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

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

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

The report that the laboratory issues can be considered the final product. ISO/IEC 17025:2017 is designed to ensure factors that can affect this final product are addressed, such as:

- Personnel are properly trained
- Appropriate procedures and practices in place
- Suitable facilities used
- Equipment utilized is fit for purpose
- Traceability of standards
- A process for handling the customers equipment

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Terms for Reports of Results

There are a few common names utilized for the documents that report the results of calibrations and tests. The most common are:

- Calibration Certificate
- Test Report
- Report of Calibration

These are largely interchangeable and is determined by each individual lab.

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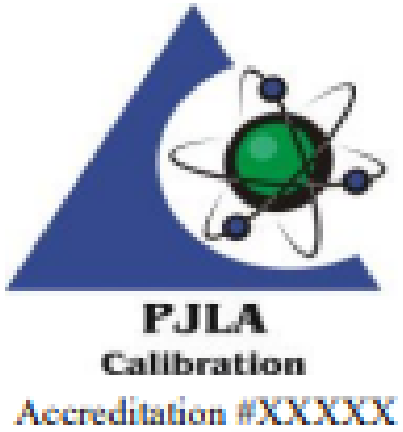
Accredited and Non-Accredited Reports of Results

There are labs that offer both accredited and non-accredited calibrations. When a calibration/test certificate utilizes the accreditation symbol or references accreditation they fall under Section 7.8 of ISO/IEC 17025:2017 and any applicable polices of the accreditation body.

PJLA's policy regarding this is SOP-3 "Use of Accreditation Claims and Symbols"



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)

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

This section covers the three areas of 17025 testing, calibration, and sampling. It is divided into the following subsections:

- 7.8.1 General (review and authorize prior to release)
- 7.8.2 Common requirements for reports (test, calibration or sampling)
- 7.8.3 Specific requirements for test reports
- 7.8.4 Specific requirements for calibration certificates
- 7.8.5 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 7.8.1 General
Reviewing and Authorizing Results

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

But who reviews and authorizes the results?

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 7.8.1 General

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.*

Unambiguous- not open to more than one interpretation.

Objectively- in a way that is not influenced by personal feelings or opinions.

"The facts, Ma'am.
Just the facts."

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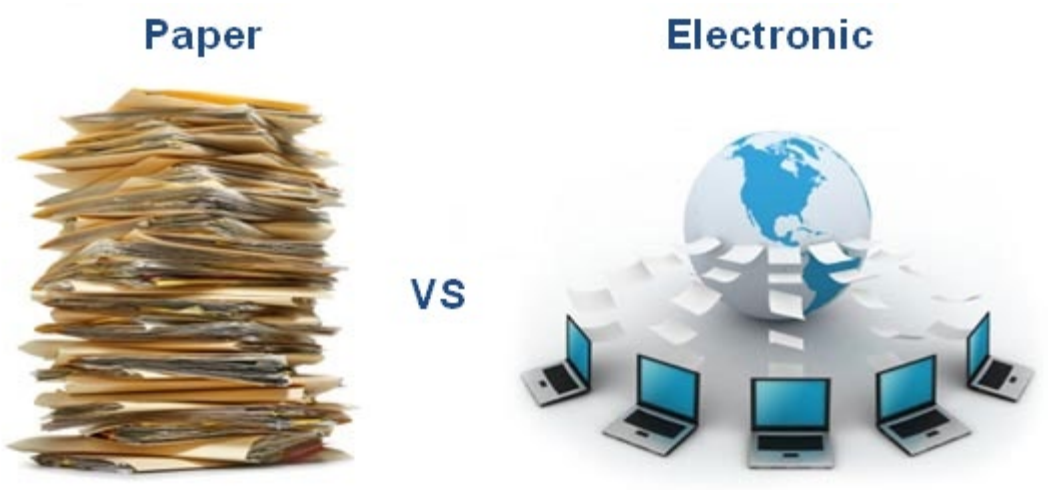
Section 7.8.1 General

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.*

Yes, ISO/IEC 17025 allows for both paper and digital copies to be used.



