SLOVENSKA AKREDITACIJA

OA12

CONTROL OF EQUIPMENT

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1 INTRODUCTION

Requirements for control of equipment and provision of measurement uncertainty are specified in the Standards containing requirements for competence (e.g., SIST EN ISO/IEC ISO 17025 paragraphs 5.5. and 5.6), and specified in the internal regulation OA02. Important items in the control of equipment are also considered by SIST EN ISO 10012, which discusses the process of metrological confirmation of equipment. In addition to measuring equipment also other equipment should be controlled whose operation affects the final result of a test, calibration, and inspection or certification process.

Calibration is needed in the set of processes for the control of measuring equipment in order to provide traceability of measurements. An accredited body may request calibration by a competent calibration laboratory, or conduct it itself (internal calibration), whereby equivalent requirements shall apply. Calibration is considered as internal when the activity is controlled within a uniform (assessed) management system, regardless of whether it is performed in an organizational unit being the operator of accredited activity or in some other unit.

2 PURPOSE AND SCOPE

This guide highlights some primary principles of equipment control, which are critical for providing measurement traceability of the results or their comparability. It sets out the basic points and summarizes the requirements to be considered while assessing the procedures of control of the equipment used by the accredited activity.

As part of the contents hereof is focused on internal calibrations, it is particularly intended for those accredited bodies that carry out calibrations for their own needs, and for those assessors who encounter internal calibrations in their assessments.

It is applicable to internal calibrations conducted by testing laboratories, and also calibration laboratories (in particular in the case of internal calibration, which is not related to the accredited activity of the laboratory). All the requirements are also relevant for inspection and certification bodies which – within the scope of their accredited activity – conduct measurements and tests, and need to comply with the requirements for the competence of laboratories.

Control of equipment also includes other verification procedures (such as testing, professional judgement) where similar items need to be considered; therefore these are also partly addressed by this guide.

3 CONTROL OF MEASURING AND TEST EQUIPMENT

The accredited body shall specify the requirements for each item of equipment with regard to its use. Then it shall draw up a schedule for calibrations and other methods of equipment verification to make sure that the equipment meets the specified requirements (see ISO 10012).

Based on the results of the activities performed, the accredited body shall make a conclusion as to the fitness for purpose of the equipment and/or any necessary action.

The procedures used (calibrations, measurements, tests) shall be such that a decision can be made as to the adequacy of the equipment with reference to the specified requirements (e.g. that measurement uncertainty of the procedures is low enough).

3.1 Specification of requirements for equipment

An accredited body shall specify the metrological and other requirements for equipment on the basis of the requirements for processes in which this equipment is used (tests, calibrations), for all equipment characteristics that contribute to the measurement uncertainty of the process. Doing so, it shall take into consideration: the requirements specified in the method; general requirements and data obtained from the literature; manufacturer's specifications and special requirements; and information obtained through own analyses and experience (e.g. in method validation or implementation).

The specification of requirements shall always be derived from the purpose of use, so that verification procedures will be different for the same equipment being used in different procedures within the accredited activity.

An illustrative example of specifying the requirements for acceptability of equipment used in various conformity assessment procedures, and of the related potential problems arising in internal calibrations

It may happen that the laboratory or inspection body uses internal calibration for equipment in procedures that have already been accredited and in which internal calibrations have previously been examined accordingly and approved as acceptable. The same item of equipment is later used in some other test, inspection or calibration method which, however, requires stricter acceptance criteria for a new purpose of use for the same measurand of this instrument. Thus the fact that internal calibration has been used properly for already accredited procedures is in itself not sufficient. A separate analysis will be necessary of the equipment acceptability, of the appropriateness of internal calibration and of the related appropriate examination in accreditation procedure.

(Of course, the same applies in the case when the laboratory requests calibration by an accredited laboratory; but the situation is much more probable in cases of internal calibration, where the complexity and thereby the end result (the required measurement uncertainty) are as much as possible adapted to the internal requirement for use – typically to the minimum – so that any higher requirement (e.g. for new purposes of use) would be unacceptable without correction of internal calibration.

Requirements for measuring equipment are derived from evaluation of measurement uncertainty of a test/calibration, and shall be specified on the basis of the measurement's contribution to total measurement uncertainty of the result. The same also applies to other equipment whose operation affects the result of test/calibration.

