SLOVENSKA AKREDITACIJA

D05-02d1

ASSESSMENT OF TESTING 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 testing laboratories.

2 ASSESSMENT FOCUS

In assessing testing laboratories, **witnessing of the performance of individual test procedures** or parts thereof at different locations shall be included. The assessor shall assess the conformity of the procedures carried out with the requirements for a given test, competence of operator, efficiency of system arrangements, and the like.

The procedures to be witnessed shall be chosen by the assessor from the accreditation scope, so that the accredited activity fields are evenly represented, with the focus being on more sophisticated methods, so that the procedures subject to witnessing in the past years are not repeated (except when appropriate). Witnessing should comprise as many test operators as possible. As far as possible (by taking into account the above rules), the tests performed in accordance with the regular laboratory work plan should be witnessed. When, at the time of the assessment visit, the laboratory is not planning any tests that the assessor would like to witness, the particular test can be performed specially for this purpose on a corresponding (e.g. already tested) sample. The laboratory should be notified in advance of intended witnessing of tests which need special preparation. When the assessor has at his/her disposal a test sample or 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 samples or specimens only. The same principles as in the organisation of ILCs shall apply.

The assessor shall find out how the **traceability of the results of individual tests** is ensured (Acceptable Measurement Traceability). This shall include reviewing the control of equipment and possible internal calibrations (of the standards and/or reference materials used).

The assessor shall assess the suitability of the procedures for **ensuring the quality of testing,** and their implementation.

The assessor shall also assess the adequateness of the procedures for continuous control of the performance of tests (e.g. control charts, repeated tests, supervision of operators, comparisons within the laboratory, control of records). The assessor shall examine the results of these activities, their analysis and further treatment.

At each assessment, the assessor shall examine the records of **the laboratory's participation in interlaboratory comparisons.** He/she shall assess the laboratory's results/success and the measures taken in the case of unsatisfactory results. At the same time, the assessor shall make sure that the chosen comparisons and scope of participation comply with the scope of the accredited activities. In fields in which the laboratory has not participated in ILCs (or where these are not available), the assessor shall assess adequate use of other, alternative mechanisms for assuring the quality of test results.

The assessor shall assess the procedures for determining the **measurement uncertainty** of the test results, taking into account the special requirements and possibilities in the given field of testing, with regard to the purpose of use of the results. The assessor shall also check how this information is presented to the customers (so that they are not misleading, e.g. too optimistic estimations, unclear presentation, incomplete information).

As the possibilities of assuring traceability, participating in ILCs and evaluating measurement uncertainty, in some testing areas, are constantly changing (improving), the assessor shall follow the developments in his/her professional field and align the consideration of these requirements with new possibilities.

In the case of accreditation of non-standard test methods, the focus shall be on checking the **validation** of these methods. For standard methods as well, the assessor shall check the records of implementing the method in the laboratory, and in the case of modifications, the appropriate partial validations.

The assessor shall also check the assurance of proper **quality of the materials and services purchased** (especially RM, CRM, ILCs, calibrations). The assessor shall find out whether the laboratory uses the appropriate criteria for **selecting its suppliers and subcontractors**, and how it verifies the fulfilment of these criteria.

In checking the **scope of accreditation**, the assessor shall check correctness of indications and determine whether the scope is given in such a way as to correctly define the accredited activity. He/she shall check the correctness of designations and indications of reference document versions, that the testing procedures in the laboratory are performed in compliance with these documents and in full compliance with the given scope, that the indicated parameters, materials, ranges, etc., are in compliance with the scope and the results of validations/verifications of this method, that any modifications, restrictions and references to other procedures are indicated, when necessary.

During the assessment, the assessor shall also find out how the laboratory follows the changes in its relevant field of activity. When the scope of accreditation is given in such a way as to provide flexibility to the laboratory, the assessor team shall, in carrying out the assessment, also take into consideration the guidelines on treating flexible scopes.

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

When the activities are performed at different locations, they shall all be paid a visit during initial assessment, while only a selected sample thereof shall be visited during surveillances, so that each location shall be paid a visit at least once within an assessment period.

At the initial assessment, and at re-assessment visits, the assessment in all sectors of the accredited activity shall be carried out by assessing a representative part of the procedures from each sub-sector of testing; the sampling of the assessed methods shall include all main testing techniques, typical groups of test-pieces, more sophisticated methods, and methods whose results are of particular importance (with regard to use).

Regular surveillance visits shall be carried out on a narrower scope than initial assessment and re-assessment. As a rule, surveillance shall be carried out in all fields of the accredited activity, but on a

smaller sample. Smaller, specific fields of activity can be left out in individual surveillance, when appropriate stability has previously been proven.

It should be ensured that each element of the activity (test method) from the scope is assessed in an integral way at least once in an assessment period. Comprehensive assessment shall be ensured by examining the key elements that affect the control and performance of this method (staff, equipment, facilities, materials, instructions, validation/verification, quality assurance system for results, recording system and contents of records, reporting, witnessing of implementation,…). Related methods, e.g. such that use the same equipment, materials, other subsystems, can be treated in sets, by checking only some of the elements in each.

In procedures where the operator has a key influence on the correctness of the test result, the witnessing of all authorised operators of the test shall be ensured within one assessment period.

4 RECORDS

Each assessor shall make records of assessment in the checklist (OB05-21), so that the scope and method of assessment of individual elements of the system are presented against the requirements of SIST EN ISO/IEC 17025 (e.g. system documents, records, equipment, facilities, personnel examined), as well as general findings and reference to the nonconformities found, and any special comments.

The technical assessor shall enter the elements of the system assessed horizontally (assessing the adequacy and efficiency of system arrangements, examining several fields of accredited activity) into the first table of the form. Into the last table, he/she shall enter the assessment of individual elements of accredited activity (test methods). Doing so, he/she shall specially mark the methods assessed in an integral way, and indicate the persons witnessed while performing individual tests. Each assessor shall also enter into the checklist the data of the vertical assessments carried out.

The form OB05-18 shall be an obligatory annex to the checklist of a technical assessor, into which the laboratory shall enter the data on participation in interlaboratory comparisons during the period since previous assessment. By this form the assessor shall confirm that he/she has checked the data and assessed the participation, and shall make a note of the findings in the checklist.

5 CHANGES SINCE THE PREVIOUS REVISION

Assessment of participation in interlaboratory comparisons and assessment of indication of scope have been additionally described in Clause 2.

Instructions on sampling according to the scope of accreditation have been upgraded in Clause 3.

6 TRANSITORY PROVISIONS

N/A.

7 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 a copy on paper format shall be accessible at the SA Head Office.

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.