KNOW-HOW

CONFORMITY STATEMENT.

Decision-making rules in conformity statement based on DIN EN ISO/IEC 17025:2018

Content

1. Introduction

"Is my device okay or not?" Many owners and users expect an answer to this question when they send their measuring and testing equipment to an accredited calibration laboratory.

During the calibration, the metrological properties of the object to be calibrated are determined by comparison with precise laboratory standards on the basis of several measurement series. These properties are compared in the conformity statement with a previously defined permissible deviation in order to determine whether the measuring instrument functions as expected. As a general rule, the allowed deviation to be verified is the accuracy specification published by the manufacturer.

Whether the measuring instrument is within or outside the allowed deviation is easy to answer at first glance. In practice, however, there is a complex construct behind this decision. Calibration laboratories and service providers are forced to deal with the following questions:

- *How good is the conformity statement and does it really help the customer?*
- *What security does the customer receive when submitting declarations of conformity?*
- *Is it sufficient to state only the uncertainty of measurement?*
- *What is the risk that a declaration of conformity is incorrect?*
- *To what extent can the customer trust the decision made?*

Answering these questions requires active cooperation between the accredited calibration laboratory and the test equipment owner.

The new **DIN EN ISO/IEC 17025:2018 General requirements for the competence of testing and calibration laboratories** supports this process by implementing the decision rule. This rule "*[...] describes how the measurement uncertainty is taken into account when conformity statements are made with a specified requirement*" [1].

© Testo Industrial Services GmbH, 2019

Testo Industrial Services – More assurance, better Service.

KNOW-HOW

CONFORMITY STATEMENT.

In the following chapters, the concept of the decision rule is introduced and explained. At first the focus is set on the central parameter of measurement uncertainty. Then the conformity statement and the related standards and directives are discussed. Finally, the decision rules, offered in the future by Testo Industrial Services GmbH, for the conformity statement will be presented. The test equipment owner thus has the option to choose a decision rule that is suitable for his processes and requirements.

2. Measurement uncertainty

"Measurements are always wrong - it's just a matter of how wrong", Dave Packard, co-founder of the technology group Hewlett-Packard.

What is the measurement uncertainty?

Measurements do not provide absolutely accurate values because they are always subject to shortcomings and imperfections that cannot be quantified precisely. The result of a measurement depends on the applied measurement method, the environmental conditions such as temperature, humidity and ambient pressure, the efficiency of the used measurement technology (offset, drift) and on the competence of the calibration technician [2].

"*Measurement uncertainty is the doubt that exists about the result of each measurement.*"
Although the word "uncertainty" does not inspire confidence in common usage, the term "measurement uncertainty" has a much more positive significance in the metrological-scientific field. The measurement uncertainty is a quantitative measure for the dispersion of the measurement results and enables a statement to be made about the quality and confidence in the results. For the quantification and evaluation of the measurement uncertainty, two aspects are therefore absolutely necessary. On the one hand the value range or the interval in which the true value of the measurand is expected. Secondly, a confidence level which indicates how reliably the true value lies within this range.

Why is the measurement uncertainty relevant?

In order to evaluate and reuse the result of a measurement, a statement on the quality of the result must be made in addition to the estimated value of the measurand.
The indication of the measurement uncertainty strengthens the confidence in the measurement results and enables the comparison of different measurements. This is a basic requirement for the national and international exchange of goods.
There are also other reasons to deal with measurement uncertainty; if, for example, the measurement is part of a calibration and must be shown on the calibration certificate or if compliance with the accuracy specification of a measuring instrument is to be evaluated [3].

Within the scope of the conformity statement, it enables the measurement uncertainty to establish a level of confidence for a correct decision and hence to consider associated risks appropriately.

How is the measurement uncertainty determined?

"*A measured value without measurement uncertainty is not a complete measurement result!*"
In order to meet the metrological requirements for the comparability of measurement results, a transparent and uniform determination of the measurement uncertainty is required from the calibration laboratories. Through the accreditation the standardization of the measurement result with the associated measurement uncertainty, indicated in the calibration certificates, is guaranteed.
The generally accepted procedure for determining a quantitative uncertainty is described in the ISO/ BIPM Guide **Guide to the Expression of Uncertainty in Measurement (GUM)** [4]. GUM follows the approach of indicating each measurement result as the best estimate of a measurand with the associated measurement uncertainty. The measurement uncertainty reflects the confidence to know the true value of the measurand. The use of the term "confidence " is of central importance as metrologists are forced to consider and quantify the results as probabilities.

