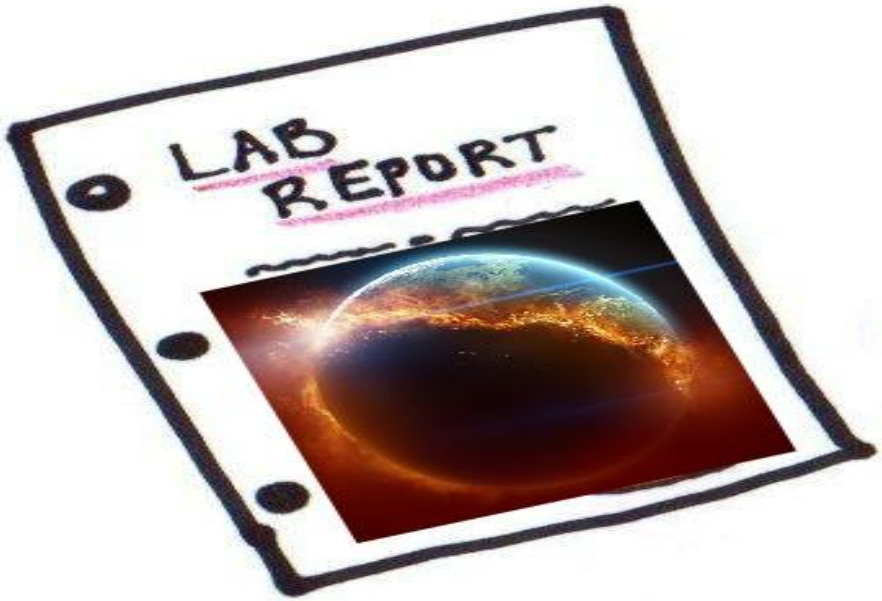
Section 7.8 of ISO/IEC 17025:2017 “Reporting of Results”



Presenter: Michael Kramer
PJLA Calibration/Inspection Program Manager
31-March-2022

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

- This webinar is being recorded
- All PJLA webinar recordings and slides are available for download from the Past Webinars section of our website
  - https://www.pjlabs.com/training/pjla-webinars
- 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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Section 7.8 of ISO/IEC 17025:2017 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

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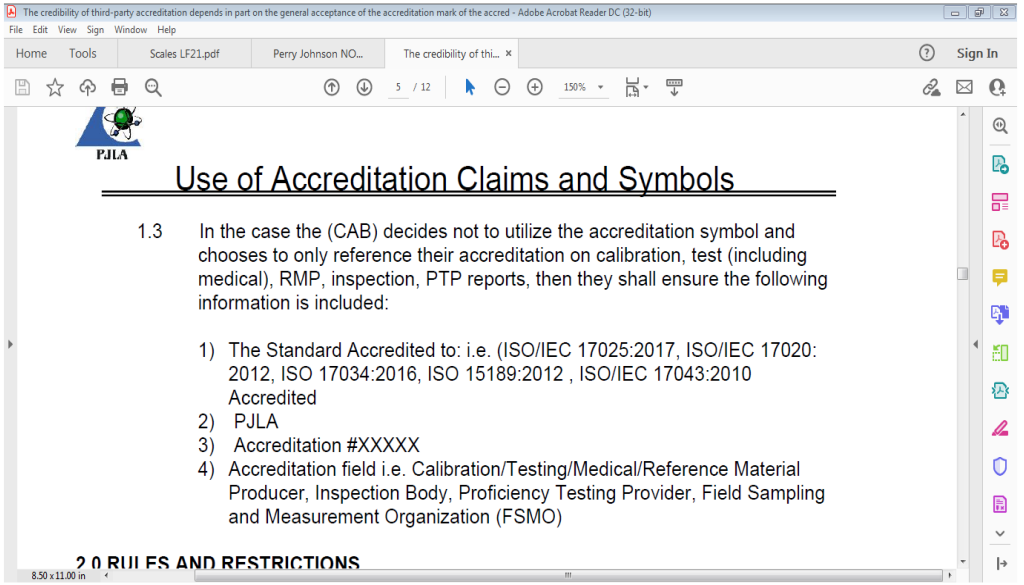
Reporting the Results

