

A background image showing a hand holding a glowing, spherical network of white nodes connected by thin white lines, set against a blurred background of a person's face and a blue sky. The network is dense and complex, resembling a molecular structure or a data network.

How to Develop and Interpret Calibration Certificates

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- Development of Calibration Certificates:
 - ✓ Contents of Calibration certificates according to the requirements of ISO/IEC 17025
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- Interpretation of Calibration Certificates
 - ✓ Examples
- Digital Calibration Certificates (DCC)

Development of Calibration Certificates

ISO/IEC 17025:2017 Requirements

The standard requires answers to 5 key questions:

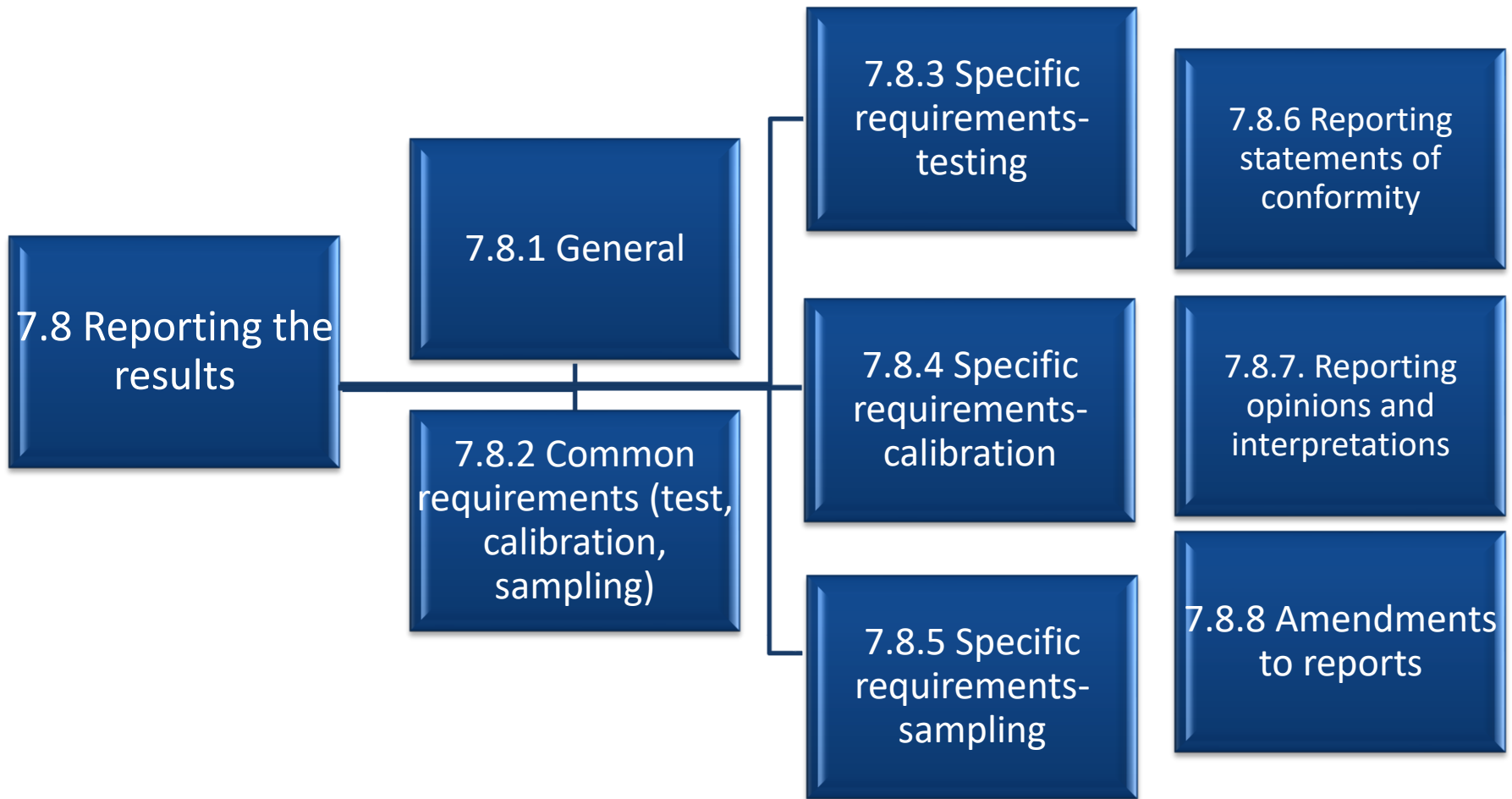
WHAT was calibrated?

WHEN was it calibrated?

WHERE was it calibrated?

WHO calibrated it?

HOW was it calibrated?



ISO/IEC 17025:2017 Requirements

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



By WHOM?

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

ISO/IEC 17025:2017 Requirements

- 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 is only one way to interpret it.
- When you do something **objectively**, you do it with an open mind, considering the facts rather than your personal feelings

ISO/IEC 17025:2017 Requirements

- 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.**

- No longer specifies internal customers or written agreement with external customers


ISO/IEC 17025:2017 Requirements

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

ISO/IEC 17025:2017 Requirements

- e) the name and **contact information** of the customer;
- i) the date(s) of performance of the laboratory activity;
- j) the date of issue of the report;
- l) a statement to the effect that the **results relate only to the items tested, calibrated or sampled**;



If calibrating 10 gauge blocks of 10 mm, it would be relevant to state which results are for which gauge block

ISO/IEC 17025:2017 Requirements

- m) the results with, where appropriate, **the units of measurement**;
- o) **identification** of the person(s) authorizing the report;



Base Quantity	Name	Symbol
Length	meter	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Amount of substance	mole	mol
Luminous intensity	candela	cd

By stating their corresponding name, title, and signature. Each authorized signatory accepts responsibility for the technical accuracy and validity of the reported results.


ISO/IEC 17025:2017 Requirements

7.8.2.1 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**.

- The calibration certificate cannot be reproduced (to make another copy) only in part, where some pages are missing.
- Certificates are allowed to be reproduced as complete documents (all pages). This ensures that the user will get the complete information, and therefore, proper interpretation of data results.
- In any case, you want to reproduce only one part (f.i. only 1 page), ask the laboratory for approval.

ISO/IEC 17025:2017 Requirements

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 calibration if environmental criteria are not within predefined limits (customer location and QS)

ISO/IEC 17025:2017 Requirements

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.

coverage factor and estimated confidence interval shall accompany the measurement result

multiple or submultiple

ISO/IEC 17025:2017 Requirements

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.

Special care shall be used when the coverage factor is not consistent for all calibrated items. The results table should be formatted to clearly identify individual coverage factors when variations exist (e.g., an additional column containing the corresponding coverage factors).

ISO/IEC 17025:2017 Requirements

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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.

When appropriate, significant uncertainty components and the rationale for their inclusion are included.

ISO/IEC 17025:2017 Requirements

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.



The use of standard industry practices or reporting units based on customer requests is permitted.

ISO/IEC 17025:2017 Requirements

7.8.4.1 In addition to the requirements listed in 7.8.2, 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;
- c) a statement identifying how the measurements are metrologically traceable (see Annex A);
- d) the results before and after any adjustment or repair, if available;
- e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);
- f) where appropriate, opinions and interpretations (see 7.8.7).

ISO/IEC 17025:2017 Requirements

7.8.4.1e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

Compliance refers to an assessment of all criteria of a referenced documentary standard and not a limited assessment of a portion or specific clauses (e.g., compliance to all specifications versus only the tolerance specification)

When a statement of conformity is made, the laboratory must clearly identify to which results the statement of conformity applies (e.g., all results or a specific portion of the results), which specifications, standards or parts thereof are met or not met, and the decision rule applied (unless the decision rule is inherent in the specification or documentary standard)

ISO/IEC 17025:2017 Requirements

7.8.4.1e) where relevant, a statement of conformity with requirements or specifications (see 7.8.6);

...the laboratory shall document the decision rule applied, take into account the level of risk associated with the decision rule employed (such as false accept, false reject, and statistical assumptions), and apply the decision rule.

Where decision rules regarding uncertainties and tolerances are not part of the documentary standard, decision rules will be agreed to by the customer and reported on the calibration certificate.

ISO/IEC 17025:2017 Requirements

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

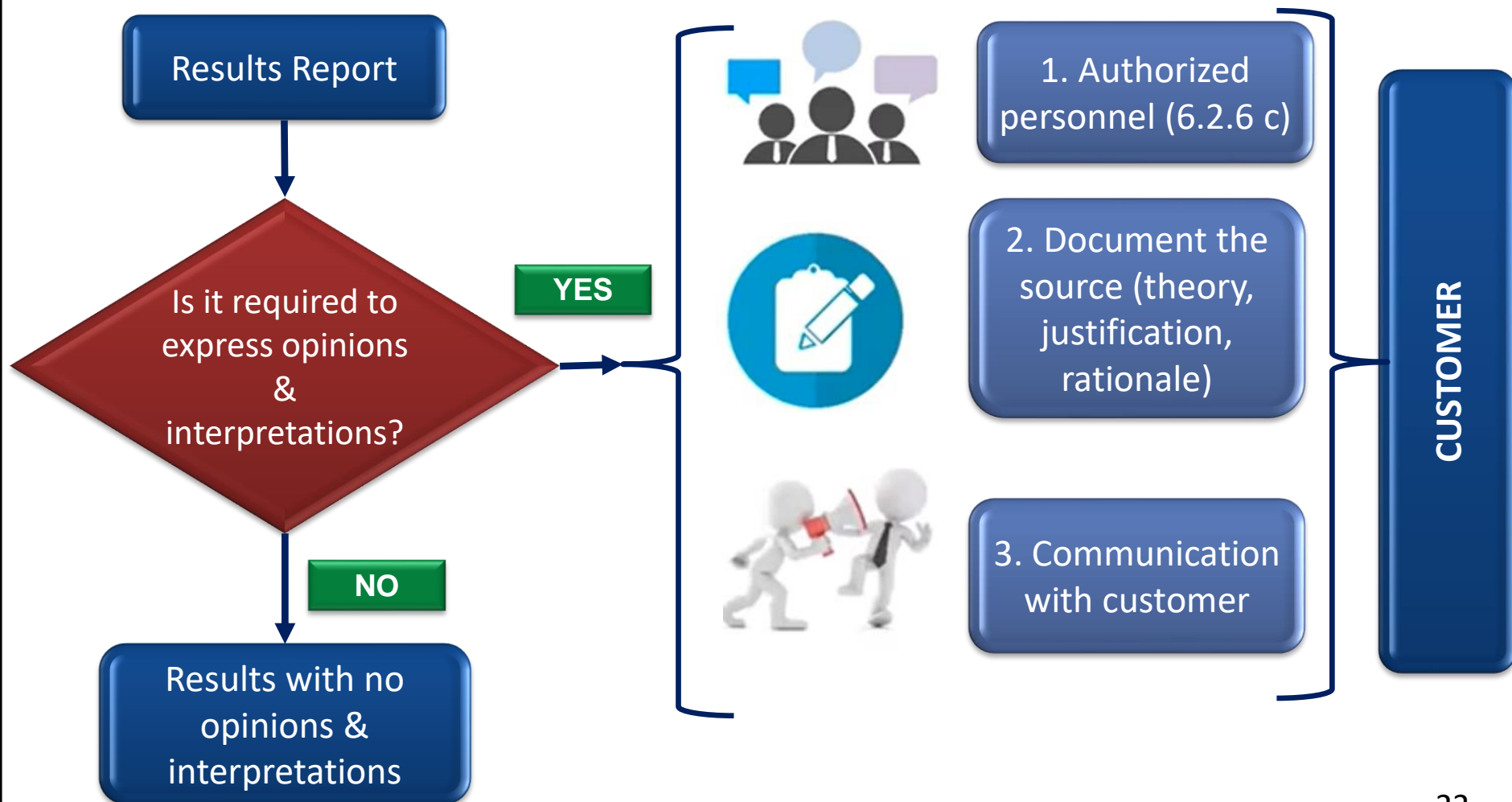
Opinions and interpretations, where appropriate and needed, shall be based on the measurement results, clearly stated, and identified as such.

Only technically competent laboratory personnel are permitted to express opinions and interpretations (e.g., an authorized signatory).

When opinions and interpretations are directly communicated and discussed with the customer, a record of the conversation shall be documented and retained.

ISO/IEC 17025:2017 Requirements

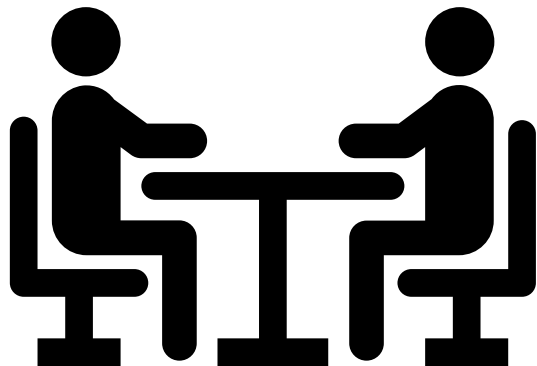
Opinions and interpretations



ISO/IEC 17025:2017 Requirements

Opinions and interpretations

1. Authorized personnel (6.2.6 c)



- Participate in the review of the relevant information from the request, offer and contract (cl. 7.1)
- Review the scope of the information that is required to be presented as an opinion and interpretation
- Reject what it is considered as a “subjective” opinion or an “groundless” interpretation

ISO/IEC 17025:2017 Requirements

Opinions and interpretations

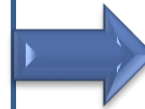
2. Document the source (theory, justification, rationale)

Not to be confused with the statement of conformity (7.8.6)



- ✓ Consistency with the results obtained
- ✓ Clearly identify in the report

“Clarity in the wording”



Recall clause 7.8.2.1:

l) a statement to the effect that the results relate only to the items tested, calibrated or sampled

ISO/IEC 17025:2017 Requirements

Opinions and interpretations

3. Communication with customer



What, When, With whom, How to
COMMUNICATE

Before or after issuing the report?

