Common Findings ISO/IEC 17025:2017

Thursday, August 29 – 1:00pm EST

Presented by:

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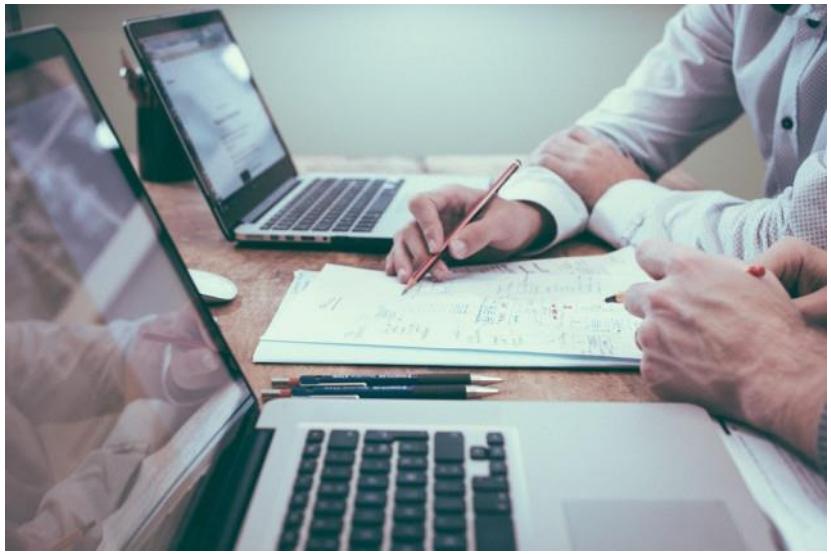

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Duration of webinar is set for one hour.

You can type any questions directly into your webinar box; We will review them at the conclusion of today's session; Please keep question presented related to the topic of today's webinar.

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Update Notification #41 Release Date: December 1, 2017

PJLA has been informed that a 3-year transition period will be granted and all laboratories must be accredited to the new standard by **November 29, 2020**.

All laboratories will be asked if they would like to transition during their normal routine visits through the period of **2018-2020**. However, all laboratories must transition by no later than **August 31, 2020** regardless of your assessment due date.

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PJLA will need to come onsite for the transition assessment. Can not be done as an offsite surveillance.

If during the offsite year the assessment will center on the key differences between the two Standards however will need to come on site.

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PJLA have been doing initial along with transition assessment to ISO/IEC 17025:2017 with regularity as are about to enter the final quarter of 2019. 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.

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#10 “8.5 Actions to address risks and opportunities”

The clause is completely new and replaces the concept of preventive actions

NOTE Although this document specifies that the laboratory plans actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process. Laboratories can decide whether or not to develop a more extensive risk management methodology than is required by this document, e.g. through the application of other guidance or standards

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#10 “8.5 Actions to address risks and opportunities”

NOTE 1 Options to address risks can include identifying and avoiding threats, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to expanding the scope of the laboratory activities, addressing new customers, using new technology and other possibilities to address customer needs.

The notes given provide clarification of the text, examples and guidance. They do not contain requirements

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#10 “8.5 Actions to address risks and opportunities”

The laboratory is recommended to develop a specific document (procedure or any other name) where risks and opportunities are identified, as well as a plan to implement action to minimize risks and maximize opportunities.

It needs to be addressed within the quality management system and records should show what has been done.

This procedure as well as the updated action plan should be analyzed during the management review (8.9.2), and the efficacy of the actions taken should be assessed.

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#10 “8.5 Actions to address risks and opportunities”

The document identifying the risks should include, at least, the following:

- 4.1.4 risks to impartiality (arise from its activities, or from its relationships, or from the relationships of its personnel.) The laboratory shall identify risks to its impartiality on an on-going basis.
- 7.8.6.1 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.
- 7.10.1 b actions (including halting or repeating of work and withholding of reports, as necessary) are based upon the risk levels established by the laboratory;

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9 “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

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 # 9 “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

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 # 8 “7.7 Ensuring the validity of results”

Formerly ISO/IEC 17025:2005 – Section 5.9 – ‘Assuring the Quality of Test and Calibration Results

Common Findings ISO/IEC 17025:2017

8 “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

 # 8 “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

 # 8 “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*

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 # 8 “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

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 # 8 “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.