- Calibration or test reports whom utilizes the symbol or references accreditation on calibration or test reports are considered accredited certificates or reports and come under the realm of Section 7.8 of ISO/IEC 17025:2017 and any applicable polices of the accreditation body. Refer to PJLA SOP 3 “Accreditation Symbol Procedure”


The credibility of third-party accreditation depends in part on the general acceptance of the accreditation mark of the accred - Adobe Acrobat Reader DC (32-bit)

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Use of Accreditation Claims and Symbols

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

1) The Standard Accredited to: i.e. (ISO/IEC 17025:2017, ISO/IEC 17020: 2012, ISO 17034:2016, ISO 15189:2012 , ISO/IEC 17043:2010 Accredited
2) PJLA
3) Accreditation #XXXXX
4) Accreditation field i.e. Calibration/Testing/Medical/Reference Material Producer, Inspection Body, Proficiency Testing Provider, Field Sampling and Measurement Organization (FSMO)

2.0 RULES AND RESTRICTIONS

8.50 x 11.00 in

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Calibration

- **Accreditation# XXXXX**

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

- This section covers all three area's 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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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

- **7.8.1 General**

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

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

e) authorization of personnel;

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

c) report, review and authorization of results.

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

7.8.1.2 The results shall be provided accurately, clearly, unambiguously and objectively, usually in a report (e.g. a test report or a calibration certificate or report of sampling), and shall include all the information agreed with the customer and necessary for the interpretation of the results and all information required by the method used. All issued reports shall be retained as technical records.

If something is unambiguous, there are no two ways to interpret it.

When you do something objectively, you do it with an open mind, considering the facts rather than your personal feelings.

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

NOTE 1 For the purposes of this document, test reports and calibration certificates are sometimes referred to as test certificates and calibration reports, respectively.

NOTE 2 Reports can be issued as hard copies or by electronic means, provided that the requirements of this document are met

Even though ISO/IEC 17025:2017 is in tune with today's electronic age, pager reports, records, and documents are still recognized.

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

7.8.1.3 When agreed with the customer, the results may be reported in a simplified way. Any information listed in 7.8.2 to 7.8.7 that is not reported to the customer shall be readily available.

The lab should however maintain a record of this agreement;

PL-3 specifies written agreement in regards to uncertainty reporting;

Records however need to be maintained where if needed can retrieve all required elements under reporting;

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

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

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”, “Calibration Certificate” or “Report of Sampling”);

b) the name and address of the laboratory;

c) the location of performance of the laboratory activities, including when performed at a customer facility or at sites away from the laboratory’s permanent facilities, or in associated temporary or mobile facilities;

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Common requirements for reports (test, calibration or sampling)

d) unique identification that all its components are recognized as a portion of a complete report and a clear identification of the end;

This can be a certificate #, report ID, test # need to be unique and not duplicated

e) the name and **contact information** of the customer;

f) identification of the method used;

This can be a lab procedure (SOP 123), or a Standard procedure such as ASTM , ASME or USP type method.

g) a description, unambiguous identification, and, when necessary, the condition of the item;

In other words what was tested or calibrated.

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Common requirements for reports (test, calibration or sampling)

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;**

Shelf life may be critical if it sample may degrade over time (moisture content), therefore it would be important to record date of receipt.

i) the date(s) of performance of the laboratory activity;

j) the date of issue of the report; "*even if same as date of performance*"

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;

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Common requirements for reports (test, calibration or sampling)

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;

Quantity	Unit	Abbreviation
Length	Meter	m
Mass	Kilogram	kg
Time	Second	s
Thermodynamic Temperature	Kelvin	K
Amount of Substance	Mole	mol
Electric Current	Ampere	A

Common requirements for reports (test, calibration or sampling)

n) additions to, deviations, or exclusions from the method;

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

This would be specified even if same person that did the test or calibration. Also see 6.2.5 below:

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

c) report, review and authorization of results;

p) clear identification when results are from external providers;

NOTE Including a statement specifying that the report shall not be reproduced except in full without approval of the laboratory can provide assurance that parts of a report are not taken out of context.