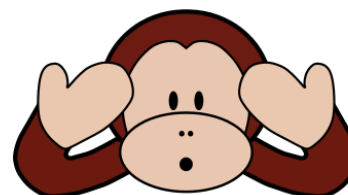
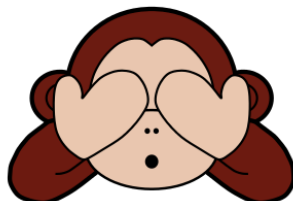
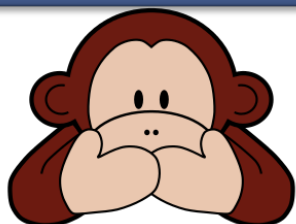
Ensure the understanding by the customer of
the provided information when presenting
opinions or interpretations

Consider the **RISK** of the customer **MAKING DECISIONS**
based on this communicated information

ISO/IEC 17025:2017 Requirements

Opinions and interpretations

“HEAR NO EVIL, SEE NO EVIL, SPEAK NO EVIL”: It shall not be used...



...IN CASE OF: Difficulty in understanding the information by the client or denial of decisions agreed between the parties



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

Record the communication in the customer's folder

Emails, Calls
Agreed recordings
Official letters

ISO/IEC 17025:2017 Requirements

Opinions and interpretation- EA-4/23

- All aspects of the arrangements for opinion and interpretation shall be documented by the laboratory including the boundaries of the offering, the contract review mechanisms, staff, competencies, methods for reporting the opinion and interpretation and the record keeping.
- Expression of opinions and interpretations relating to results is considered to be an inherent part of calibration and the AB shall not accredit expression of opinions and interpretations in reports as a separate activity.

ISO/IEC 17025:2017 Requirements

Opinions and interpretation-EA-4/23

- It is necessary to ensure that the scope of use of opinions and interpretations is clearly defined. The main criterion that applies:
- The opinions and interpretations expressed in calibration reports must be based **on the results obtained from the calibrated item**. They are not to be used for product certification as they only input to that process.
- **Statements of conformity are not considered as opinion and interpretation since they are based on unambiguous data and clarified by decision rules**

ISO/IEC 17025:2017 Requirements

Opinions and interpretations-EA-4/23

- The laboratory must clearly detail the policies and relevant procedures related to opinion and interpretation if the laboratory includes opinion and interpretation in what it reports to the client (management system documentation).



Documents reflecting the process



Criteria for competence of personnel



Records of qualifications, experience and training of personnel



Internal audit records


ISO/IEC 17025:2017 Requirements

Opinions and interpretations-EA-4/23

- The contract review procedure needs to cover:




Confirmation that the client's needs and wishes have been understood




The client has understood and accepted the implications of such statements



The laboratory has the necessary professional competencies authorised to make such statements



That any legal requirements are understood and can be complied with



The O&I given cannot be used for product certification in isolation and are based on the results of the items tested.

ISO/IEC 17025:2017 Requirements

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.**

CALIBRATION
BY _____ DATE _____
DUE _____

CALIBRATION
COMMENTS _____
BY _____ DATE _____
NEXT CALIBRATION _____

...or when required for legal applications

ISO/IEC 17025:2017 Requirements

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.

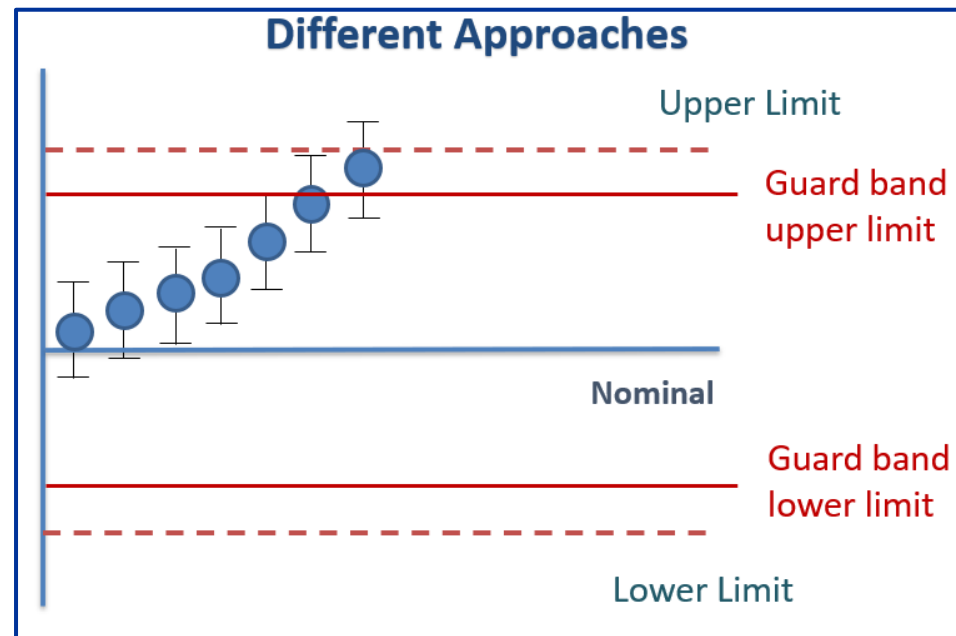
decision rule: rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

ISO/IEC 17025:2017 Requirements

7.8.6 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).



Reporting Statements of Conformity

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

The results will be marked as “pass” if, accounting for the uncertainty will be taken to mean that at a 95% confidence level, the measurement results plus and minus the expanded uncertainty ($k=2$) are totally within the specification limits

Reporting Statements of Conformity

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.

The standard recognizes that no single decision rule can address all statements of conformity across the diverse scope of (testing and) calibration.



**Guidelines on Decision Rules and
Statements of Conformity**

Refresh terminology:

Tolerance Limit (TL) (Specification Limit)

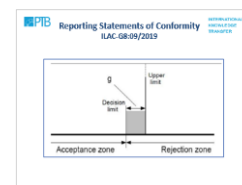
specified upper or lower bound of permissible values of a property

Acceptance Limit (AL)

specified upper or lower bound of permissible measured quantity values

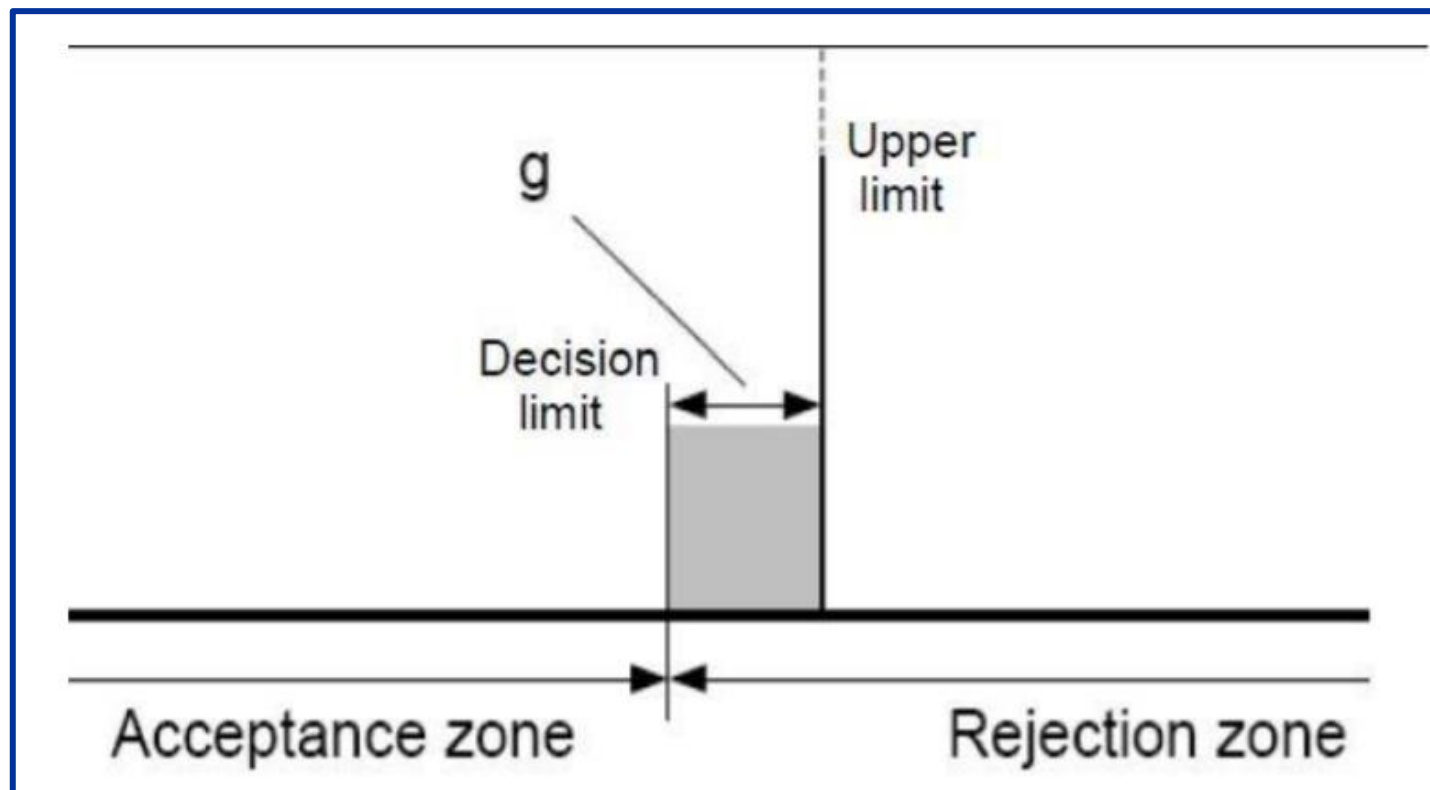
Guard Band (w)

interval between a tolerance limit and a corresponding acceptance limit where length $w = |TL - AL|$.



Reporting Statements of Conformity

ILAC-G8:09/2019



Refresh terminology:

Simple Acceptance

a decision rule in which the acceptance limit is the same as the tolerance limit, i.e. $AL=TL$

Maximum Permissible Error (MPE) (of Indication)

for a measuring instrument, maximum difference, permitted by specifications or regulations, between the instrument indication and the quantity being measured

Test Uncertainty Ratio (TUR)

the ratio of the tolerance, TL , of a measurement quantity, divided by the 95% expanded measurement uncertainty of the measurement process where $TUR=TL/U$.

Refresh terminology:

Specific Risk

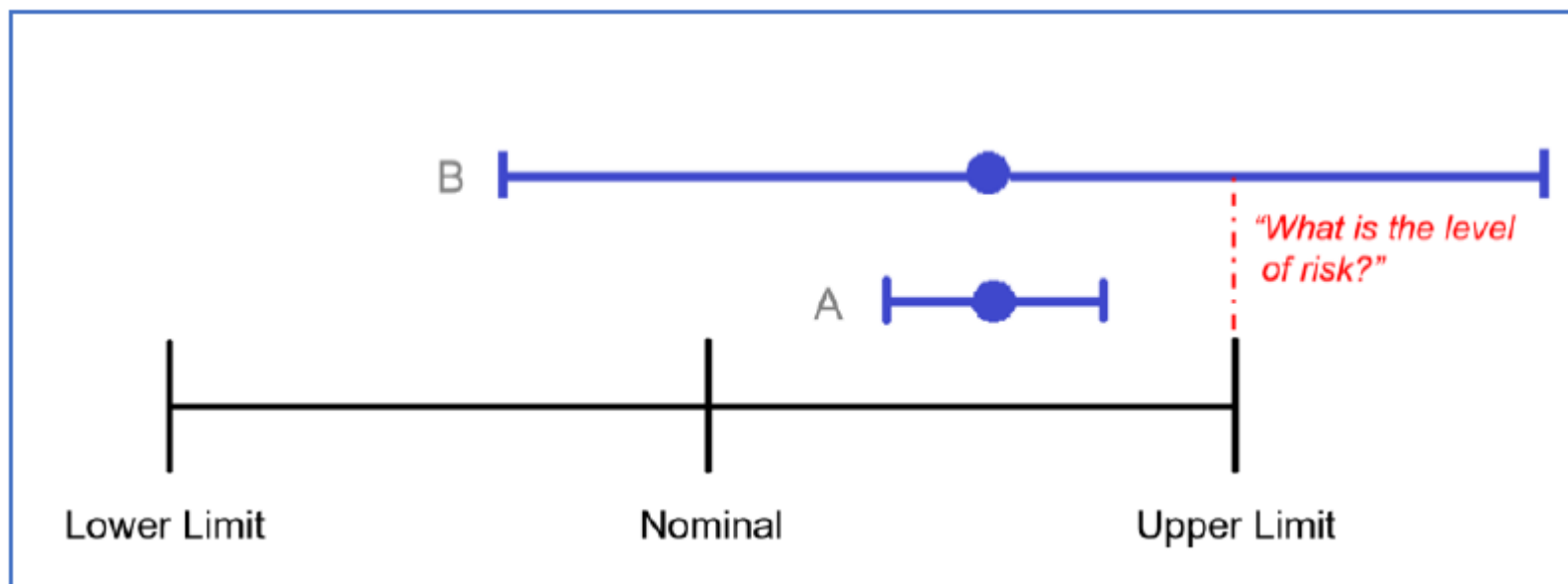
is the probability that an accepted item is non-conforming, or that a rejected item does conform. This risk is based on measurements of a single item.