© Testo Industrial Services GmbH, 2019

KNOW-HOW

CONFORMITY STATEMENT.

The determination of the measuring uncertainty is usually determined according to the procedure shown in Fig.1. The individual influencing variables Xi are described according to their distribution as probability functions u(Xi), calculated with the corresponding sensitivities from the measurement model Y = f(Xi) and combined via the method of quadratic addition to form a standard measurement uncertainty u(Y). The standard measurement uncertainty u(Y) is the measure for the scatter of the measurement. In order to express a value range in which the true measured value lies with a probability of generally 95%, the stand measurement uncertainty is multiplied by a coverage factor. In most cases a normal distribution is correct. The multiplier corresponds to the numerical value 2.

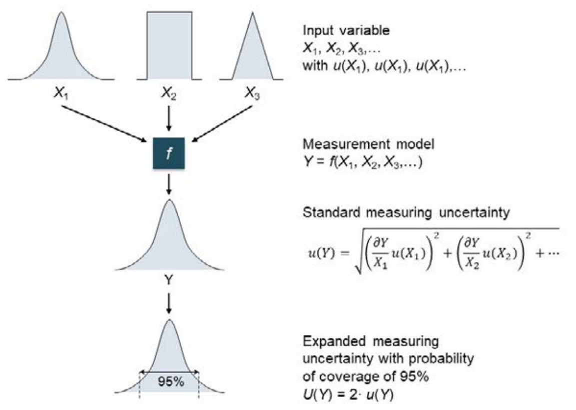


Fig. 1: Calculation of the measurement uncertainty according to GUM.

3. Conformity statement

The focus of a calibration is based on confidence. From the perspective of the calibration laboratories, it is trusted that the applied reference facilities lie within their specified uncertainty limits. In contrast, the customer relies on the measurement results issued in the calibration certificate and on the assumption that his measuring instrument works within the limits of it's accuracy specification.

What is a conformity statement?

In the past, results were mostly recorded in calibration certificates as measured values with their associated measurement uncertainties. However, this is often not sufficient in case the customer wishes a statement concerning the suitability of his measuring instrument with regard to specified requirements. In such cases, an objective pass/fail evaluation regarding the metrological determined characteristic features of the calibration object is required. Such an assessment is referred to as conformity statement. The term is defined as "*the statement that specified requirements relating to a product, process, system, person or bodies are met*" [5].
The defined requirements can be presented in normative documents such as legal regulations, standards and technical specifications. In addition, customer-specific tolerances or estimates of the permissible deviation are allowed by the executing calibration personnel.

What does the norm say?

The essential reference to the statement of conformity in the previous edition of DIN EN ISO/IEC 17025:2005 is found in Section 5.10.4.2 (Calibration Certificate) and states "*When statements of compliance are made, the uncertainty of measurement shall be taken into account*" [6]

What does "*taking measurement uncertainty into account*" mean and why is this necessary? An intuitive explanation of these questions is given with the help of Fig.2. For the assessment of conformity to a defined permissible deviation, five different calibration results are presented. These contain in each case the determined measured value with associated extended measurement uncertainty ±U (coverage probability of 95%) and the permissible deviation for the measuring instrument.

© Testo Industrial Services GmbH, 2019

KNOW-HOW

CONFORMITY STATEMENT.

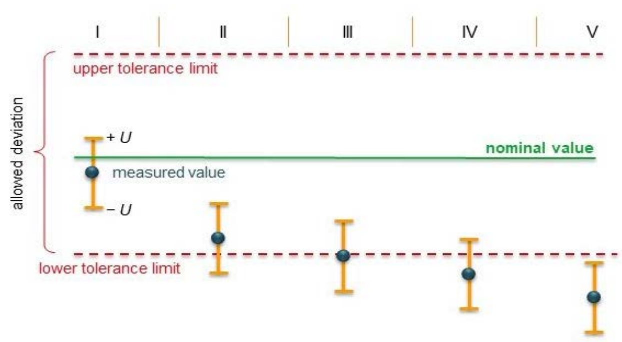


Fig. 2: Five possible calibration results for the conformity statement.

In cases I to III, a legitimate way could be found that the measurement result is within the allowed deviation. Without taking the measurement uncertainty into account, the observation could also be misleading or even wrong. As already mentioned, all measurements reflect only estimates of the true value of a measurand. The true value can never be determined exactly due to the measurement uncertainty. A reliable statement as to whether the measuring device lies within its allowed deviation can only be made for case I. The risk of a false statement here is extremely low for the following reasons: The measurement deviation is small and the allowed deviation is large enough in relation to the expanded measurement uncertainty. The latter is quantified by the so-called TUR value (test uncertainty ratio). A reliable statement for the nonconformity is therefore only possible for case V. This is where the calibration object, including the measurement uncertainty, lies outside its allowed deviation.

