

Swedacs policy on metrological traceability, calibration and measurement uncertainty

1. Introduction

Accredited bodies shall fulfil the requirements in Swedac's regulations. In addition, the accredited body shall fulfil the requirements in the relevant conformity assessment standard used for accreditation. The requirement of metrological traceability, and by that calibration and measurement uncertainty, can be different between the different standards. However when metrological traceability is required by any conformity assessment standard the same requirements apply. Swedac have established this policy for the purpose to harmonize it's assessments and at the same time give the accredited body's some guideline about metrological traceability, calibration and measurement uncertainty. Swedac has based this policy document on ILAC P10 and ILAC P14.

The intention of this policy document is not to add any other requirements to the assessments except those already stated in Swedac regulations and the relevant conformity assessment standards. This means that where the words "shall" and "must" is used throughout this policy document it is used to indicate an obligations that are already considered mandatory in view of the requirements of accreditation.

2. Definitions and explanations of certain concepts

Calibration

Calibration is a comparison between a reference and the device that shall be calibrated. The comparison determines how much the performance of the device deviates from the reference. Uncertainty of measurement is a measure of how well this deviation may be determined. If a calibration is to be reliable, one must use a reference calibrated by a national metrology institute or by a calibration laboratory accredited for the work. The uncertainty of measurement when calibrating the reference should be considerably lower (1/5 or better) than the uncertainty of measurement that is required for the calibrated object. If not, the 'error contribution' from the reference would be much too high in the total uncertainty of measurement for the calibrated object. In addition, there must be written instructions defining how the calibration is to be performed. These instructions must define how the work is to be done, the particular measurement points to be calibrated, sources of error to be avoided, the measurement uncertainty factors associated with the particular calibration process, and so on. The personnel shall also be qualified to perform the qualification.

Check

1) The word 'check is sometimes used to indicate a more simply calibration. Even a check requires a written instructions and in some cases even qualified personnel depending on the level of difficulty to perform the check. A check can in some cases include the need for a calibrated reference and

calculation of the measurement uncertainty of the results. A check may e.g. be used as an intermediate step between ordinary calibrations.

2) The word 'check' is sometimes used for functional test of a device. A written procedure should preferably be used to be sure that these functional tests are done in the same way every time.

Metrological Traceability

Characteristic of a result of a measurement or of a value of a measurement standard which means that it can be traced back to named references, normally national or international standards through an unbroken chain of comparisons, each of which has stated levels of uncertainty (SS 02 01 06).

National Metrology Institute (NMI)

Bodies under Swedish law designated for a certain measurand to officially respond to such measurement as compared to national standards or scientifically defined units of measure, ensuring accuracy of measurements performed within the country and ensure that these national standards and units of measure are linked to internationally accepted units.

Reference Material Producer (RMP)

Body (organization of company, public or private) that is fully responsible for the project planning and management, assignment of, and decision on property values and relevant uncertainties, authorization of property values; and issuance of a reference material certificate or other statement for the reference materials it produces (EN ISO 17034:2016)

JCTLM

The CIPM, IFCC and ILAC Joint Committee for Traceability in Laboratory Medicine (ILAC P10).

Measurement standard

Material measure, measuring devices, reference material or measuring system intended to define, realize, conserve or reproduce a unit or one or more quantities to serve as a reference (SS 02 01 06).

Certified reference material (CRM)

Reference material characterized by a metrological valid procedure for one or more specified properties, accompanied by an RM certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability (EN ISO 17034:2016)

Reference material (RM)

Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process (EN ISO 17034:2016)

Calibration and measurement capability (CMC)

CMC provides information on which measurement uncertainty the calibration result can be presented with. An accredited calibration laboratory is not allowed to offer better measurement uncertainty to its customers than what they have in their CMC.

3. Swedacs policy

3.1. Metrological traceability and calibration

3.1.1. Swedacs policy is that when metrological traceability is required the equipment shall be calibrated by:

- An accredited calibration laboratory that has a scope of accreditation that includes the particular quantity and measurement range required for the equipment. The laboratory must be accredited by Swedac or by an accreditation body with which Swedac has a multilateral or bilateral agreement within the frameworks of EA (European co-operation for Accreditation) and ILAC (International Laboratory Accreditation Cooperation).
- A national metrology institute for the quantity concerned, either in Sweden or in a country having an internationally recognised national metrology institute structure. Approved CMC values for different countries NMI:s are listed in BIPM KCDB (International Bureau of Weights and Measures Key Comparison Database), which can be found on the BIPM website. (www.bipm.org)
- If there is no access to an accredited laboratory or NMI for the calibration, the accredited body may need to employ the services of a calibration facility that can prove their competence to perform the calibration in another way. The following then apply:
 - The accredited body shall perform a supplier assessment of the calibration facility against the relevant requirements in EN ISO/IEC 17025. This kind of supplier's assessments may need to be carried out at appropriate intervals.
 - The provider of the calibration service need to make available to the accredited body its documented calibration methods, description of traceability for the quantities to be calibrated, analysis and estimation of the uncertainty of measurement (performed according to GUM)
 - The documentation from the supplier assessment needs to be present for review by Swedac at the time of our assessments.
 - Swedac may have the opportunity to do an on-site observation of the accredited body when it carries out the supplier assessment of the calibration service.

