



National Accreditation Scheme

Guide to the content and structure of non-standard calibration pro- cedures

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1. Introduction

Pursuant to Act XXIV of year 2015 on the accreditation of laboratories, certification and inspection organisations, the National Accreditation Authority performs the accreditation of calibration laboratories in accordance with Standard MSZ EN ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories, NAR-EA Guides and the technical, specific requirements elaborated by the Authority.

Standard MSZ EN ISO/IEC 17025:2005 (guidelines on the application in certain specific fields) allows accreditation bodies to elaborate explanations on technical specific application as additional requirements to the general requirements of the Standard in the specific application field, which, however, cannot contain requirements exceeding the general requirements of the Standard.

The present document is an application aid to Section 5.4.4 Non-standard methods of Standard MSZ EN ISO/IEC 17025:2005. The calibration procedures should follow the structure of the document as appropriate. Parts in *Italics* contain additional explanations and examples.

1. Scope of the procedure

Name, nature of the measuring instrument to be calibrated in the procedure - if it is a limitation, or relevant in any other way - and measuring range.

Under this point, the measuring instrument to be calibrated, the quantity(ies) to be measured, the quantities potentially influencing the measuring range(s) shall be clearly identified if it is important from the aspect of the use of the instrument or the result of calibration.

Such a quantity influential from the viewpoint of the use of the instrument may be:

- *the surface tension of the medium to be measured in case of calibration of floating densimeters;*
- *the signal shape of alternating current or voltage in case of calibration of electromechanical instruments;*
- *the elasticity modulus, the Poisson number, and the thermal expansion coefficient of gauge block material in case of calibration of gauge blocks.*

In this Chapter, the principle of operation and characteristics of the measuring instrument to be calibrated shall be described to the extent as it is necessary.

2. Calibration/measurement principle

The calibration principle, the method to be applied shall be described in this Chapter. The measurement equation should possibly also be provided.

It is advisable to give a concise definition of the principle of calibration and in a manner that allows the client to receive sufficient information about the procedure in essence, the method of implementation, and this could just as well be communicated in the certificate of calibration.

3. Metrological characteristics to be determined by calibration

The metrological characteristics to be determined by calibration and the document(s) specifying these value(s) (e.g., standard, instrument manual, etc.) shall be provided in this Chapter.

The method of determining certain metrological characteristics and the procedure to be followed in certain cases when the customer does not request the determination of all of the metrological characteristics and limitations applicable to such cases shall be laid down in the calibration procedure.

4. Markings, measurement units and definitions

The name, marking/mark and unit or units for use of quantities suitable for measurement

or calculation, which are used in some other part of the procedure shall be enlisted in this Chapter. Furthermore, the definition of concepts used in a special sense in the procedure or not defined or differently defined elsewhere, as well as definitions the communication of which is advisable for the purpose of clarity of the procedure, shall be provided here.

5. *Instruments*

- a) Reference standards and reference materials
- b) Aids

Reference standard(s), reference material(s) (as appropriate) and other measuring instruments and aids necessary for performing calibration shall be enlisted in this section, and their principle of operation or specificities shall be described to the extent necessary.

The method, principle of selecting the reference standard(s) and aid(s) to be applied in calibration shall be identified here.

Tolerance arising from specification shall be the basis of selection and appropriateness of the reference standard used in calibration.

6. **Environmental conditions and stabilisation time**

The permitted limit values of influencing quantities shall be identified under this point.

The value of all influencing and disturbing quantities shall be indicated, in respect of which the operating manual or instrument manual of the item to be calibrated and the reference standard used in calibration contain requirements or limit values; values measured shall be between the limit values specified.

The values of influencing and disturbing quantities shall be recorded even if calibration is performed not in the laboratory of the accredited organisation (but on the site or in the laboratory of the customer), if the instrument measuring the influencing quantity is a responsibility of the calibration organisation.

The time required for stabilization prior to commencing the calibration of metrological characteristics of the measuring instrument shall be specified in this section.