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Section 7.8.1 General (Simplified Reporting)

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.*

- A record of these agreements should be maintained by the lab
- Records need to be maintained where, if needed, all required elements under reporting can be retrieved.
- PL-3 specifies written agreement regarding uncertainty reporting;

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Section 7.8.2
Common requirements for reports

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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Section 7.8.2.1
Common requirements for reports (Continued)

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 #, etc. But it needs to be unique and cannot be duplicated.

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

f) identification of the method used;

This can be an internal procedure, a Standard procedure (ASTM , ASME, NIST, etc.) or USP type method.

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

What was calibrated or tested? Ex: Truck Scale

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Section 7.8.2.1
Common requirements for reports (Continued)

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;*

Even if the date of calibration/test and the date issue are the same both need to appear.

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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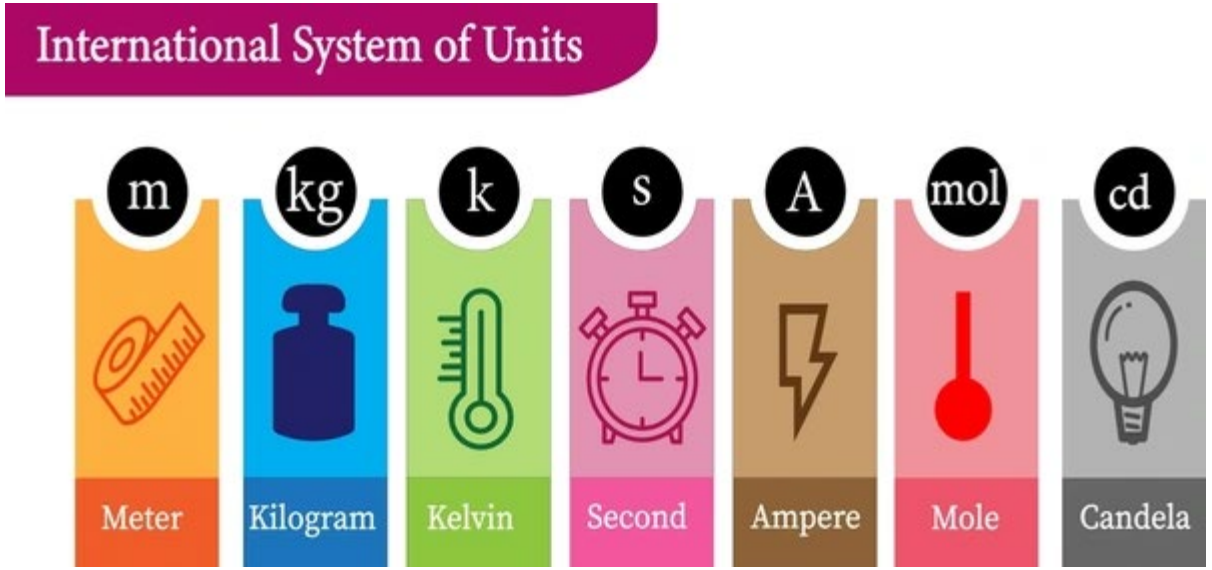
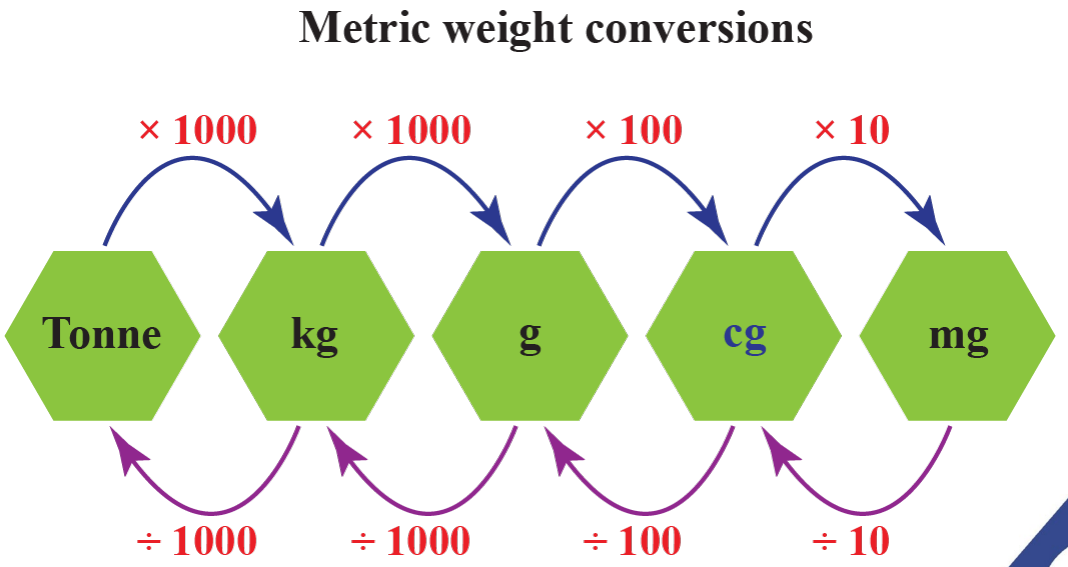
Section 7.8.2.1
Common requirements for reports (Continued)

