# Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2021


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24-January-2022

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# Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2021

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

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# Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2021

We have looked back at assessment done by PJLA during the 2021calencar 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.


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# Common Findings 2021 #10

## 8.3 Control of management system documents

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

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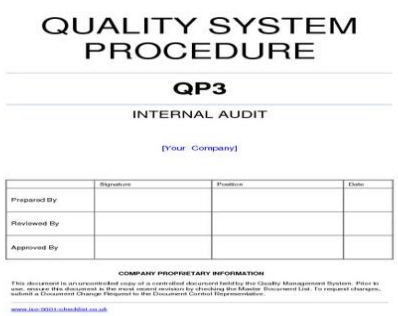
# #10 8.3 Control of management system documents

**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

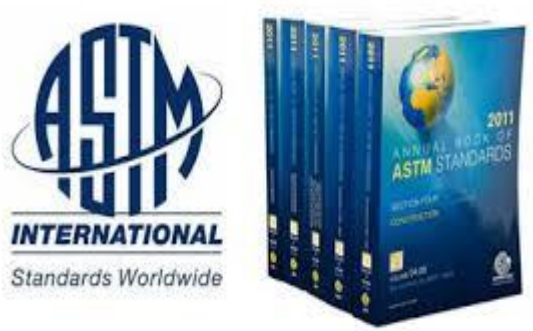
INTERNAL AUDIT

[Your Company]

| | Signature | Position | Date |
|---|---|---|---|
| Prepared By | | | |
| Reviewed By | | | |
| Approved By | | | |

COMPANY PROPRIETARY INFORMATION

External

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# #10 8.3 Control of management system document

This can still me accomplished through the utilization of a master list (no longer required)

**Master Document List**

Register Document

| No. | Doc. No. | Doc. Title | Revision | Doc. Type | Department | Create Date | Owner Name | File |
|---|---|---|---|---|---|---|---|---|
| 1 | DocCon003 | Testing Verification | 1 | QM | Marketing | 07-Oct-2006 | Dev Anand Balan | View |
| 2 | Doccon001 | New procedures | 1 | QM | Marketing | 07-Oct-2006 | Dev Anand Balan | View |
| 3 | F-02 | QUALITY RECORDS TABLE | 1 | Forms | Department 4 | 08-Aug-2005 | Dev Anand Balan | View |
| 4 | FORM-03 | TRAINING ACTION PLAN | 1 | Forms | Department 4 | 08-Aug-2005 | Dev Anand Balan | View |
| 5 | QM-01 | Quality System Manual | 1 | QM | Department 4 | 08-Aug-2005 | Dev Anand Balan | View |
| 6 | QM-04 | Management Responsibilty | 1 | QM | Marketing | 22-Aug-2005 | Dev Anand Balan | View |
| 7 | SOP-01 | 2. Document Control | 1 | SOP | Department 4 | 05-Aug-2005 | Dev Anand Balan | View |
| 8 | SOP-03 | DOCUMENT CONTROL | 1 | SOP | Department 4 | 08-Aug-2005 | Dev Anand Balan | View |
| 9 | f-01 | Design Plan | 1 | QM | Marketing | 05-Aug-2005 | Dev Anand Balan | View |
| 10 | qa011 | title | 1 | QM | Marketing | 05-Aug-2005 | Sally Sally | View |

However it can also be accomplished through a sophisticated electronic document control system which links the entire quality management system together electrically.

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# #10 8.3 Control of management system document

**8.3.2** The laboratory shall ensure that:

a) documents are approved for adequacy prior to issue by authorized personnel

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

c) changes and the current revision status of documents are identified;

d) relevant versions of applicable documents are available at points of use and, where necessary, their distribution is controlled;

e) documents are uniquely identified;

f) the unintended use of obsolete documents is prevented, and suitable identification is applied to them if they are retained for any purpose


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# #10 8.3 Control of management system document

## Example of Nonconformance Written

**Finding -** The CAB has proven not to effectively control the documents related to the fulfilment of the standard. It is evident that documents have not been reviewed and updated as necessary. The master document list provided has not been kept up to date.

