Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2023

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Friday January 19, 2024

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- All attendees are muted.
- Feel free to utilize the questions tab and they will be answered at the end of the session.

Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2023

We have looked back at assessment done by PJLA during the 2023 calendar year and have compiled data from these assessments. This webinar will look at the sections of ISO/IEC 17025:2017 which were identified **in the top list of nonconformance's** which PJLA assessors wrote during the year.

Common Finding #10

8.8 Internal Audits

An internal audit is a formal laboratory activity that must be performed in accordance with a predetermined schedule. Laboratories may choose to conduct a full laboratory audit annually or biannually, or to audit parts of their system every month.

#10 – 8.8 Internal Audits

8.8.1 The laboratory shall conduct internal audits **at planned intervals** to provide information on whether the management system:

a) conforms to:

— the laboratory's own requirements for its management system, including the laboratory activities;

— the requirements of this document;

#10 – 8.8 Internal Audits

at planned intervals:

The internal audit needs to follow a predetermined schedule established by the laboratory. The audit will need to cover all activities over a reasonable period of time. It may be inconvenient to audit all activities in a single audit, so it can be spread over several quarterly or monthly audits. The schedule for such audits can be conveniently drawn as a matrix covering, for example, a year in which dates are set for each part of the quality system.

Audit Item	Q1	Q2	Q3	Q4
Organization	x			
Documentation		x		
Personnel			x	
Sampling				x
Equipment		x		
Methods			x	
----------				x
Many others	x			

#10 – 8.8 Internal Audits

to provide information on whether the management system:

a) conforms to:

— the laboratory's own requirements for its management system, including the laboratory activities

Words are meaningless without intent and follow through

Do as you say

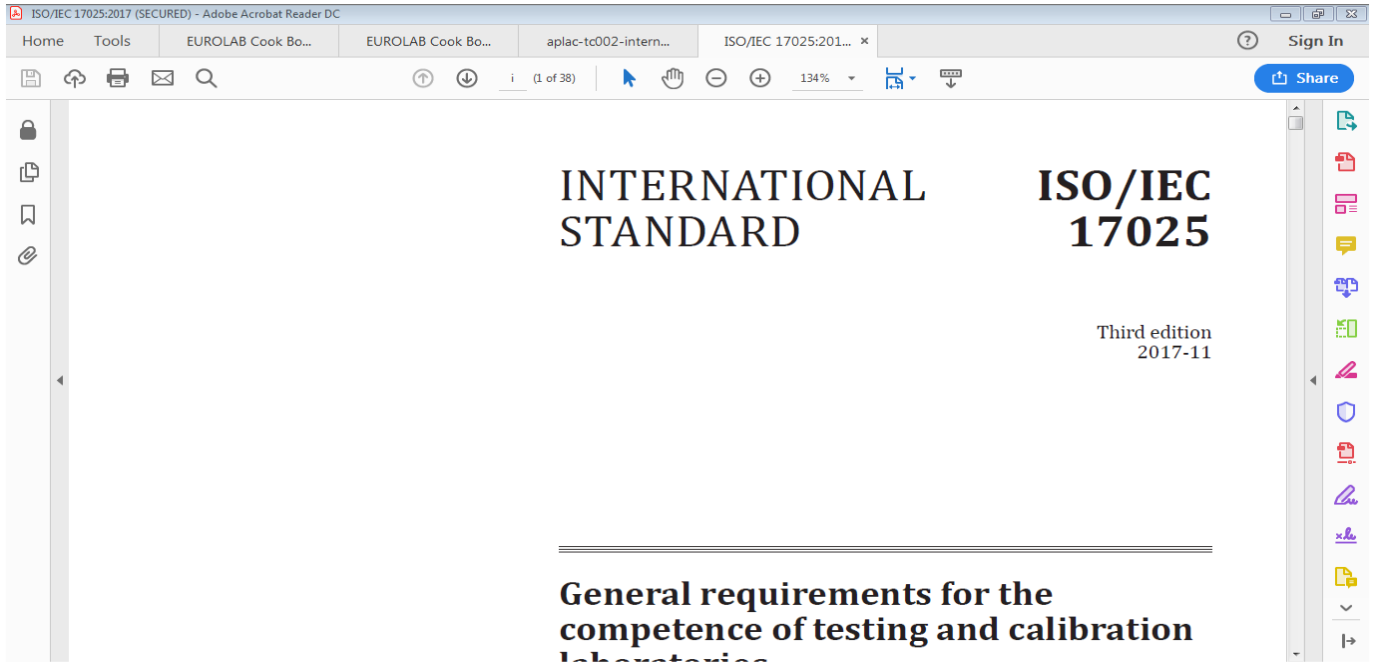
Say as you do

#10 – 8.8 Internal Audits

to provide information on whether the management system:

a) conforms to:

— the requirements of this document

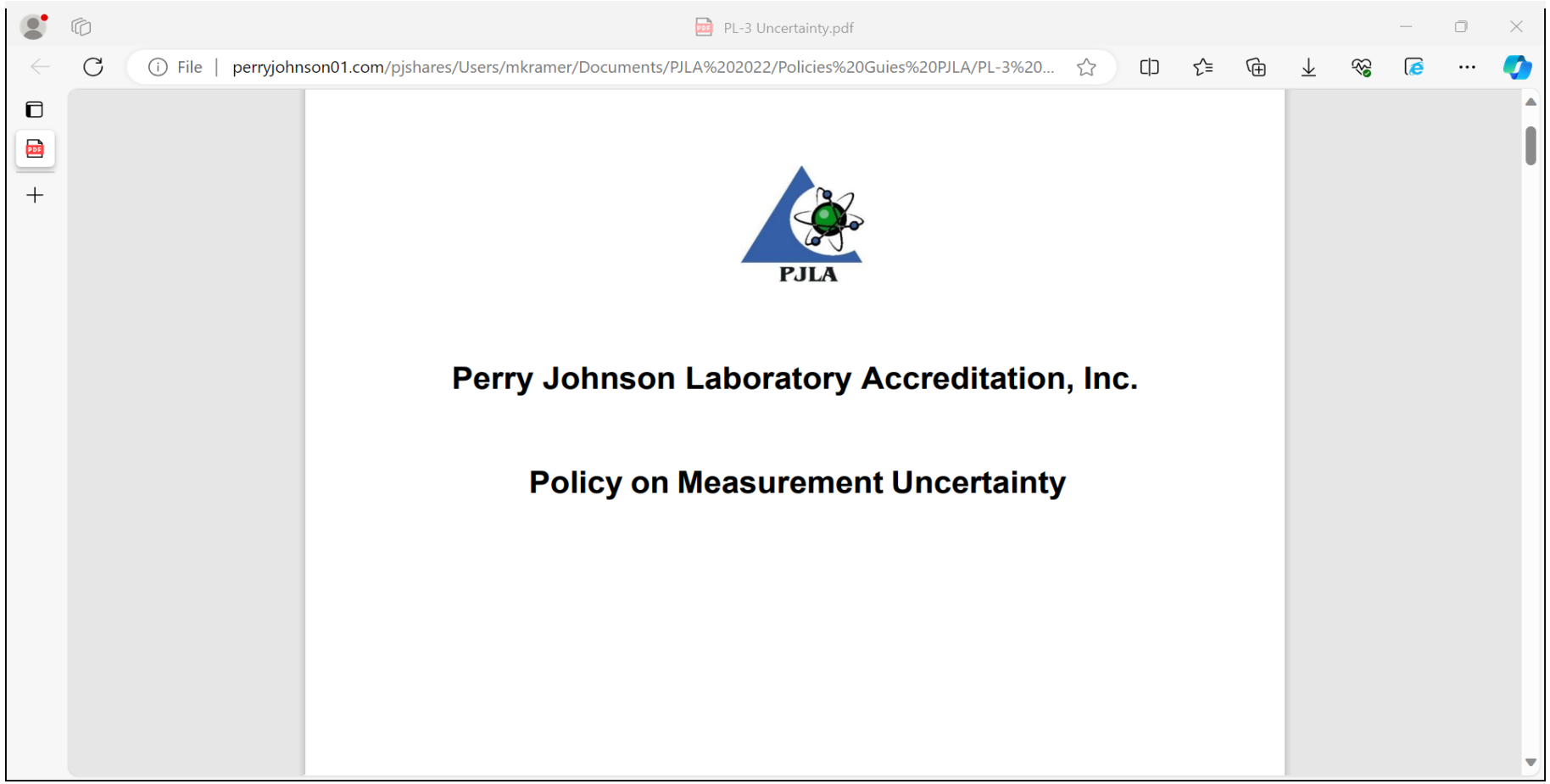


#10 – 8.8 Internal Audits

to provide information on whether the management system:

b) is effectively implemented and maintained.

Common Finding #9
PL-3 Uncertainty



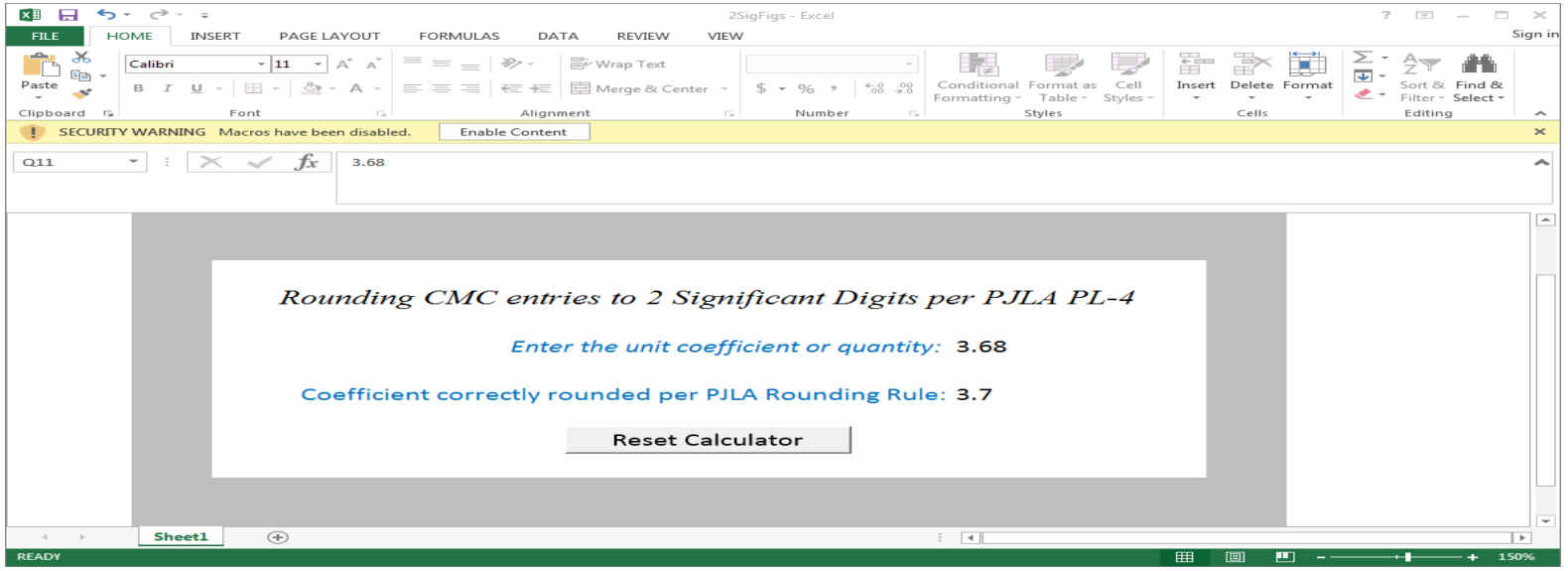
#9 - PL-3 Uncertainty

The organization must define the method by which it classifies sources as significant or insignificant. The organization shall then prepare an uncertainty budget (where applicable and appropriate) containing all relevant information related to the identified significant sources of uncertainty.

Source of Uncertainty	Value a_i	Units	Probability Distribution	Divisor	Sensitivity Coefficient c_i	Standard Uncertainty $U_i(y)$ (mm)
Calibration Uncertainty	0.01	mm	Normal (k=2)	2	1	0.005
Resolution	0.005	mm	Triangular	√6	1	0.002
Cosine error	3	deg	Rectangular	√3	0.046	0.080
Temperature	2	C	Rectangular	√3	0.0023	0.003
Repeatability	0.02	mm	Normal (k=1)	1	1	0.020
					Combined Standard Uncertainty $u_c(y)$	**0.082**
					Expanded Uncertainty (k=2, 95% confidence) U	**0.165**

#9 - PL-3 Uncertainty

As entered on the scope and uncertainty as reported on the calibration certificate, test report, or reference material certificate shall be expressed using no more than 2 significant digits and no insignificant digits.



