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

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There is a space on your screen to ask questions. Please keep question related to today's topic. At the conclusion of the webinar, received questions will be reviewed and answered.

Duration of webinar is set for one hour.

Transition period for ISO/IEC 17025 extended

https://ilac.org/latest_ilac_news/transition-period-for-iso-iec-17025-extended/

As a result of the recent ILAC ballot the transition period for ISO/IEC 17025:2017 adopted as part of the ILAC Resolution GA 20.15 (November 2016) has been extended from 30 November 2020 to 1 June 2021.

This extension has been granted to ensure all accreditation bodies and the accredited laboratories are able to achieve the remaining transitions in a robust manner under the restrictions imposed as a result of the global coronavirus disease 2019 (COVID-19) outbreak.

At the end of the transition period, the accreditation of a laboratory to ISO/IEC 17025:2005 will not be recognized under the ILAC Arrangement.

Common Findings ISO/IEC 17025:2017

PJLA have been doing initial along with transition assessment to ISO/IEC 17025:2017 with regularity This webinar will look at the latest tabulations of findings and identify the top 10 Sections where PJLA assessors have been writing nonconformance's. Will also look at some differences between the 2017 Standard and 2005 Standard in regards to the top 10 sections.

Common Findings ISO/IEC 17025:2017

#10 (tie) “6.6 Externally provided products and services”

This section incorporates the requirements for both purchasing and also subcontracting.

6.6.2 The laboratory shall have a **procedure** and retain **records** for:

a) defining, reviewing and approving the laboratory’s requirements for externally provided products and services;

b) defining the criteria for evaluation, selection, **monitoring** of performance and **re-evaluation** of the external providers;

Common Findings ISO/IEC 17025:2017

#10 tie "Externally provided products and services"

6.6.2 The laboratory shall have a **procedure** and retain **records** for:

c) ensuring that externally provided products and services conform to the laboratory's established requirements, or when applicable, to the relevant requirements of this document, before they are used or directly provided to the customer;

d) taking any actions arising from evaluations, monitoring of performance and re-evaluations of the external providers.

- *Got rid of the list, more electronic driven - Added re-evaluation*

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Criteria for defining evaluation, selection, monitoring of performance and re-evaluation of the external providers may include:

- Accreditation to ISO.IEC 17025
- ISO/IEC 17011
- ISO/IEC 17043
- ISO 9001
- On time delivery
- Supplier Audits
- Testimonials and references these are valuable if you can check that the vendor is reliable and as they claim to be
- Years in business - need to know that the organization is established and ready to service your requirements
- Accuracy requirements and capabilities: Scope of Accreditation “Range and CMC’s

Common Findings ISO/IEC 17025:2017

#10 tie "6.6 Externally provided products and services"

6.6.3 The laboratory shall **communicate** its requirements to external providers for:

a) the products and services to be provided;

b) the acceptance criteria;

c) competence, including any required qualification of personnel;

d) activities that the laboratory, or its customer, intends to perform at the external provider's premises

Have to communicate, there is no requirement for a purcha

From ISO/IEC 17025:2005 **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.

Common Findings ISO/IEC 17025:2017

 # 10 tie 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.

Sounds like an uncertainty budget as specified in PL-3 “PJLA Policy on Measurement Uncertainty”

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2015 Uncertainty Budget - - Excel