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;





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Section 7.8.2.1
Common requirements for reports (Continued)

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

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

This needs to be specified even if the same person performed the calibration/test.

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.*

An example of this would be cutting and pasting part of the calibration certificate.

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Section 7.8.2.2
Common requirements for reports

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 the calibration/test if environmental criteria are not within predefined limits (customer location)

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Section 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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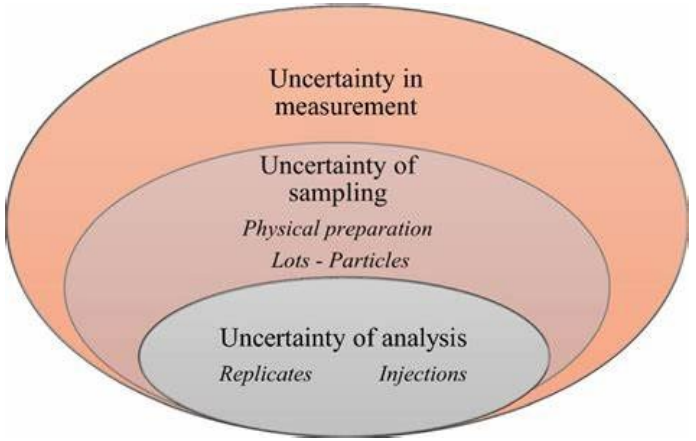
Section 7.8.3
Specific requirements for test reports (Cont.)

c) ***Where applicable**, the measurement uncertainty presented in the same unit as that of the measurand or in a term relative to the measurand (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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Section 7.8.3
Specific requirements for test reports (Cont.)

f) ***Where appropriate****, opinions and interpretations (see 7.8.7);*

g) 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 would apply when the Laboratory is collecting the samples to be tested.

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Section 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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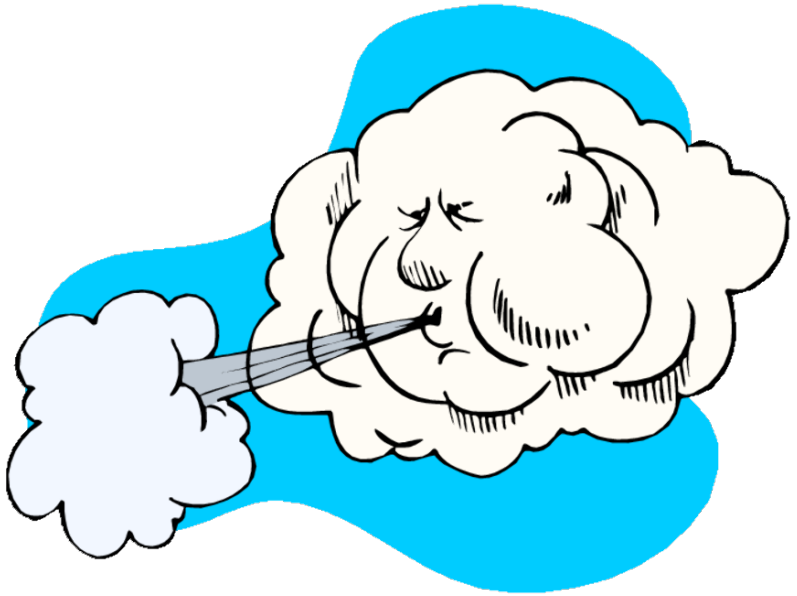
Section 7.8.4
Specific requirements for calibration certificates

