Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2022

Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
Friday January 27, 2023

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Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2022

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Common Findings in Assessments to the ISO/IEC 17025:2017 Standard in 2022

We have looked back at assessment done by PJLA during the 2022 calendar year and have compiled data from these assessments. This webinar will look at the sections of ISO/IEC 17025:2017 which were identified **in the top list of nonconformance's** which PJLA assessors wrote during the year.

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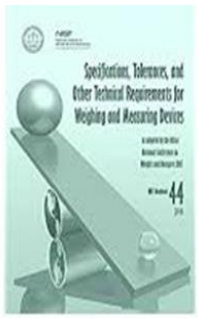
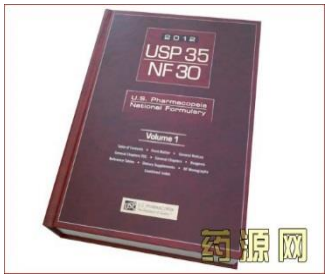
Common Findings 2022 #10

7.2 Selection, verification and validation of methods





EPA

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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10 7.2 Selection, verification and validation of methods

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

Records may consist of :

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

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10 7.2 Selection, verification and validation of methods

- **7.2.2.1** *The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application.*
- *NOTE 1: Validation can include procedures for sampling, handling and transportation of test or calibration items. NOTE 2: The techniques used for method validation can be one of, or a combination of, the following:*
- *a) calibration or evaluation of bias and precision using reference standards or reference materials;*
- *b) systematic assessment of the factors influencing the result;*
- *c) testing method robustness through variation of controlled parameters, such as incubator temperature, volume dispensed;*
- *d) comparison of results achieved with other validated methods;*
- *e) interlaboratory comparisons*

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10 7.2 Selection, verification and validation of methods

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

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

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

c) suitability of policies and procedures;

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Common Findings 2022 #9

8.6 Improvement

8.6.2 The laboratory shall **seek feedback**, both positive and negative, from its customers. The feedback shall be analysed and used to improve the management system, laboratory activities and customer service.

NOTE Examples of the types of feedback include customer satisfaction surveys, communication records and review of reports with customers.

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Common Findings 2022 #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:

a) use of reference materials or quality control materials b) use of alternative instrumentation that has been calibrated to provide traceable results; c) functional check(s) of measuring and testing equipment; d) use of check or working standards with control charts, where applicable; e) intermediate checks on measuring equipment; 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; j) intralaboratory comparisons; k) testing of blind sample(s

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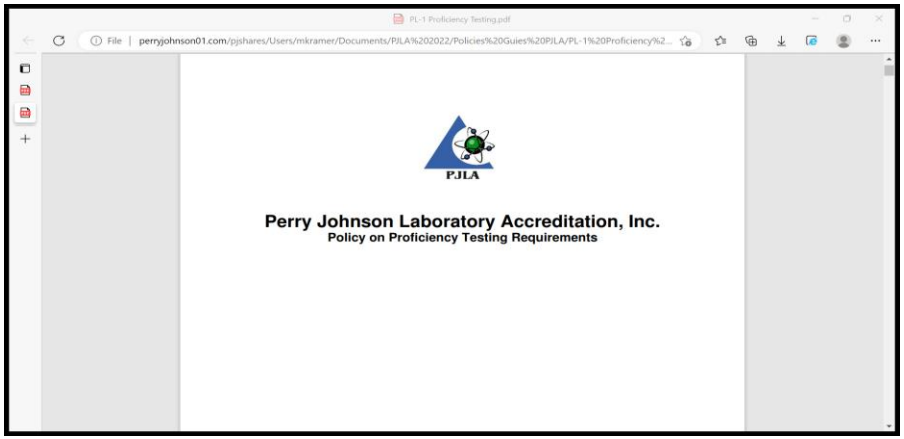
#8 7.7 Ensuring the validity of results

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;

b) participation in interlaboratory comparisons other than proficiency testing.

Requirements specified in PL-1 are in harmony with ISO/IEC 17025:2017



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Common Findings 2022 #7

8.7 Corrective actions

Corrective action is an activity that shall be used to stop **the re-occurrence** of non-conformities

Corrective action has to be initiated when a problem exists. Remedial action can easily be confused with corrective action. Remedial action or correction is taken to rectify the mistake. Corrective action is an action to eliminate defined non-conformities and prevent reoccurrences.