In the case of complex tests the specification of these requirements will be more difficult, since the measurement uncertainty of the test is often not evaluated by explicitly taking into account the contributions of individual influence factors. In such a case, the requirements for individual

instrument's characteristics can be determined by means of data from technical literature (articles, studies), on the basis of previous experience with the same or similar equipment, on the basis of manufacturer's requirements or recommendations, or on the basis of consensus within the profession. However, we should keep in mind that our purpose of use could be different from that considered when specifying such data. Often, in cases of complex measuring equipment (e.g. gas or liquid chromatographs in combination with various detectors), the operation of the complete measuring system is verified using appropriate control materials.

Sometimes the requirements indicated by the Standard in relation with individual measurements (or providing ambient conditions) may not have been conceived as a requirement for total measurement uncertainty when drawing up the Standard, but maybe just for the resolution of the measuring instrument. When the laboratory has reason to believe that such situation is the case, it must analyse and specify the requirements for the remaining relevant characteristics.

An illustrative example of standard methods in which the interpretation of specified requirements for ambient test conditions is questionable

Temperature chambers, which are used for incubation in microbiological tests, should provide for constant temperature conditions within a rather narrow range. The Standards specifying microbiological methods indicate as a condition the temperature of incubation (e.g. 37±0.5 ^{o}C). In order to prove the fulfilment of this condition, the temperature of the chamber shall be controlled during the performance of the test by constantly measuring the temperature at the same place using a controlling thermometer. When trying to prove the temperature of 37±0.5 ^{o}C at any place in the chamber, taking into consideration the contribution of non-homogeneity of temperature in the chamber, a correspondingly narrower interval of acceptable results of control measurements will be obtained. Therefore the control measurement has to be conducted with a sufficiently low measurement uncertainty to enable appropriate evaluation of the results of controlling the temperature conditions in the chamber. And correspondingly lower must be the measurement uncertainty of calibration of the controlling thermometer, which is just one of the contributions to the measurement uncertainty of the control measurement. (see also example under 3.2).

An opinion is frequently heard saying that all this has not been taken into account during method standardisation, and that the temperature ranges set in Standards are too narrow without there being need for it. If this is the case, the laboratory may set a different criterion for the control (e.g. extend the acceptable temperature range), provided that it has objective and professional grounds for such decision. It cannot, however, omit the control of temperature and/or the specification of reasonable criteria (in particular measurement uncertainty) for the equipment and procedures used in the control process.

3.2 Calibrations

In SIST EN ISO/IEC 17025, the requirements for performing internal calibrations in calibration and testing laboratories are aligned with the requirements for calibrations performed by calibration laboratories.

An accredited body who decides to perform its own internal calibrations shall get to know the requirements applying to calibration, and become properly qualified for such activities. The following are particularly important for the control of calibration procedure:

- sufficiently precise specification of calibration procedure,
- control of influence factors (e.g. control of ambient conditions),
- evaluation and calculation of measurement uncertainty of calibration,
- operators' competencies,
- traceability (and adequately low measurement uncertainty) of reference standard,
- appropriate data management (records, calculations) and reporting, and
- quality assurance of the results.

Of course, the difficulty in fulfilling the above-listed requirements will depend primarily on the permissible level of measurement uncertainty of the calibration procedure. When high measurement uncertainty is acceptable, the requirements for performing calibration will be relatively easily met.

An illustrative example of various levels of complexity of calibration of the same item of measuring equipment used for different purposes

It will not be difficult to calibrate a thermometer for controlling the temperature in a refrigerator for storing samples, where the acceptable temperature interval for refrigerator operation is wide (e.g. 0–8 ^{o}C) (we can content ourselves with a high measurement uncertainty of the thermometer, using an adequately narrower acceptability range in checking the refrigerator, which will in most cases still be easily achievable). But the calibration of the thermometer we would like to use to monitor the temperature in the chamber may pose a greater problem, as according to specifications the chamber should maintain a constant temperature (37±0.5)^{o}C. In the test/measurement procedure, this temperature is for example the key parameter for the validity of measurement results. Considering other influence factors of importance in such measurement (e.g. technical properties of chamber, dimensions, content and its distribution, location of measurement point, etc.), such thermometer will only be fit for use if its measurement uncertainty is relatively low. The difference in the required accuracy between such measuring equipment and the equipment intended for use in the first part of the example is considerable, and the possibility of properly performed "internal calibration" of this thermometer is accordingly lesser; (presuming the use of an unchanged procedure and other invested resources for such internal calibration). See also examples 1 and 3 under 3.1.