For example cut and paste parts of a report

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Common requirements for reports (test, calibration or sampling

7.8.2.2 The laboratory shall be responsible for all the information provided in the report, except when information is provided by the customer. Data provided by a customer shall be clearly identified. In addition, a disclaimer shall be put on the report when the information is supplied by the customer and can affect the validity of results. Where the laboratory has not been responsible for the sampling stage (e.g. the sample has been provided by the customer), it shall state in the report that the results apply to the sample as received

Information provided by the customer may be needed to proceed with test or calibration if environmental criteria are not within predefined limits (customer location) *see: 6.4.1 "Handling of Test or Calibration Items"*
When the customer requires the item to be tested or calibrated acknowledging a deviation from specified conditions, the laboratory shall include a disclaimer in the report indicating which results may be affected by the deviation.;

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

7.8.3 Specific requirements for test reports

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

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

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

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Specific requirements for test reports

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

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

— a customer's instruction so requires, or

— the measurement uncertainty affects conformity to a specification limit

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Specific requirements for test reports

d) where appropriate, opinions and interpretations (see 7.8.7);

e) additional information that may be required by specific methods, authorities, customers or groups of customers;

7.8.3.2 Where the laboratory is responsible for the sampling activity, test reports shall meet the requirements listed in 7.8.5 where necessary for the interpretation of test results.

This is when the laboratory is actually collecting the samples to be tested.

Sampling Clover Seed

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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

- **7.8.4 Specific requirements for calibration certificates**

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

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

NOTE According to ISO/IEC Guide 99, a measurement result is generally expressed as a single measured quantity value including unit of measurement and a measurement uncertainty.

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Specific requirements for calibration certificates

7.8.4.1 calibration certificates shall include the following:

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

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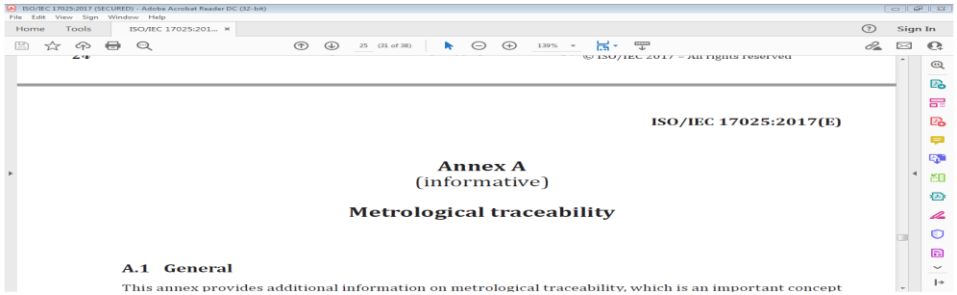
Specific requirements for calibration certificates

7.8.4.1 calibration certificates shall include the following:

c) a statement identifying how the measurements are metrologically traceable (see Annex A);

Also see PL-2 “To SI through NIST”

NIST  Commercial Lab



ISO/IEC 17025:2017(E)

Annex A
(informative)

Metrological traceability

A.1 General

This annex provides additional information on metrological traceability, which is an important concept

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Specific requirements for calibration certificates

7.8.4.1 calibration certificates shall include the following:

d) the results before and after any adjustment or repair, if available;

Before can be considered as "as used"

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

- Pass/Fail In Tolerance/Out of Tolerance

f) where appropriate, opinions and interpretations (see 7.8.7).

7.8.4.2 Where the laboratory is responsible for the sampling activity, calibration certificates shall meet the requirements listed in 7.8.5 where necessary for the interpretation of calibration results

Sampling is primarily associated with testing labs.

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Specific requirements for calibration certificates

:

7.8.4.3 A calibration certificate or calibration label shall not contain any recommendation on the calibration interval, except where this has been agreed with the customer.

Not required to be on reports however if it is then it is required to be customer specified.