**Objective Evidence –** During the assessment, three separate documents were submitted that all contained sections addressing the same requirements of the standard in different and sometimes contradicting ways.

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# Common Findings 2021 #9

## ISO/IEC 17025:2017

## Section 8.9 Management Review Requirements


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# # 9 Section 8.9 Management Review Requirements

**8.9.1** The laboratory management shall review its management system at **planned intervals**, in order to ensure its continuing suitability, adequacy and effectiveness, including the stated policies and objectives related to the fulfilment of this document;

Make sure they get completed in accordance to the planned interval;



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# # 9 Section 8.9 Management Review Requirements

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

a) changes in internal and external issues that are relevant to the laboratory;

**b)** fulfilment of objectives; **c)** suitability of policies and procedures;

**d)** status of actions from previous management reviews;

**e)** outcome of recent internal audits; **f)** corrective actions;

**g)** assessments by external bodies; **h)** changes in the volume and type of the work or in the range of laboratory activities; **i)** customer and personnel feedback; **j)**complaints; **k)** effectiveness of any implemented improvements

**l)** adequacy of resources; **m)** results of risk identification; **n)** outcomes of the assurance of the validity of results; and **o)** other relevant factors, such as monitoring activities and training.

**8.9.3** The outputs from the management review **shall record** all decisions and actions related to at least: **a)** the effectiveness of the management system and its processes; b) improvement of the laboratory activities related to the fulfilment of the requirements of this document;c) provision of required resources; d) any need for change.

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# # 9 Section 8.9 Management Review Requirements

In preparation of the meeting and to assure the inputs and outputs requirements are captured an agenda containing  those required elements can be prepared;


For compliance for ISO/IEC 17025:2017 you can always do more however those required inputs and outputs must be included.

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# # 9 Section 8.9 Management Review Requirements

Example of Nonconformance Written

**Finding -** The CAB did not discuss applicable outputs during the management review process.

**Objective Evidence –**The records submitted for management reviews dated 8-August-2021 included bullet by bullet evidence of the discussion of required inputs to management review, but did not include any recorded evidence of discussing relevant outputs.

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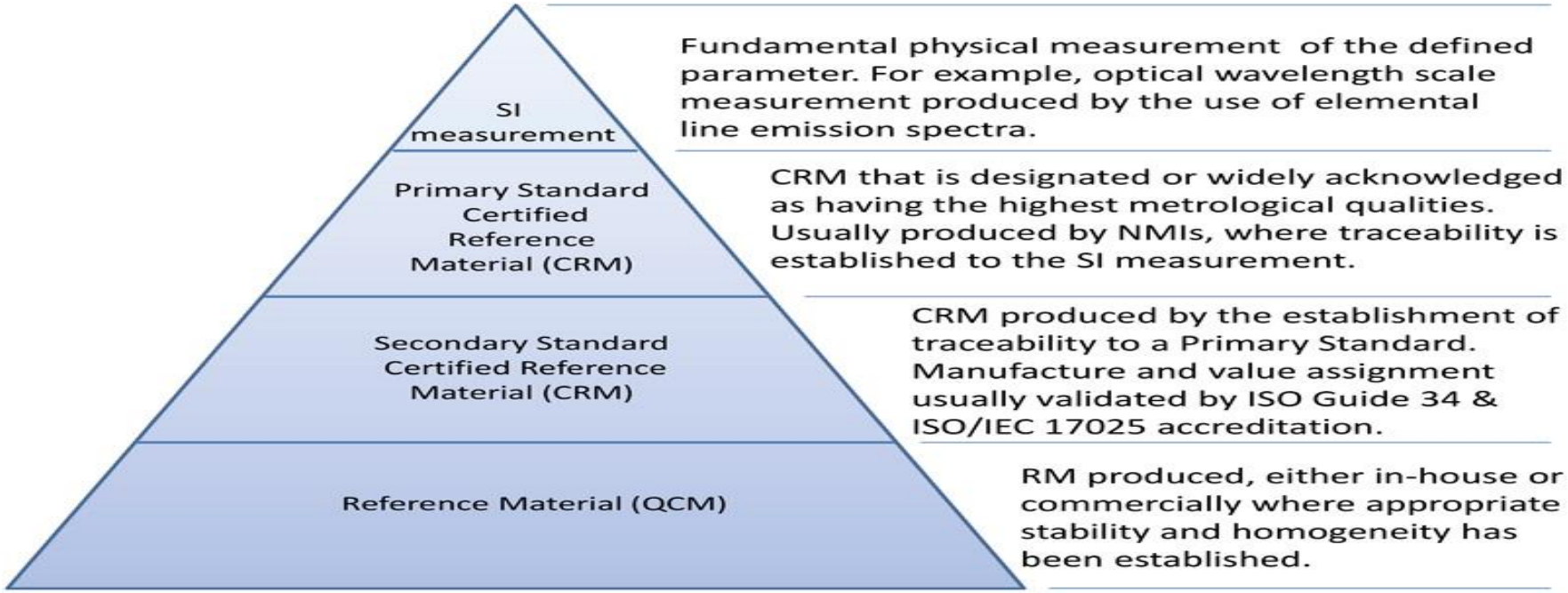
# Common Findings 2021 #8