Global Risk

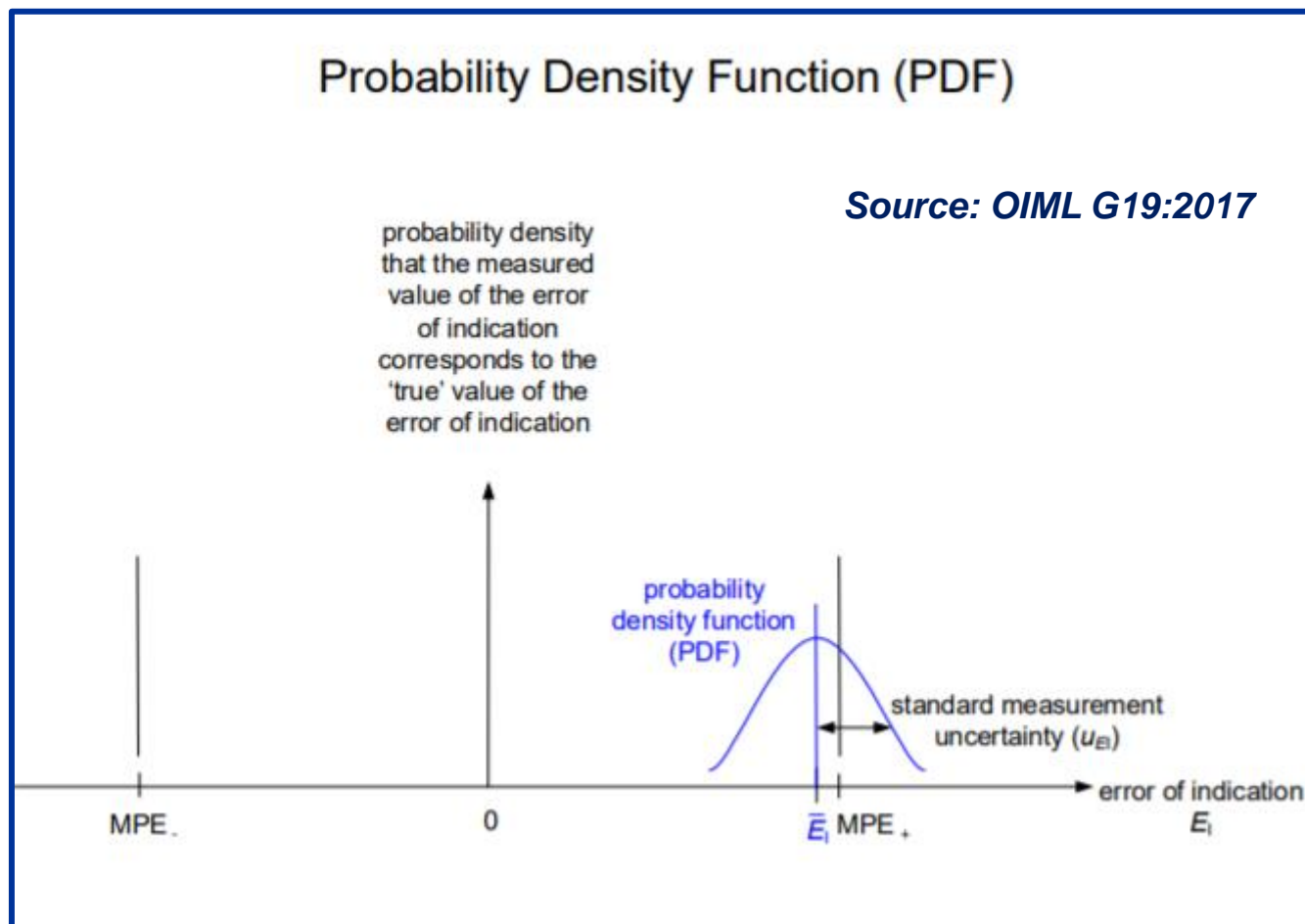
is the average probability that an accepted item is non-conforming, or that a rejected item does conform. It does not directly address the probability of false accept to any single item, discrete measurement result or individual workpiece.

Making a statement of conformity: Two main cases:

- a. A correct decision is made regarding conformance to specification
- b. An incorrect decision is made regarding conformance to specification



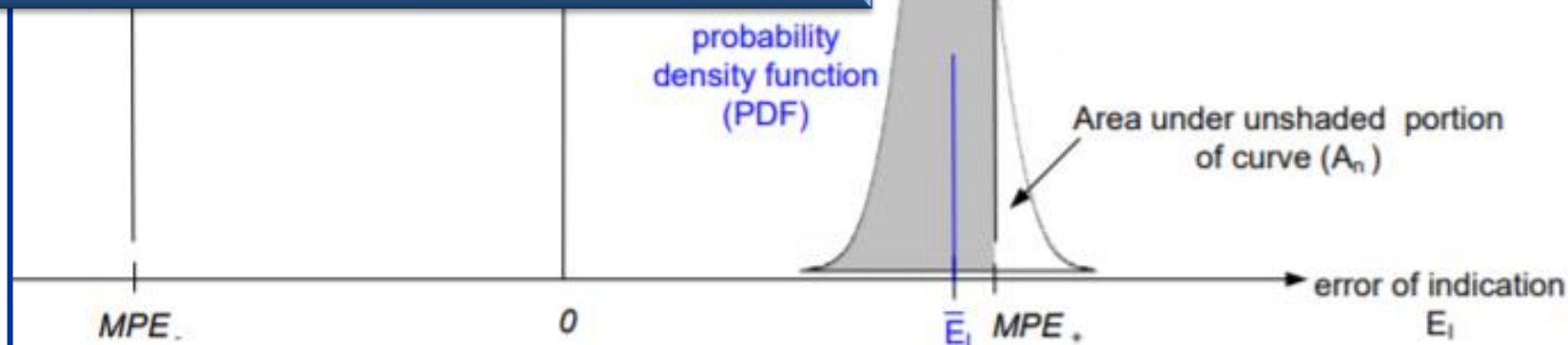
Making a statement of conformity: Importance of uncertainty



Making a statement of conformity: Importance of uncertainty

A decision about whether or not the device is considered to pass the particular test could depend upon whether acceptable levels of probability (risk) were met for that kind of test. For example, the device could be considered to pass the particular test if there was less than a 10 % probability that it was non-conforming, meaning $A_n < 0.1 = 10\%$

Source: OIML G19:2017



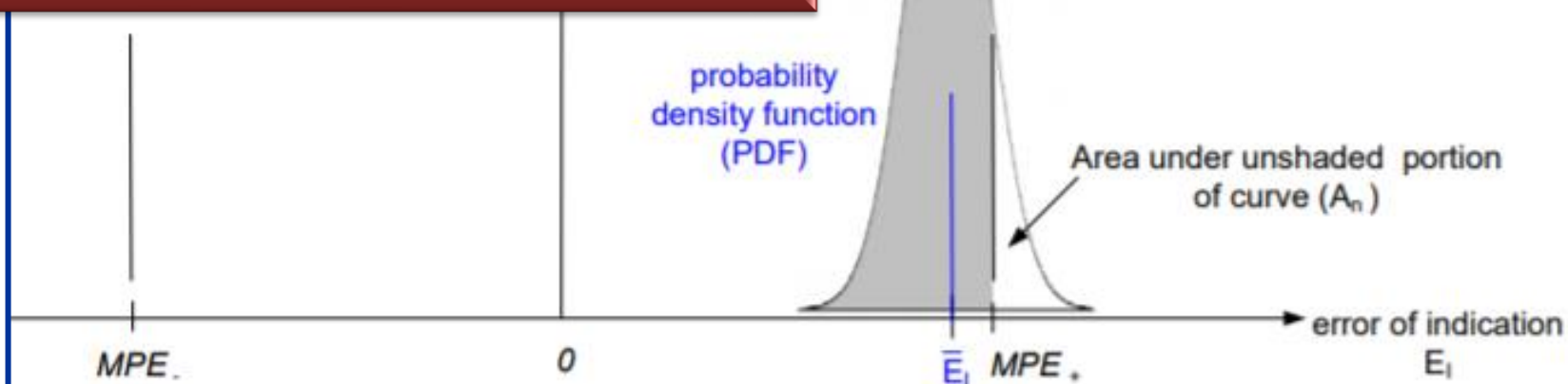
Making a statement of conformity: Importance of uncertainty

If \bar{E}_I is exactly equal to MPE_+ :

a) which is the probability that the error of indication lies within the conformance zone?

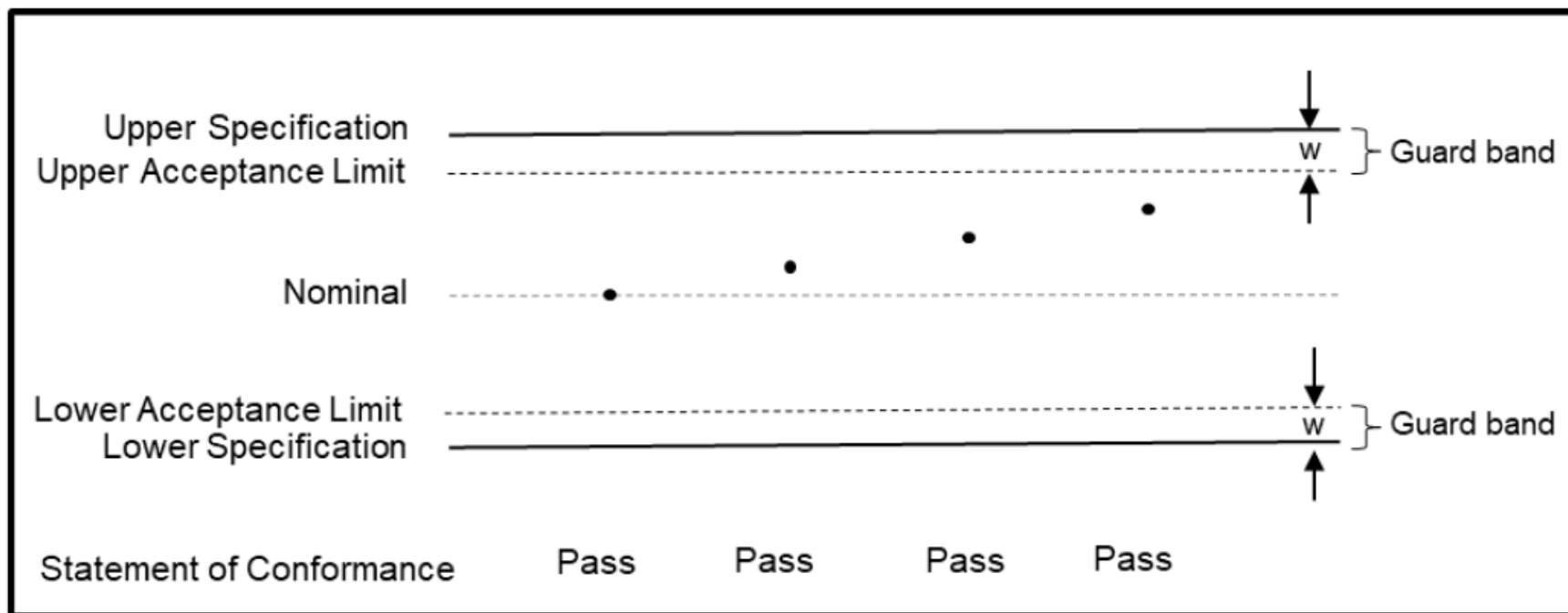
b) which is the probability that the error of indication is outside the conformance zone?

Source: OIML G19:2017



Guard Bands:

Can reduce the probability of making an incorrect conformance decision.