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Specific requirements for reporting sampling

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.

a) the date of sampling;

b) unique identification of the item or material sampled (including the name of the manufacturer, the model or type of designation and serial numbers, as appropriate);

;

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Specific requirements for reporting sampling

7.8.5 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.

c) the location of sampling, including any diagrams, sketches or photographs;

d) a reference to the sampling plan and sampling method

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Reporting sampling – specific requirements

7.8.5 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

e) details of any environmental conditions during sampling that affect the interpretation of the results

f) information required to evaluate measurement uncertainty for subsequent testing or calibration

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Reporting Statements of Conformity

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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Reporting Statements of Conformity

7.8.6 Reporting statements of conformity

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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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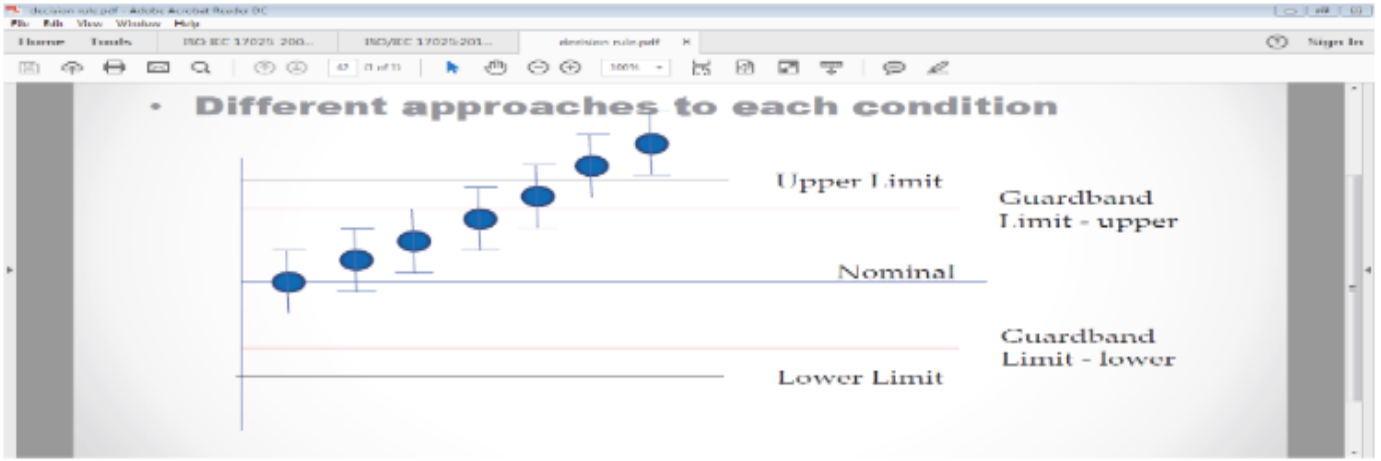
Reporting statements of conformity

7.8.6.2 The laboratory shall report on the statement of conformity, such that the statement clearly identifies:

a) to which results the statement of conformity applies;

b) which specifications, standards or parts thereof are met or not met;

c) the decision rule applied (unless it is inherent in the requested specification or standard



