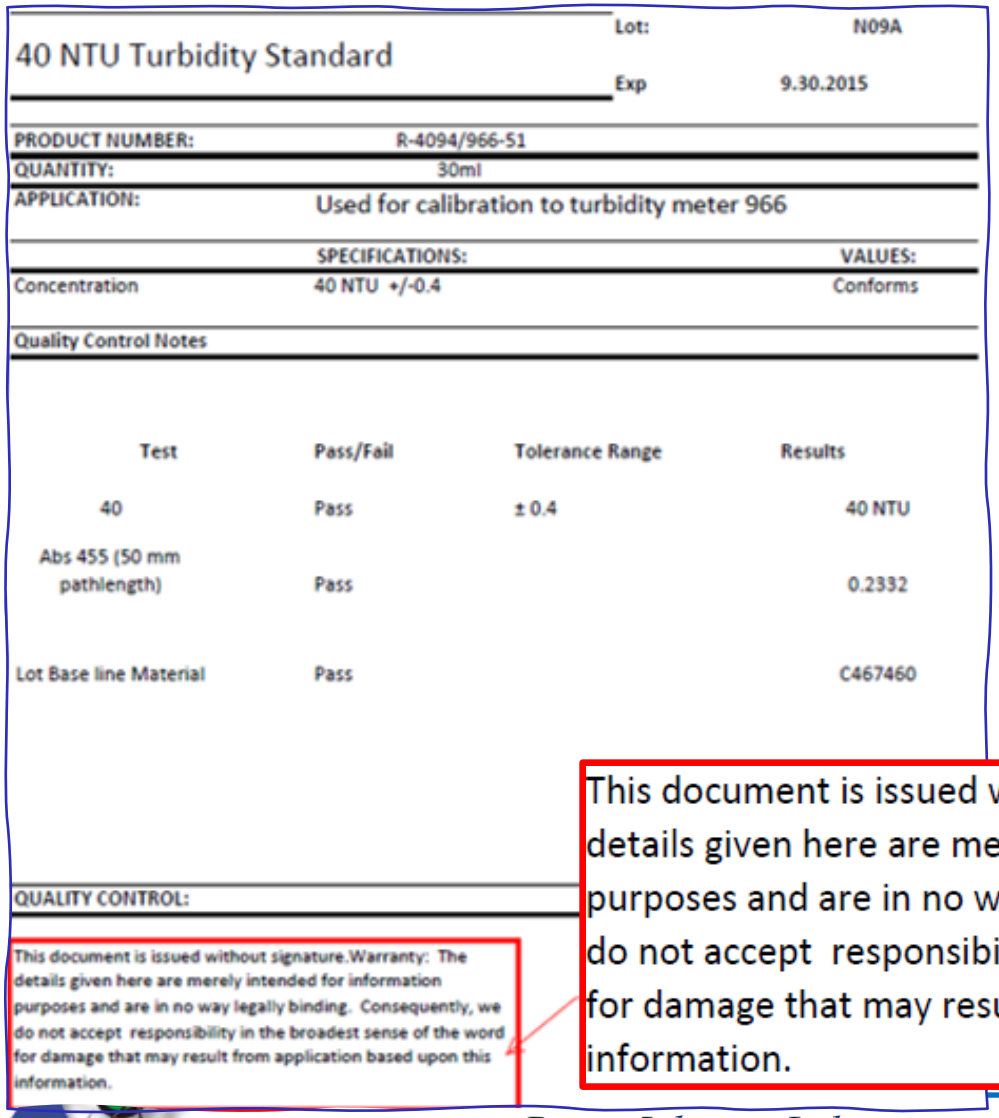
5.5 Calibration Requirements

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.

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.

Common Findings
(TNI and DoD/DOE QSM)



40 NTU Turbidity Standard

Lot: N09A

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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Common Findings
(TNI and DoD/DOE QSM)

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements
5.5.13.1 Support Equipment

TNI 2016	DoD/DOE QSM 5.4
Temperature measuring devices	
Temperature measuring devices shall be calibrated or verified at least annually	• Liquid in glass: Before first use and annually • Electronic: Before first use and quarterly

PJLA PL-2 *Policy On Measurement Traceability*
Measuring equipment shall be calibrated by:
- NMI
- ISO/IEC 17025 accredited provider
- Approval LF-123

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements
5.5.13.1 Support Equipment