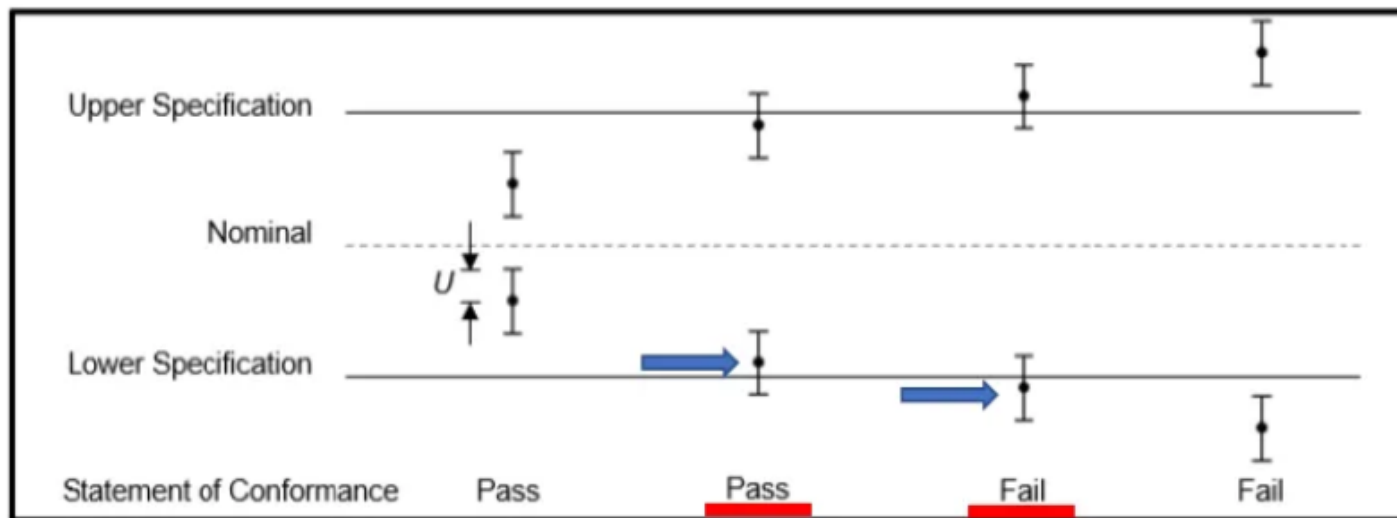


However: Decision rule: rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

Binary Acceptance for simple acceptance rule ($w=0$)

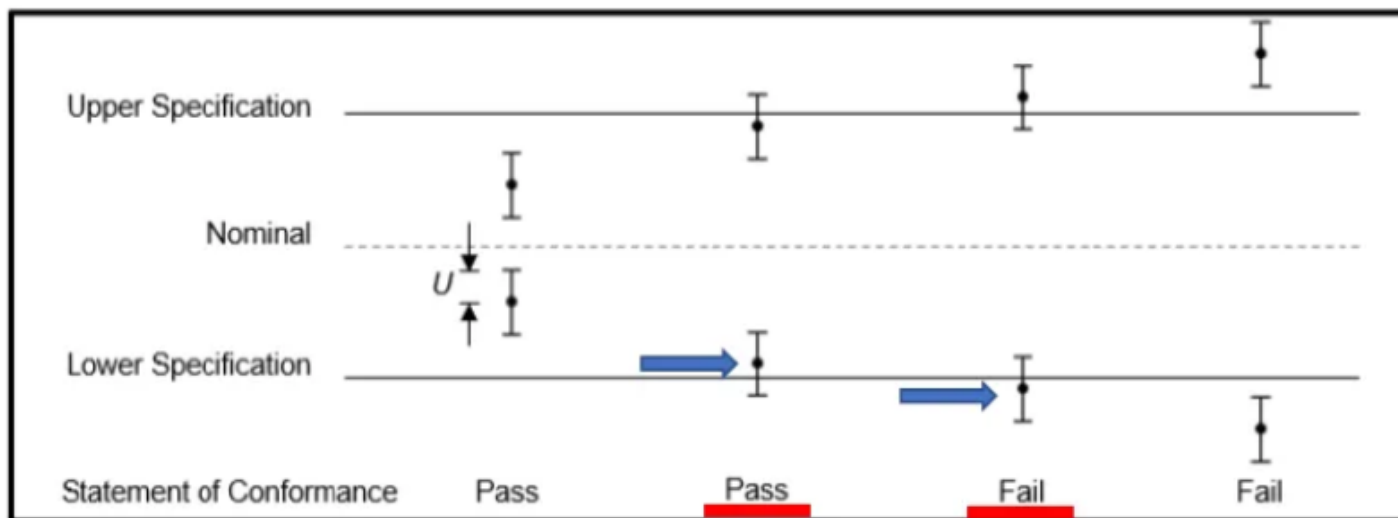
pass or a fail without taking any risk of making a wrong decision into account, as long as the mean measured value falls inside the acceptance zone

- **Pass**- acceptance based on simple acceptance; if the measurement result is below the acceptance limit, $AL=TL$
- **Fail**- rejection based on simple acceptance; if the measurement result is above the acceptance limit, $AL=TL$



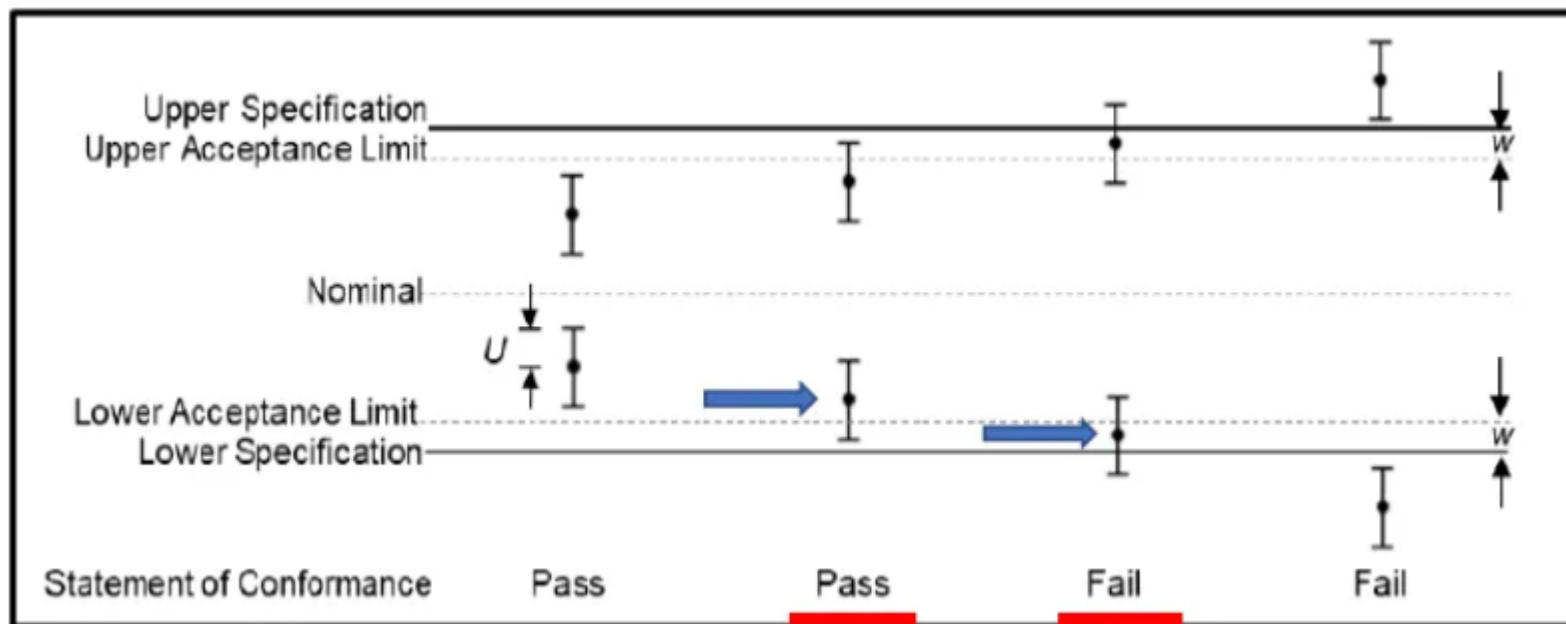
Binary Acceptance for simple acceptance rule ($w=0$)

- The maximum risk that the laboratory is assuming when declaring conformity to a specification limit is 50% when the test result is on the dot of the specification limit.
- Would this be too high a risk for the laboratory to take?

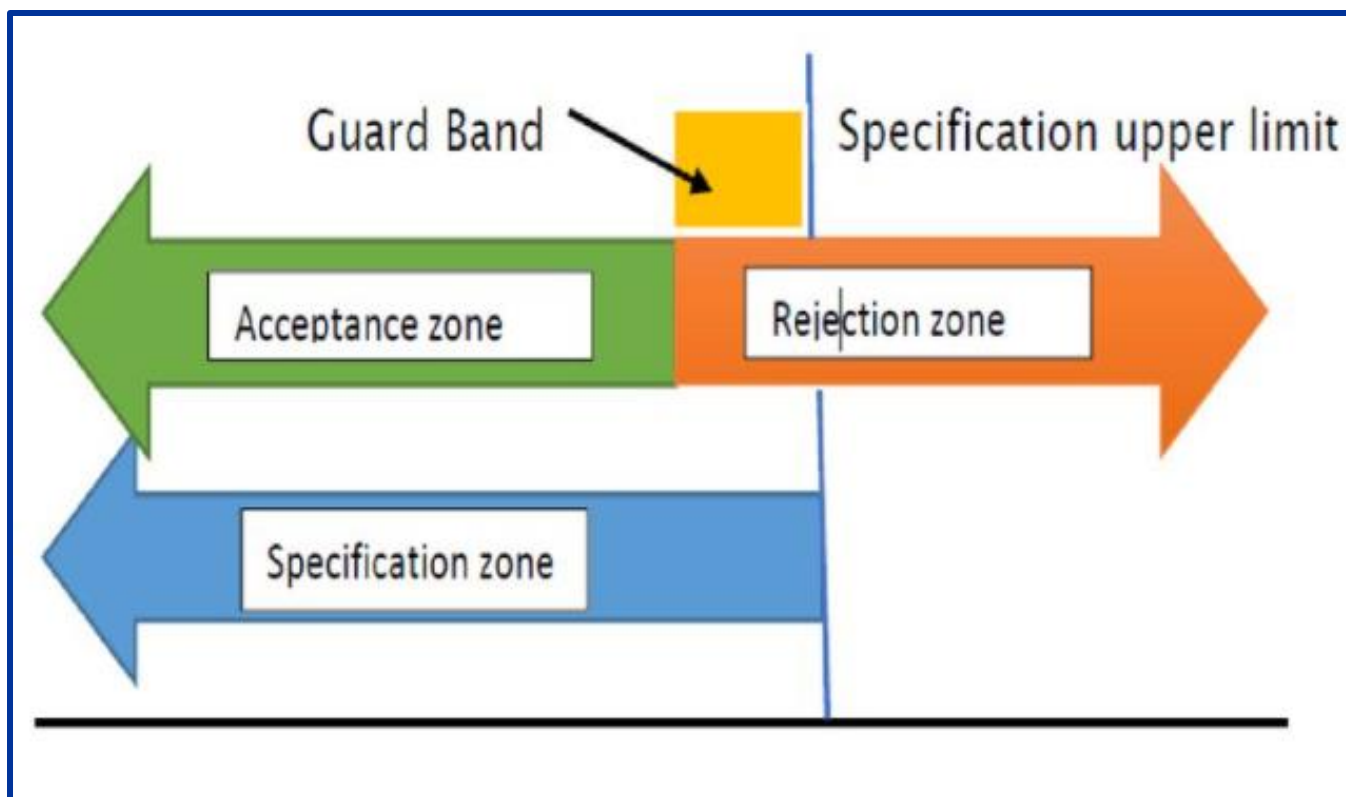


Binary statement with guard band

- Pass- acceptance based on guard band; if the measurement result is below the acceptance limit, $AL = TL - w$
- Fail- rejection based on guard band; if the measurement result is above the acceptance limit, $AL = TL - w$
- Usually: $w = U$



Binary statement with guard band



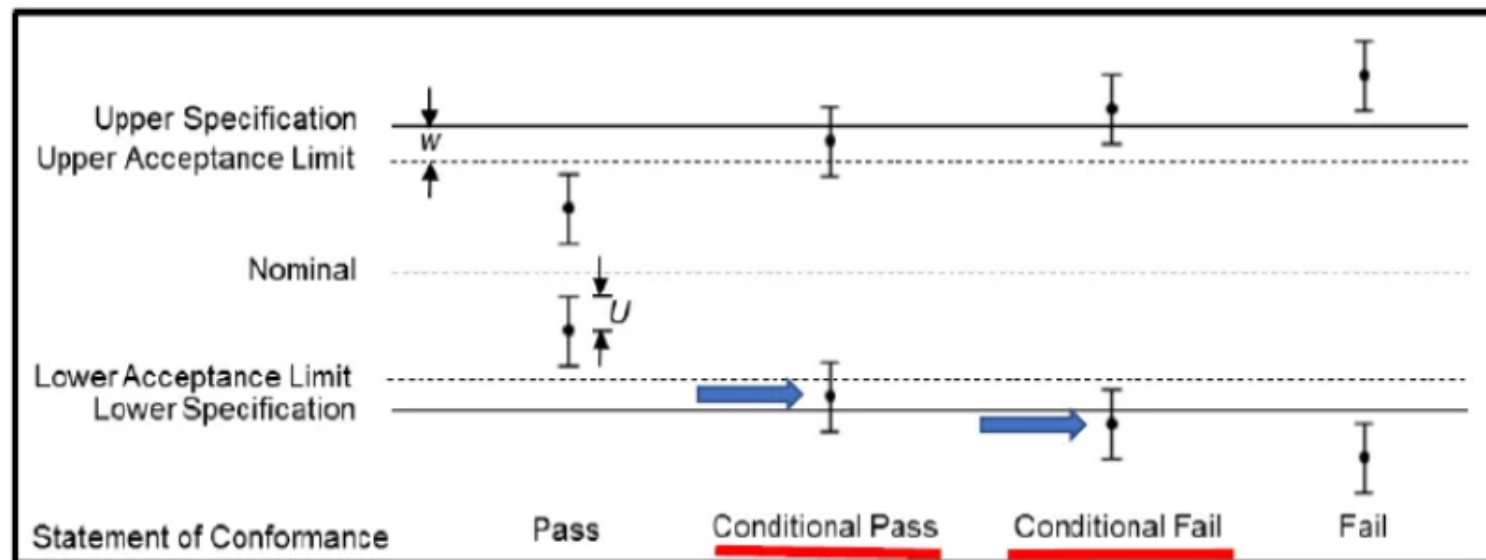
Binary statement with guard band

- The decision to give a pass for the measurement found within the acceptance zone is to the full advantage of the laboratory (zero risk as long as the laboratory is confident of its measurement uncertainty, U),
- However, to state a clear “fail” in the case where the measurement is within the w -zone of the acceptance zone may not be received well by the customer who would expect a “pass” based on the numerical value alone, which has been done all this while.
- Shouldn't the laboratory determine and bear a certain percentage of risk by working out with the customer on its acceptable critical measurement value where a certain portion of U lies outside the upper and lower specification limits?