But what about cases II to IV? Due to the measuring uncertainty, the true value could be both within and outside the allowed deviation. Whether the calibration object is conforms to its accuracy specification cannot be determined without a quantifiable control limit, for example as the risk of a false assumption. In the current version of DIN EN ISO/IEC 17025:2005, it might be useless to search for a practical guide that specifies which method could be used to define such a control limit.

With the publication of the new revision of DIN EN ISO/IEC 17025:2018, the term decision rule was introduced. It provides the basis for the definition of quantifiable control limits on which the decision rule is based.

4. Decision rules

Since each measurement is associated with an uncertainty of measurement, the conformity statement based on it also becomes uncertain per se. Decision rules define the criteria how the measurement uncertainty is to be considered in the conformity statement. Quantitative control limits in the form of guard bands will be introduced, which can reduce the range of acceptance in comparison to the allowed deviation (see Fig. 3). The size of the guard band in relation to the measurement uncertainty defines the largest expected risk of a false assumption.

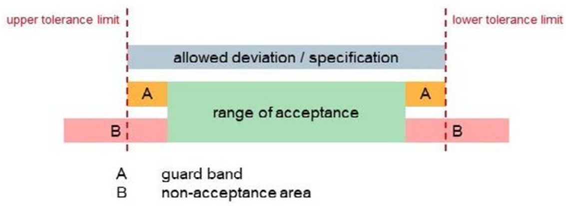


Fig. 3: llustration for defining a binary decision rule. The object is accepted as conforming if the measured value is within the acceptance range. Otherwise, the non-conformity is certified.

Basically, decision rules for conformity statements are not new for accredited calibration laboratories. Even before the publication of DIN EN ISO/IEC 17025:2018, conformity was issued on the basis of regulations and standards. In turn these provide the specifications for the consideration of the measurement uncertainty. The most common normative regulations and the associated conformity statements for cases I to V are shown in Fig. 4.

KNOW-HOW

CONFORMITY STATEMENT.

DIN EN ISO 14253-1:2018 – Decision rules for the verification of conformity or non-conformity with specifications

"5.2.1 Compliance with a specification is verified if the measured value is within the acceptance range. The acceptance range is the specification range minus the protective distances under consideration of the limit of the probability of conformity [...] of 95% [...]" [7]

"6.1 The rules in this document apply if no prior agreement has been made between the supplier and the customer [7]

The standard describes a binary decision rule which, by default, only confirms the conformity with a specification in case the measured value with a confidence level of at least 95% is within the allowed deviation. If this criterion is not met, then the measurement result is outside the range of acceptance and the non-conformity with the specification is indicated. In addition, the standard leaves open the possibility of agreeing a different level of confidence with the test equipment owner.

DAkkS-DKD-5:2010 - Instructions for creating a calibration certificate

„2.4 If it is confirmed that a parameter is within the specified tolerances, the difference and the sum of the measured value and the expanded measuring uncertainty calculated according to DAkkS-DKD-3 (replaced by EA-4/02 M: 2013; editor's note) should also be within the applicable specification limits." [8]
In this specification, the conformity with a specification will only be certified if a corresponding protective distance is maintained. This distance is rigid defined as the extended measurement uncertainty. Accordingly, the acceptance range is reduced by this contribution compared to the allowed deviation.

"Note 2: If the difference or sum of measured value and expanded uncertainty of measurement are outside the specified tolerance, while the measured value itself is within the tolerance, neither conformity nor non-conformity can be proven. In the calibration certificate, only the measurement result and associated uncertainty can then be indicated without a statement of conformity." [8]

Should the measured values, including the extended measurement uncertainty, exceed the permissible deviation, a statement of conformity is not possible. Evidence of non-conformity shall be certified if the pure measured value is outside the allowed deviation (cases IV and V).

ILAC-G8:2009 - Guidelines on the reporting of compliance with specification

"2.3 (a) Compliance: If the specification limit is not exceeded by the measurement result plus the expanded measurement uncertainty with a coverage probability of 95%, the compliance with the specification can be determined." [9]

The requirement is identical to DAkkS-DKD-5. Both standard specifications are based on a rigid control system which defines the extended measurement uncertainty as a fixed protective distance.