3.3 Other equipment verification procedures

In order to ensure the quality of measurements it is often necessary to verify the equipment, both from the point of view of traceability of measurements (intermediate checks between calibrations) and other aspects of operation.

Intermediate checks may serve to maintain confidence in the status of calibrations, or they can serve to check other properties of measuring equipment. Considering the purpose of verification and the previously specified requirements for acceptability of the equipment, also in these cases the appropriate procedures for verifying and assessing the conformity of the equipment with the requirements must be defined and controlled.

When not dealing with measuring equipment but with equipment which establishes a controlled ambient influence/condition, this equipment shall be checked for its capability to provide such a condition within the defined limits. E.g., control of temperature regulation in a thermostatic chamber – agreement between the set and the actual temperature, temperature distribution inside the chamber, temperature stability in time, etc.

When measurements are performed as a part of verification, and the results of these measurements influence the conclusion on the conformity of the equipment with the requirements, provision shall be made for these measurements to be performed with appropriate (sufficiently low) measurement uncertainty.

3.4 Deciding on suitability and further use of equipment

After each calibration or any other way of verification, the decision shall be made as to the fitness of the equipment for its purpose, and any necessary measures (considering correction factors, adjustments, repair, checking impact on the results of measurements, etc.)

For the decision to be possible, the measurement uncertainty of calibration and/or other procedures carried out as a part of verification should meet the decision making criteria (requirements for equipment).

4 CONSIDERATION IN ASSESSMENT PROCEDURE

The technical assessor shall, when assessing the control of equipment, determine the adequacy of the requirements set and of the control systems. The key questions shall be:

– Does the equipment serve to perform measurements for which the provision of traceability is required (calibration needed), or must the equipment fulfil the defined conditions?

– Taking into account the specified requirements for the equipment, what is the permissible measurement uncertainty of these measurements?

– Is the procedure used in calibration and/or verification appropriate and the operator qualified? Under this question, at least the following must be checked:

1. That the laboratory possesses a written calibration procedure;
2. That it ensures and provides evidence of adequate traceability of the standards and measuring instruments used;
3. That it ensures and provides evidence of adequate ambient conditions;
4. That the laboratory possesses an adequate record of evaluation/assessment of measurement uncertainty;
5. Evidence that the personnel conducting internal calibrations possess adequate metrological knowledge.

An assessment regarding these items shall be given by the technical assessor for testing or some other accredited activity of the body being assessed. When the equipment needs calibration, which is conducted internally, the participation of a technical assessor for calibration will be necessary in the

case of complex internal calibrations. That is because the assessor of the activity being accredited is often not familiar with the requirements and concepts of calibration, and is not qualified for assessing calibration.

5 CONSIDERATION IN ACCREDITATION PROCEDURE

Upon initial application or application for extension of accredited activity, the applicant shall state that he will be using internal calibrations in this activity (whether they are performed within the unit which includes the accredited activity or in some other unit), for which he does not hold accreditation. This mainly includes calibrations which could typically be provided by competent external calibration laboratories, but does not include e.g. calibrations using reference materials, which constitute a part of testing procedures and are assessed within this scope.

Based on the above information or on information from previous assessments, SA may include a properly qualified assessor or an expert in calibration into the assessor team.

This assessment is typically carried out in the course of initial assessments or re-assessments, as well as surveillance assessments, in particular when SA obtains new information or notifications of changes, or when nonconformities have been identified which could be related to internal calibration procedures.

When internal calibrations are not particularly demanding, or when the assessment involves minor changes of the procedure, the assessor may conduct the assessment using the documentation only, and visiting the laboratory will not be necessary.

The accredited body shall notify SA of any important aspects related to internal calibrations, and the assessors shall pay particular attention to this during assessments, and shall clearly indicate their conclusions regarding any internal calibrations in their reports.

6 REFERENCES

- SIST EN ISO 10012:2003 – Measurement management systems – Requirements for measurement processes and measuring equipment (ISO 10012:2003)
- Nordtest report 226, February 1994 (http://www.nordicinnovation.net/nordtestfiler/tec226.pdf)
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- Guide ISO/CEI 99:2007, Vocabulaire international de métrologie – Concepts fondamentaux et généraux et termes associés (VIM)

- Sources of uncertainty in gas chromatography and high-performance liquid chromatography (Vicki J. Barwick, J. Chromatography A, 849, 1999, p. 13-33)

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