*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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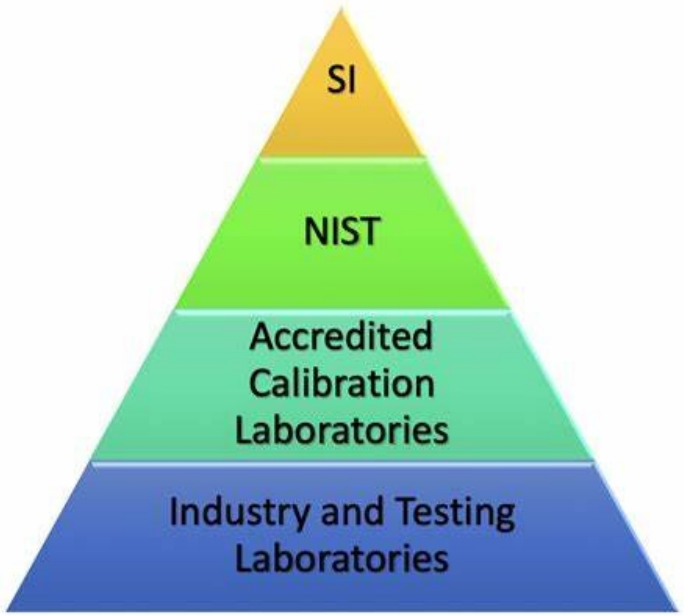
Section 7.8.4
Specific requirements for calibration certificates

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

PJLA's PL-2 "Measurement Traceability Policy" also provides additional guidance.

"NIST traceable" is technically incorrect.

But "Traceable to SI through NIST" is correct



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Section 7.8.4
Specific requirements for calibration certificates

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

This is commonly shown as “As-Found” and “As-Left” data

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

Examples: “Pass/Fail” or “In Tolerance/Out of Tolerance”

f) ***where appropriate****, opinions and interpretations (see 7.8.7);*

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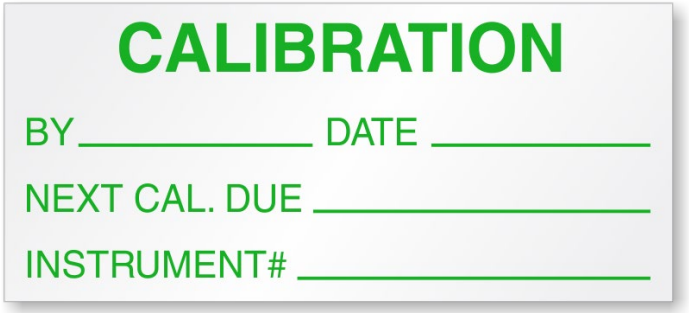
Section 7.8.4
Specific requirements for calibration certificates

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 applicable to testing Labs.

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.*



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Section 7.8.5
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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Section 7.8.5
Specific requirements for reporting Sampling

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

d) *a reference to the sampling plan and sampling method;*

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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Section 7.8.6
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.*

NOTE *Where the decision rule is prescribed by the customer, regulations or normative documents, a further consideration of the level of risk is not necessary.*

ISO/IEC 17025 defines "decision rule" as- *rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement.*

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Section 7.8.6
Reporting statements of conformity (Continued)