"2.3 (c) If the measurement result plus/minus exceeds the expanded measuring uncertainty with a coverage probability of 95% of the specification limit, it is not possible to certify a statement of conformity or non-conformity" [9]

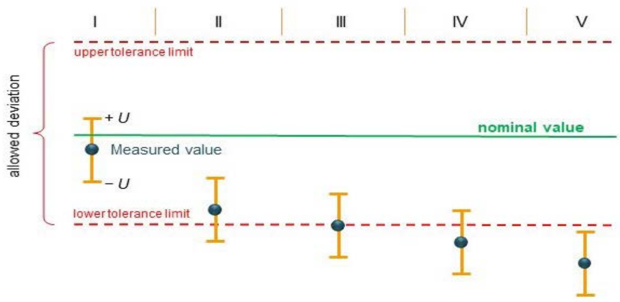
In contrast to the DAkkS-DKD-5, a conformity statement is also then not possible - even if the measured value is outside the allowed deviation, but the extended measurement uncertainty is within (see case IV).

The decision rules according to DAkkS-DKD-5 and ILAC-G8 often do not lead to conformity statements in everyday life and therefore are usually not helpful for the test equipment owner or user.

© Testo Industrial Services GmbH, 2019

KNOW-HOW

CONFORMITY STATEMENT.



Conformity Satement:
✓ – pass X – fail O – without rating

Decision rule according to norm	I	II	III	IV	V
DIN EN ISO 14253-1	✓	X	X	X	X
DAkkS-DKD-5	✓	O	O	X	X
ILAC G-8	✓	O	O	O	X

Fig. 4: Illustration of conformity statement on the basis of normatively regulated decision rules.

What does the new DIN EN ISO/IEC 17025:2018 say about the decision rules?

Section 3.7 of DIN EN ISO/IEC 17025:2018 states that the term "*decision rule*" is defined as "*Rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement*"

Further is stated:
"7.1.3 When the customer requests a statement of conformity to a specification or standard for the test or calibration (e.g. pass/fail, in-tolerance/out-of-tolerance), the specification or standard and the decision rule shall be clearly defined. Unless inherent in the requested specification or standard, the decision rule selected shall be communicated to, and agreed with, the customer." [1]

"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 ". [1]

In accordance with DIN EN ISO 14253-1, the new DIN EN ISO/IEC 17025:2018 declares the risk of a false statement or the level of confidence of the correct assumption to the quantitative control medium in conformity statement. The level of confidence of the correct acceptance can be chosen flexibly and must be coordinated with the test equipment owner or user without normative specifications.

This new regulation of DIN EN ISO/IEC 17025:2018 enables to evaluate the measurement results of the calibrations respectively to select the protective distance in such a way, which the customer consider suitable an appropriate for his company and processes.

What should customers of accredited laboratories consider?

When choosing the decision rule, a level of confidence of at least 95% should be a priority. This will ensure confidence and security in a proper functioning of the measuring instruments and guarantees a reliable conformity statement in all cases. In addition, this choice offers a high level of audit security for the client and avoids a differentiated risk assessment in statistical process control to the greatest extent.

In practice, however, scenarios repeatedly occur in which the extended measurement uncertainty of the calibration is relatively large compared to the accuracy specification. This applies particularly for length measurements. In some cases, the limit values of the permissible errors are in the order of the theoretically achievable measurement uncertainty. But also in other areas of measurement technology, the manufacturers increasingly specify smaller tolerances that are hardly inferior to the measurement uncertainty of most accredited calibration laboratories. The application of the 95% decision rule is only possible to a limited extent in these cases, as this would result in high rejection rates for the measuring equipment.

© Testo Industrial Services GmbH, 2019

KNOW-HOW

CONFORMITY STATEMENT.

Not to evaluate the calibration object but does not help in most cases, because someone has to make the decision about the suitability of the test equipment.

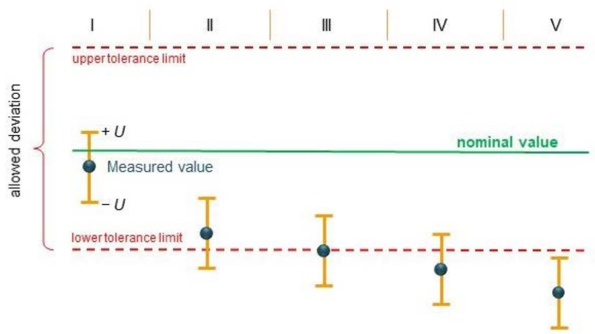
In such cases, a weaker decision rule, on the basis of DIN EN ISO/IEC 17025:2018 can be applied. Reduction of the uncertainty of measurement to be taken into account usually leads to a higher rate of compliant measuring instruments and reduces the costs for repairs and replacement of measuring instruments. However, the consideration of economic aspects by the client is accompanied by an increased risk of making the wrong decisions. For example, if the measured value is on the tolerance limit (case III), there is a considerable risk of a false statement.