## 6.5 Metrological traceability

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# # 8 Section 6.5 Metrological Traceability

In Annex A, possibilities have been included on how to establish and demonstrate traceability:

- through the use of a NMI
- accredited calibration laboratory
- reference material producers conforming to ISO 17034




- **Accreditation# XXXXX**

# # 8 Section 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.

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.

c) direct realization of the SI units ensured by comparison,

directly or indirectly, with national or international standards.

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# # 8 Section 6.5 Metrological Traceability

## PL-2 “PJLA Policy on Measurement Traceability

Use of non-accredited external calibration providers and NMI’s not recognized by the CIPM MRA will be approved on a case-by-case basis.

Copies of all documents and records associated with the organizations verification shall be submitted to PJLA headquarters along with a completed copy of PJLA form LF-123 (available upon request from PJLA headquarters) summarizing the evidence that the non-accredited external calibration provider is capable of producing traceable results.

*The LF 123 utilizes The six common elements for all valid statements or claims of traceability (taken from NIST website)*

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# # 8 Section 6.5 Metrological Traceability

Example of Nonconformance Written

Finding: Equipment used for Gas Flow calibrations are not supported with traceable calibration certificates.

Objective Evidence: Current report from Roots Meter 56,000 CFH and Bronkhorst standards are not supported by a traceable calibration.

Finding - . Environmental monitoring devices are being utilized however not supported by a traceable calibration.

Objective Evidence – Unable to produce report of calibration for environmental monitoring equipment.

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# Common Findings 2021 #7

ISO/IEC 17025:2017 Section 6.2 “Personnel”


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# # 7 Section 6.2 “Personnel”

**6.2.5** The laboratory shall have procedure(s) and retain records for:

*An assessor would expect to see a **procedure** - How it is done And a **record** – What was done*

a) determining the competence requirements;

-Job descriptions/postings (evidence of determination of competency)

b) selection of personnel;

-posting, interview notes, competency cross reference

c) training of personnel;

-Training attendance and agendas (evidence that competency was met

d) supervision of personnel;

-Training Record

e) authorization of personnel;

*This can be an authorization matrix or training record sign off*

continued

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# # 7 Section 6.2 “Personnel”

**6.2.5** The laboratory shall have procedure(s) and retain records for

f) monitoring competence of personnel. new

*Laboratory will need to specify how it is done and records maintained showing it was done. This can utilize such vehicles as checking personnel’s data and reports, or participation in inter lab or intra lab testing.*

*This section covers All personnel of the laboratory, either internal or external, that could influence the laboratory activities This would include internal auditors, purchasing, maintenance and contracted personnel;*



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# # 7 Section 6.2 “Personnel”

**6.2.6** The laboratory shall authorize personnel to perform specific laboratory activities, including but not limited to, the following:

a) development, modification, verification and validation of methods;

b) analysis of results, including statements of conformity or opinions and interpretations;

**c) report, review and authorization of results**.

- *Can be an expanded matrix  to Incorporate these authorizations.*

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# # 7 Section 6.2 “Personnel”

Example of Nonconformance Written

**Finding -** The authorization to perform calibrations under ABC Scale scope of accreditation is not being captured

**Objective Evidence** – Reports for calibrations performed for on 12/9/21 indicates that bench, floor and vehicle scales were calibrated by John Doe however a record of these authorizations to perform these calibrations were not produced as requested.