Non Binary statement with guard band

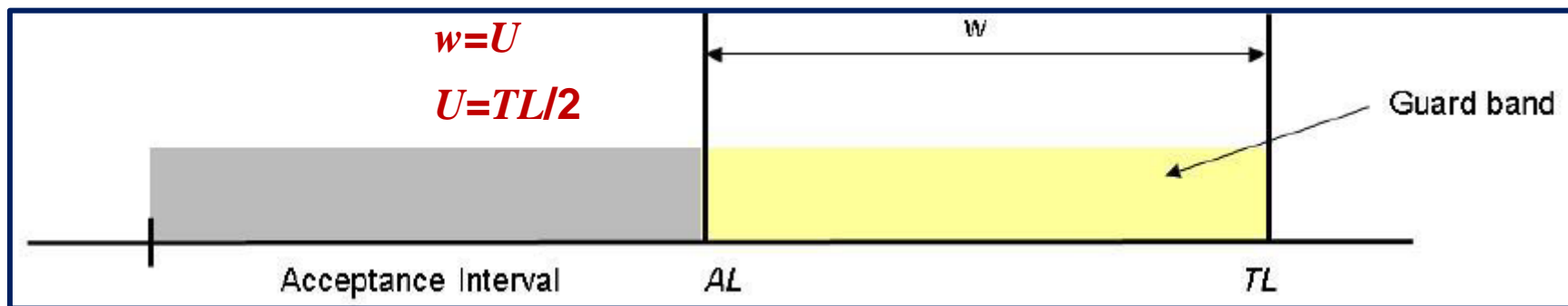
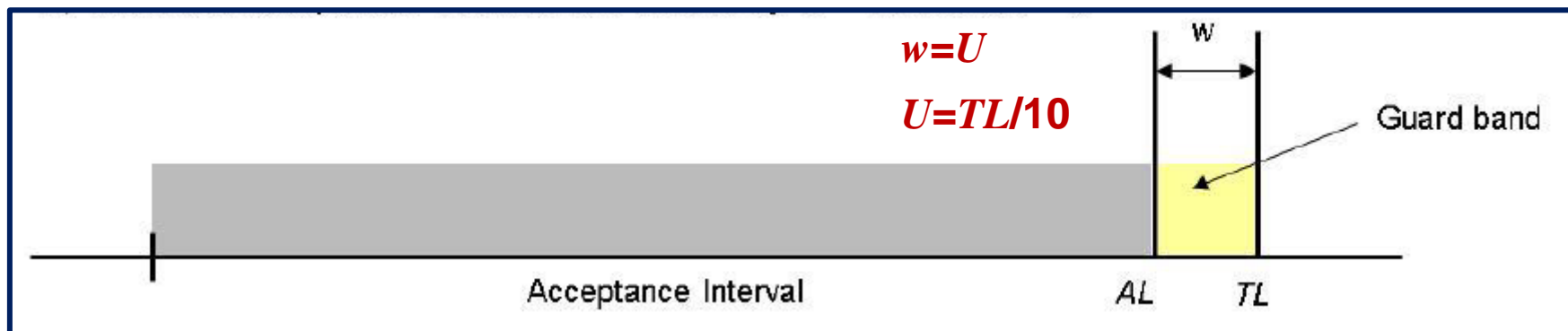
- **Pass-** if the measurement result is below the acceptance limit,
 $AL = TL - w$
- **Conditional Pass-** if the measurement result is inside the guard band and below the tolerance limit, in the interval $(TL - w; TL)$
- **Conditional Fail-** if the measurement result is above the tolerance limit added the guard band, in the interval $(TL; TL + w)$
- **Fail-** if the measurement result is above the tolerance limit but below the tolerance limit added the guard band, $TL + w$

Non Binary statement with guard band



The “Conditional Pass / Fail” needs further clarification and explanations with the customer after considering a certain percentage of risk to be borne for the critical measurement values to be reported by the test laboratory. A statement to the effect that “a conditional pass / fail with 95% confidence” might be necessary to clarify the situation.

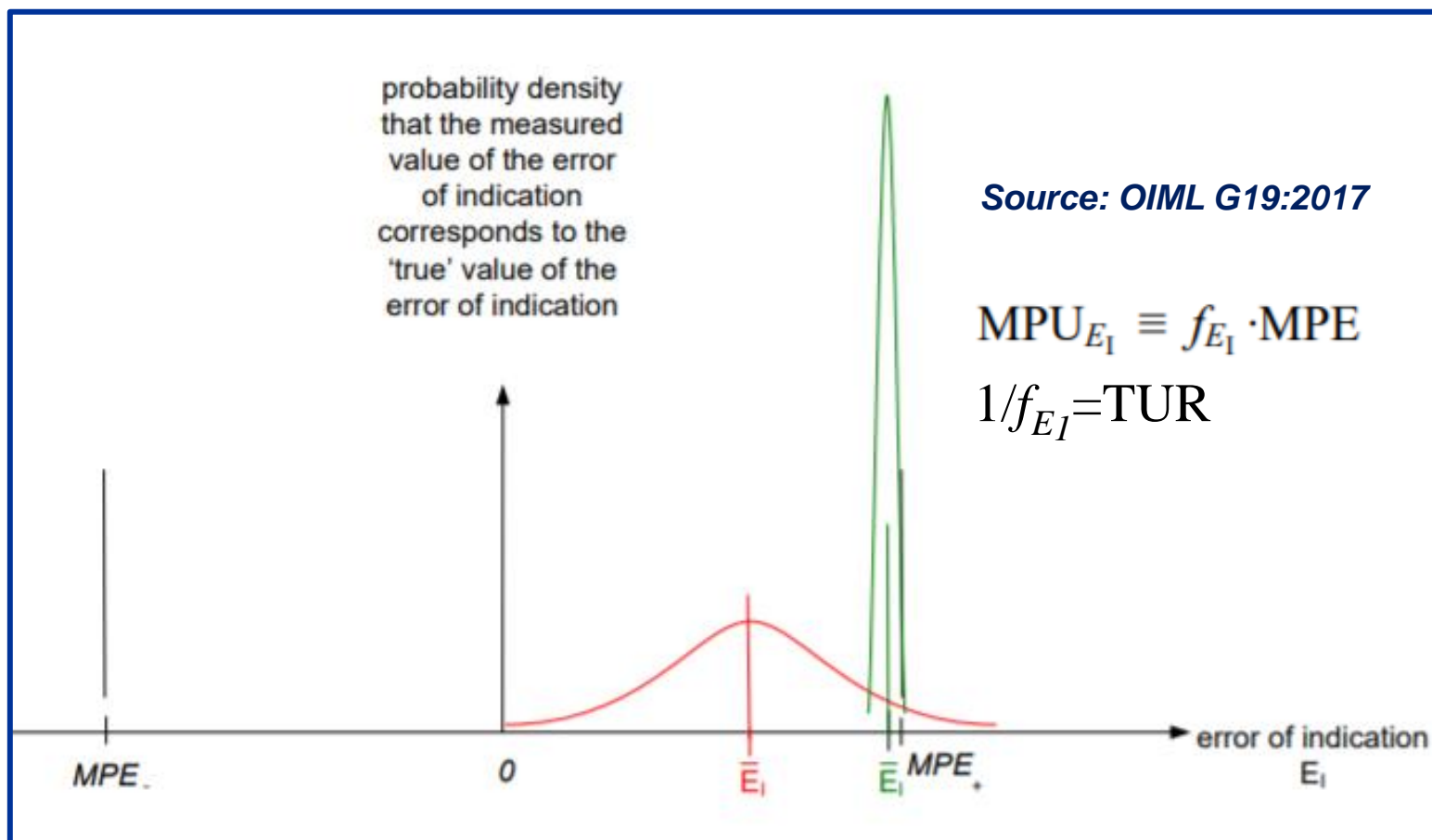
Measurement Uncertainty, Indirectly Taken into Account: Challenge



Measurement Uncertainty, Indirectly Taken into Account: Challenge- How to solve it:

- *OIML R76-1:2006 (NAWIs)* requires that “...the standard masses used for the type examination or verification of an instrument ... shall not have an error greater than $1/3$ of the MPE. If they belong to class E2 or better, their uncertainty is allowed to be not greater than $1/3$ of the MPE of the instrument (the tolerance)”
- *OIML R117-1:2007 Dynamic measuring systems for liquids other than water Part 1: Metrological and technical requirements A.2* Uncertainties of measurement: When a test is conducted, the expanded uncertainty of the determination of errors on indications of volume or mass shall be less than one-fifth of the maximum permissible error (MPE) (the tolerance)

Measurement Uncertainty, Indirectly Taken into Account: Challenge- How to solve it:



Measurement Uncertainty, Directly Taken into Account:

- ISO/IEC 17025:2017: laboratories evaluate measurement uncertainty and shall apply a documented decision rule when making statements of conformity.
- Various approaches depending on the different guard bands that can be applied.
- Often: $w=rU$. Usually: $w=U$

Measurement Uncertainty, Directly Taken into Account:

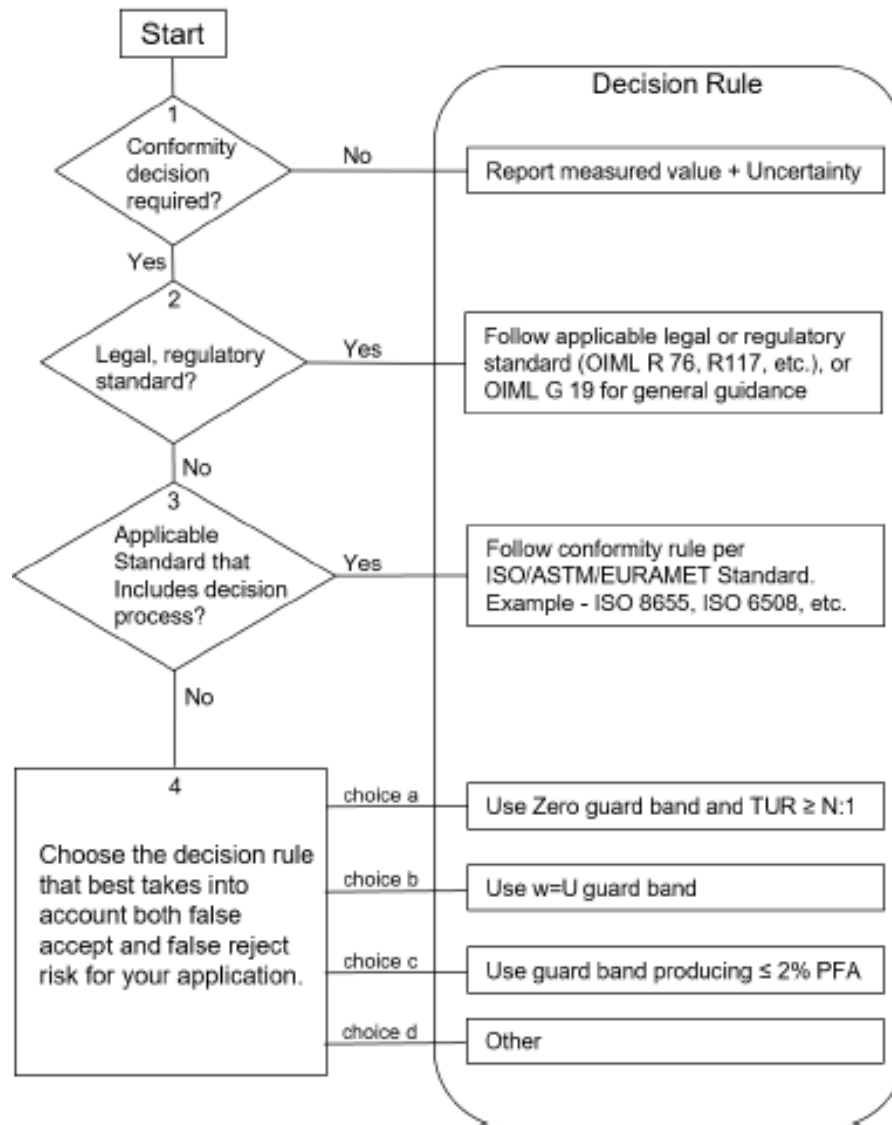
- Other approaches:

Decision rule	Guard band w	Specific Risk
6 sigma	$3 U$	$< 1 \text{ ppm PFA}$
3 sigma	$1,5 U$	$< 0.16\% \text{ PFA}$
ILAC G8:2009 rule	$1 U$	$< 2.5\% \text{ PFA}$
ISO 14253-1:2017 [5]	$0,83 U$	$< 5\% \text{ PFA}$
Simple acceptance	0	$< 50\% \text{ PFA}$
Uncritical	$-U$	Item rejected for measured value greater than $AL = TL + U$ $< 2.5\% \text{ PFR}$
Customer defined	$r U$	Customers may define arbitrary multiple of r to have applied as guard band.