Refer to PL-4 for additional guidance;

#9 - PL-3 Uncertainty

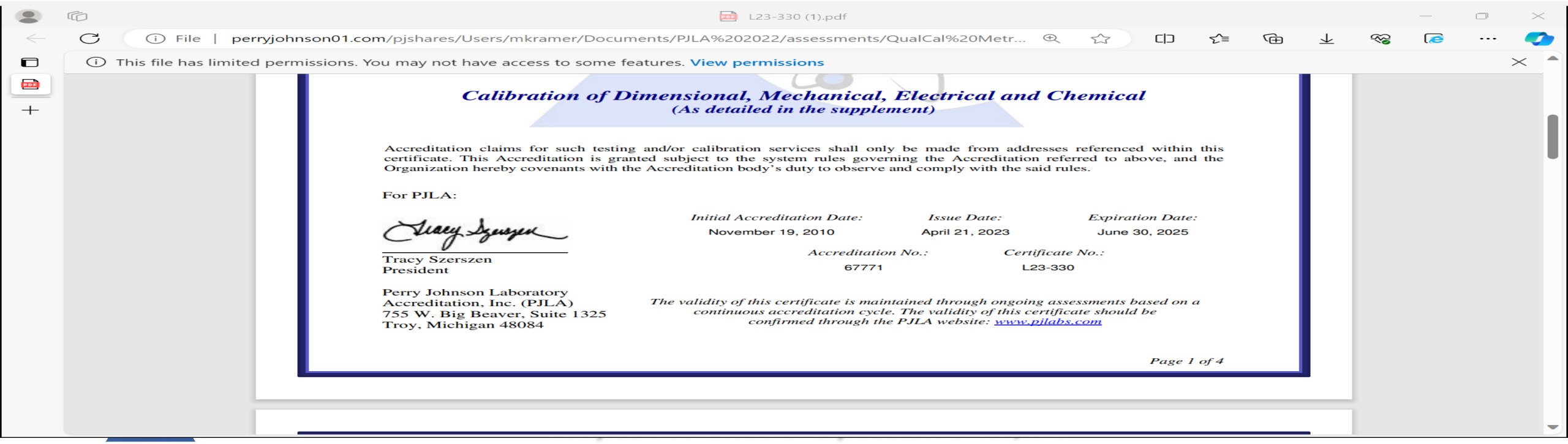
Upon achieving accreditation, the uncertainty calculations (including CMCs for calibration laboratories) and the decisions regarding sources of uncertainty shall be **periodically reviewed** and updated by the organization to **reflect changes** in the organization, its equipment, procedures or personnel that might influence the ability of the organization to perform specific calibrations or tests for which they are accredited. This information must be provided to the PJLA assessor during any assessment or to PJLA staff upon request.

Common Finding #8
6.5 Metrological Traceability

6.5.2 The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through:

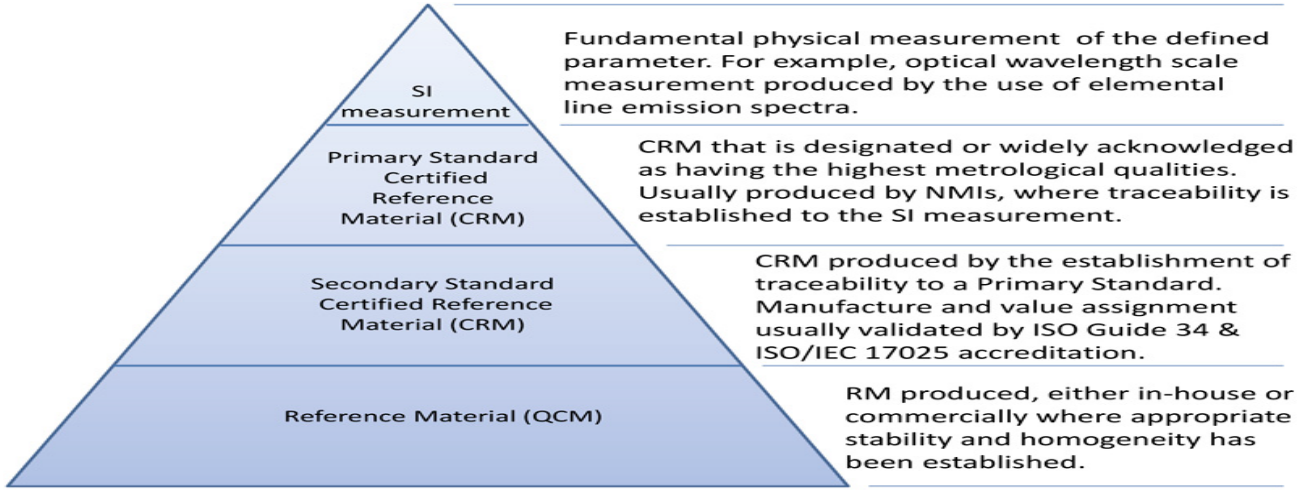
a) calibration provided by a competent laboratory; or

- NOTE 1 Laboratories fulfilling the requirements of this document are considered to be competent.



#8 - 6.5 Metrological Traceability

- **6.5.2** The laboratory shall ensure that measurement results are traceable to the International System of Units (SI) through
- **b)** certified values of certified reference materials provided by a competent producer with stated metrological traceability to the SI; or
- NOTE 2 Reference material producers fulfilling the requirements of ISO 17034 are considered to be competent.



#8 - 6.5 Metrological Traceability

Annex A “Metrological Traceability” Informative

This closely correlates to the requirements already specified in PL-2 which recognizes the use of 17025 accredited sources or producing objective evidence in regard to 6 elements of traceability;

To SI through NIST

Commercial Lab

If your organization complies with PL-2 “PJLA Policy on Traceability” you will meet the requirements of Section 6.5 of ISO/IEC 17025: 2017.

Common Finding #7
7.6 Evaluation of Measurement Uncertainty

7.6.1 Laboratories shall identify the contributions to measurement uncertainty. When evaluating measurement uncertainty, all contributions that are of significance, including those arising from sampling, shall be taken into account using appropriate methods of analysis.