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# Common Findings # 6

Section 8.8 “Internal Audit”


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# #6 Section 8.8 Internal Audit

**8.8.2** The laboratory shall:

b) define the audit criteria and scope for each audit;

Example: Internal audit conducted against the requirements of ISO/IEC 17025:2017, PJLA Policies, and ABC company quality management system and incorporates these requirements with laboratory operations at ABC calibration/testing laboratories


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# #6 Section 8.8 Internal Audit

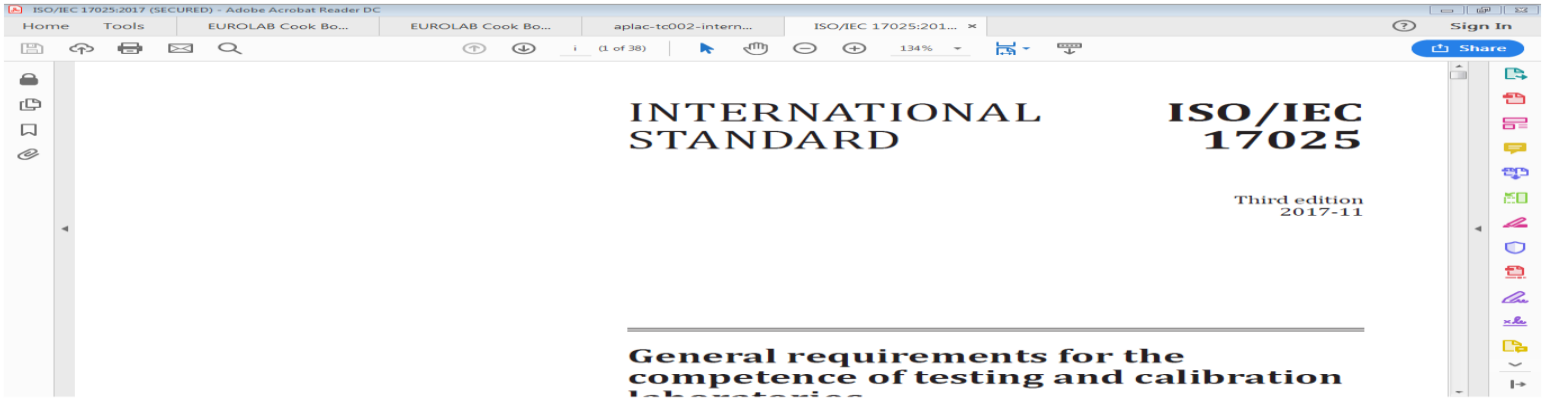
**8.8.1** The laboratory shall conduct internal audits **at planned intervals** to provide information on whether the management system:

a) conforms to:

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

*Words are meaningless without intent and follow through*


— the **requirements of this document**

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# #6 Section 8.8 Internal Audit

Example of Nonconformance Written

**Finding -** Internal audit submitted does not support that all applicable requirements in ISO/IEC 17025:2017 were audited.

**Objective Evidence** – Internal audit submitted and dated 07/12/2021


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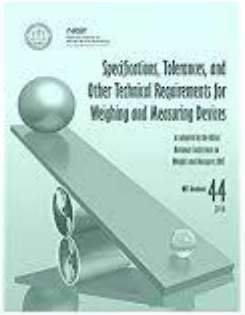
# Common Findings 2021 #5

## 7.2 Selection, verification and validation of methods







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# # 5 Section 7.2 “Selection, verification and validation of methods”

Section has been organized, mainly to differentiate between when the lab has to “verify” (7.2.1), that it can properly perform methods vs when the lab has to “validate (7.2.2) 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

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# # 5 Section 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.