Example: To recall a test report and make necessary changes is a remedial action or correction because making changes in the report does not help to prevent **re-occurrence** of non-conformities. if this is the third correction this month due to errors then may need to take it further and look into the review, and authorization of reports.

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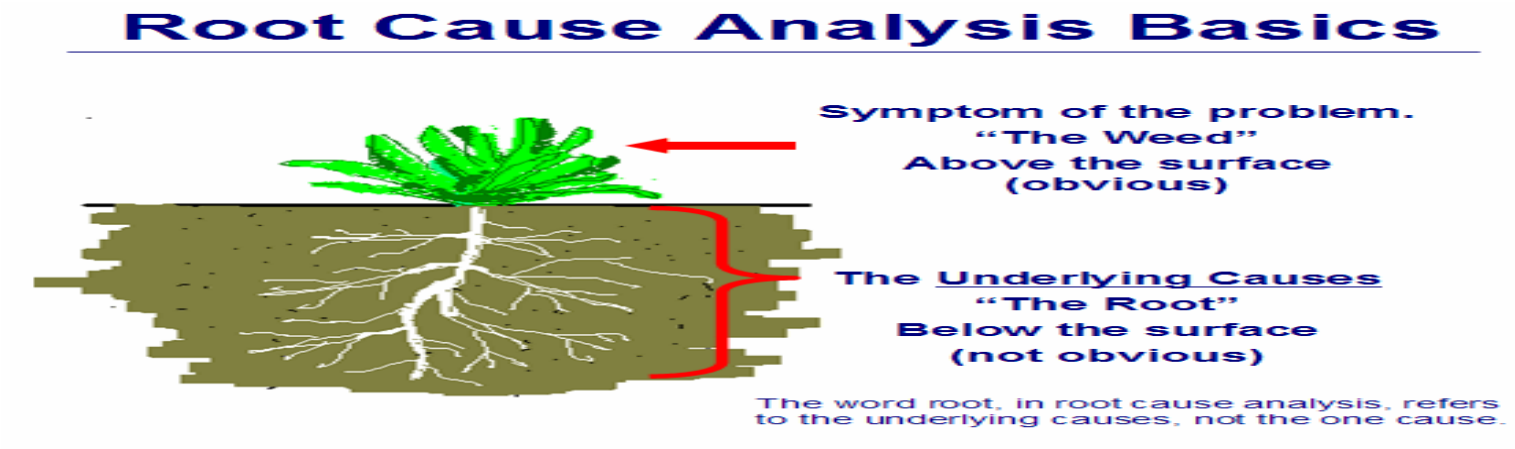
#7 ‘8.7 Corrective Actions’

8.7.1 When a nonconformity occurs, the laboratory shall: a) react to the nonconformity and, as applicable: — take action to control and correct it; — address the consequences; b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: — reviewing and analysing the nonconformity; — determining the causes of the nonconformity; — determining if similar nonconformities exist, or could potentially occur;



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Common Findings 2022 #6

7.6 Evaluation of measurement uncertainty

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

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

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

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#6 “7.6Evaluation of measurement uncertainty”

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

Notes are provided in Standard for guidance.

Test labs can not ignore and will need to address.

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

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

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Common Findings 2022 #5

6.6 Externally provided products and services

This section combines the concepts of purchasing and subcontracting

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

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

Should provide document showing how it is done and produce records for critical suppliers showing that it was done.