Source of Uncertainty	Value a_i	Units	Probability Distribution	Divisor	Sensitivity Coefficient c_i	Standard Uncertainty $U_i(y)$ (mm)
Calibration Uncertainty	0.01	mm	Normal (k=2)	2	1	0.005
Resolution	0.005	mm	Triangular	√6	1	0.002
Cosine error	3	deg	Rectangular	√3	0.046	0.080
Temperature	2	C	Rectangular	√3	0.0023	0.003
Repeatability	0.02	mm	Normal (k=1)	1	1	0.020
					Combined Standard Uncertainty $u_c(y)$	0.082
					Expanded Uncertainty (k=2, 95% confidence) U	0.165

Sounds a lot like an uncertainty budget referenced in PL-3.

#7 - 7.6 Evaluation of Measurement Uncertainty

7.6.3 A laboratory performing testing shall **evaluate** measurement uncertainty. Where the test method precludes rigorous evaluation of measurement uncertainty, an **estimation** shall be made based on an understanding of the theoretical principles or practical experience of the performance of the method.

Notes are provided in Standard for guidance.

Test labs cannot ignore and will need to address.

NOTE 1 In those cases where a well-recognized test method specifies limits to the values of the major sources of measurement uncertainty and specifies the form of presentation of the calculated results, the laboratory is considered to have satisfied 7.6.3 by following the test method and reporting instructions.

NOTE 2 For a particular method where the measurement uncertainty of the results has been established and verified, there is no need to evaluate measurement uncertainty for each result if the laboratory can demonstrate that the identified critical influencing factors are under control.

Common Finding #6
8.3 Control of Management System Documents

Document Control can be looked at as controlled processes and practices for the creation, review, modification, issuance, distribution and accessibility of documents.

A document is anything that tells a person in the laboratory “what to do” or “how to do it”

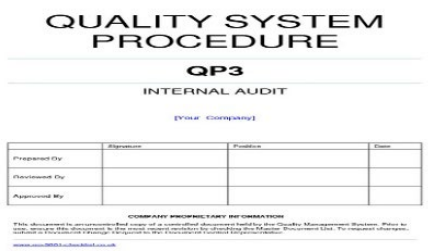
As noted in ISO/IEC 17025:2017: NOTE In this context, “documents” can be policy statements, procedures, specifications, manufacturer’s instructions, calibration tables, charts, textbooks, posters, notices, memoranda, drawings, plans, etc. These can be on various media, such as hard copy or digital.

Software? 7.11 Control of data and information management

#6 - 8.3 Control of Management System Documents

8.3.1 The laboratory shall control the documents (internal and **external**) that relate to the fulfilment of this document

internal

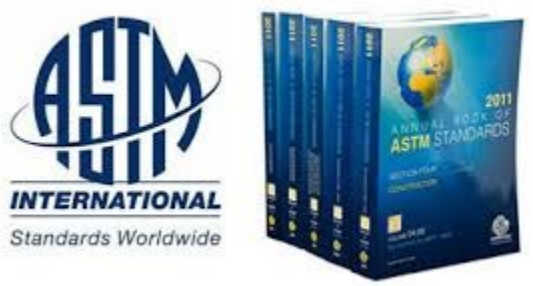

QUALITY SYSTEM PROCEDURE

QP3

INTERNAL AUDIT

[Your Company]

external



Procedure or a master documents list is not required however can be used to assure documents are being controlled appropriately.

#6 - 8.3 Control of Management System Documents

8.3.2 The laboratory shall ensure that:

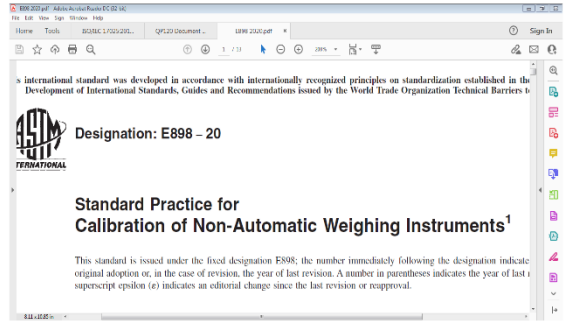
b) documents are periodically reviewed, and updated as necessary;

Internal documents need to reflect what the laboratory is actually doing;

Example: ABC organization shall back up electronic data daily using an external hard drive which is kept in a fireproof safe in the Quality Managers office.

Does it reflect what is being done to maintain compliance?

External documents should be the latest;

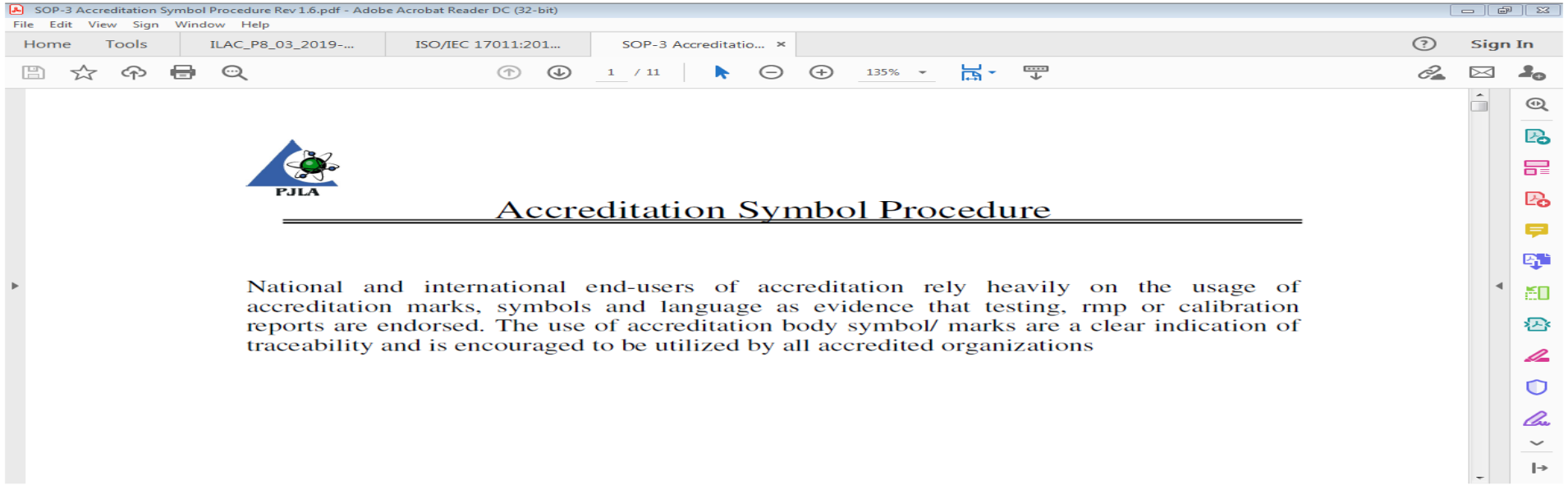

Designation: E898 – 20

Standard Practice for
Calibration of Non-Automatic Weighing Instruments[1]

Input for management review – 8.9.2c - suitability of policies and procedures;

Common Finding #5
SOP 3 & The Use of Accreditation Symbols and References to Accreditation

PJLA has SOP 3 which is written in harmony with those requirements specified in ISO/IEC 17011 & ILAC P8.