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I2

expanded uncertainty for infrared temperature

uncertainty	description	uncertainty [in K]	source	distribution	divisor	standard uncertainty [in K]	comments
u1	homogeneity of black body	0.4	testing	Gaussian	2	0.20	Temperature profile from top to bottom of the black body
u2	repeatability	0.07	testing	Gaussian	1	0.07	Comparison of results of calibrations using two reference instruments
u3	uncertainty reference system	0.0034	Calibration Certificate	Gaussian	2	0.00	Measurement uncertainty of the reference calibration
u4	drift of reference	0.03	calibration certificate derivation	rectangular	$\sqrt{3}$	0.02	Reference standard drift - derived from past 2 years' calibration data
u5	digit error reference 2	0.0005	manufacturer information/ estimation	rectangular	$\sqrt{3}$	0.00	Least significant digit on digital display
u6	influence of emissivity	0.5	manufacturer information/ estimation	rectangular	$\sqrt{3}$	0.29	Temperature difference due to deviation of stated emissivity from actual
simple uncertainty with k=1 (68.3%) (RSS Method)						0.36	Emissivity is a measure of the efficiency in which a surface emits thermal energy. It is defined as the fraction of energy being emitted relative to that emitted by a thermally black surface (a black body)
expanded uncertainty with k=2 (95%)						**0.72**	

Summary Uncertainty Infrared | uncertainty Infrared

READY 100%

Common Findings ISO/IEC 17025:2017

*# 10 "***7.6 Evaluation of measurement uncertainty"**

7.6.2 A laboratory performing calibrations, including of its own equipment, shall **evaluate** the measurement uncertainty for all calibrations.

From ISO/IEC 17025:2005

5.4.6.1 A calibration laboratory, or a testing laboratory performing its own calibrations, shall have and shall apply a procedure to estimate the uncertainty of measurement for all calibrations and types of calibrations

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

Common Findings ISO/IEC 17025:2017

*# 10 "***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.

What does this Mean?

Common Findings ISO/IEC 17025:2017

Where the test method precludes rigorous evaluation of measurement uncertainty, an **estimation** shall be made

A laboratory performing calibrations, including of its own equipment, shall **evaluate** the measurement uncertainty

Common Findings ISO/IEC 17025:2017

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.

Rapid method kits that specify limits to the values of the major sources (contributors) of uncertainty, as well as well-recognized rapid methods where kits are used to determine qualitative results,

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 Findings ISO/IEC 17025:2017

 # 9 “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:**

From ISO/IEC 17025:2005

This monitoring shall be planned and reviewed and **may include**, but not be limited to, the following:

May = permission Shall = requirement

Common Findings ISO/IEC 17025:2017

 # 9 “7.7 Ensuring the validity of results”

This monitoring shall be planned and reviewed and shall include, where appropriate, but not be limited to:

a) use of reference materials or quality control materials;

b) use of alternative instrumentation that has been calibrated to provide traceable results; *new*

c) functional check(s) of measuring and testing equipment; *new*

d) use of check or working standards with control charts, where applicable*; new*

e) intermediate checks on measuring equipment; *new*

Common Findings ISO/IEC 17025:2017

 # 9 “7.7 Ensuring the validity of results”

f) replicate tests or calibrations using the same or different methods;

g) retesting or recalibration of retained items;

h) correlation of results for different characteristics of an item;

i) review of reported results; *new*

j) intralaboratory comparisons; *new*

k) testing of blind sample(s). *New*

Common Findings ISO/IEC 17025:2017

 # 9 “7.7 Ensuring the validity of results

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;

NOTE: ISO/IEC 17043 contains additional information on proficiency tests and proficiency testing providers. Proficiency testing providers that meet the requirements of ISO/IEC 17043 are considered to be competent.

b) participation in interlaboratory comparisons other than proficiency testing

Common Findings ISO/IEC 17025:2017

 # 9 “7.7 Ensuring the validity of results

CHANGE!

7.7.2 – Requirement for participation in **either or both** Proficiency Testing (3.5) (PT) or Interlaboratory comparisons (3.3)

If your organization currently complies with PL-1 “PJLA Policy on Proficiency Testing”, then your organization will be meeting this requirement.