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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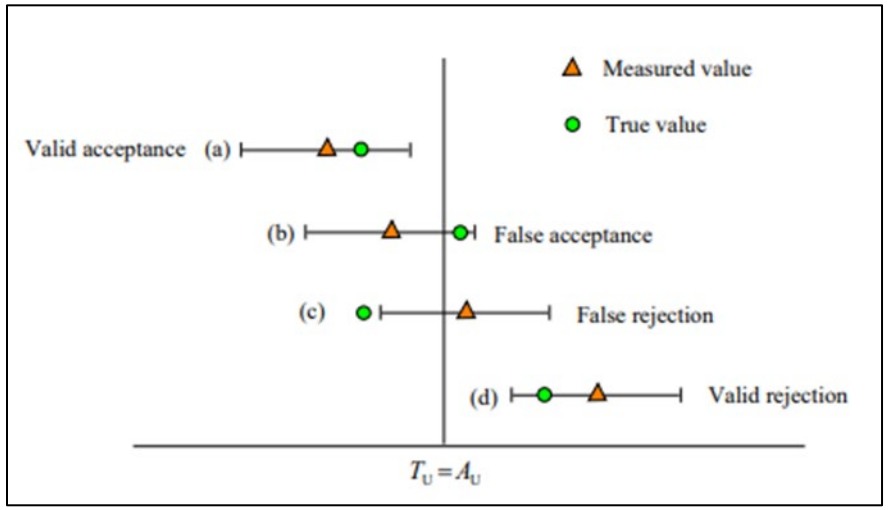
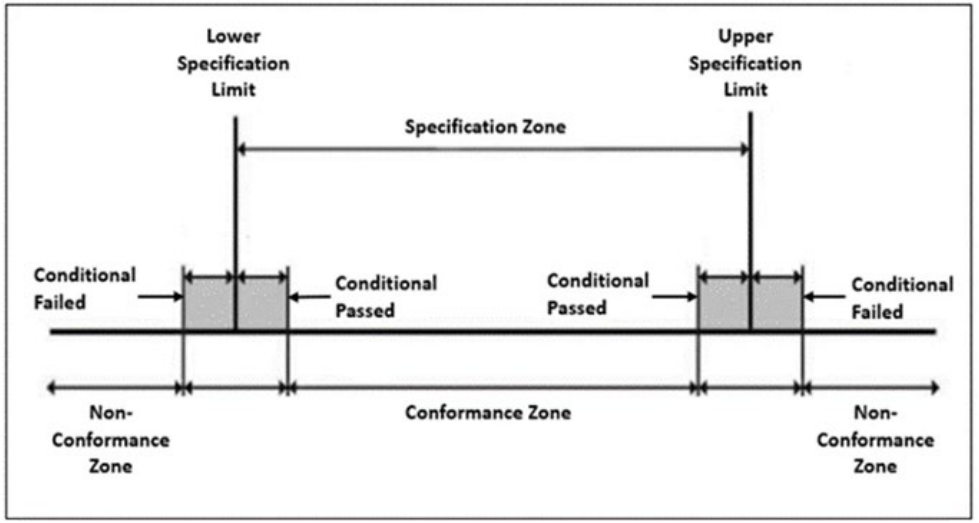
Reporting statements of conformity (Factoring in Uncertainty)





Decision Rule is a statement describing how you will use the Measurement Uncertainty in relation to the measurement results and tolerance to produce a pass/fail decision.

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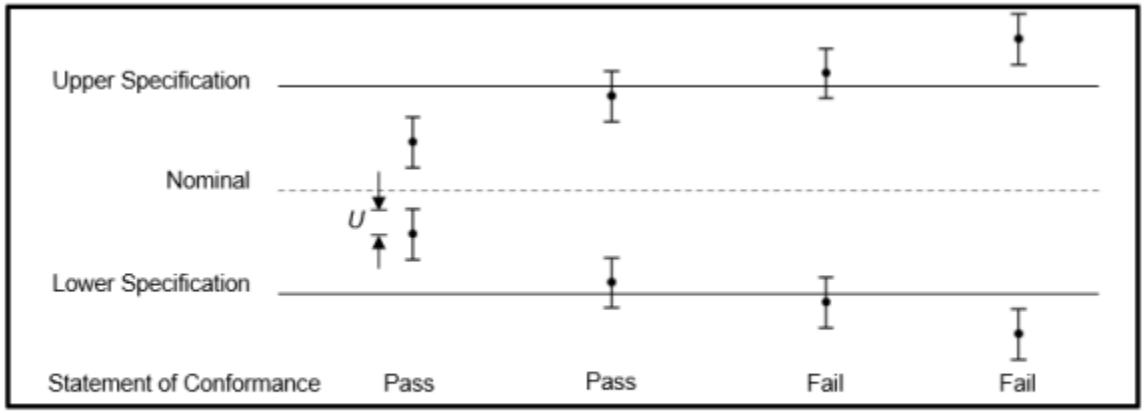
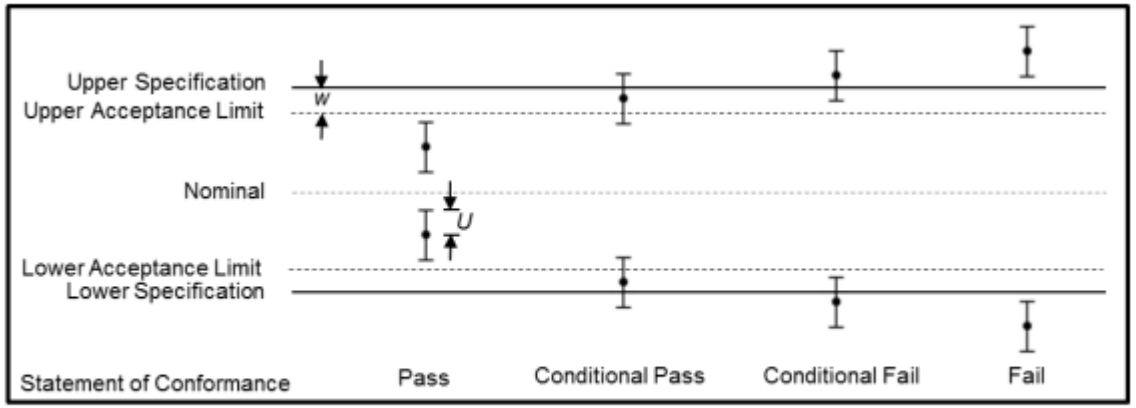
Reporting statements of conformity (Factoring in Uncertainty)