**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.

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# # 5 Section 7.2 “Selection, verification and validation of methods”

Example of Nonconformance Written

**Finding**: Balance calibration is not following all elements of Euramet cg 18.

**Objective Evidence**: Sample calibration witness and corresponding report did not utilize at least 5 readings to capture repeatability along with capturing the error of indication at various loads.

**Requirement not being met: 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.

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# Common Findings 2021 #4

Section 7.7 Ensuring the Validity of Results

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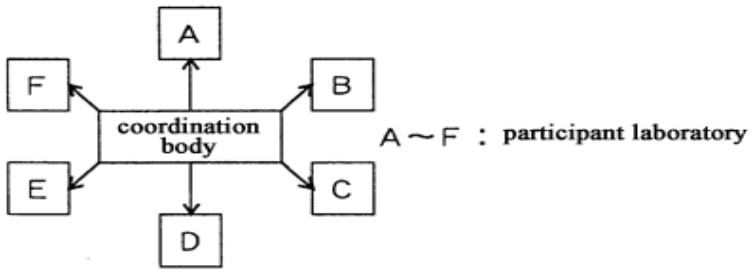
# #4 Section 7.7 Ensuring the Validity of Results

ISO/IEC 17025:2017 emphasizes interlaboratory comparison and proficiency testing. Other than the fact that ISO/IEC 17025:2017 and PJLA PL-1 requires it. They are beneficial tools for the laboratory to check the reliability of their results by comparison within their peer group and to demonstrate their performance to clients and accreditation bodies. With the increasing availability of PT schemes in many technical fields, the criteria for the selection of an appropriate scheme are becoming more important.

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# #4 Section 7.7 Ensuring the Validity of Results

**7.7.1** The laboratory **shall have a procedure** for monitoring the validity of results. **The resulting data shall be recorded** in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to review the results. This monitoring shall be planned and reviewed and shall include**, where appropriate**, but not be limited to: a-k


**7.7.2** The laboratory shall monitor its performance by comparison with results of **other laboratories**, **where available and appropriate**. This monitoring shall be planned and reviewed and shall include, but not be limited to, either or both of the following:a) participation in proficiency testing; b) participation in interlaboratory comparisons other than proficiency testing

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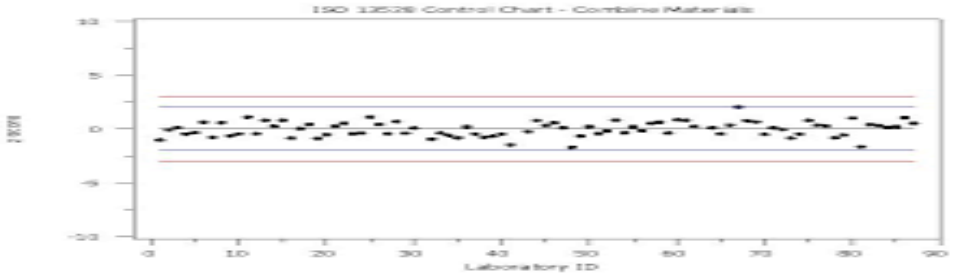
# #4 Section 7.7 Ensuring the Validity of Results

**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.

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# #4 Section 7.7 Ensuring the Validity of Results

## Example of Nonconformance Written

**Finding -** Proficiency testing results do not show analysis between ABC and XYZ results. The data needs to state criteria which is being used to determine whether or not they are in agreement with each other such as an En analysis for example

**Objective Evidence** – Proficiency testing data submitted

**Requirement not being met 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.

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# Common Findings 2021 #3

Requirements Specified in PJLA Policy on Proficiency Testing "PL-1"


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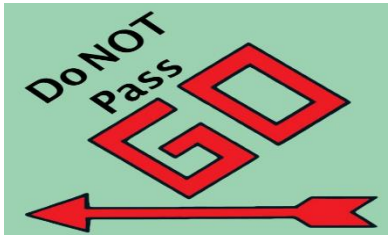
# #3 PJLA Policy on Proficiency Testing "PL-1

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. This needs to be done within the requirements set down in PL-1.