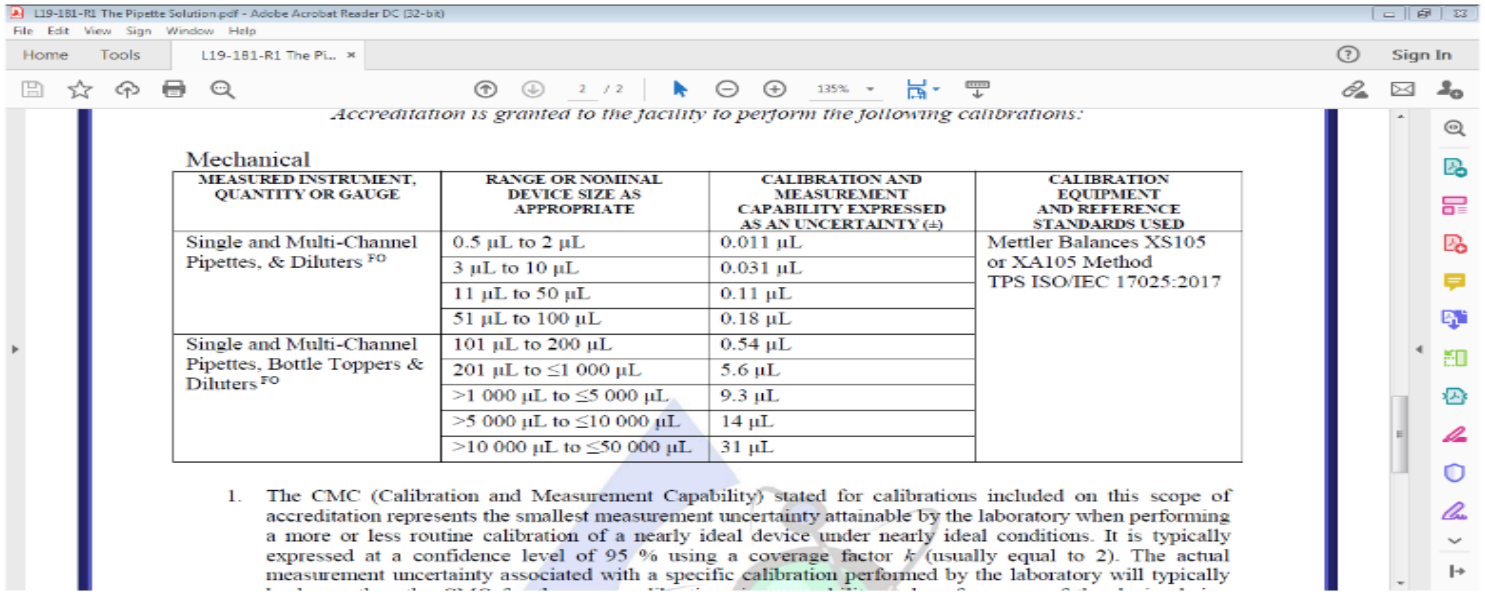
#5 - SOP 3

The use of accreditation symbol(s) or references to accreditation is voluntary. However, when accredited organizations intend to issue an accredited/endorsed report to their customers they shall include the appropriate references to their accreditation and/or using the PJLA accreditation symbol or language as described SOP 3.

Any misuse of the PJLA accreditation symbol, ILAC MRA Mark, or any other governed mark as mentioned in SOP 3 are treated very seriously and handled through PJLA's corrective action process.

#5 - SOP 3

Symbols or references to accreditation **shall only be associated with the services covered in the scope of accreditation, and not with any other activities in which the accredited organization may be involved.**



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Accreditation is granted to the facility to perform the following calibrations:

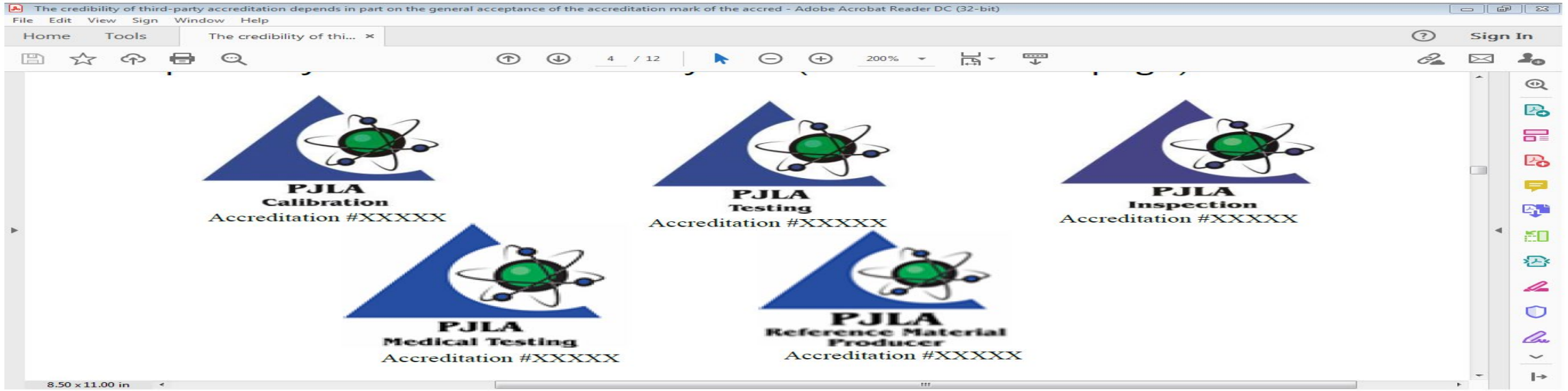
Mechanical

MEASURED INSTRUMENT, QUANTITY OR GAUGE	RANGE OR NOMINAL DEVICE SIZE AS APPROPRIATE	CALIBRATION AND MEASUREMENT CAPABILITY EXPRESSED AS AN UNCERTAINTY (±)	CALIBRATION EQUIPMENT AND REFERENCE STANDARDS USED
Single and Multi-Channel Pipettes, & Diluters [FO]	0.5 µL to 2 µL	0.011 µL	Mettler Balances XS105 or XA105 Method TPS ISO/IEC 17025:2017
	3 µL to 10 µL	0.031 µL	
	11 µL to 50 µL	0.11 µL	
	51 µL to 100 µL	0.18 µL	
Single and Multi-Channel Pipettes, Bottle Toppers & Diluters [FO]	101 µL to 200 µL	0.54 µL	
	201 µL to ≤1 000 µL	5.6 µL	
	>1 000 µL to ≤5 000 µL	9.3 µL	
	>5 000 µL to ≤10 000 µL	14 µL	
	>10 000 µL to ≤50 000 µL	31 µL	

1. The CMC (Calibration and Measurement Capability) stated for calibrations included on this scope of accreditation represents the smallest measurement uncertainty attainable by the laboratory when performing a more or less routine calibration of a nearly ideal device under nearly ideal conditions. It is typically expressed at a confidence level of 95 % using a coverage factor k (usually equal to 2). The actual measurement uncertainty associated with a specific calibration performed by the laboratory will typically

#5 - SOP 3

The authorized symbol or reference to accreditation shall be clearly identified with the unique accreditation number assigned by PJLA to the accredited organization. PJLA prefers accredited organizations to include the accreditation number as shown below. If and organizations desires to include the accreditation number in a different area, then they shall ensure that it is placed within close proximity of the accreditation symbol (i.e., on the same page).



#5 - SOP 3

In the case the (CAB) decides **not** to utilize the accreditation symbol and chooses to only reference their accreditation on calibration, test (including medical), RMP, inspection, Proficiency Testing reports, then they shall ensure the following information is included:

1) The Standard Accredited to: (i.e., ISO/IEC 17025:2017, ISO/IEC 17020: 2012, ISO 17034:2016, ISO 15189:2012 , ISO/IEC 17043:2010)

2) PJLA

3) Accreditation #XXXXX

4) Accreditation field i.e., Calibration/Testing/Medical/Reference Material Producer, Inspection Body, Proficiency Testing Provider, Field Sampling and Measurement Organization (FSMO)

#5 - SOP 3

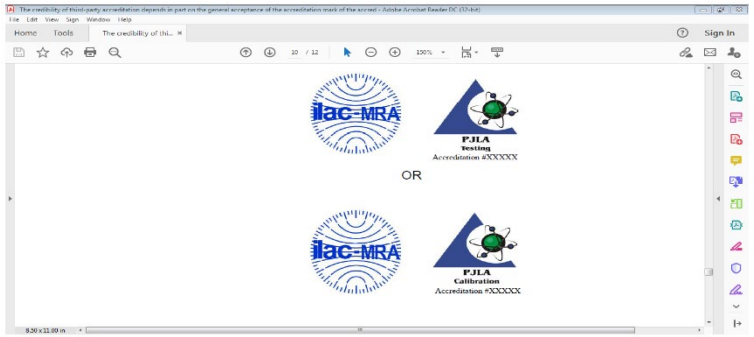
Acceptable

- ABC Laboratory is accredited to the ISO/IEC 17025:2017 standard
- ISO/IEC 17025:2017 Accredited
- Accredited to ISO/IEC 17025:2017
- Accredited to ISO 17034:2016
- Accredited to ISO/IEC 17020:2012
- Accredited to ISO 15189:2012

Unacceptable

- ISO 17025 Accredited
- 17025/9001
- ISO/IEC 17025:2017 Registered

#5 - SOP 3



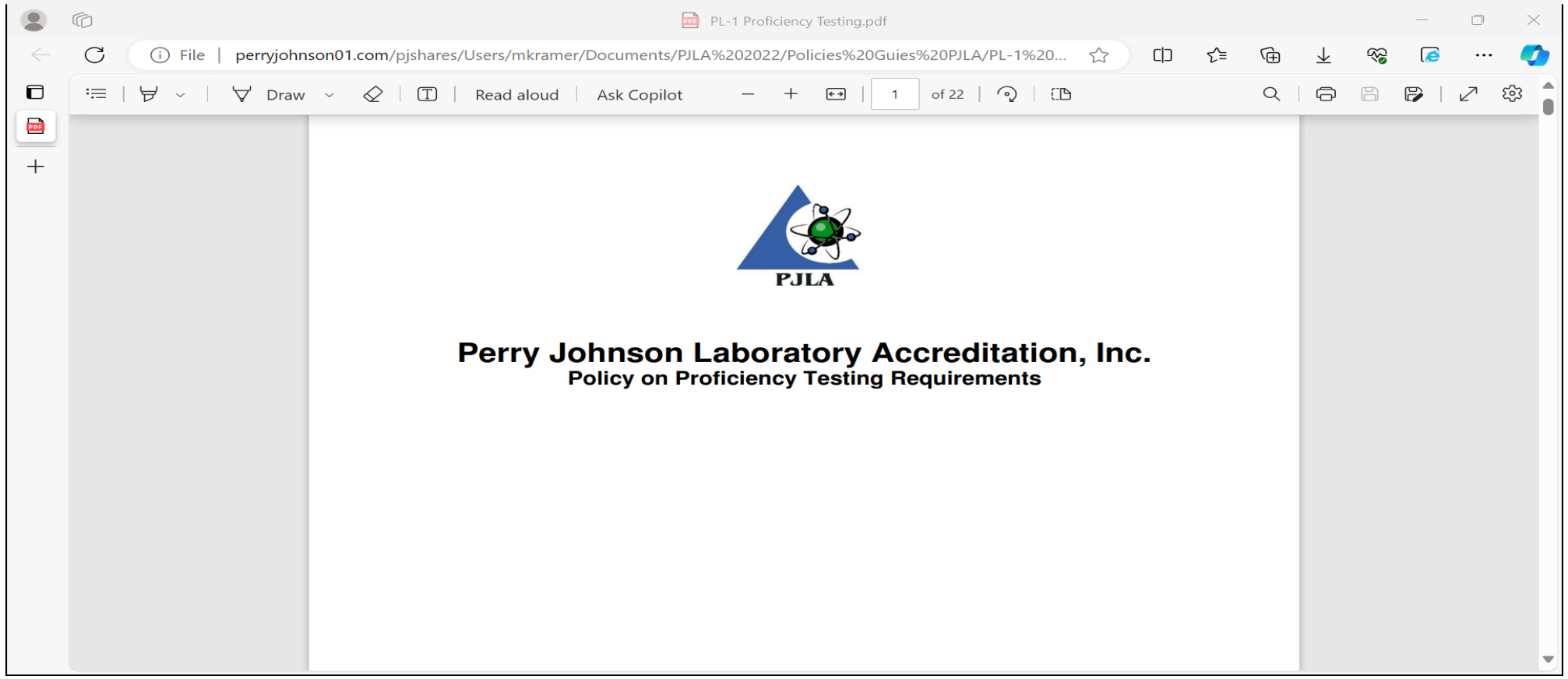
PJLA allows the use of the ILAC MRA Mark in combination with the PJLA accreditation symbol to promote international recognition of the ILAC MRA and the accredited services covered under the international agreement.