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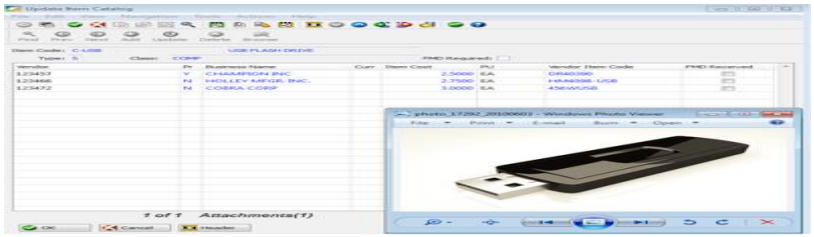
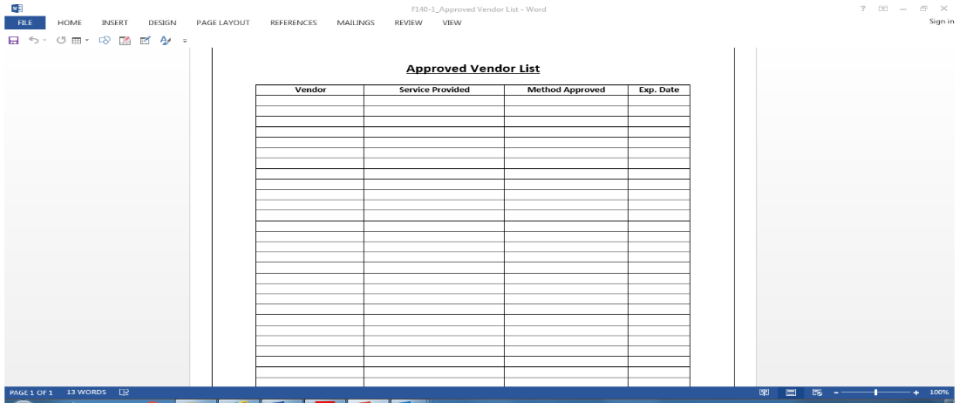
#5 “6.6 Externally provided products and services”

Labs has flexibility on showing a record that the requirements are being met; the criteria for approving the supplier will need to be captured.

7	Excellence	Exceeds company’s and customers’ expectations, demonstrates extra effort
5	Good	Meets the company’s expectations
3	Acceptable	Meets company’s minimum requirements
1	Poor	Does not meet company’s and customers’ minimum acceptable level
2,4,6,8,9		Annectent grades





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Common Findings 2022 #4

8.8 Internal audits

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

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#4 “8.8 Internal audits”

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

a) conforms to:

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

— the requirements of this document;

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#4 “8.8 Internal audits”

at planned intervals:

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

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

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#4 “8.8 Internal audits”

to provide information on whether the management system:

a) conforms to:

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

Words are meaningless without intent and follow through

Do as you say

Say as you do

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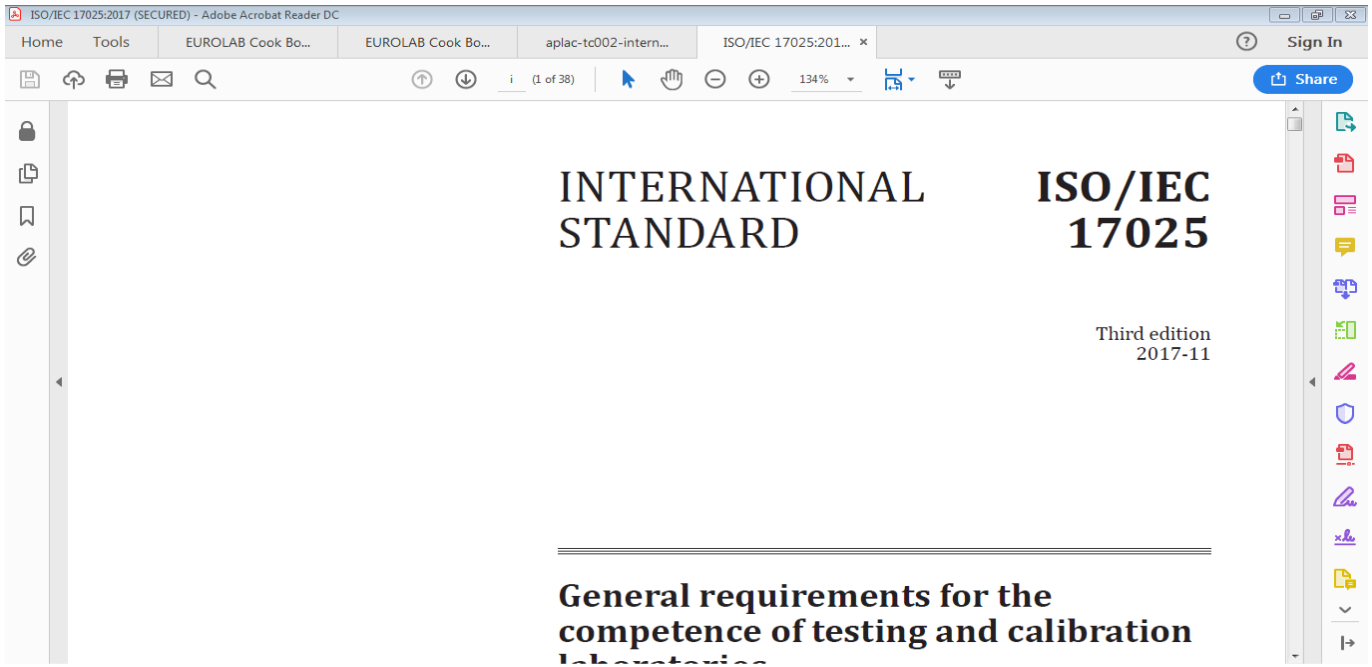
#4 “8.8 Internal audits”