As a matter of priority, competent calibration laboratories should continue to be fully committed to improve their measurement uncertainty in order to be able to offer conformity statements based on a confidence level of at least 95%.

5. Decision rules at Testo

Calibration laboratories must convert their accreditation to the revised DIN EN ISO/IEC 17025:2018 by the end of November 2020. Accreditations that have not been converted would then lose their accreditation. At the beginning of the year, Testo Industrial Services GmbH already submitted its application for the conversion to the German Accreditation Body (DAkkS). The required examinations, according to the new standard version, are already firmly scheduled for 2019.
In the course of the changeover, Testo Industrial Services has defined new decision rules, which are actively offered to the test equipment owners for selection. If a customer wishes a conformity statement for his calibration, two binary decision rules are available to him in the future. These differ in their level of confidence in the pronounced conformity statement and thus in the acceptance range of the determined measured values. Decision rules with an uncertainty range between acceptance and rejection were deliberately avoided. Thereby we guarantee the customer in each case a statement of conformity with the specified tolerance. The customer does not have to decide alone whether his test equipment is in order.

A summary of the possible conformity statements, depending on the underlying decision rule, is shown in Fig. 5. In the decision rule "High level of confidence' means the level of confidence of a correct assumption is in any case at least 95%. With the decision rule "Low confidence level", the acceptance range increases so that calibration results with a confidence level of at least 50% are also accepted. If the measured value lies outside the allowed deviation, the non-conformity is certified in both decision rules. The decision rules can be selected independently for factory calibrations (ISO) as well as for accredited calibrations (DAkkS). If the measured value is outside the allowed deviation, the non-conformity is certified in both decision rules. Naturally, calibrations without conformity statements are still possible on customer request.



Conformity Statement
✓ – pass X – fail

Decision rule according to Testo Industrial Services GmbH	I	II	III	IV	V
high confidence level ≥95%	✓	X	X	X	X
low confidence level ≥50%	✓	✓	✓	X	X

Fig. 5: Conformity statement based on decision rules at Testo Industrial Services GmbH.

© Testo Industrial Services GmbH, 2019

KNOW-HOW

CONFORMITY STATEMENT.

What should Testo's customers do next?

In our *Customer letter "Decision rules for the conformity statement"* the offered decision rules are explained. On the second page, the test equipment owner can select the decision rule, which is suitable for his company. The selection applies for both DAkkS as well as for factory/ISO calibrations. The completed and signed customer letter is then sent to the contact person at Testo Industrial Services and will then be archived. From this point on, the selected decision rules are applied during the calibrations at Testo Industrial Services' - either in the lab or on-site.

>>> Fill in and confirm now

The feedback regarding the selected decision rule should be provided by the beginning of the second half of 2019. Should we not have received a feedback by then, DAkkS calibrations will be evaluated by default according to the "High confidence level" rule and factory (ISO) calibrations according to the "Low confidence level" rule.

Bibliography

[1] DIN ISO/IEC 17025:2018, General requirements for the competence of testing and calibration laboratories.
[2] S. Bell, "A Beginner's Guide to Uncertainty of Measure-. ment," in Measurement Good Practice Guide, 1999.
[3] B. Pesch, Determination of the measurement uncertainty according to GUM, Nordersted, 2003.
[4] JCGM 100:2008 Evaluation of measurement data- Guide to the expression of uncertainty in measurement.
[5] DIN ISO/IEC 17000:2005, Conformity statement - Terms and general principles.
[6] DIN ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories.
[7] Geometrical product specifications (GPS) - Inspection of work pieces and measuring instruments by measure ment - Part 1: Decision rules for demonstrating conformity or non-compliance with specifications.
[8] DAkkS-DKD-5 Guide to Creating a Calibration Certificate, 2010.
[9] ILAC-G8:03/2009 Guidelines on the Reporting of Compliance with Specification

Author
Dr.-Ing. Christian Sander
Manager Metrology
Testo Industrial Services GmbH

CONTACT FOR FURTHER QUESTIONS:

Testo Industrial Services GmbH
Gewerbestraße 3
79199 Kirchzarten

Tel. 07661/90901-8000
E-Mail: info@testotis.com

© Testo Industrial Services GmbH, 2019