The joint ILAC MRA Mark may only be used under the following conditions:

1) The ILAC Combined MRA Mark Agreement has been signed between PJLA and the accredited CAB.

2) A draft of the use of this combined mark has been approved by PJLA.

Common Finding #4
PL-1 “Proficiency Testing”



#4 - PL-1 “Proficiency Testing”

3.1 Prior to accreditation by PJLA, an applicant organization must provide objective evidence of proficiency testing activity for at least one item included in its desired scope of accreditation.

4.1 Upon achieving accreditation by PJLA, organizations are required to perform proficiency testing **annually**.

From ISO/IEC 17025:2017:

7.7.3 Data from monitoring activities shall be analyzed, used to control and, if applicable, improve the laboratory's activities. If the results of the analysis of data from monitoring activities are found to be outside pre-defined criteria, appropriate action shall be taken to prevent incorrect results from being reported

#4 - PL-1 “Proficiency Testing”

The following activities (listed in their order of preference and acceptability) have been approved by PJLA for the purpose of demonstrating proficiency:

a) participation in proficiency testing programs sponsored by a third-party accredited provider

b) participation in proficiency testing programs sponsored by a third-party provider)

c) inter laboratory comparisons.

#4 - PL-1 “Proficiency Testing”

When use of the above approved methods is considered by the organization as being impractical as a means of demonstrating proficiency the following activities (listed in their order of preference) may be used pending prior approval by PJLA:

a) intra laboratory comparisons

b) repeatability studies

Note - If an organization wishes to proceed with one of the above-mentioned means, they must state in writing why third party or inter laboratory comparisons are not feasible and how they plan to conduct the test and analyze the data. . This document shall be submitted to PJLA headquarters for review and approval

From ISO/IEC 17025:2017

7.7.2 The laboratory shall monitor its performance by comparison with results of other laboratories, where available and appropriate.

Common Finding #3
7.8 Reporting of Results

This section covers all three areas of ISO/IEC 17025: 2017 which includes testing, calibration, and sampling.

7.8.1 General – review and authorize prior to release

7.8.2 Common requirements for reports (test, calibration & sampling)

7.8.3 Specific requirements for test reports

7.8.4 Specific requirements for calibration certificates

7.8.5 Specific requirements for reporting sampling

7.8.6 Reporting statements of conformity

7.8.7 Reporting opinions and interpretations

7.8.8 Amendments to report

#3 - 7.8 Reporting of Results

7.8.2.1 Each report shall include at least the following information, **unless the laboratory has valid reasons for not doing so**, thereby minimizing any possibility of misunderstanding or misuse: **a**) a title (e.g. "Test Report", **b)** the name and address of the laboratory; **c)** the location of performance of the laboratory activities, **d)** unique identification **e)** the name and contact information of the customer; **f)** identification of the method used; **g)** a description, unambiguous identification, and, when necessary, the condition of the item; **h)** the date of receipt of the test or calibration item(s), and the date of sampling, where this is critical to the validity and application of the results; **i)** the date(s) of performance of the laboratory activity; j) the date of issue of the report; **k)** reference to the sampling plan and sampling method used by the laboratory or other bodies where these are relevant to the validity or application of the results; **l)** a statement to the effect that the results relate only to the items tested, calibrated or sampled; **m)** the results with, where appropriate, the units of measurement; **n)** additions to, deviations, or exclusions from the method; **o)** identification of the person(s) authorizing the report; **p)** clear identification when results are from external provider.

#3 - 7.8 Reporting of Results

7.8.3.1 In addition to the requirements listed in 7.8.2, test reports shall, **where necessary for the interpretation of the test** results, include the following:

a) information on specific test conditions, such as environmental conditions;

b) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

c) **where applicable**, the measurement uncertainty presented in the same unit as that of the measured or in a term relative to the measured (e.g. percent) when:

— it is relevant to the validity or application of the test results;

— a customer's instruction so requires, or

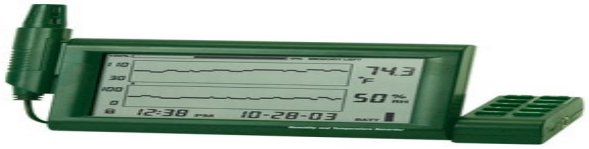
— the measurement uncertainty affects conformity to a specification limit

#3 - 7.8 Reporting of Results

7.8.4.1 In addition to the requirements listed in 7.8.2, calibration certificates **shall** include the following:

a) the measurement uncertainty of the measurement result presented in the same unit as that of the measurand or in a term relative to the measurand (e.g. percent);

b) the conditions (e.g. environmental) under which the calibrations were made that have an influence on the measurement results;



#3 - 7.8 Reporting of Results

7.8.6 Reporting statements of conformity

7.8.6.1 When a statement of conformity to a specification or standard is provided, the laboratory shall document the **decision rule** employed, taking into account the level of risk (such as false accept and false reject and statistical assumptions) associated with the decision rule employed, and apply the decision rule.