to provide information on whether the management system:

a) conforms to:

— the requirements of this document



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#4 “8.8 Internal audits”

to provide information on whether the management system:

b) is effectively implemented and maintained.

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Common Findings 2022 #3

6.2 Personnel

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

As an auditor you 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

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#3 “6.2 Personnel”

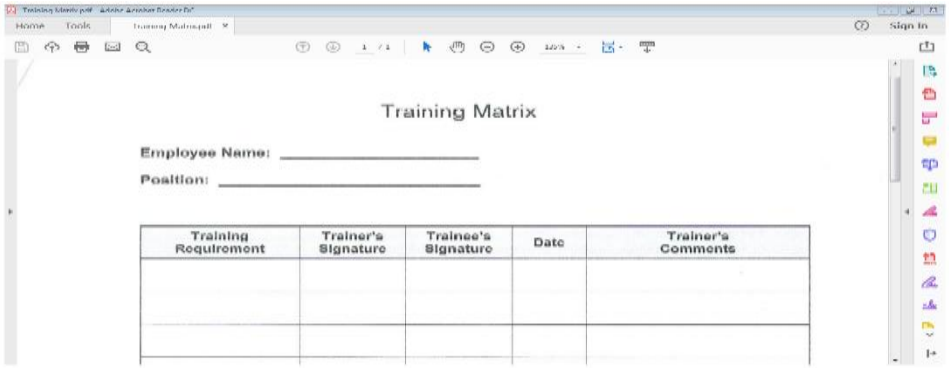
6.2.5 The laboratory shall have procedure(s) and retain records for:

d) supervision of personnel;

-Training Record

e) authorization of personnel;

-Can be an authorization matrix or training record sign off



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#3 “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.
- Lab determines how to monitor however this can utilize such vehicles as checking personnel’s data and reports, or participation in inter lab or intra lab testing.

Other methods can incorporate:

- Recertification
- Written Test
- Supervisor follow up after training is complete (60 days)

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#3 “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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Common Findings 2022 #2

7.8 Reporting of results

This section covers all three areas of 17025 which includes testing, calibration, and sampling

REPORTING THE RESULTS (7.8)

7.8.1 General – review and authorize prior to release

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

7.8.3 Specific requirements for test reports

7.8.4 Specific requirements for calibration certificates

7.8.5 Specific requirements for reporting sampling

7.8.6 Reporting statements of conformity

7.8.7 Reporting opinions and interpretations

7.8.8 Amendments to reports

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#2 “7.8 Reporting of results”

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

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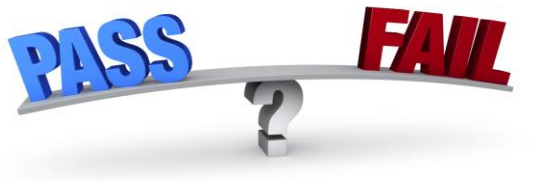
#2 “7.8 Reporting of results”