TNI 2016	DoD/DOE QSM 5.4
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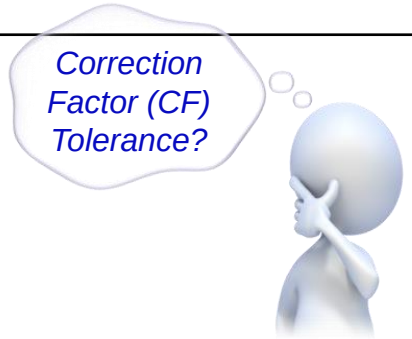

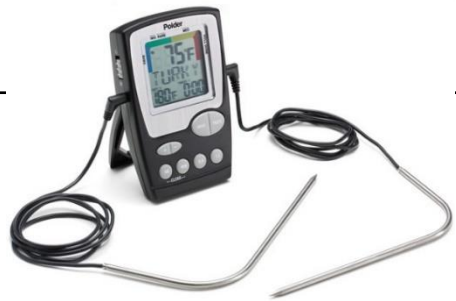

Observed Temp. **and** Corrected Temp.

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements
5.5.13.1 Support Equipment

TNI 2016	DoD/DOE QSM 5.4
Mechanical volumetric pipette	
Prior to first use and on a quarterly basis. Variable pipettes: • Bracket range of use • Mid-point	Daily before use • Bias: Mean within ± 2% of nominal volume • Precision: RSD ≤ 1% of nominal volume (based on minimum of 3 replicate measurements) Variable pipettes: • Bracket range of use

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements
5.5.13.1 Support Equipment

TNI 2016	DoD/DOE QSM 5.4
glass microliter syringes and Class A glassware are exempt from any verification requirements beyond what is stated in Section 4.6.2	
Exempt from any verification requirements beyond what is stated in Section 4.6.2. 4.6.2 … 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.	Upon receipt General Certificate of Bias & Precision upon receipt

Common Findings (TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements
5.0 Technical Requirements

5.5 Calibration Requirements
5.5.13.1 Support Equipment

TNI 2016	DoD/DOE QSM 5.4
Balance Calibration	
On each day the equipment is used. The acceptability fo shall be accordi application fo used.	Annual alance: ± 2% or ± 0.02g, reater nce: ± 0.1% or ± 0.5 mg, eater ation from ISO/IEC 17025 n laboratory
All other support ent shall be calibrated or verified at least an ally, using a recognized National Metrology Institute, such as NIST, traceable reference when available, bracketing the range of use.	Every 5 years Certificate of Calibration from ISO/IEC 17025 accredited calibration laboratory

PJLA PL-2 *Policy On Measurement Traceability*
Measuring equipment shall be calibrated by:
- NMI
- ISO/IEC 17025 accredited provider
- Approval LF-123

Common Findings
(TNI and DoD/DOE QSM)

Company maintains a quality management system compliant to ISO/IEC 17025.

Company maintains a quality management system accredited to ISO/IEC 17025.

Company is an *AB Name* ISO 17025 accredited company.

PJLA SOP-3 *Use of Accreditation Claims and Symbols*

[The calibration supplier] shall ensure that all customers requesting services are not misled when non-accredited or non-endorsed reports are provided.
[If the accreditation symbol is not used, the calibration supplier] shall ensure the following information is included:
1) The Standard Accredited to (e.g., ISO/IEC 17025:2017Accredited)
2) PJLA
3) Accreditation #XXXXX
4) Accreditation field (e.g., Calibration)

Requirements for claims of accreditation

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General Requirements

Available certificates include:

- Certificate of Weight Calibration (Accredited)
- Certificate of Weight Calibration (Non-accredited)
- Statement of Accuracy (Not a Legal for Trade or traceable document)

- ☐ Accredited calibration report
- ☐ Report with data
- ☐ NIST traceable calibration report

Common Findings
(TNI and DoD/DOE QSM)

Module 2: Quality Systems General 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 [redacted].

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

Although [redacted] is an accredited laboratory, the results of this calibration and customer requested reporting is NOT considered an accredited calibration and therefore does not meet the requirements of ISO-17025:2005. With a Level 1 Calibration, the actual calibration data points are verified, however, these values are not recorded at the customer's request. A Level 1 calibration cannot be converted to any other level (2 through 4) without performing a re-calibration and recording the data. Additional fees may apply.

Common Findings
(TNI and DoD/DOE QSM)

Company maintains a quality management system compliant to ISO/IEC 17025.

Company maintains a quality management system accredited to ISO/IEC 17025.

Company is an *AB Name* ISO 17025 accredited company.