As defined in ISO/IEC 17025:2017

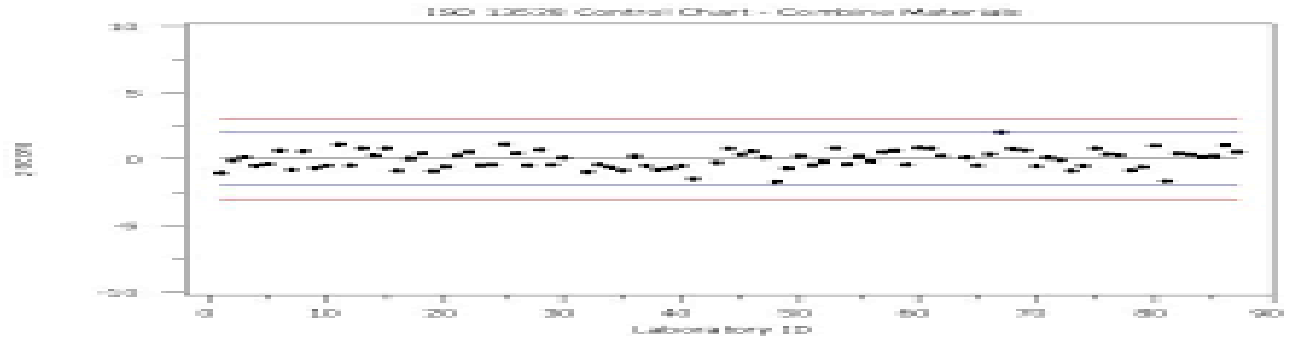
Decision rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.

#3 - 7.8 Reporting of Results

6.4.1 The laboratory shall have access to equipment (including, but not limited to, measuring instruments, software, measurement standards, reference materials, reference data, reagents, consumables or auxiliary apparatus) that is required for the correct performance of laboratory activities and that can influence the results.

Common Finding #2
Section 6.4 Equipment

6.4.4 The laboratory shall verify that equipment conforms to specified requirements before being placed or returned into service.



6.4.5 The equipment used for measurement shall be capable of achieving the measurement accuracy and/or measurement uncertainty required to provide a valid result.

#2 - Section 6.4 Equipment

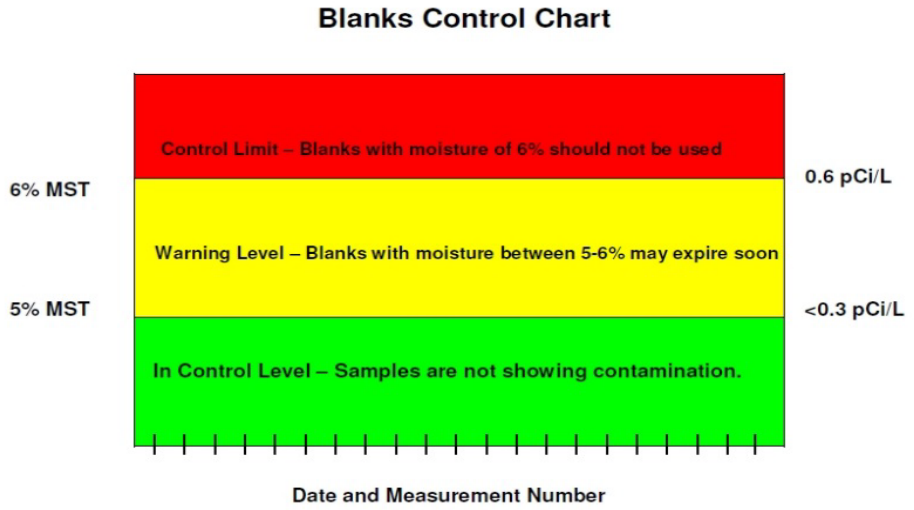
6.4.6 Measuring equipment shall be calibrated when

— the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or;

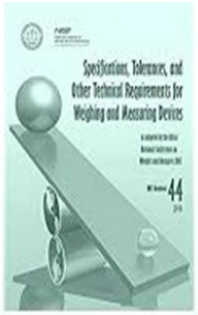
— calibration of the equipment is required to establish the metrological traceability of the reported results.

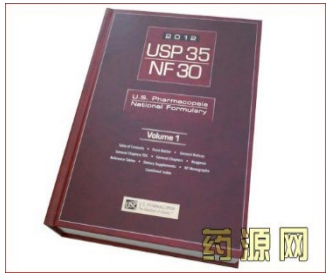
#2 - Section 6.4 Equipment

6.4.10 When intermediate checks are necessary to maintain confidence in the performance of the equipment, these checks shall be carried out according to a procedure.



Common Finding #1
7.2 Selection, Verification and Validation of Methods





7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

#1 - 7.2 Selection, Verification, and Validation of Methods

7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

Should be brought to light during the management review and compliance with,

8.9.2 The inputs to management review shall be recorded and shall include information related to the following:

c) suitability of policies and procedures;

#1 - 7.2 Selection, Verification, and Validation of Methods

7.2.1.5 The laboratory shall verify that it can properly perform methods before introducing them by ensuring that it can achieve the required performance. **Records of the verification shall be retained**. If the method is revised by the issuing body, verification shall be repeated to the extent necessary.

Records may consist of :

Compare to a known reference value, PT with other lab, Intra Lab with repeatability check and En analysis.

#1 - 7.2 Selection, Verification, and Validation of Methods

7.2.2.1 *The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.*

7.2.2.4 The laboratory shall retain the following records of validation:

a) the validation procedure used;

b) specification of the requirements

c) determination of the performance characteristics of the method;

d) results obtained;

e) a statement on the validity of the method, detailing its fitness for the intended use.

Common Findings 2023

This time is allocated for questions. You should have a space provided for submitting questions.

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If a question is not answered, please submit directly to pjlabs@pjlabs.com

VIRTUAL (LIVE) TRAINING COURSE

This ISO/IEC 17025:2017 Overview Course will be taught as a LIVE virtual course by Technical Program Manager, Matthew Sica.

Course Dates:

- February 6-7, 2024
- May 21-22, 2024
- August 20-21, 2024

Cost:

$500.00 per attendee

The Course Includes:

- A full overview of the standard requirements
- Simple & user-friendly implementation techniques
- Case studies & exercises focusing on common laboratory findings and troublesome areas