Such are the following:

- *The warm-up time in case of an electronic measuring instrument.*
- *The duration – in case of length measuring instruments – in the course of which the measuring instrument reaches a temperature value near to the reference temperature.*
- *The duration – in case of temperature measuring instrument – required that the instrument be capable of measuring the real temperature of the medium within the extent of the statistical error.*

7. Receipt and preparation

a) Receipt conditions (control)

How the given type of measuring instrument is to be checked when received in addition to the general receipt control(s) described in the manual, and under what conditions the item should not be received shall be described in this section.

Since the measuring instrument may only be transported in a way specified in its operating or instrument manual, it is to be checked at the time of receipt whether the specified transport conditions (specified short-circuiting, fixation, protective caps and corrosion prevention) are met.

The instruments shall remain in a condition ready for transport until they arrive at the laboratory or directly at the instrument warehouse or preparation room near to the laboratory. This is the reason why the completeness (the existence of all the accessories listed in the operating manual and by the ordering customer) and the intact condition of the measuring instrument can only be checked by visual inspection at the time of taking it over from the client who ordered the calibration.

In order to avoid later complaints, it is expedient to make sure already at that time whether the device is operational, if it is possible and justified.

b) Marking (labelling) and entry into the records

The measuring instruments to be calibrated shall be clearly marked and entered into the calibration records.

The method of marking can be labelling, but in case they can be individually identified, before commencing calibration they can be marked by storing them on a shelf or some other place bearing 'measuring instruments for calibration' or similar, clear inscription.

c) Preparation, control of settings and operation

The operation may be checked and the transport specifications and conditions may be terminated, that is, the measuring device may be properly put in operation after carrying out the required preparatory operation(s) and setting(s).

In the course of checking whether the instrument is operational, it is expedient that at least two persons are present – one of them as a witness – if minutes are to be drawn up because of inoperability or non-proper operation of the instrument.

The preparations shall include carrying out all the setting operations (levelling, aeration, pre-loading, resetting, etc.) required by the operating manual or operating instructions of the measuring device, as well as also checking the operation (and fixation) of the controls.

d) Preparation (if necessary) and control of reference standards/etalons

Preparation of reference standard(s) and aid(s) for calibration shall be described

under this point. If calibration of the standard(s) or control in any other way is necessary, the details shall be specified in this section or reference should be made to the relevant procedure.

The preparations shall include carrying out all the setting operations (levelling, aeration, pre-loading, resetting, etc.) required by the operating manual or operating instructions of the reference standard/etalon, as well as also checking the operation (and fixation) of the controls.

e) Safety measures

Safety measures - if necessary, and/or appropriate - that must be complied with and must get complied with in the preparation of the measuring instrument or reference standard(s), aid(s) for calibration, or in the transportation, putting in operation of reference standard(s) and aid(s) and during the pursuit of calibration when calibration is performed on an external site shall be enlisted in this section.

For example:

Those who handle the bottles containing the gas samples shall have passed a bottle handling examination. Bottles may only be transported in the specified condition and under the specified circumstances.

In case of oil thermostats, the flash point of the oil shall always exceed the highest calibration temperature.

In case of transportation of reference standards/etalons, their fixation shall be arranged for.

f) Preparation of a report

Before starting calibration, the initial data according to the form, the name, type, manufacturing and other ID numbers/marks of the measuring instrument to be calibrated, its major metrological characteristics, name of the reference standards to be used in calibration and reference to documents certifying traceability shall be recorded in the report.

A separate form for the minutes is not a requirement but a recommendation only. For making records, the workbook is also suitable if the required and listed data are recorded therein.

8. Calibration/measurement

a) Order of operations and data recording

The operation principle of the measuring instrument to be calibrated and the reference standard used in calibration, and the operations to be performed in calibration shall be described in such a detail that enables an officer competent in the given

measurement field and performing similar tasks to understand the calibration procedure and perform it independently without further consultation or explanation. If necessary, and it is advisable and possible, block, connecting, and arrangement drawing can be made available, thus requiring less explanation.