- *An applicant lab should plan ahead and assure that the initial proficiency test is successfully completed prior to the initial assessment.*




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

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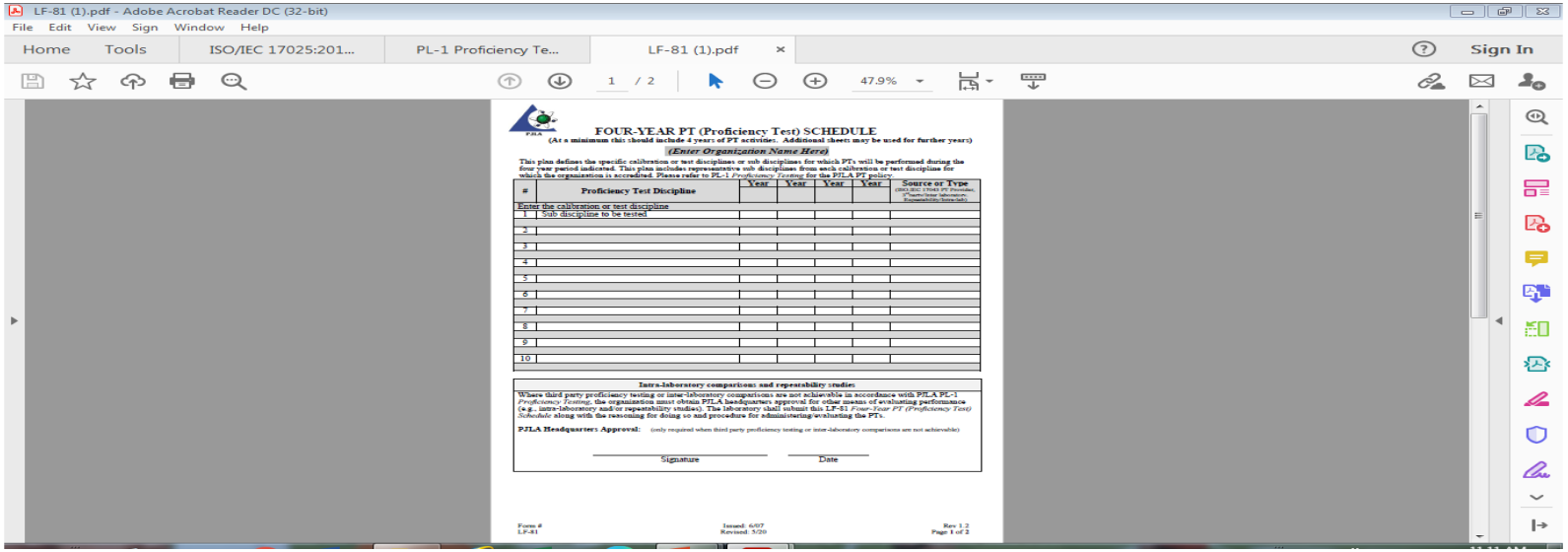
# #3 PJLA Policy on Proficiency Testing PL-1

- Organizations seeking accreditation shall develop a 4 year PT plan using the PJLA template PT Plan Form (LF-81) or other equivalent document prior to initial assessments. Organizations are responsible for updating 4 year PT plans prior to expiration of any current plan; available at www.pjlabs.com; resource tab under forms;

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# #3 PJLA Policy on Proficiency Testing PL-1

When use of third party or inter laboratory 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:

-intra-laboratory comparisons, and;

-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 f**or review and approval

*If an organization provides a 4-year plan with intra lab or repeatability studies without prior authorization from PJLA headquarters, a nonconformance can be written against this policy*

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# #3 PJLA Policy on Proficiency Testing  PL-1

Example of Nonconformance Written

**Finding:** Inter-laboratory proficiency testing results yielded En failures with no investigation or corrective action being taken.