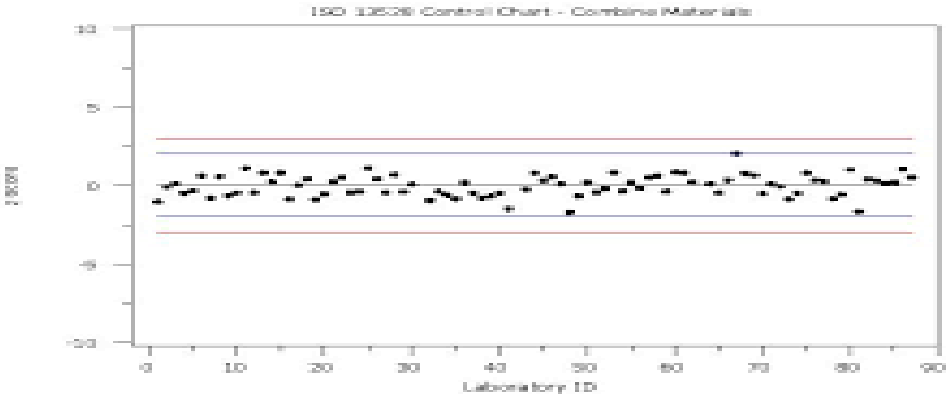
Comparing to values externally outside the confines of laboratory internal operations.

Common Findings ISO/IEC 17025:2017

 # 9 "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.*

– concept of analyzing QC data to "control" and "improve" laboratory activities is additional



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#8 “4.1 Impartiality”

Was included in the 2005 Standard however magnified in 2017

New harmonized text has been included, so these are completely new clauses.

ISO/IEC 17025:2017 defines partiality

Impartiality - *presence of objectivity*

now more important for laboratories to show how they have handled the issue about impartiality. It is more of an ongoing activity

Common Findings ISO/IEC 17025:2017

#8 "4.1 Impartiality"

ISO/IEC 17025:2017 requirements Sec 4.1 "Impartiality"

4.1.1 *Laboratory activities shall be undertaken impartially and structured and managed so as to safeguard impartiality.*

- It is therefore now more important for laboratories to show how they have handled the issue about impartiality
- The laboratory shall be responsible for the impartiality of its laboratory activities
- Laboratories activities extend beyond the testing or calibration activities. It also incorporates activities such as internal auditing, procurement, or maintenance;

Common Findings ISO/IEC 17025:2017

#8 “4.1 Impartiality”

4.1.2 *The laboratory management shall be committed to impartiality.*

This may be demonstrated by:

- have a special impartiality policy or involve a statement about impartiality in the quality policy;
- discuss impartiality on the management review and to include the discussions and decisions in the minutes of meeting;
- documented training and agreement of staff, including the top management, on potential threats to impartiality;

Common Findings ISO/IEC 17025:2017

#8 “4.1 Impartiality”

4.1.3 *The laboratory shall be responsible for the impartiality of its laboratory activities and shall not allow commercial, financial or other pressures to compromise impartiality*.

- Puts the responsibility on the laboratory;
- Safeguards should be put in place;

Common Findings ISO/IEC 17025:2017

#8 “4.1 Impartiality”

4.1.4 The laboratory **shall identify risks** to its impartiality on **an on-going basis.**

- The laboratory shall make a risk analyses.
- should be incorporated in contract reviews (to identify if there is risk connected to the customer or the activity)
- management reviews, internal audits and performance review can provide inputs to identify any potential risk to personnel.
- Since this shall be an ongoing activity it is important to identify changes in the laboratories activities that may become a risk. Even if there are no changes in the laboratories activities the impartiality risk analyses should at least be reviewed during the management review.

Common Findings ISO/IEC 17025:2017

 # 7 "*PL-1* Perry Johnson Laboratory Accreditation, Inc. Proficiency Testing Requirements"

2.1 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. The item that the organization chooses for proficiency testing must be

one that is suitable to demonstrate the competence of the organization for the main field of activities either calibration or testing. The results of this proficiency testing must be meaningful, in that the organization not only needs to perform the proficiency testing, the resulting data must demonstrate the organization's competence in performing the specified test or calibration.