7.8.6 Reporting statements of conformity

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

As defined in ISO/IEC 17025:2017

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



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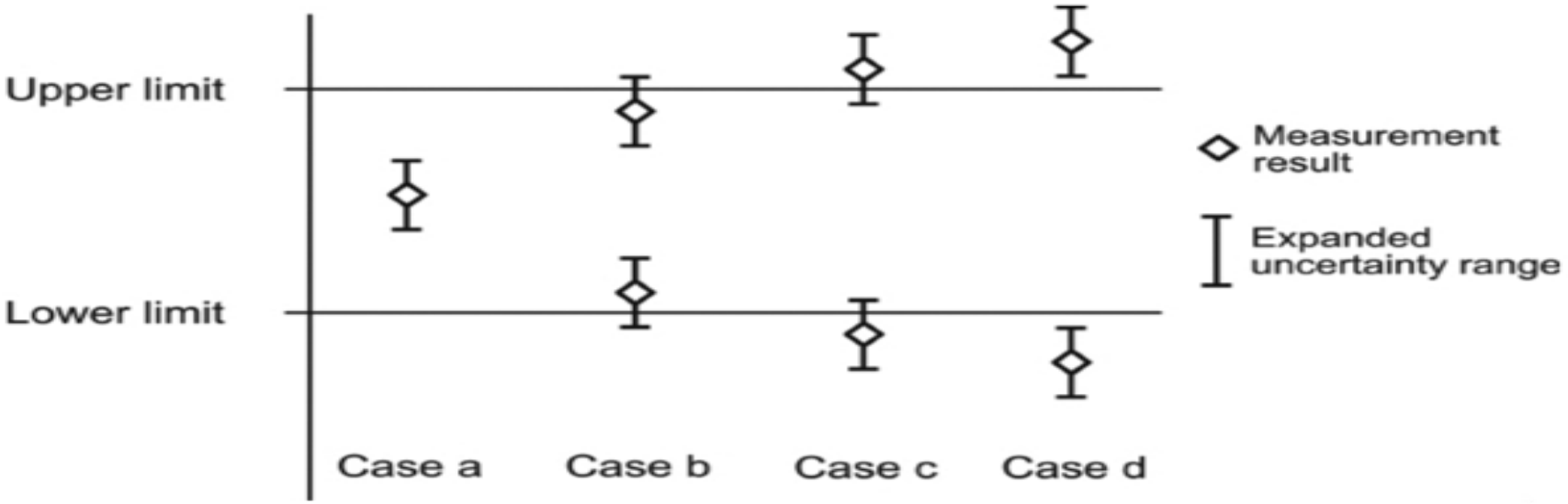
#2 “7.8 Reporting of results”

Taking Uncertainty into account



Case a = pass Case b =? Case c =? Case d = fail

Decision Rule is a statement of rules describing how you will use the Measurement Uncertainty in relation to the measurement results and tolerance to come up with a pass or failed decision

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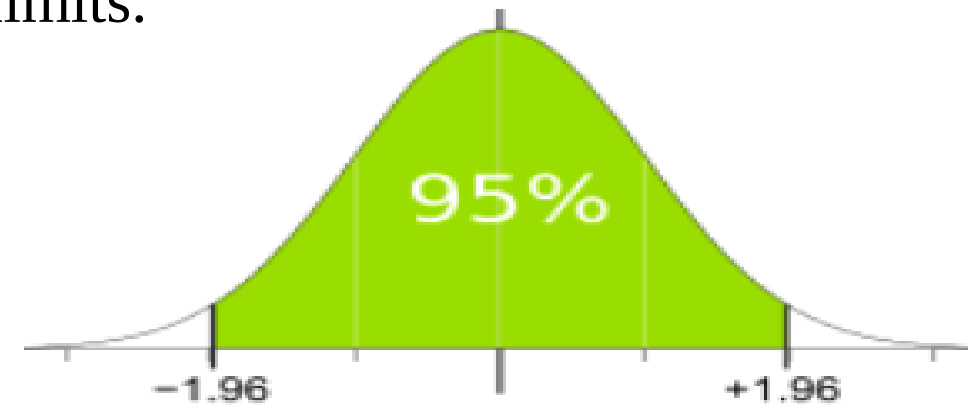
#2 “7.8 Reporting of results”

If accepted by the customer as per the requirements specified in 7.1.3, the following decision rules can be documented:

Accounting for the uncertainty will be taken to mean that at a 95% confidence level the measurement result plus and minus the expanded uncertainty (k=2) shall be totally within the specification limits.