**Objective Evidence**: Inter-lab comparison with ABC Calibration lab En failures at 10 μL and 100 μL dated 11-August-2021

**Requirement not being met**: PL-1 (4.3.2) Failure to produce meaningful, acceptable results shall necessitate an investigation and, if required, corrective action by the organization.

**Finding** - Annual proficiency test results for 2021 were not available for review.

**Objective Evidence** –Unable to produce proficiency testing results for 2021 in accordance with four year approved proficiency testing plan.

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# Common Findings 2021 #2

## Section 7.8 Reporting of Results

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# #2 Section 7.8 Reporting of Results

If you think about it, the report that a laboratory is providing it's customers is the final product. Things that can impact the final results may include having trained, personnel, appropriate procedures, appropriate facilities, traceability, equipment, and a handling process. All of which are addressed within ISOIEC 17025:2017


This section covers all three area's of 17025 which includes testing, calibration, and sampling

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# #2 Section 7.8 Reporting of Results

Assure all applicable shall are being reported as required by ISO/IEC 17025:2017. Ideally your internal audit will sample reports produced to assure they are meeting the applicable requirements.


“shall” indicates a requirement;

“should” indicates a recommendation;

“may” indicates a permission;

“can” indicates a possibility or a capability

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

7.8.3 Specific requirements for test reports

7.8.4 Specific requirements for calibration certificates

7.8.5 Reporting sampling – specific requirements

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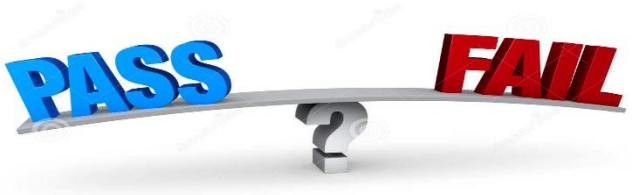
# #2 Section 7.8 Reporting of Results

## 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;





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# #2 Section 7.8 Reporting of Results

Example of Nonconformance Written

**Finding**: Reports are not capturing all required elements stated within ISO/IEC 17025:2017

**Objective Evidence**: Report issued to ABC Corporation through Report #_00006920

**Requirement not being met - 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

f) identification of the method used;

j) the date of issue of the report;

o) identification of the person(s) authorizing the report;

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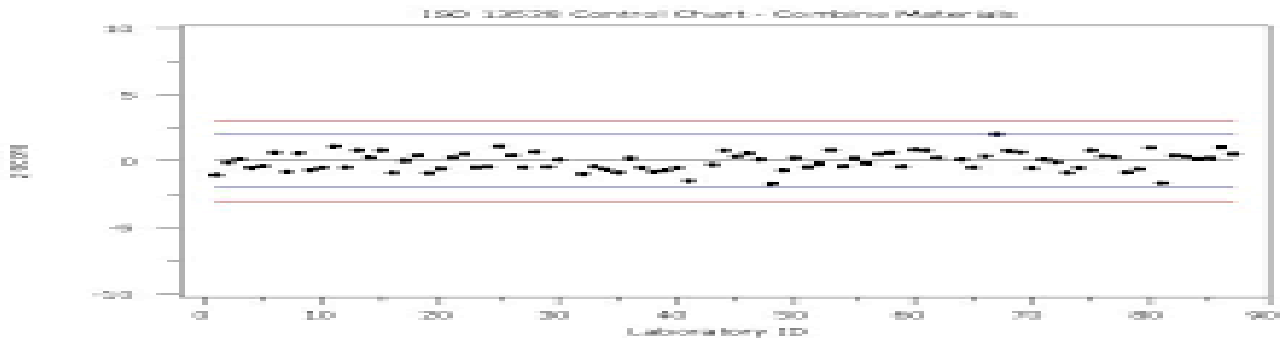
# Common Findings 2021 #1

Section 6.4 Equipment

# #1 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.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# #1 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.

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# #1 Section 6.4 Equipment

**6.4.9** Equipment that has been subjected to overloading or mishandling, gives questionable results, or has been shown to be defective or outside specified requirements, 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 verified to perform correctly. The laboratory shall examine the effect of the defect or deviation from specified requirements and shall initiate the management of nonconforming work procedure (see 7.10).