- NOTE For further information, see ISO/IEC Guide 98-4

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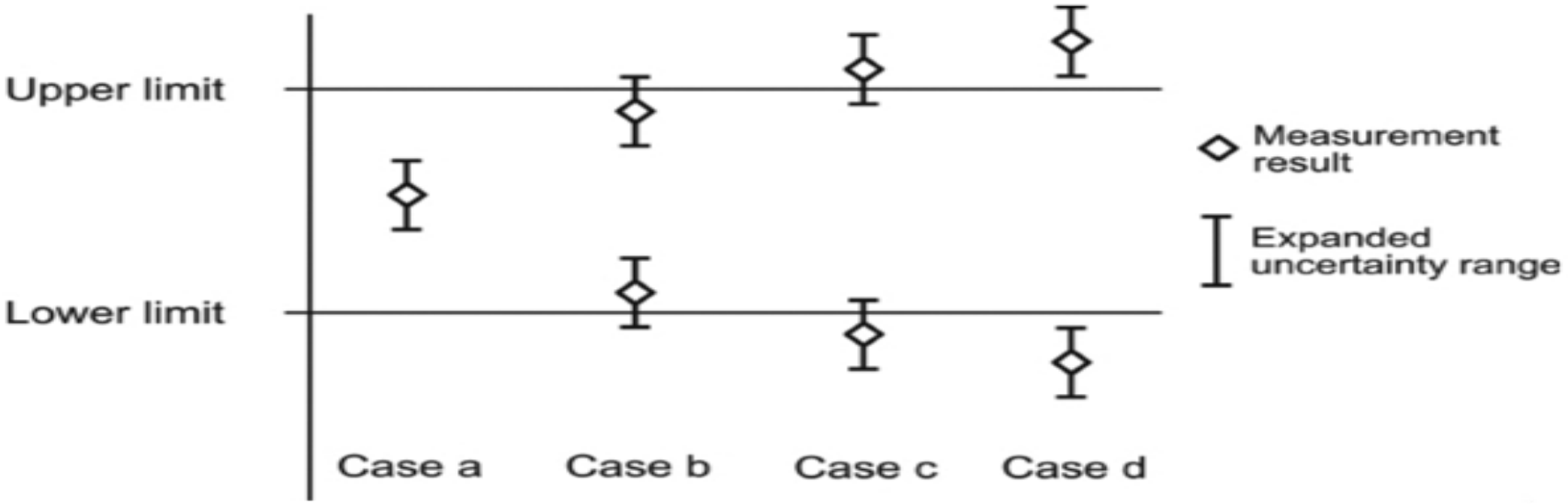
Reporting statements of conformity

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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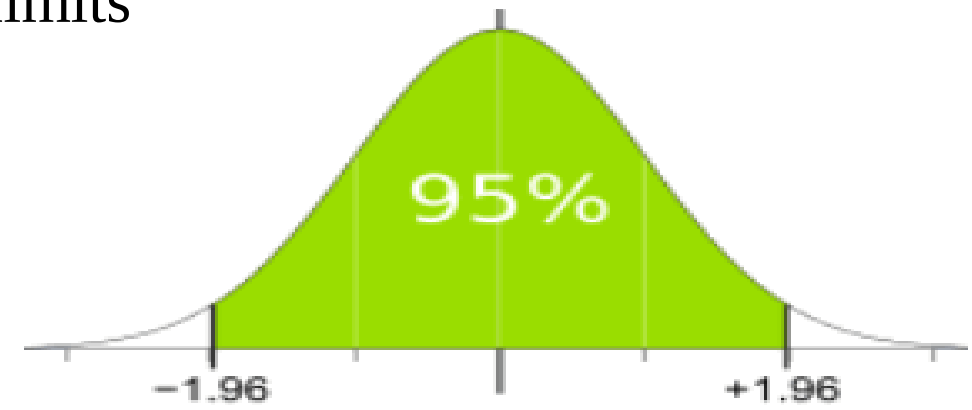
Reporting statements of conformity

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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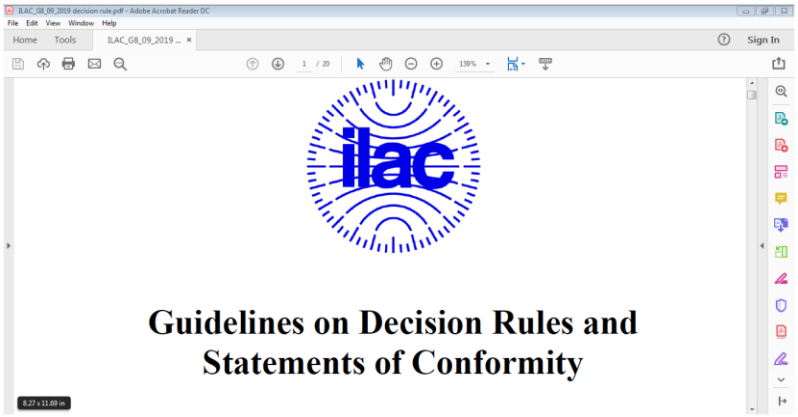
ILAC-G8:09/2019 Guidelines on Decision Rules and Statements of Conformity