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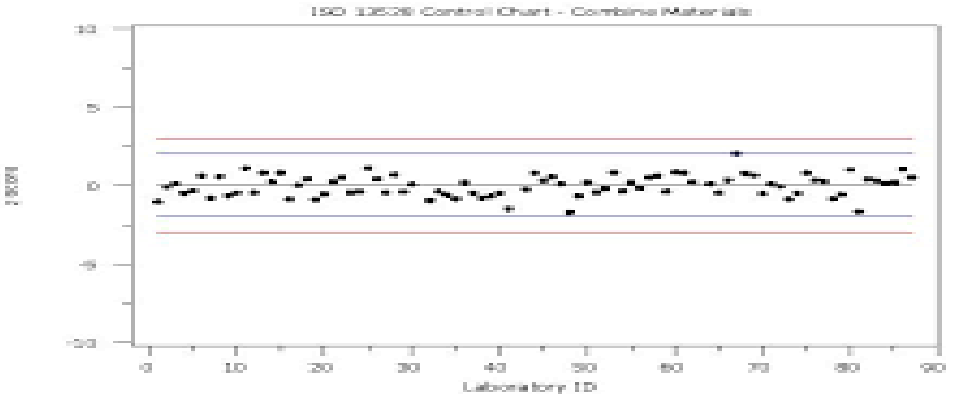
 # 8 "7.7 Ensuring the validity of results

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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#7 “8.9 Management reviews”

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

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#7 “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”

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Common Findings ISO/IEC 17025:2017

#7 “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

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#7 “8.9 Management reviews”

The outputs have been detailed:

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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#6 “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

#6 "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

#6 “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;

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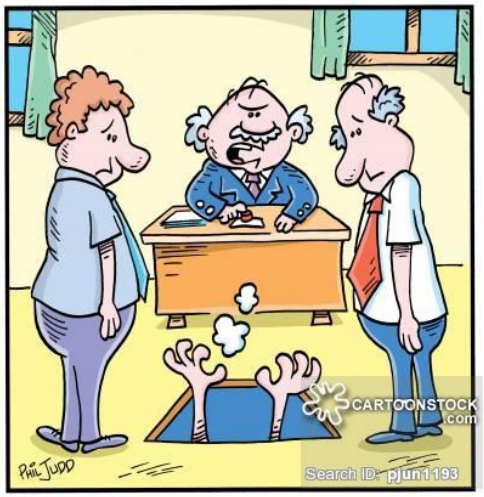
#6 “4.1 Impartiality”

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;

"We're a democracy here, as long as everyone votes in favour of what I want!"



"Does anyone else have any complaints?"

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#6 “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

#6 "4.1 Impartiality"

4.1.5 *If a risk to impartiality is identified, the laboratory shall be able to demonstrate how it eliminates or minimizes such risk.*

- Can eliminate or reduce to an acceptable level (risk mitigation*);*
- The laboratory should be able to show how it has handled the issue of impartiality so these activities should be documented;

Examples may include:

- Change the personnel if the initial personnel are compromised
- Letting other parts of the laboratory perform the test if the initial part is compromised
- Segregation period of compromised employee from activity

Common Findings ISO/IEC 17025:2017

#5 “6.6 Externally provided products and services”

Purchasing and Subcontracting are now compiled in one section.

4.5 Subcontracting of tests and calibrations

4.6 Purchasing services and supplies

Common Findings ISO/IEC 17025:2017

#5 “6.6 Externally provided products and services”

6.6.1 The laboratory shall ensure that only **suitable** externally provided products and services that affect laboratory activities are used, when such products and services:

a) are intended for incorporation into the laboratory’s own activities;

b) are provided, in part or in full, directly to the customer by the laboratory, as received from the external provider;

c) are used to support the operation of the laboratory.

NOTE Products can include, for example, measurement standards and equipment, auxiliary equipment, consumable materials and reference materials. Services can include, for example, calibration services, sampling services, testing services, facility and equipment maintenance services, proficiency testing services and assessment and auditing services

-- *Brings risk into it as lab has to determine level of suitability*

Common Findings ISO/IEC 17025:2017

#5 "6.6 Externally provided products and services"

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;

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*

Common Findings ISO/IEC 17025:2017

#5 “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

#4 “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

#4 “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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#4 “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*.