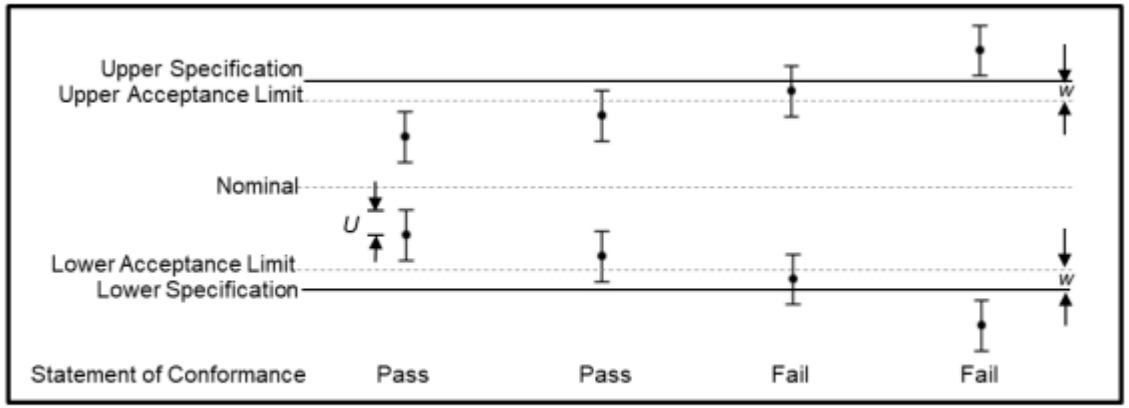
U = 95% expanded measurement uncertainty

Figure 3 Graphical representation of a Binary statement - Simple Acceptance



U = 95% expanded measurement uncertainty

Figure 5 Graphical representation of a non-Binary statement with a guard band (shown for $w = U$)



U = 95% expanded measurement uncertainty

Figure 4 Graphical representation of a Binary statement with a guard band

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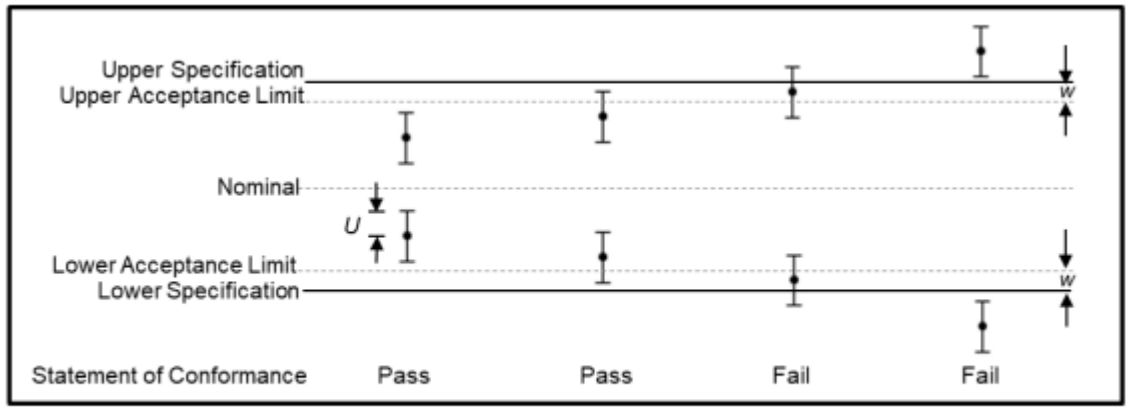
Reporting statements of conformity (Continued)