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[The calibration supplier] shall ensure that all customers requesting services are not misled when non-accredited or non-endorsed reports are provided.
[If the accreditation symbol is not used, the calibration supplier] shall ensure the following information is included:
1) The Standard Accredited to (e.g., ISO/IEC 17025:2017Accredited)
2) PJLA
3) Accreditation #XXXXX
4) Accreditation field (e.g., Calibration)

Requirements for claims of accreditation

Common Findings (TNI and DoD/DOE QSM)

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.

ISO/IEC 17025 accredited supplier

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

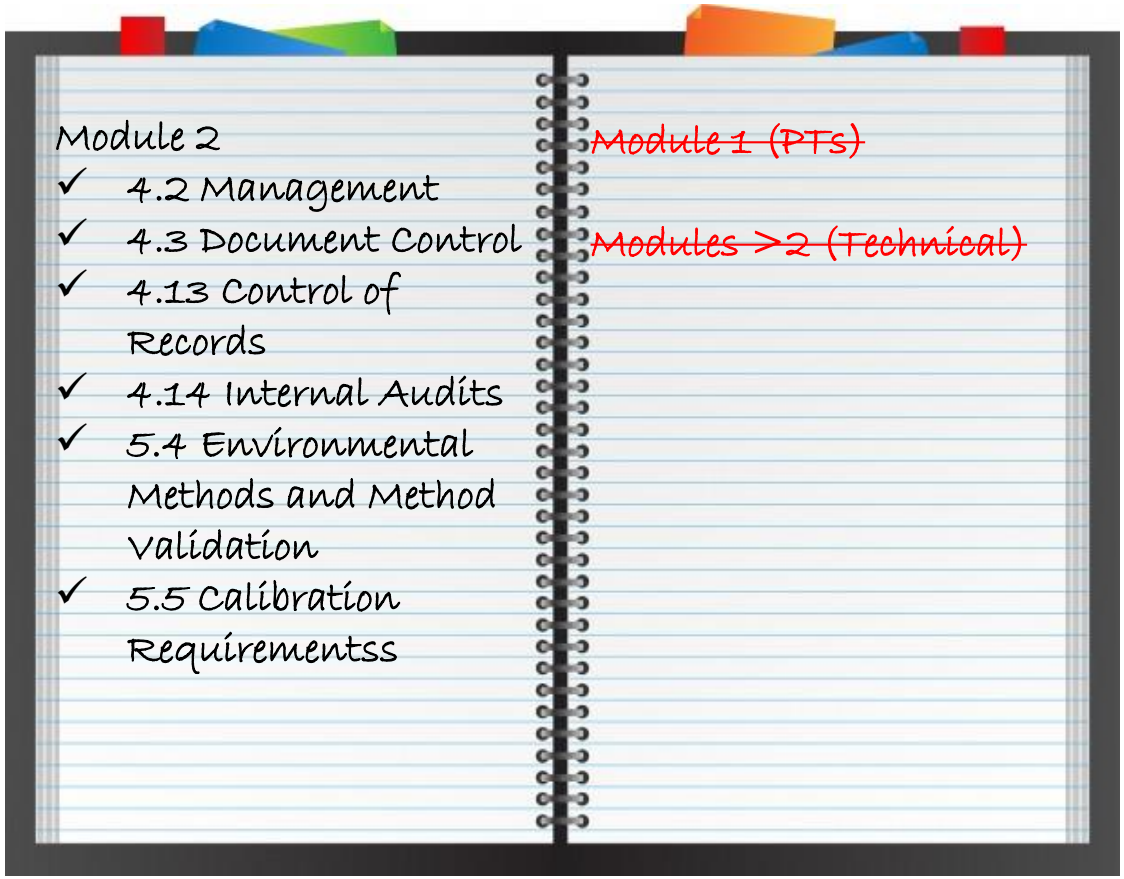
ISO/IEC 17025 accredited calibration report

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.

ISO/IEC 17025 accredited calibration report

Example Finding:
Not all calibration reports were accredited calibration reports to provide traceability that the calibration service was performed under the calibration supplier's accredited program. In addition, although the supplier was approved based on their ISO/IEC 17025 accreditation, the procurement document did not request an ISO/IEC 17025 accredited calibration.

