SLOVENSKA AKREDITACIJA

D05-02d2

ASSESSMENT OF CALIBRATION LABORATORIES

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1 PURPOSE

The purpose of this Annex to D05-02 is to lay down the scope and methods of assessment applying specifically to calibration laboratories.

2 ASSESSMENT FOCUS

In addition to the general assessment rules in accreditation procedures, the following points shall be taken into consideration in assessing calibration laboratories.

- **Methods, uncertainties, CMC:**

In assessing a calibration laboratory, it is essential to find out whether the laboratory applies **adequate** methods, which render **correct** and **credible** results. In this context it is important to assess the procedures for selecting a method, especially when the object of calibration can be calibrated according to several methods. The main and obligatory task in this respect is to assess, in each calibration procedure, the methodology and all the procedures for giving an estimation of **measurement uncertainties** and the related Calibration and Measurement Capabilities (CMCs)**.** In this context, conformity with the requirements of the documents EA-4/02 (Evaluation of the Uncertainty of Measurement in Calibration), and ILAC-P14 (ILAC Policy for Measurement Uncertainty in Calibration), is obligatory.

In the case that a calibration laboratory in the role of a national metrology laboratory publishes its measurement capabilities for the same accredited calibration methods in the BIPM Base of Calibration and Measurement Capabilities (CMCs), the data shall be used, taking into account all important circumstances, as an additional source of information for checking the correctness of CMC estimate in accreditation procedure. (For exactly the same calibrations made under the same conditions there shall in principle be no differences between the CMCs recognised by SA and those stated in the BIPM Base.)

- **Resources, validations:**

The **availability** of the appropriate **resources** for carrying out calibrations shall be checked, the **facilities** and the **equipment** shall be examined, and any other **influence factors** having an important impact on the assessed calibration procedures shall be estimated. Taking these into account, the **validation procedures** and **validation records** shall be assessed, which should, among other, confirm the correctness of the estimated measurement uncertainties. The assessor should also check the records of implementing the standard methods into the laboratory, and in the case of modifications, the corresponding partial validations.

- **Traceability, internal calibrations:**

The assessor shall find out how the **traceability of the results of individual calibrations** is assured (acceptable measurement traceability). This shall include checking the equipment and any **performance of internal calibrations** (of the standards and/or reference materials used). Assessment of acceptability of the demonstrated traceability shall be based on SA's document "Acceptable metrological traceability of measurement results" (OA02), which fully implements the EA policy towards this issue. The assessor shall assess the control of the equipment and any internal calibrations in accordance with the guidelines and rules provided in SA document "Control of equipment" (OA12).

- **Witnessing the performance of procedures**

In assessment of calibration laboratories, **witnessing of the performance of individual calibration procedures** – or at least the key parts of these procedures, when long-lasting procedures are concerned – must be included. The assessor shall assess the conformity of the procedures performed against the requirements for the given calibration procedure. When selecting the procedures to be witnessed, the starting points under Clause 3 hereof shall be taken into consideration. When practicable, the assessor should witness the calibrations carried out according to the regular work plan of the laboratory. When, at the time of the assessment visit, the laboratory is not planning any calibrations that the assessor would like to witness, the particular calibration can be performed specially for this purpose on a corresponding (e.g. already calibrated) sample. This should be agreed upon at the introductory meeting. If the assessor intends to witness calibrations which need special preparation, the laboratory should be notified in advance to that effect. When the assessor has at his/her disposal a calibration specimen, which is characterised well enough, he/she may also **evaluate the result** obtained by the laboratory. Evaluation of the result shall only be possible under the specified conditions and for some types of specimens only. The same principles as in the organisation of ILCs (e.g. SIST EN ISO/IEC 17043) shall apply.

- **Quality of results (participation in interlaboratory comparisons – ILCs):**

Each time the assessor shall examine the records of **the laboratory's participation in interlaboratory comparisons.** The assessor should determine whether the selected comparisons and the scope of participation are conforming (with reference to the accredited procedures) to the accredited procedures. The assessment shall include the results/performance of the laboratory. Particular attention should be paid to any possible negative results of participations, and the assessor shall examine the adequateness of the corrective actions implemented by the laboratory in this respect. The assessor shall assess and report of the importance and relation of these results to the scope of accreditation, and as an ultimate consequence, propose a change of the scope (e.g. suspension, withdrawal, changes) of accreditation.

- **Scope of accreditation:**

Each time the assessor shall check the valid **Annex to Accreditation Certificate** for the complete scope under assessment. In addition, assessor shall also check the compliance with the provisions of S14d4 regarding possible references to standards and international guidelines and the like for all references to calibration procedures within the scope of accreditation. In the assessment report he/she shall obligatorily give his/her comments regarding the scope, which may include the failures identified, estimates of expected incorrect values (e.g. within the scope of quantities or CMC or other restrictions in calibrations), or estimates of intended demonstrated changes given by the laboratory, which shall finally be confirmed through considering the nonconformities found by the assessment. Otherwise, when the assessment identifies no changes or corrections to the scope of accreditation, and also no impacts on the granted scope are to be expected from notified corrective action, the assessor shall clearly and concisely report on this as well.