3.1.2 If the accredited body intends to calibrate its own equipment

(other concepts are e. g. in-house calibration) Swedac will assess that activity according to the corresponding requirements for a calibration laboratory according to EN ISO/IEC 17025. This can be summarized as follows:

- The Body shall ensure that the personnel that carry out the calibration have the relevant competence.
- The Body shall have access to a measurement standard that is calibrated according to decided/suitable intervals (with a sufficiently low uncertainty of measurement) at a national metrology institute or a calibration laboratory accredited for this purpose. It shall be able to take responsibility for the reference standard calibration status and suitability and shall have access to it whenever needed.
- The Body shall have instructions for performing the calibration.
- The Body shall have procedures for estimating/evaluating uncertainty of measurement for the calibrations in question.

- The Body shall report the calibration results along with their uncertainty of measurement.
- The Body shall, based on the calibration results, be able to decide if their own device should be approved or rejected for its area of use. Appropriate decision-making rule shall apply to this evaluation.
- The Body must have procedures to ensure the validity of the results. This includes both internal and external activities.

3.1.3 If metrological traceability is provided by use of reference material, Swedacs policy is that this shall have been produced by:

- An accredited reference material producer (RMP) in accordance with the requirement in EN ISO 17034
- A national metrology institute, either in Sweden or in a country having an internationally recognised national metrology institute structure.
- Certified reference values published in the JCTLM database (Medical)
- A reference material producer that can demonstrate that the reference material (RM) is sufficiently homogeneous and stable with respect to specified properties for a specific task. It is the accredited body's responsibility to secure the competence of the reference material producer and also that the reference material (RM) is suitable for its intended use. When evaluating the competence of the reference material producer's competence you should refer to relevant requirements in EN ISO 17034.

3.2 Measurement uncertainty

Accredited bodies that shall report measurement uncertainty shall calculate these uncertainties in accordance with statistical acceptable methods.

An accredited calibration laboratory shall estimate the measurement uncertainty in accordance with EA 4/02. This document is based on the "Guide to the Expression of Uncertainty in Measurement" – GUM.

Accredited calibration laboratories shall present the measurement uncertainty in calibration certificates with maximum 2 significant digits. Based on this Swedacs also recommend to round off the calibration result to the same significant digit in order to avoid that the reader of the certificate overestimate to what precision the measurement result is presented.

The measurement uncertainty should be round off upwards when needed before presented in a calibration certificate.

References

2. EN ISO/IEC 17020:2012 Requirements for the operation of various types of bodies performing inspection
3. EN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
4. EN ISO 15189:2022 Medical laboratories - Requirements for quality and competence
5. EN ISO 17034:2016 General requirements for the competence of reference material producers
6. STAFS 2020:1 The Swedish Board for Accreditation and Conformity Assessment's (Swedac) Regulations and General Guidelines on Accreditation
7. ILAC G8:09/2019 Guidelines on Decision Rules and Statements of Conformity

8. EA-4/02 M:2022 Evaluation of the Uncertainty of Measurement in Calibration
9. ILAC P10:07/2020 ILAC Policy on Traceability of Measurement Results
10. ILAC P14:09/2020 ILAC Policy for Uncertainty in Calibration

Appendix 1 Some comments on the concepts of uncertainty, tolerance and decision rule

The terms 'uncertainty' and 'tolerance' are often used interchangeably, although this is incorrect!

- Tolerances are 'external': for example, what I can tolerate, such as expressed in my 'normative document'.
- Uncertainty of measurement, on the other hand, is 'internal': originating from the method of measurement and the measuring equipment (the measuring process).
- A diagram can help:

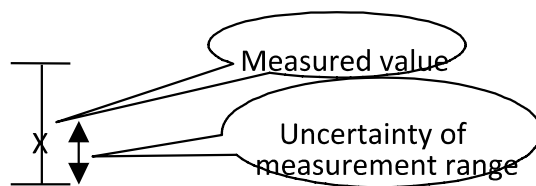


Figure 1 A measured value and its uncertainty of measurement. It's necessary to realise that the vertical 'pillars' represent probabilities, which are assumed to include 'the true value'. Uncertainty of measurement is arrived at as a result of analysis of estimated sources of error, repeated measurements etc. The procedure for this is described in EA-4/02.