This guidance document has been prepared to assist laboratories in the use of decision rules when declaring statements of conformity to a specification or standard as required by ISO/IEC 17025:2017

ISO/IEC 17025:2017 recognizes that no single decision rule can address all statements of conformity across the diverse scope of testing and calibration



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Reporting statements of conformity

- There are testing methods that determine how the rules are applied. One good, common illustration is ASTM E18 for Rockwell Hardness where the testing and calibration decision rules take uncertainty into account effectively in the repeat testing and other "limits" as to the spread of the data etc. and the rules are defined in the method.
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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

- **7.8.7 Reporting opinions and interpretations**

7.8.7.1 When opinions and interpretations are expressed, the laboratory shall ensure **that only personnel authorized** for the expression of opinions and interpretations release the respective statement. The laboratory shall document the basis upon which the opinions and interpretations have been made.

This authorization needs to be captured per

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

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

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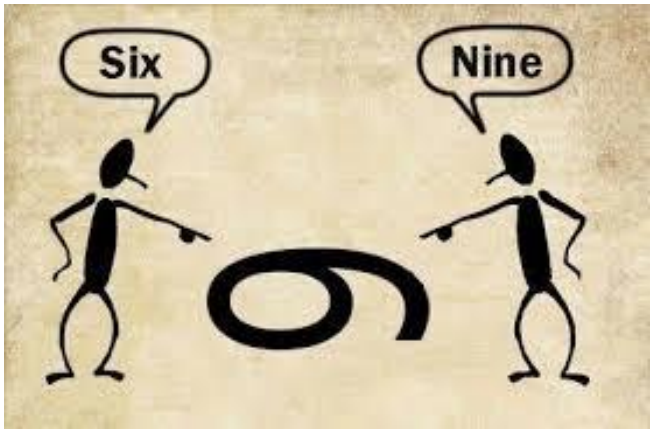
7.8.7 Reporting opinions and interpretations

7.8.7.2 The opinions and interpretations expressed in reports shall be based on the results obtained from the tested or calibrated item and shall be clearly identified as such.

7.8.7.3 When opinions and interpretations are directly communicated by dialogue with the customer, a record of the dialogue shall be retained



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Section 7.8 of ISO/IEC 17025:2017 Reporting of Results

7.8.8 Amendments to reports

7.8.8.1 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.

7.8.8.2 Amendments to a report after issue shall be made only in the form of a further document, or data transfer, which includes the statement "Amendment to Report, serial number... [or as otherwise identified]", or an equivalent form of wording.

Such amendments shall meet all the requirements of this document

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Amendments to reports

- **7.8.8.3** When it is necessary to issue a complete new report, this shall be uniquely identified and shall contain a reference to the original that it replaces

- Certificate # 1234AR
- This report replaces certificate #1234

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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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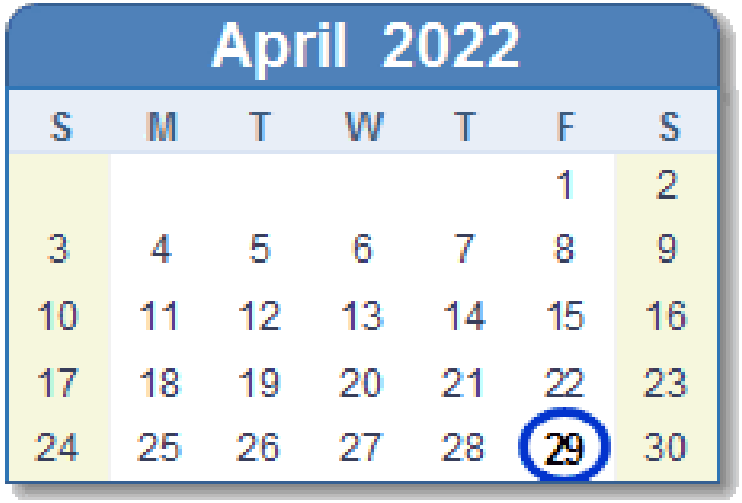
Save the Date

ISO/IEC 17025:2017 Requirements Concerning Document Control and Control of Records



Friday, Apr 29th 2022

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