Common Findings ISO/IEC 17025:2017

 # 7 "PL-1

3.1 Upon achieving accreditation by PJLA, organizations are required to perform proficiency testing annually. Results of this testing shall be monitored during the organization's subsequent surveillance or reaccreditation assessment. At minimum organizations are required to have objective evidence of

favorable proficiency testing results for each discipline in their scope of accreditation within a four year cycle.

3.2 Organizations seeking accreditation shall develop a 4 year PT plan using the PJLA template PT Plan Form (LF-81) or equivalent document prior to initial assessments. This plan will be reviewed by the assessment team during the on-site visit for compliance to this policy

Common Findings ISO/IEC 17025:2017

 # 7 "PL-1

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

Common Findings ISO/IEC 17025:2017

 # 7 "PL-1

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

Common Findings ISO/IEC 17025:2017

#6 “6.2 Personnel”

There are no substantial changes. The most prominent are:

The need to supervise (before authorization) and to monitor (after authorization) the personnel (6.2.5 c and f) has been taken up.

The need to document job descriptions has been erased. However, it is required to define competence requirements for each function (not only managerial functions but all of those that have an impact on the results of the laboratory).

Common Findings ISO/IEC 17025:2017

#6 “6.2 Personnel”

6.2 Personnel

6.2.1 All personnel of the laboratory, either internal or external, that could influence the laboratory activities shall **act impartially, be competent** and work in accordance with the laboratory’s management system.

- *This of course covers personnel involved directly in laboratory testing, calibration, or sampling activities however this will also apply to internal auditors*.

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#6 “6.2 Personnel”

6.2.2 The laboratory **shall document** the competence requirements for each function influencing the results of laboratory activities, including requirements for education, qualification, training, technical knowledge, skills and experience.

6.2.3 The laboratory shall ensure that the personnel have the competence to perform laboratory activities for which they are responsible and to evaluate the significance of deviations.

6.2.4 The management of the laboratory shall communicate to personnel their duties, responsibilities and authorities

- *There is no longer a requirement for a formal job description*.

Common Findings ISO/IEC 17025:2017

#6 “6.2 Personnel”

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

a) determining the competence requirements;

b) selection of personnel;

c) training of personnel;

d) supervision of personnel;

e) authorization of personnel;

f) **monitoring** of competence of personnel

Common Findings ISO/IEC 17025:2017

#6 “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;

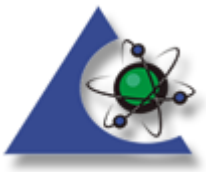
b) analysis of results, including statements of conformity or opinions and interpretations;

c) report, review and authorization of results

Common Findings ISO/IEC 17025:2017

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

- In general, not many changes in the requirements themselves
- The section has been re-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.
- *Definitions added and examples (section 3 terms and definitions).*
- **Verification** provision of objective evidence that a given item fulfils specified requirements;
- **Validation** where the specified requirements are adequate for an intended use;



Common Findings ISO/IEC 17025:2017

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

- ***7.2.2.4*** *The laboratory shall retain the following* ***records*** *of validation:*

Added to the 2017 Standard

- *determination of the performance characteristics of the method;*
- *a statement on the validity of the method, detailing its fitness for the intended use.*

As always:

- **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

Common Findings ISO/IEC 17025:2017

4 “8.8 Internal audits”

New

8.8.2 The laboratory shall:

a) plan, establish, implement and maintain an audit program including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration **the importance of the laboratory activities concerned, changes affecting the laboratory, and the results of previous audits.**

No other significant changes

Competence and impartiality covered in 4.1 & 4.2 applies to internal auditor

Common Findings ISO/IEC 17025:2017

4 “8.8 Internal audits”

Your lab will be assessed to the 2017 Standard and not 2005. Your internal audit should be directed at compliance with that Standard.

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

Common Findings ISO/IEC 17025:2017

#3 “8.9 Management reviews”

We are assessing to the 2017 Standard and not the 2005 Standard. You should have completed your management review to the 2017 Standard requirements.