Let us now enter this into a tolerance so that we can be 'sufficiently' sure that the tested product is approved or failed.

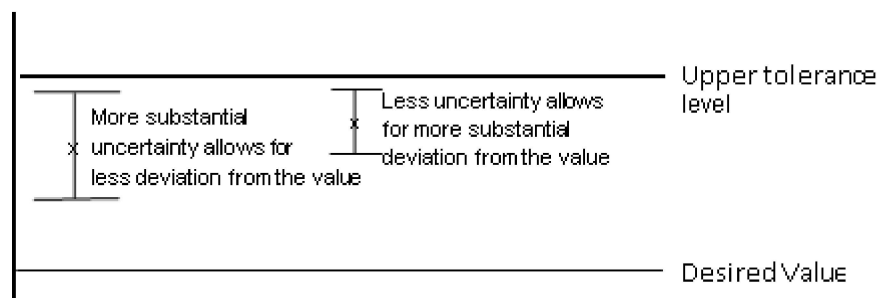


Figure 2 Illustration of how less uncertainty of measurement provides greater scope for avoiding failure.

Decision rule (Laboratory requirements)

A decision rule is something that describes how measurement uncertainty is handled when making a statement of compliance with a specified requirement (tolerance). There are several different ways to issue a decision rule and a rule applicable in an area may not fit in to another. However, the rule of thumb is that the greater risk accepted for not being correct in the declaration of conformity (false acceptance or false rejection), the less consideration needs to be taken to the measurement uncertainty.

Additional information on compliance statements can be found in ILAC G8. Some examples of commonly used decision rules are described below:

1. Simple acceptance / Shared risk. There is no safety distance to the tolerance limit, which means that the acceptance limit and tolerance limit is the same. This means that the laboratory only secure that the measurement value (single or average values) is within or outside the tolerance limit. This type of decision rule means, if the result is close to agreed tolerance limit, the risk is shared with the client that the laboratory's statement of conformity may be incorrect (by "close to agreed tolerance limit" in the reasoning is meant that the result $\pm$ MU risks falling outside). This decision rule means that you can in worst case accept a risk of up to 50% for an incorrect statement.
This decision rule may be relevant when the customer considers that measurement uncertainty doesn't affect their use of the statement. If this decision rule is agreed upon, it is also important to agree with the client how large uncertainty that can be accepted when a statement is made and that the laboratory is in control of the size of the measurement uncertainty and preferably report it in the report / certificate.
This type of decision rule is also applied if the tolerance is already specified in view of an expected measurement uncertainty for the measurement. The tolerance has then already been reduced to correspond to the expected measurement uncertainty. Many regulatory authorities in Sweden apply this type of decision rule in their regulations, but it can also be the case in standards that have tolerances presented.
With this type of decision rule, the laboratory shall not make a statement of conformity with an approved result if the measured value falls outside the agreed limit value, i.e. the laboratory only evaluate whether the value of the measurement quantity is within or outside the agreed limit, and at that time does not take into account the size of the measurement uncertainty. However, according to the above, the parties should already have agreed on what is an acceptable size for the measurement uncertainty.
2. The tolerance is reduced with the measurement uncertainty applicable to the laboratory results at its compliance statements. This is common in areas where it is not known in advance how much measurement uncertainty will be for each measurement and the client wants to rely on the statement to 97.5 %. Thus, there is still a risk of 2.5 % that the statement becomes false. If the client needs to reduce this risk, then the coverage factor $k = 3$, instead of the normal $k = 2$, could be applied to the uncertainty, which means that the risk is less than 0,2 %.
3. A third variant may be that the laboratory reports its compliance statements when the measured value is in the grey zone (the zone that occurs when the measurement value is so close to the tolerance that its measurement uncertainty could make the statement inaccurate with a greater probability than 2.5 %) with word choice as "Conditional approved" "Conditional disapproved" or "Possible approved" "Possible disapproved". The laboratory

then leaves to the client to decide whether these values can be accepted or if they are to be rejected.

What magnitude of uncertainty of measurement should be chosen in relation to the permitted tolerance (or permitted error) of the measurement?

The portion of the maximum permitted error represented by the uncertainty of measurement that is acceptable varies from one sector to another, over the range from $1/10$ to $1/3$. A reasonable relationship in order to ensure correct decision and use appropriate equipment, methods and knowledge, may in connection with inspection (according to OIML-recommendations) be e.g. that the uncertainty of measurement may account for $1/5$ to $1/3$ of the maximum permissible error concerned. In these cases, possible authority regulations must be considered.