Table 1. PFA – Probability of False Accept and PFR – Probability of False Reject
(Assumes a single sided specification and normal distribution of measurement results)

Reporting Statements of Conformity

ILAC-G8:09/2019



Pass/Fail Conformity Decision Rule selection flow chart

Source: ILAC-G8:09/2019

Reporting Statements of Conformity

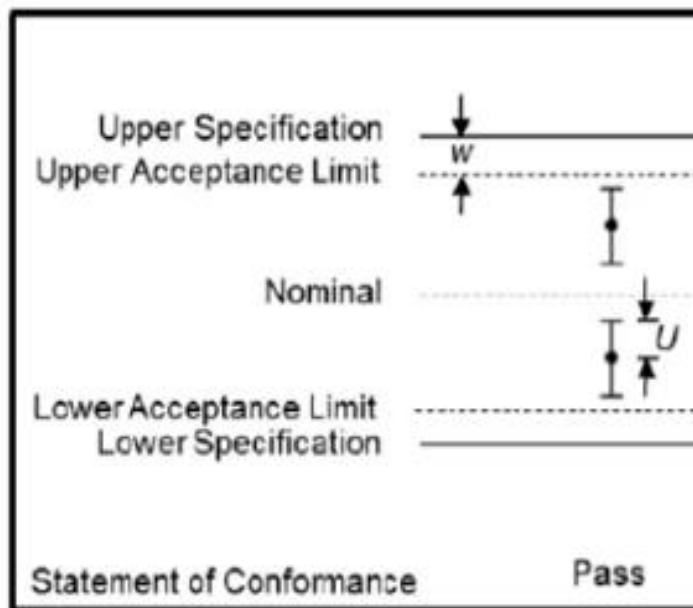
ILAC-G8:09/2019

Statement of compliance and associated symbol	Description
PASS	The absence of a symbol indicates that the measurement result is inside the specification limit by a margin greater than its associated expanded uncertainty; the instrument meets its accuracy specification
Conditional PASS Symbol: £	The measurement result is inside the specification limit by a margin less than or equal to its associated expanded uncertainty; it is therefore not possible to state compliance. There is a risk that the instrument fails to meet its specification.
Conditional FAIL Symbol: &	The measurement result is on the specification limit or is outside by a margin less than or equal to its associated expanded uncertainty; it is therefore not possible to state non-compliance.
FAIL Symbol: \$	The measurement result is outside the specification limit by a margin greater than its associated expanded uncertainty; the instrument fails to meet its accuracy specification.
Unc. > Spec Symbol: #	The expanded measurement uncertainty is greater than the instrument's accuracy specification. It is not possible to determine compliance or otherwise with the specification. The user should expand the in-use accuracy specification to make allowance for the calibration uncertainty.

Reporting Statements of Conformity

ILAC-G8:09/2019

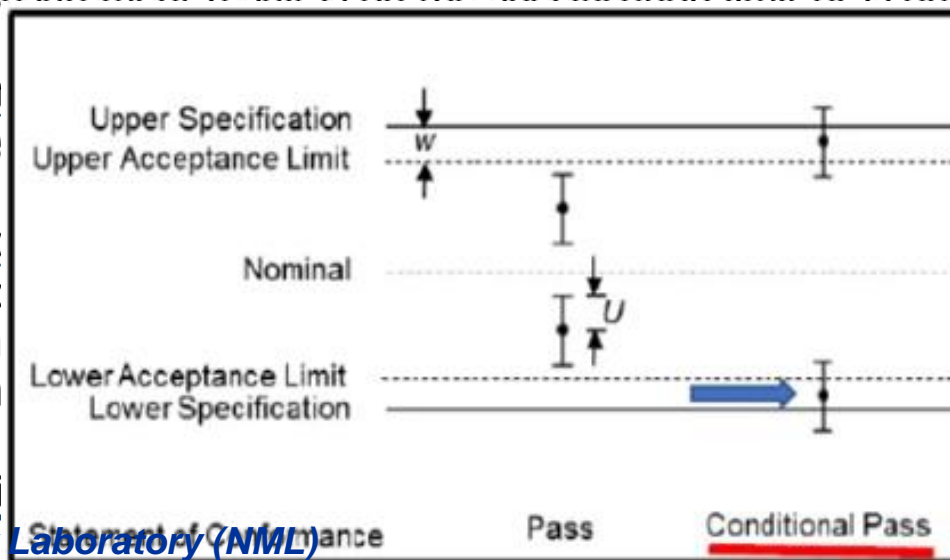
Statement of compliance and associated symbol	Description
PASS	The absence of a symbol indicates that the measurement result is inside the specification limit by a margin greater than its associated expanded uncertainty; the instrument meets its accuracy specification
Conditional PASS Symbol: £	The measurement result is inside the specification limit by a margin less than or equal to its associated expanded uncertainty; therefore not possible to state with certainty that the instrument fails to meet its accuracy specification
Conditional FAIL Symbol: &	The measurement result is outside the specification limit by a margin less than or equal to its associated expanded uncertainty; it is therefore not possible to state with certainty that the instrument fails to meet its accuracy specification
FAIL Symbol: \$	The measurement result is outside the specification limit by a margin greater than its associated expanded uncertainty; the instrument fails to meet its accuracy specification
Unc. > Spec Symbol: #	The expanded measurement uncertainty is greater than the instrument's accuracy specification or otherwise the instrument does not comply with the specification. The user should expand the in-use accuracy specification to make allowance for the calibration uncertainty.



Reporting Statements of Conformity

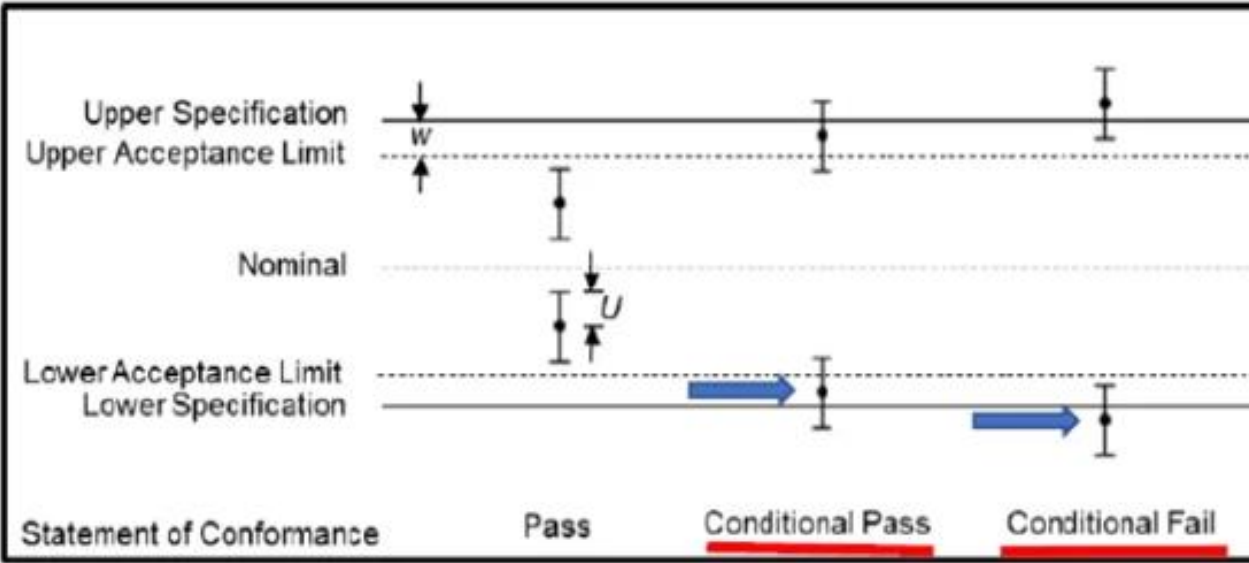
ILAC-G8:09/2019

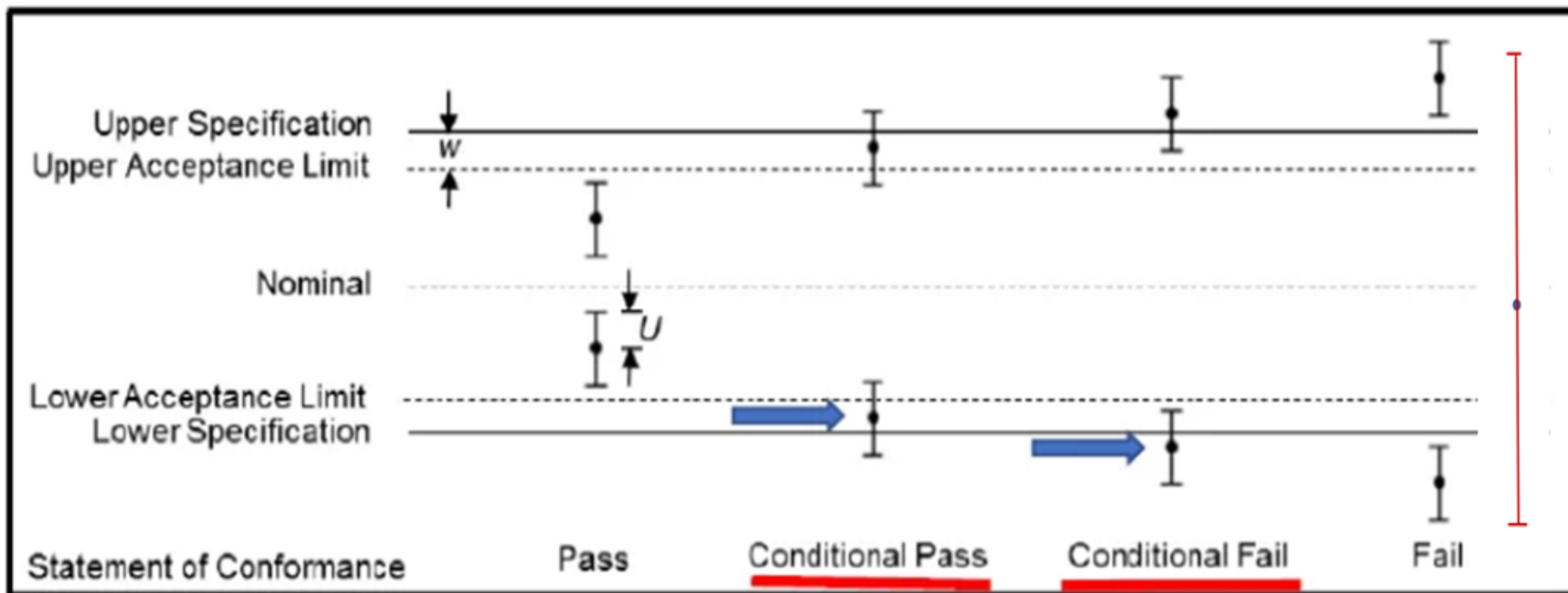
Statement of compliance and associated symbol	Description
PASS	The absence of a symbol indicates that the measurement result is inside the specification limit by a margin greater than its associated expanded uncertainty; the instrument meets its accuracy specification
Conditional PASS Symbol: £	The measurement result is inside the specification limit by a margin less than or equal to its associated expanded uncertainty; it is therefore not possible to state compliance. There is a risk that the instrument fails to meet its specification.
Conditional FAIL Symbol: &	The measurement result is on the specification limit or is outside by a margin less than or equal to its associated expanded uncertainty; it is therefore not possible to state compliance. There is a risk that the instrument fails to meet its specification.
FAIL Symbol: \$	The measurement result is outside the specification limit by a margin greater than its associated expanded uncertainty; the instrument fails to meet its accuracy specification
Unc. > Spec Symbol: #	The expanded uncertainty is greater than the specification limit; the instrument compliance cannot be determined. A statement of compliance should be issued for the instrument after recalibration.



Reporting Statements of Conformity

ILAC-G8:09/2019

Statement of compliance associated symbol		
PASS	<p>result is associated specification margin is at the</p>	
Condition PASS Symbol: #		
Conditional FAIL Symbol: &	<p>The measurement result is on the specification limit or is outside by a margin less than or equal to its associated expanded uncertainty; it is therefore not possible to state non-compliance.</p>	
FAIL Symbol: \$	<p>The measurement result is outside the specification limit by a margin greater than its associated expanded uncertainty; the instrument fails to meet its accuracy specification.</p>	
Unc. > Spec Symbol: #	<p>The expanded measurement uncertainty is greater than the instrument's accuracy specification. It is not possible to determine compliance or otherwise with the specification. The user should expand the in-use accuracy specification to make allowance for the calibration uncertainty.</p>	



	therefore not possible to state non-compliance.
FAIL Symbol: \$	The measurement result is outside the specification limit by a margin greater than its associated expanded uncertainty; the instrument fails to meet its accuracy specification.
Unc. > Spec Symbol: #	The expanded measurement uncertainty is greater than the instrument's accuracy specification. It is not possible to determine compliance or otherwise with the specification. The user should expand the in-use accuracy specification to make allowance for the calibration uncertainty.

ISO/IEC 17025:2017 Requirements

- 7.8.8 Amendments to reports.**

Issued Calibration
Certificate can be:

- Changed
- Amended
- Re-issued

Clearly
identify any
change

Where
appropriate,
include the
reason of the
change

Supplements



Further document/New certificate –
Reference to the certificate it
replaces/amends

ISO/IEC 17025:2017 Requirements

- 7.8.8 Amendments to reports.**

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Use and Interpretation of Calibration Certificates

What to do once we receive a calibration certificate?



General Recommendations

Most companies/laboratories file the calibration certificate as a historical record. **Not a good practice!**

Enter the certificate data into your local database that you use to track the status of your equipment inventory.