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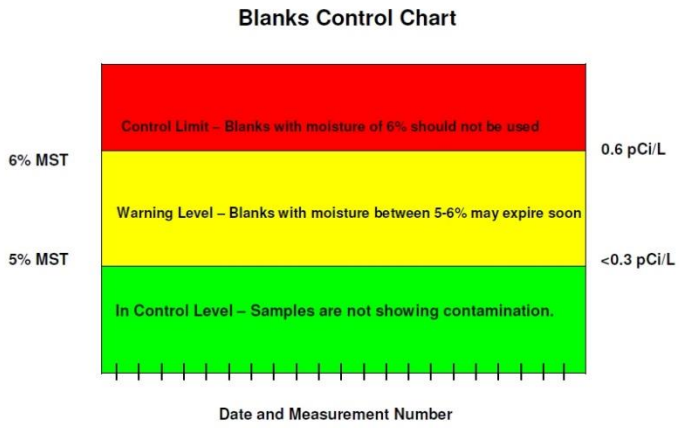
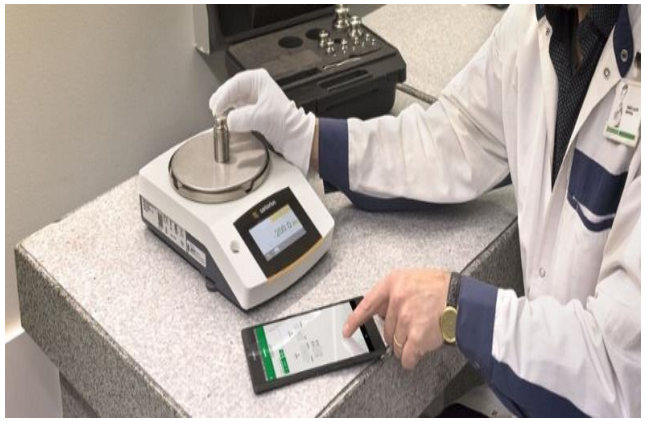
# #1 Section 6.4 Equipment

- **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.



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# #1 Section 6.4 Equipment

- **Finding**: Proposed scope of accreditation is stating analytical type balances however Manny Moe and Jack Scale and Balance Company do not have the Class 1 weights needed to perform these calibration. Current weights are Class F
- **Objective Evidence**: Unable to produce traceable standards to cover the 1 g to 300 g analytical balance calibration being proposed**.**

**Requirement** not being met 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

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# Thank You


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 webinar@pjlabs.com

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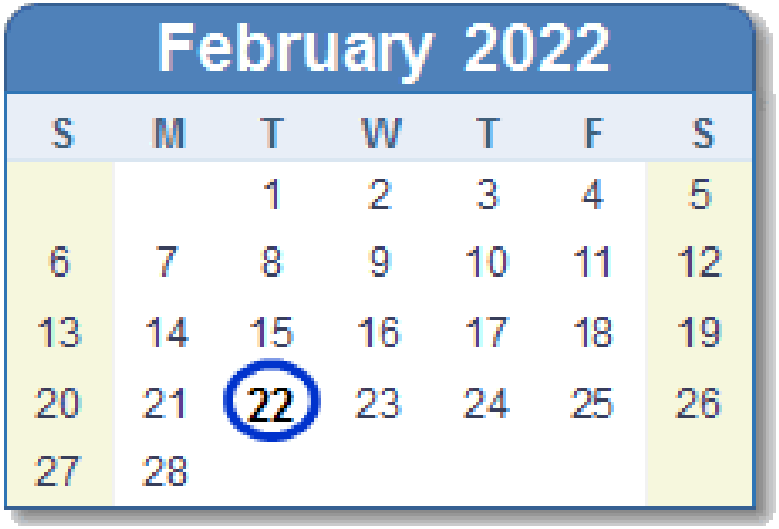
# Save the Date

ISO/IEC 17025:2017: Section 7.1 “Review of Requests, Tenders, and Contracts”




**Tuesday, Feb 22nd 2022**

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