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#4 “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

#4 “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

#3 "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

#3 "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) instead of a signature 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

#3 “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

#3 "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

#3 "7.8 Reporting of results

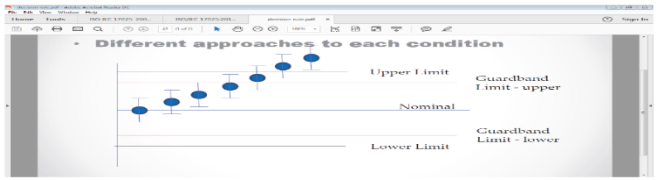
new

- **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

#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.*
- **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).



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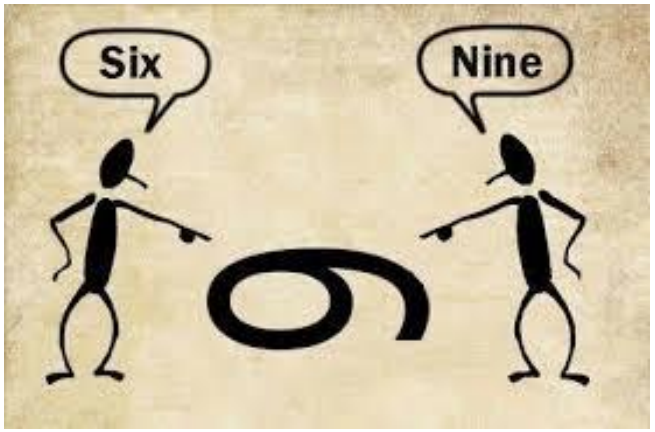
#3 "7.8 Reporting of results

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*



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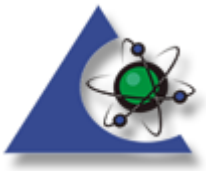
#3 "7.8 Reporting of results

- **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*

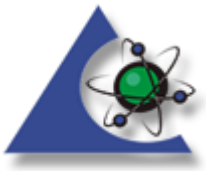
The concept of where appropriate the reason for the change included in the report is an addition.



Common Findings ISO/IEC 17025:2017

 # 2 “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

 # 2 “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

#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 that equipment needed to be calibrated or checked to establish that it meets the laboratory's specification requirements

Common Findings ISO/IEC 17025:2017

#1 “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

#1 “6.4 Equipment”

6.4.7

- Establish calibration programs which shall be;

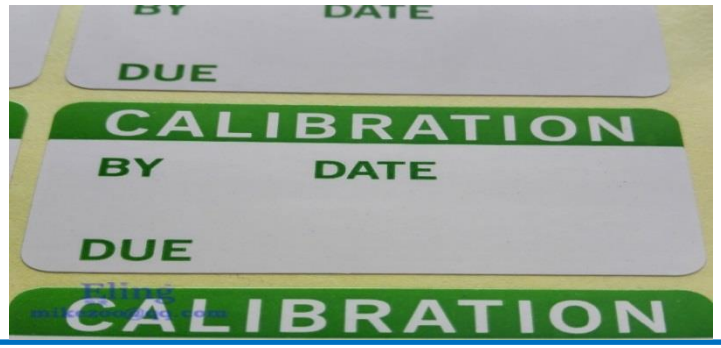
new

- 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



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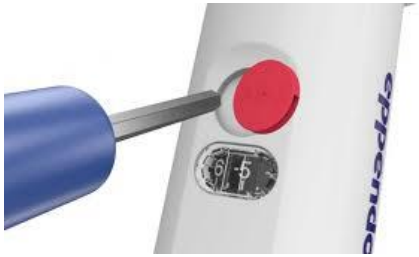
#1 “6.4 Equipment”

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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#1 “6.4 Equipment”

 # 2 “7.2 Selection, verification and validation of methods”

Not many changes and are lacked in the area of equipment

#11 is the first appearance of PJLA Policies in the list which is PL-1 “Proficiency Testing”

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

Please keep questions related to the topic covered in this webinar;

Save the Date

Next PJLA Webinar

Friday, September 20 – 1:00pm EST

Decision Rules and Their Application to Meeting the Requirements of ISO/IEC 17025:2017