Use the information from the calibration certificates to your fullest benefit.

Review the calibration certificate before using the equipment. This will ensure that the proper information is received and that the calibration results show that the equipment will perform as intended.

Calibration Certificate Items to Review

Accreditation or CIPM-MRA Logo

- Confirmation of the technical capability of the laboratory
- This logo identifies the organization that accredited the laboratory and will contain the accreditation certificate number of the calibration provider.



Deutsche
Akkreditierungsstelle
D-K-17543-01-00

Kalibrierzeichen
Calibration mark

17715
D-K-
17543-01-00
2020-12



This certificate is consistent with the capabilities that are included in Appendix C of the CIPM MRA drawn up by the CIPM. Under the CIPM MRA, all participating institutes recognize the validity of each other's calibration and measurement certificates for the quantities, ranges and measurement uncertainties specified in Appendix C (for details see <http://www.bipm.org>).

Calibration Certificate Items to Review

Accreditation or CIPM-MRA Logo	Proper Equipment Information:										
<ul style="list-style-type: none"> Confirmation of the technical capability of 	<ul style="list-style-type: none"> Does the certificate list the correct information for the specific instrument? Manufacturer, model, description and serial number. If any of this information is incorrect, it will invalidate the traceability of the certificate 										
<table> <tr> <td>Gegenstand <i>Object</i></td><td>Digital Multimeter</td></tr> <tr> <td>Hersteller <i>Manufacturer</i></td><td>FLUKE</td></tr> <tr> <td>Typ <i>Type</i></td><td>8808A</td></tr> <tr> <td>Fabrikat/Serien-Nr. <i>Serial number</i></td><td>4722015</td></tr> <tr> <td>Ident-Nr. <i>Asset number</i></td><td>4722015</td></tr> </table>	Gegenstand <i>Object</i>	Digital Multimeter	Hersteller <i>Manufacturer</i>	FLUKE	Typ <i>Type</i>	8808A	Fabrikat/Serien-Nr. <i>Serial number</i>	4722015	Ident-Nr. <i>Asset number</i>	4722015	
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Calibration Certificate Items to Review

Accreditation or CIPM-MRA Logo	Proper Equipment Information:	Traceability Information
<ul style="list-style-type: none">• Confirmation of the technical capability of the laboratory• This logo identifies the organization that accredited the laboratory and will contain the accreditation certificate number of the calibration provider.	<ul style="list-style-type: none">• Does the certificate list the correct information for the specific instrument?• Manufacturer, model, description and serial number.• If any of this information is incorrect, it will invalidate the traceability of the certificate	<ul style="list-style-type: none">• A list of the calibration standards used to perform the calibration (+ the description of the calibration standards + their appropriate calibration due dates.• Proof that the calibration standards were compared with national or international standards.• The traceability of the certificate cannot be determined without this information.

Calibration Certificate Items to Review

Accreditation or CIPM-MRA Logo	Proper Equipment Information:	Traceability Information
<ul style="list-style-type: none"> Confirmation of the technical capability of the laboratory This logo identifies 	<ul style="list-style-type: none"> Does the certificate list the correct information for the specific instrument? 	<ul style="list-style-type: none"> A list of the calibration standards used to perform the calibration (+ the description of the calibration standards + their appropriate calibration due dates. Proof that the calibration standards
<p>Calibration Standards Fluke 1595A Superthermometer, ID:0962, Due Date: 27 May 2021 25 Ω Platinum Resistance Thermometer, ID:1010, Due Date: 09 Jul 2021 Tinsley 100 Ω Standard Resistor, ID:0650, Due Date: 04 Jul 2021 Tinsley 100 Ω Standard Resistor, ID:0340, Due Date: 10 Aug 2021 Hart 1590 Superthermometer, ID:0620, Due Date: 13 Jul 2021 25 Ω Platinum Resistance Thermometer, ID:1040, Due Date: 20 Apr 2022 25 Ω Platinum Resistance Thermometer, ID:1100, Due Date: 25 Nov 2021 25 Ω Platinum Resistance Thermometer, ID:1200, Due Date: 10 Dec 2021</p>		
<p>This thickness instrument was calibrated using calibrated Ultrasonic Step Blocks traceable to NIST by certificate 20-29702-C</p>		
<p>The reported measurement results are traceable, via national standards maintained by <<NMI>> or by other National Metrology Institutes in accordance with the International Temperature Scale of 1990 (ITS-90)</p>		
		<p>this information.</p>

Calibration Certificate Items to Review

Measurement Data

- The actual calibration measurement results need to be provided for all accredited calibrations.
- The data should include the 'As Found' and 'As Left' data along with specific identification for items that were found outside of the calibration specifications.

Measurement Uncertainty Values

- Every measurement should have its corresponding measurement uncertainty value provided.
- This number is important to determine the true error associated with the reported measurement value.



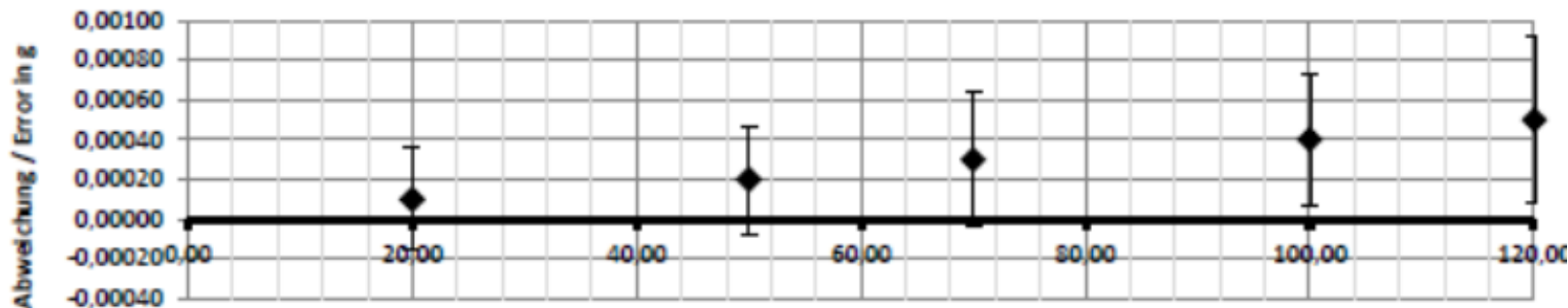
Statements of Conformity

- Statements such as pass/fail or in-tolerance/out-of-tolerance need to be reviewed to determine the initial calibration status of the equipment
- Out-of-tolerance condition might have had adverse effect on the measurements made with that item. If so, appropriate action may need to be taken.

Calibration Certificate Items to Review

Prüflast <i>Load</i>	Abweichung <i>Error</i>	Erweiterungs- faktor k <i>Coverage factor</i>	Unsicherheit <i>Uncertainty</i>	relative Unsicherheit <i>Rel. uncertainty</i>
20 g	0,0001 g	2,27	0,00026 g	0,00129 %
50 g	0,0002 g	2,18	0,00028 g	0,00054 %
70 g	0,0003 g	2,05	0,00035 g	0,00049 %
100 g	0,0004 g	2,06	0,00034 g	0,00033 %
120 g	0,0005 g	2,02	0,00043 g	0,00035 %

Darstellung im Diagramm / Representation as chart



CONFORMITY WITH REQUIREMENTS^{*)}

On the basis of calibration results, it has been found that (*name of measuring instrument*) meets metrological requirements specified in (*law provisions, standards, recommendations or other relevant documents - identification data of reference document(s)*).

Calibration Certificate Items to Review

Instrument Specification	$\pm 0.004\text{ }^{\circ}\text{C}$ from $-100\text{ }^{\circ}\text{C}$ to $+420\text{ }^{\circ}\text{C}$
Sensor Specification	$\pm 0.014\text{ }^{\circ}\text{C}$ from $-100\text{ }^{\circ}\text{C}$ to $+420\text{ }^{\circ}\text{C}$
Client Specification	$\pm 0.020\text{ }^{\circ}\text{C}$ from $-50\text{ }^{\circ}\text{C}$ to $+200\text{ }^{\circ}\text{C}$ $\pm 0.025\text{ }^{\circ}\text{C}$ from $200\text{ }^{\circ}\text{C}$ to $400\text{ }^{\circ}\text{C}$ $\pm 0.050\text{ }^{\circ}\text{C}$ above $400\text{ }^{\circ}\text{C}$

As found results

Reference Reading ($^{\circ}\text{C}$)	UUT Reading ($^{\circ}\text{C}$)	Correction ($^{\circ}\text{C}$)	Expanded Uncertainty ($^{\circ}\text{C}$)
-0.0005	0.009	-0.0095	0.0055
-38.9980	-38.987	-0.0110	0.0055
30.0049	30.013	-0.0081	0.0055
155.9970	156.000	-0.0030	0.0095
232.0018	232.011	-0.0092	0.0105
419.9934	420.005	-0.0116	0.0325
-0.0008	0.006	-0.0068	0.0045

Calibration Certificate Items to Review

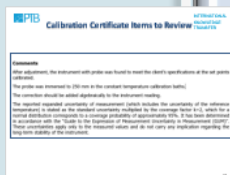
Environmental Conditions	Certificate Remarks
<ul style="list-style-type: none"> • Most instruments are sensitive to the conditions in which they are operated. These influence quantities include environmental factors, operating methods and conditions, and instrument settings. • For factors that may affect the performance of the instrument, the calibration conditions will be specified on the certificate. • The results reported on the certificate apply only for the conditions specified. 	<ul style="list-style-type: none"> • There is usually a 'Remarks' section on the calibration certificate that is used to record specific issues on the performance of the equipment that were found during the calibration process that may impact the use of the equipment. • This section may include information on 'limited calibrations' where the calibration did not cover the full range of capabilities for the equipment or the item failed to meet the required instrument accuracy and new specifications were assigned



Ambient Conditions	Daily variation range during calibration
Temperature [°C]:	$(23,5 \dots 23,8) \pm 0,2$
Relative Humidity [%]:	42 ± 2
Air Pressure [mbar]:	$(1015,0 \dots 1017,0) \pm 0,7$

- Most instruments are sensitive to the conditions in which they are operated. These influence quantities include environmental factors, operating methods and conditions, and instrument settings.
- For factors that may affect the performance of the instrument, the calibration conditions will be specified on the certificate.
- The results reported on the certificate apply only for the conditions specified.

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Calibration Certificate Items to Review

Comments

After adjustment, the instrument with probe was found to meet the client's specifications at the set points calibrated.

The probe was immersed to 250 mm in the constant temperature calibration baths.

The correction should be added algebraically to the instrument reading.

The reported expanded uncertainty of measurement (which includes the uncertainty of the reference temperature) is stated as the standard uncertainty multiplied by the coverage factor $k=2$, which for a normal distribution corresponds to a coverage probability of approximately 95%. It has been determined in accordance with the "Guide to the Expression of Measurement Uncertainty in Measurement (GUM)". These uncertainties apply only to the measured values and do not carry any implication regarding the long-term stability of the instrument.

Calibration Certificate Items to Review

Review specific measurement values:

01

Determine if the instrument was out of tolerance when it was received by the calibration laboratory or if the measurement data is near their tolerance limits.

02

Evaluate the instrument's performance and determine long-term trends by comparing the current values to the values from previous calibrations.

03

If it is found that certain measurements are trending toward their tolerance limits or they are frequently out-of-tolerance, adjustments can be made to the equipment's calibration interval

Applying Corrections to Instrument Readings

Certificates are presented in a manner that simplifies the application of the results to your measurements

The calibration certificate reports results at selected points over the range of interest, as **it is not practical to take or report measurements at every possible reading of most instruments**

The spacing and number of points selected are sufficient to allow corrections for any reading to be deduced with sufficient accuracy by **linear interpolation**

If linear interpolation is considered inadequate, then an appropriate equation for the correction terms will be given. As a general rule, **extrapolation of corrections is not recommended**

Applying Corrections to Instrument Readings- Examples

1. A certificate reporting a table of corrections

- Consider a calibration certificate reporting corrections:

Instrument reading (units)	Correction (units)
100	-0.2
110	-0.3
120	-0.3

The result of a measurement in which the instrument gave a reading of 110 units is obtained by adding the correction to the reading:

$$\text{corrected result} = 110 + (-0.3) = 109.7 \text{ units.}$$

**By convention a correction is added to the instrument reading,
while a deviation is subtracted**

Applying Corrections to Instrument Readings-

Examples

2. A certificate reporting a correction equation

- The corrections may be presented as a simple polynomial equation. Consider a certificate that reports the corrections as

$$\text{correction} = 0.1 + 0.004 \times \text{reading} - 0.001 \times \text{reading}^2$$

- The result of a measurement in which the instrument gave a reading of 50.0 units is obtained by adding the correction to the result:

$$\begin{aligned} \text{corrected result} &= 50.0 + 0.1 + 0.004 \times 50 - 0.001 \times 50^2 \\ &= 50.0 + 0.1 + 0.2 - 0.5 = 49.8 \end{aligned}$$

As with the table of corrections the equation should be chosen to be valid over the range of interest to the user.

Applying Corrections to Instrument Readings- Examples

3. A certificate reporting instrument readings

- For instruments that are expected to be used at particular points in their range or as calibration sources (e.g. voltage sources) it is often more convenient to **present the results in terms of a measured value versus the instrument reading**. This simplifies the use of the certificate at the points reported.

Applying Corrections to Instrument Readings

Examples

3. A certificate reporting instrument readings (cont'd)

- Consider a certificate for a calibration source with the following table of results.