3 SCOPE OF ASSESSMENT (WITH REGARD TO THE COMPLETE SCOPE OF ACCREDITATION OF THE LABORATORY)

3.1 Principles

In the initial assessment, and in re-assessments, the competence of the calibration laboratory against the **complete scope** of accreditation from Annex to Accreditation Certificate shall be assessed.

Regular surveillance visits can be carried out in a **narrower scope**. This shall include a representative part of the scope of accreditation, which is selected for a given surveillance visit. In this context it shall be ensured that, during three surveillance assessments within one accreditation cycle, each method within the scope of accreditation be assessed at least once more.

3.2 Starting points for defining a representative part of the scope under assessment

For a calibration laboratory, competence means its continuous fulfilment of certain requirements, provided by the laboratory through its operation. The operation includes a number of influence factors, which are more or less clearly interrelated and which provide more or less fixed frameworks of operation, or which are distinctly variable.

A formal description of competence is given in the Annex to the Accreditation Certificate, which specifies the scope of accreditation. The scope of accreditation provides, no matter how detailed the description, just a summary of the main properties that condition competence. In calibration laboratories, the scope of accreditation has a distinctive focus on information about the field (physical quantity), and on the capability data (CMC).

Besides, assessment of competence has clearly defined criteria in the structure of the rules defining competence requirements (standards, schemes, SA rules, guidelines, laws). All assessments in accreditation procedures are based on the sampling principle. It is therefore not urgently necessary to provide for an adequate representativeness of the sample, which in this respect, is represented for the particular assessment by the selected part of the scope of accreditation.

Sampling of the scope to be assessed shall be based upon a preliminary **analysis**, which shall take into account the starting points described above. It shall provide for the coverage of the **appropriate part of the scope of accreditation** of the calibration laboratory on the one hand, and take into account the **necessary focus points deriving from the competence requirements**, on the other hand.

In defining the appropriate part of the scope of accreditation with regard to the description given in Annex to Accreditation Certificate, existing classification shall be used to the greatest possible extent and sufficiently in depth (physical quantity, field, sub-field, measure type, measure sub-type, etc.). It should be pointed out, however, that no universal principle can be defined.

In defining correct focus points with regard to the given competence requirements (methods, personnel, facilities, locations, equipment, etc.), it is necessary, when analysing the suitability of a sample of the accredited activity's scope, to correctly estimate the impact and variability of individual influences on a unit of represented scope of accreditation, and thus to assign appropriate priorities to the influence factors that condition the selection of scope to be assessed.

Example 1: The scope of accreditation includes the indication of:

a) Mechanical quantities, pressure, high pressure, pressure balance; (indirect calibration; by calibration of corresponding quantities – mass, area);

b) Mechanical quantities, pressure, high pressure, pressure transducers; (direct calibration; by comparison);

In the above example of description of the scope of accreditation, the conditions providing for the capabilities as stated at the 4th level of description (pressure balance – pressure transducer) differ essentially. Should one, in analysing the sampling in order to define the part of the scope to be assessed in the above example, range both activities into a single unit selected as sample for examining competence (e.g. "mechanical quantities, pressure"), such sampling would systematically not provide adequate representativeness. The example shows that, in the concrete case, the essential influence factor is the very method used to carry out calibration, whereas other influence factors might be relatively less important (in this particular example).

Example 2: The scope of accreditation includes the indication of:

a) Mechanical quantities, balances (in lab);

b) Mechanical quantities, balances (in the field, at client's site);

In Example 2, the location of the balance in the field at the client's site can (indirectly) constitutes one of the extremely important influence factors (e.g. influence of acceleration due to gravity, *g*). In this case, too, an analysis for defining the part of the scope to be assessed, which would range both activities into one unit of the selected scope, e.g. "calibration of balances", would not provide adequate representativeness.

4 CHANGES WITH REGARD TO PREVIOUS REVISION

Introduced general reference to ILAC P14 and SIST EN ISO/IEC 17043. In chapter 2, emphasis added regarding the assessment of the adequacy of the references to calibration procedures in the scope of accreditation. Some minor text corrections have been made and use of some terms has been harmonized.

5 TRANSITORY PROVISIONS

N/A

6 CONTROL OF THE DOCUMENT

A valid document shall be located in i4 (SA Information System). A clean copy shall be published on SA’s website, and available in printed form at SA’s head office.

Individual copies may be controlled in physical form. The recipients or places of storage shall be shown in records on issuance of the document.

Other printouts and copies of the document shall have informative nature and shall not be considered as controlled copies. The validity of these documents should be checked in i4 or on SA’s website.