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Common Findings 2022 #1

Section 6.4 Equipment

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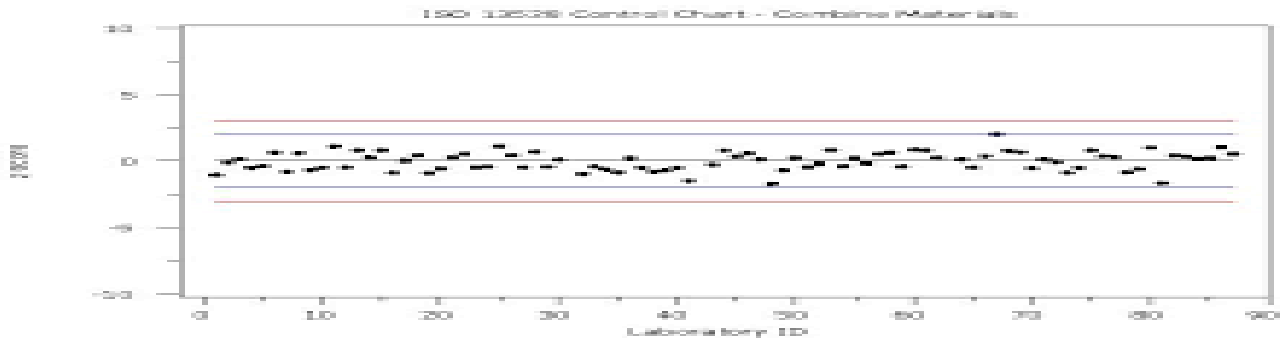
#1 Section 6.4 Equipment

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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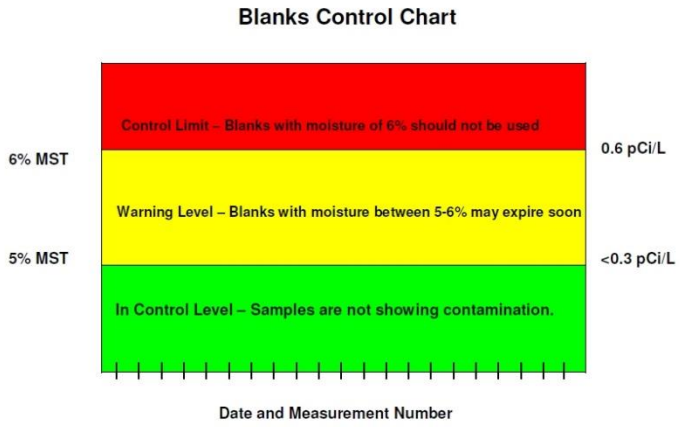
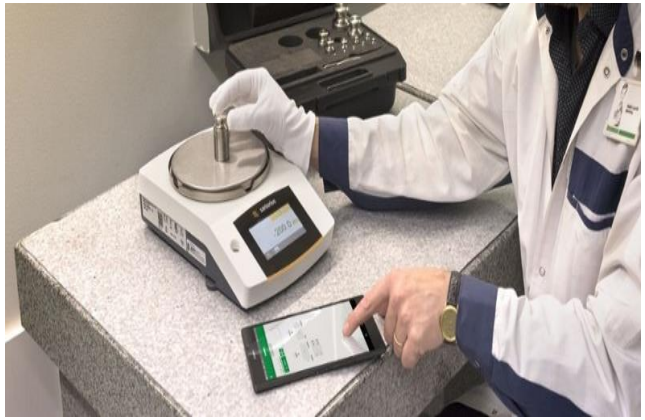
#1 Section 6.4 Equipment

- **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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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

A Look at ISO/IEC 17025: 2017 - Section 7.6 “Evaluation of Measurement Uncertainty” for Testing Laboratories

Tuesday, Feb 21st 2023

Presented by:

Matthew Sika, PJLA Testing Program Manager

February 21, 2023 1:00 PM - 2:00 PM EST

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