Common Findings ISO/IEC 17025:2017

#3 “8.9 Management reviews”

Identification of changes

This clause has been rewritten.

The recommendation of performing the management review every 12 months has been erased.

Some inputs have been changed:

• "customer feedback" has been modified to "customer and personnel feedback"

• Instead of "recommendations for improvements", it has been modified to: "effectiveness of any implemented improvements”

.

Common Findings ISO/IEC 17025:2017

#3 “8.9 Management reviews”

Some inputs have been added:

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

b) fulfilment of objectives;

d) status of actions from previous management reviews;

l) adequacy of resources;

m) results of risk identification

Common Findings ISO/IEC 17025:2017

#3 “8.9 Management reviews”

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

Common Findings ISO/IEC 17025:2017

#2 “6.4 Equipment”

ISO/IEC 17025:2017 updated this section to include:

- Standards, reference materials, reagents, and software are now also considered as equipment (6.4.1).
- Conditions to calibrate equipment are set (6.4.6):
  - ➢ if accuracy or uncertainty affect the validity of results
  - ➢ if calibration is needed to establish metrological traceability
- Reference to ISO 17034 has been included to emphasis the competence of reference material producers

Common Findings ISO/IEC 17025:2017

#1 “6.4 Equipment”

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

Clause 6.4.4 specifies the requirement to verify equipment conforms to specified requirements before being placed or returned into service. This is stated differently from what is in the 2005 Standard which specifies that equipment needed to be calibrated or checked to establish that it meets the laboratory's specification requirements

Common Findings ISO/IEC 17025:2017

#2 “6.4 Equipment”

As you can see clause 6.4.6 is specific as to when equipment is required to be calibrated.

6.4.6 *Measuring equipment shall be calibrated when:*

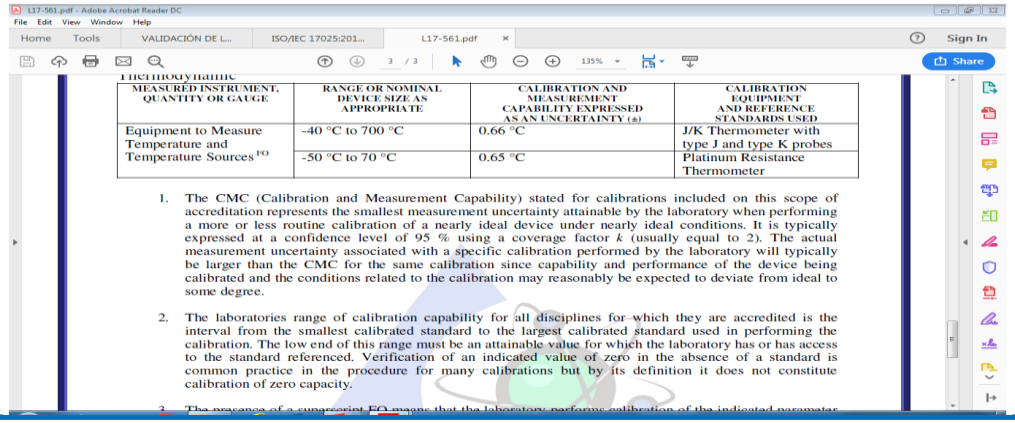
- *the measurement accuracy or measurement uncertainty affects the validity of the reported results, and/or*
- *calibration of the equipment is required to establish the metrological traceability of the reported results.*

Common Findings ISO/IEC 17025:2017

#2 “6.4 Equipment”

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.

Temperature accuracy shall be within 0.5°C



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Thermodynamic

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
Equipment to Measure Temperature and Temperature Sources [FO]	-40 °C to 700 °C	0.66 °C	J/K Thermometer with type J and type K probes
	-50 °C to 70 °C	0.65 °C	Platinum Resistance Thermometer

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 be larger than the CMC for the same calibration since capability and performance of the device being calibrated and the conditions related to the calibration may reasonably be expected to deviate from ideal to some degree.