Data that are to be recorded in the process of calibration, including the measured values of influencing quantity(ies) and all circumstances which influence the result, validity of calibration and the resultant expanded measurement uncertainty shall be specified under this point.

b) Calculation of metrological characteristics

The method used in evaluating the data received in calibration, formulae used for the calculation of metrological characteristic(s) and the IT tools, software used for this purpose occasionally shall be described under this point. Software used in evaluation and in the calculation of uncertainty shall be validated and controlled in a documented way.

c) Determination of the measurement uncertainty of calibration

The measurement uncertainty shall be determined based on the document EA-4/02, taking into consideration all factors that are influential to the resultant measurement uncertainty. The estimation of the particular measurement uncertainty contributions shall be shown in a tabular format, and the calculations, as well as the coverage factor based on which the laboratory determined its best measuring capability shall be given.

If the resultant expanded uncertainty is constant, its value is included in the calibration procedure. If the resultant expanded uncertainty is a function of the measurable quantity or of some influential quantity, the formula(e) based on which the resultant expanded measuring uncertainty shall be determined is/are to be given.

According to the instructions of document EA-4/02, the expanded measuring uncertainty (U) is the standard uncertainty ($u(y)$) multiplied by the coverage factor $k=2$; $U=k \cdot u(y)$ that corresponds to a coverage probability of nearly 95% in case of normal distribution.

The expanded measuring uncertainty of the particular calibration shall not be less than the best measuring capability reported by the laboratory that is found in the annex to the accreditation document.

In case of calibration carried out in an external location, the best measuring capability shall not be less than that of the calibration carried out under laboratory circumstances.

d) Qualification

Upon the written request of the customer, in the ‘Comment’ section of the certificate of calibration, the laboratory may qualify the measuring instrument as compliant or non-compliant. If the laboratory is undertaking to provide qualification, then it must record the criteria of acceptance, that is, the permitted limit values of the metrological characteristics under this point, whose source can be a requirement well/clearly identified; e.g., the operating manual issued by the manufacturer, a standard, rule of law, or tolerance margins derived by the user from intended application and communicated in writing. The certificate can only be relevant for the metrological characteristics, and it should be specified which point (or points) of the relevant specification the statement of conformity is valid for.

A parameter may be specified as that falling within the tolerance limits if the sum of the measured value(s) and the calculated measuring uncertainty/uncertainties falls between the specified limits.

Compliance may be certified only if the measuring uncertainty is low enough compared to the specified tolerance.

Neither compliance, nor non-compliance can be certified if the sum of the measured value and uncertainty falls outside, and the difference between the measured value and uncertainty falls within the tolerance limits. In such a case only the measured value and the measuring uncertainty but no statement relating to compliance may be included in the certificate.

e) Preparation for transportation and return

The method of preparation of the calibrated measuring instrument for transportation or return shall be described under this point.

They may include special procedures such as operations aiming at maintenance of conditions, preservation of found metrological characteristics, or procedures for packaging.

If the laboratory uses a label for marking the calibrated status of the measuring instrument, its model shall be presented under this point, instructions on where to place the label, shall be specified, responsibilities and sphere of powers shall be regulated in this section.

9. Display (of a model report and certificate)

Instructions on how to issue a certificate of calibration, as well as the sphere of competence, responsibility of the person/persons signing the certificate and the conditions to issuance, if it is not regulated by the manual in general terms, shall be described under this point.

In the manual a model report containing data, information, calculations (if necessary) to be recorded in the course of calibration and a model certificate of calibration to be issued on the basis thereof shall be displayed filled in with the data of a real calibration.

If the laboratory performs the storage of the calibration result by the help of an electronic device and not by storing a copy of the issued certificate of calibration, the special rules on the confidential handling of cases, accessibility and archiving shall be provided for under this point, as necessary. Archiving on a floppy disk is not sufficient, archiving on a hard drive is acceptable only with frequent backup saving in two or more copies; archiving on a removable hard disk is more preferable. The best solution is writing on a CD at determined periods, with attention to and compliance with the foregoing.

5. Closing Provisions

5.1. The present rule is issued by the Deputy Director General in the interest of ensuring the continuity of the certification activities of the accredited management system by way of the Director General's Instruction No. 10/2016.

5.2. Publication of the Rules on the website of NAH (www.nat.hu) is considered publication.