Common Findings (TNI and DoD/DOE QSM)



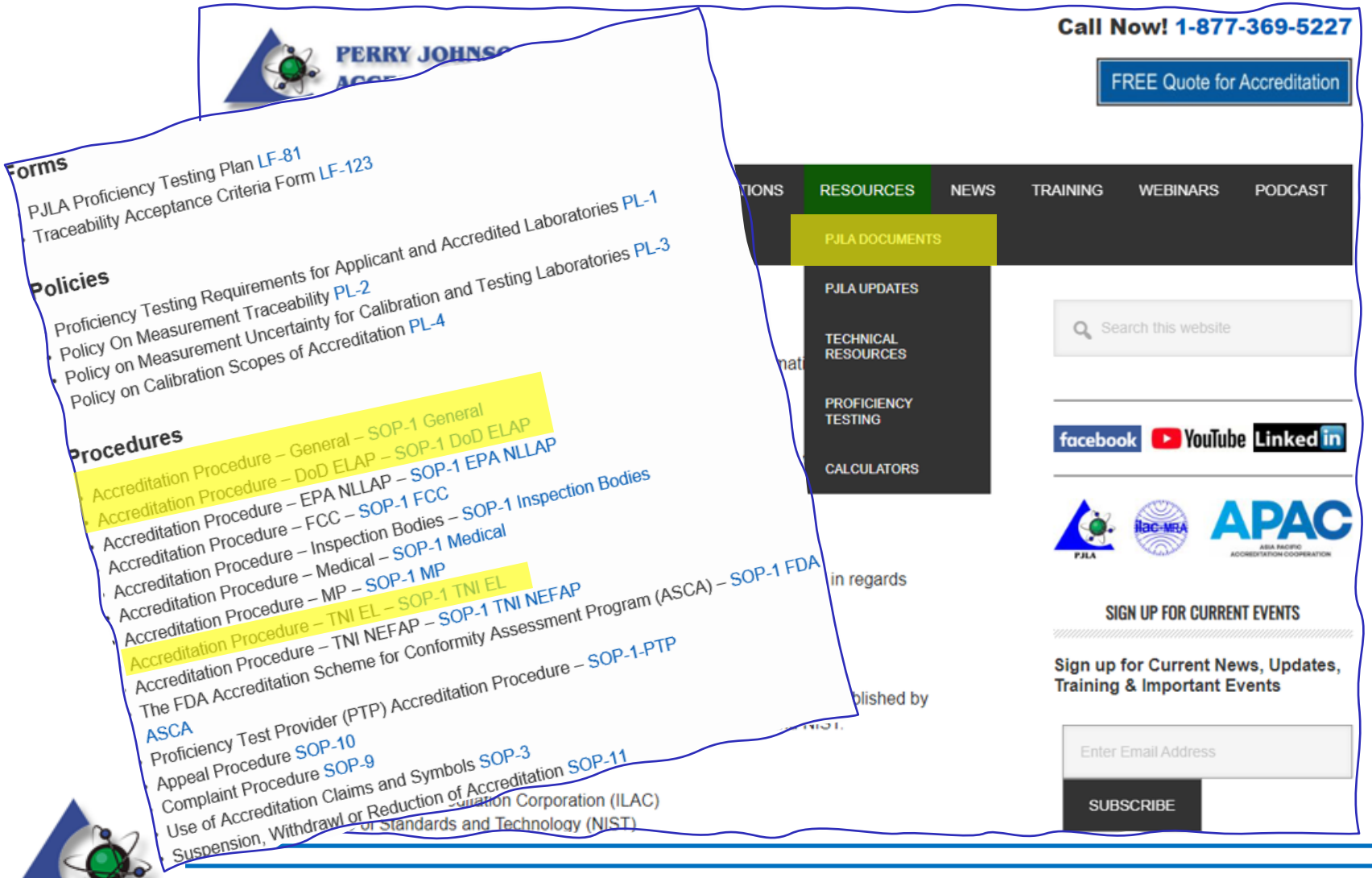
Resources (TNI and DoD/DOE QSM)

- **TNI** (http://nelac-institute.org)
  - Guidance Documents
  - TNI Standard Interpretation Requests (SIRs)
  - Training

- **DoD EDQW** (https://denix.osd.mil/edqw/home)

Resources (PJLA)

www.PJLA.com



Resources (PJLA)

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- ISO/IEC 17025:2017 and Section 8.8 on Internal Audits
- Common Findings in Assessments to the ISO/IEC 17025:2017 Standard
- more….

Time for Questions and Answers

Join us for our Next Webinar

PJLA

Thursday, June 30, 2022 – 1:00pm EST

A Look at ISO/IEC 17025:2017 – Section 6.5 Evaluation of Measurement Uncertainty “Requirements and Fundamentals”

PJLA

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Thank You!