2. The laboratories range of calibration capability for all disciplines for which they are accredited is the interval from the smallest calibrated standard to the largest calibrated standard used in performing the calibration. The low end of this range must be an attainable value for which the laboratory has or has access to the standard referenced. Verification of an indicated value of zero in the absence of a standard is common practice in the procedure for many calibrations but by its definition it does not constitute calibration of zero capacity.

3. The presence of a superscript FO means that the laboratory performs calibration of the indicated parameter

Common Findings ISO/IEC 17025:2017

#2 “6.4 Equipment”

6.4.7

- Establish calibration programs which shall be;

new

- reviewed and adjusted if necessary

6.4.8

- Equipment calibration status need to be **readily identifiable;**

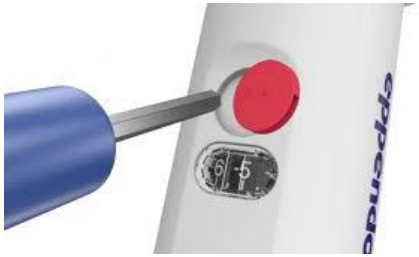
the concept of a calibration label being placed on the equipment is no longer required

Common Findings ISO/IEC 17025:2017

#2 “6.4 Equipment”

6.4.12 The laboratory shall take practicable measures to prevent unintended adjustments of equipment from invalidating results.

The requirement specifying safeguards from unintended adjustments is still in place however it is now referred to taking practicable measures to prevent unintended adjustments



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#2 “6.4 Equipment”

6.4.13 Records shall be retained for equipment which can influence laboratory activities. The records shall include the following, **where applicable**:

a) the identity of equipment, including software and firmware version;

b) the manufacturer's name, type identification, and serial number or other unique identification;

c) evidence of verification that equipment conforms with specified requirements

Common Findings ISO/IEC 17025:2017

#2 “6.4 Equipment”

d) the current location;

e) calibration dates, results of calibrations, adjustments, acceptance criteria, and the due date of the next calibration or the calibration interval;

f) documentation of reference materials, results, acceptance criteria, relevant dates and the period of validity;

g) the maintenance plan and maintenance carried out to date, where relevant to the performance of the equipment;

h) details of any damage, malfunction, modification to, or repair of, the equipment.

Common Findings ISO/IEC 17025:2017

#1 "7.8 Reporting of results"

7.8.1 General

new

7.8.1.1 The results shall be **reviewed and authorized prior to release**

7.8.1.3When agreed with the customer, the results may be reported in a simplified way

The requirement from the 2005 Standard that specified a written agreement was required for external customer is no longer required. The lab should however maintain a record of this agreement

Common Findings ISO/IEC 17025:2017

#1 "7.8 Reporting of results"

7.8.2 Common requirements:

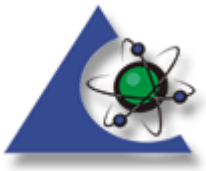
7.8.2.1 The following has been included:

j) The date of issue of the report

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

From ISO/IEC 17025:2005 the name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing

p) clear identification when results are from external providers.



Common Findings ISO/IEC 17025:2017

#1 “7.8 Reporting of results”

7.8.2.2 *new*

- ✓ . Lab shall be responsible for all information in the report, except when information is provided by the customer
- ✓ Data provided by the customer shall be clearly identified
- ✓ Disclaimer put on the report when the information is supplied by the customer and can affect the validity of the results
- ✓ When the sample is provided by the customer, it shall state in the report that the results apply to the sample “as received

Common Findings ISO/IEC 17025:2017

#1 "7.8 Reporting of results"

7.8.4 Specific requirements for calibration certificates

7.8.4 Calibration certificates shall include the following:

new

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

No longer states the uncertainty of measurement and/or a statement of compliance;