If accepted by the customer, per the 7.1.3 requirements, 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.



U = 95% expanded measurement uncertainty

Figure 4 Graphical representation of a Binary statement with a guard band

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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.

This document provides:

a) *overall guidance on how to select appropriate decision rules; and*

b) *guidance on compiling the required elements of a decision rule if no standard published rules apply.*

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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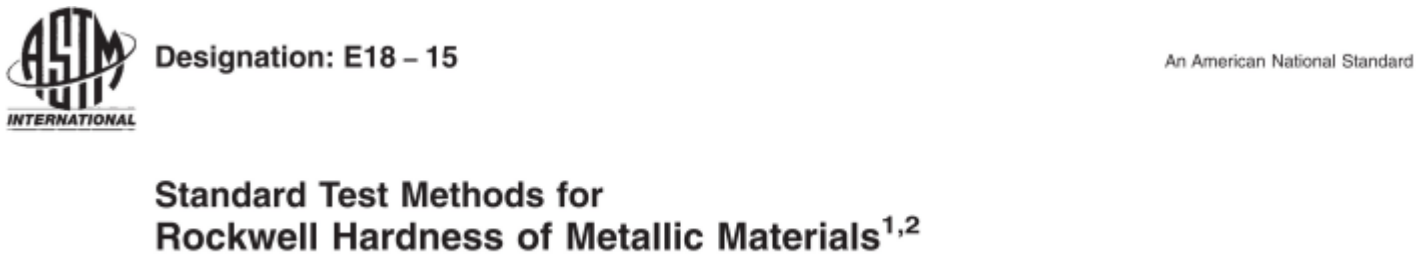
Reporting statements of conformity (Method based Rules)

There are testing methods that determine how the decision rules are to be applied.

A good example being ASTM E18 for Rockwell Hardness.

- The rules are defined in the method
- The decision rules effectively take uncertainty into account by utilizing repeat testing and other "limits" to the spread of the data, etc.


Designation: E18 – 15

An American National Standard

Standard Test Methods for
Rockwell Hardness of Metallic Materials[1,2]

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Section 7.8.7
Reporting opinions and interpretations

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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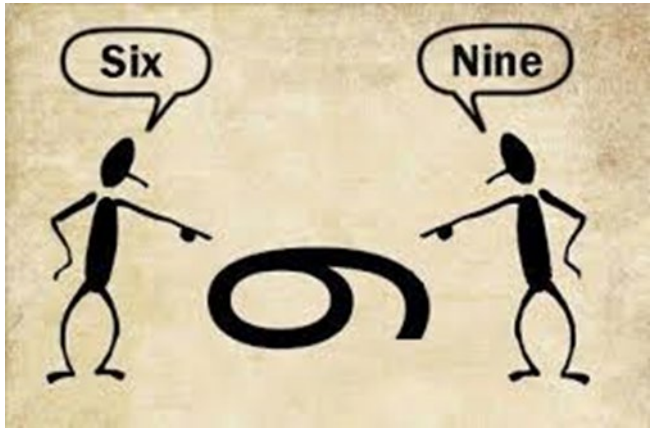
Section 7.8.7
Reporting opinions and interpretations

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 7.8.8
Amendments to reports

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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Section 7.8.8
Amendments to reports (Continued)

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.*

Examples include:

- Certificate# 1234AR
- Certificate# 1234, Rev.1
- Certificate# 1234 (10/3/2024 revision)
- “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.

If a question is not answered, send an email directly to webinar@pjlabs.com

Save the Date!

Approaches to Competence of Personnel

Free Live Workshop

presented by Matthew Sica

October 15, 2024

1:00 to 3:00 pm EST