Reference Value (units)	Instrument Reading (units)
10	14.7
20	24.9
30	35.2

- To obtain a value of 10 units at the output of the source, the user simply adjusts the instrument to read 14.7 units.
- For values not listed on the table linear interpolation is used. There are two cases:

Applying Corrections to Instrument Readings- Examples

3. A certificate reporting instrument readings (cont'd)

- i. The user **requires a value of 15 units**:

$$\text{instrument reading} = 14.7 + \frac{15 - 10}{20 - 10} \times (24.9 - 14.7) = 19.8 \text{ units}$$

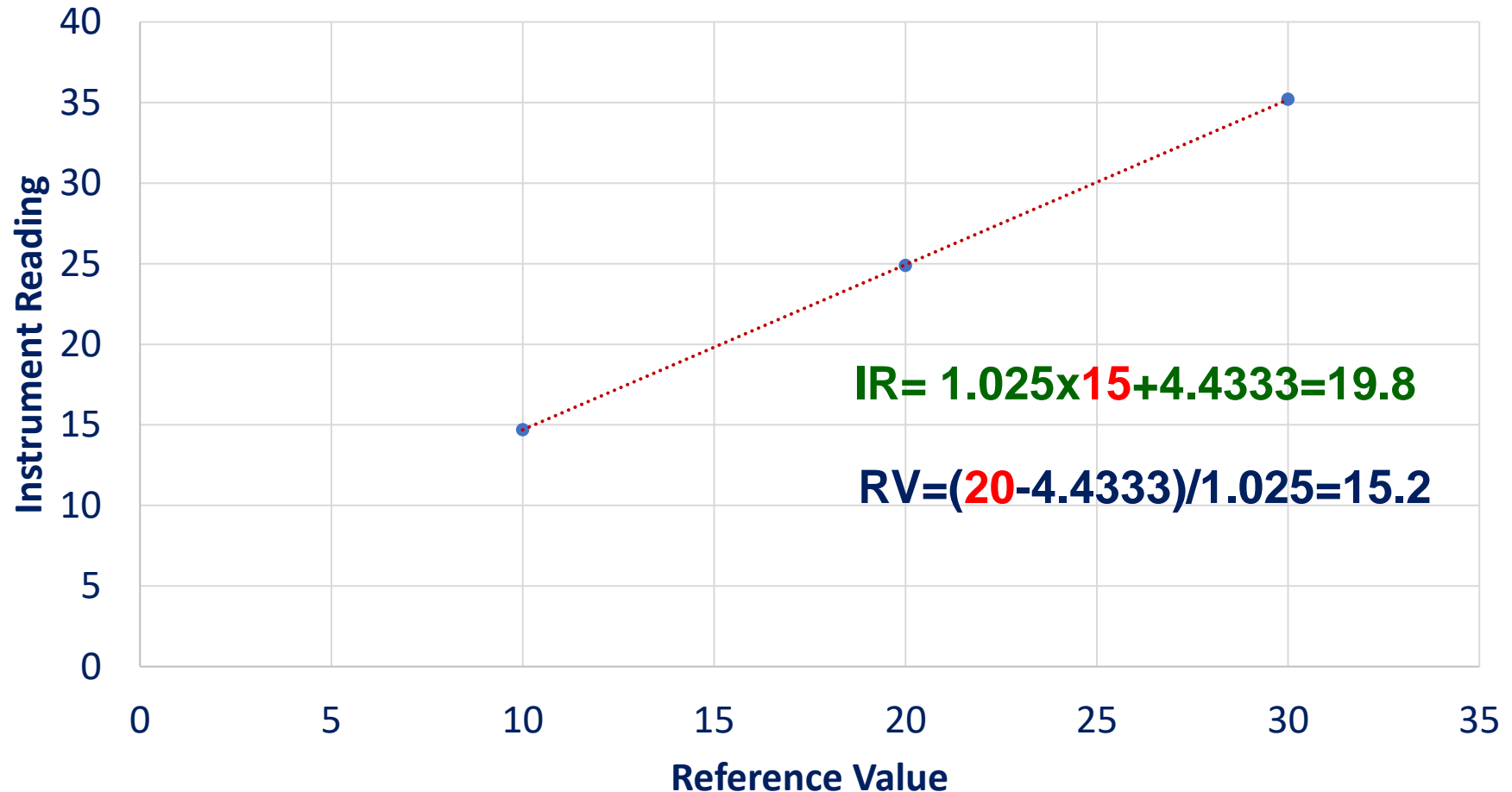
- ii. The instrument **gives a reading of 20 units**:

$$\text{reference value} = 10 + \frac{20 - 14.7}{24.9 - 14.7} \times (20 - 10) = 15.2 \text{ units}$$

Applying Corrections to Instrument Readings- Examples

Instrument Response

$$IR = 1.025 \times (RV) + 4.4333$$



Applying Corrections to Instrument Readings- Examples

4. A certificate reporting the value for a material measure

- The calibration result for a material measure is conventionally reported as a measured value:

Nominal Value (units)	Measured Value (units)
100	100.32

A calibration is not an assurance that the measured value is equal to the nominal value or any value previously marked on the material measure.

Calibration does not necessarily involve adjustment.

Applying Corrections to Instrument Readings- Examples

4. A certificate reporting the value for a material measure (cont'd)

- Consider a material measure having a measured value as given by the table.

Nominal Value (units)	Measured Value (units)
100	100.32

Suppose the material measure is used with an indicating instrument and a reading of 100.01 units is obtained.

The correction for the indicating instrument is then:

$$\begin{aligned}\text{correction} &= \text{measured value of reference standard} - \text{reading} \\ &= 100.032 - 100.01 = 0.02 \text{ units}\end{aligned}$$

where the **correction has been rounded to the resolution of the instrument.**

Applying corrections for changes in conditions

- Most instruments are sensitive to the conditions in which they are operated. These influence quantities include environmental factors, operating methods and conditions, and instrument settings.
- For factors that may affect the performance of the instrument, the calibration conditions will be specified on the certificate.

The results reported on the certificate apply only for the conditions specified.

Applying corrections for changes in conditions

- Where the instrument may be operated in different conditions the calibration laboratory may report information on the sensitivity of the instrument to the influence quantity.

- Consider the example of a material measure of value 100.032 units calibrated at a temperature of 20.5 °C.
- The measure is used at 25 °C and the user ascertains, by separate measurement or from the certificate or from manufacturer's specifications, that value will increase with temperature by 0.01 units per °C.
- The correction to the value reported on the certificate is then:

$$\text{correction} = (0.01) \times (25 - 20.5) = 0.045 \text{ units} .$$

Applying corrections for changes in conditions

- The temperature coefficient may have been reported as 0.01% per °C or as 100×10^{-6} units/unit per °C. In this case the correction is calculated as

$$\text{correction} = 100.032 \times (0.0001) \times (25 - 20.5) = 0.045 \text{ units.}$$



If a correction is not applied then a term accounting for the change in temperature should be included in the uncertainty.

Digital Calibration Certificates (DCC)

Digital Calibration Certificates (DCC)

Overview



-  Transformation of a physical format to a digital one
-  Use of digital technologies to change a business model and supply new opportunities with added value

Digital Calibration Certificates (DCC)

Benefits

Machine readable

Easiness in the exchange of calibration results

Customers can receive and analyse certificates faster, reducing execution times and costs associated to the metrological confirmation process

Reduce human errors and their consequences

Digital Calibration Certificates (DCC)

Main Features

Based on the internationally accepted and approved exchange format XML (Extensible Markup Language)

All indications, including the numerical calibration curves, can be directly and automatically transferred into all digitally supported processes

Cryptographic signatures are used as security procedures to guarantee that the integrity and the authenticity of a calibration certificate is still ensured

Digital Calibration Certificates (DCC)- Structure:

Four areas:

1. Administrative data (regulated area)

- Essential information of central interest
- The data fields are fixed.
- The information is usually on the first page of an analogue calibration certificate.
- The data are used to clearly identify the calibration laboratory, the calibration object and the calibration customer

2. Measurement results (partially regulated area)

- Representation of the measurement results: one of the most challenging tasks to be solved
- A simple structure can be presented for those who do not already have an existing data exchange format
- Strongly regulated: the measurement results must be presented completely and only on the basis of the SI

Digital Calibration Certificates (DCC)- Structure:

3. Comments (not regulated area)

- Information about a measurement process, which provides further information on the measurement results.
- Can be used optionally and without requirement.
- Possible data: graphics from measurement curves, video or audio information, individual measurement series in any format.

4. Document (additional area)

- In this area, an optional version of the calibration certificate stored in PDF-A can be stored according to the previous paper publication.
- Users of the DCC can thus see an image of their usual calibration certificate during the transition to a digital world.

1.: Administrative Data

- regulated

2.: Results of the Calibration

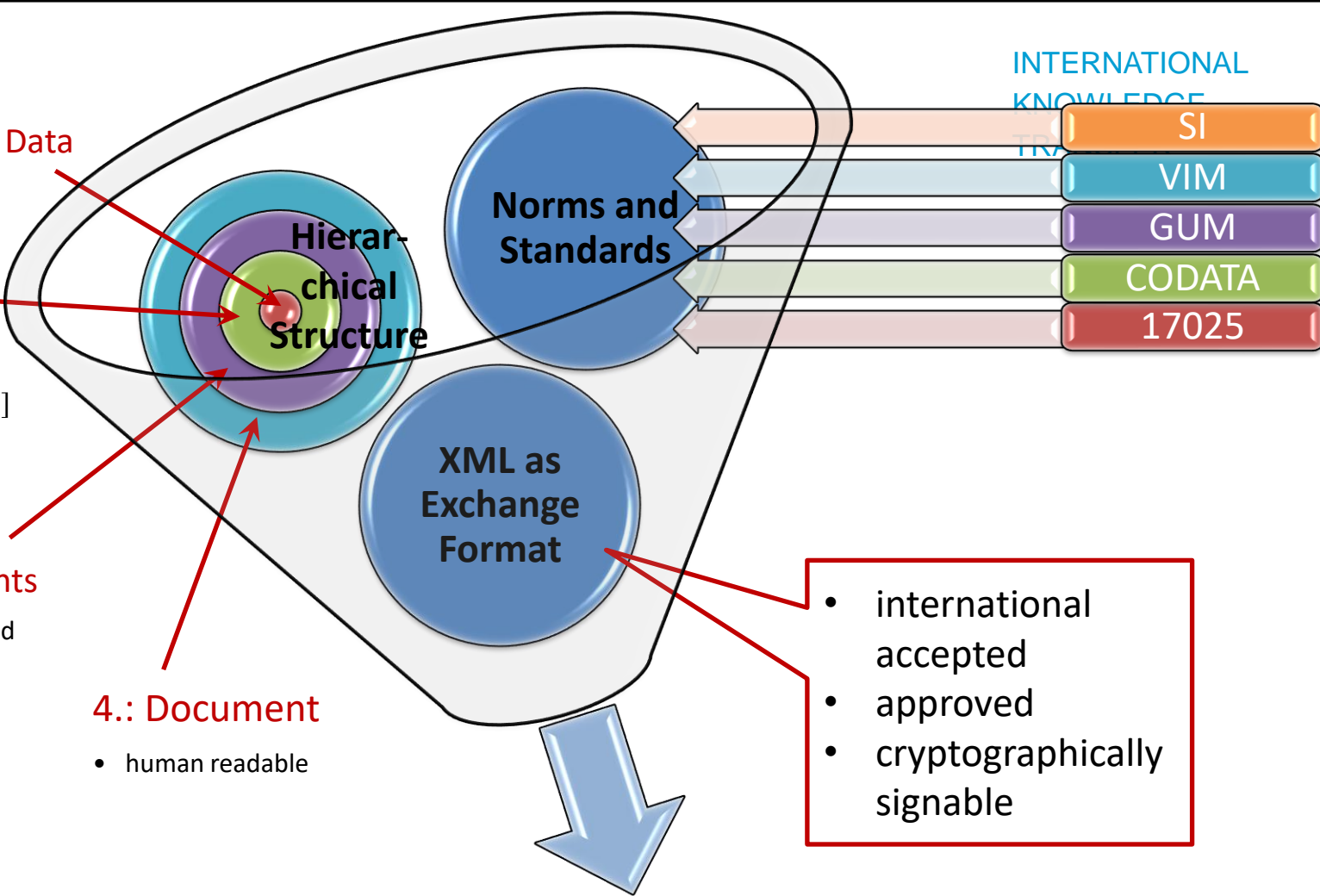
- regulated:
 - $Y = y \pm U(k) [SI]$
- not regulated:
 - individual data
 - ...

3.: Comments

- not regulated

4.: Document

- human readable



Source: The Digital Calibration Certificate
Siegfried Hackel, Frank Härtig, Julia Hornig,
Thomas Wiedenhöfer, PTB



References

- ILAC-G8:09/2019 “Guidelines on Decision Rules and Statements of Conformity” (www.ilac.org)
- EA-4/23 INF : 2019 “The Assessment and Accreditation of Opinions and Interpretations using ISO/IEC 17025:2017” (<https://european-accreditation.org/>)
- EUROLAB Technical Report No.1/2017 “Decision rules applied to conformity assessment” (www.eurolab.org)
- UKAS Lab 5:2019 “Reporting Calibration Results” (www.ukas.com)
- PTB “The Digital Calibration Certificate”, Siegfried Hackel, Frank Härtig, Julia Hornig, Thomas Wiedenhöfer

Thank you for your attention!

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