Common Findings ISO/IEC 17025:2017

#1 “7.8 Reporting of results

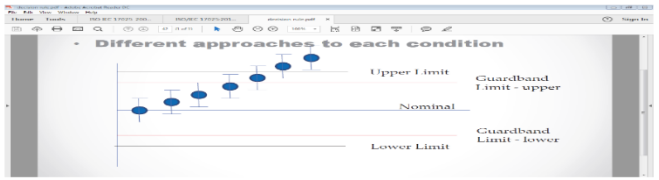
new

- **7.8.5 Reporting sampling – specific requirements**
- Where the laboratory is responsible for the sampling activity, in addition to the requirements listed in 7.8.2, reports shall include the following, where necessary for the interpretation of results:
- f) information required to evaluate measurement uncertainty for subsequent testing or calibration

Common Findings ISO/IEC 17025:2017

#1 “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.*
- **7.8.6.2** The laboratory shall report on the statement of conformity, such that the statement clearly identifies:
- **c)** the **decision rule** applied (unless it is inherent in the requested specification or standard).



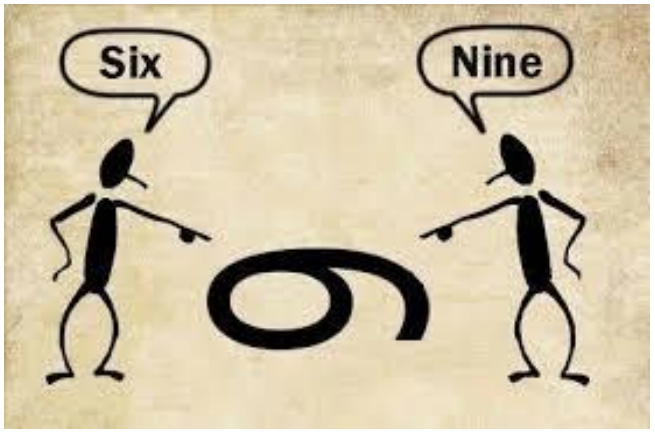
Common Findings ISO/IEC 17025:2017

#1 “7.8 Reporting of results

new

- **7.8.7 Reporting opinions and interpretations**
- Only personnel authorized for the expression of opinions and interpretations
- When communicated by dialogue with the customer, a record of the dialogue shall be retained.

- *this was a note in the 2005 Standard*

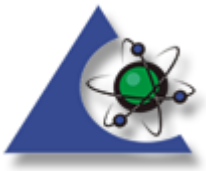


Common Findings ISO/IEC 17025:2017

#1 "7.8 Reporting of results

- **7.8.8 Amendments to reports**
- *When an issued report needs to be changed, amended or re-issued, any change of information shall be clearly identified and**, where appropriate**, the reason for the change included in the report*

The concept of where appropriate the reason for the change included in the report is an addition.



Common Finidings

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

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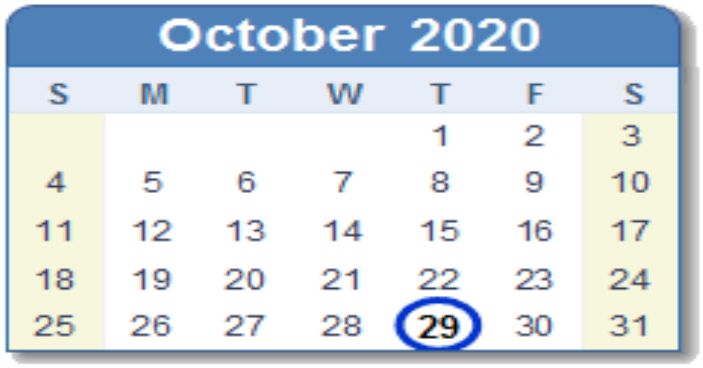
If a question is unanswered please submit directly to webinar@pjlabs.com

Common Findings

Next scheduled webinar is set for 29 October 2020

. ***ISO/IEC 17025:2017 Section 8.9 Management Review Requirements and Utilization***



Thursday, Oct 29th 2020