International Journal for Quality research
UDK - 006.3
Professional Paper (1.04)

Flexible Scope in Accreditation – Introducing Vagueness or Better Expression of Scope

Miloš Jelić

Accreditation Board of Serbia

Abstract: *Historically, laboratory accreditation has been grounded on fixed scope of accreditation to establish precisely and unambiguously the range of tests and calibrations covered by a granted accreditation. By the time elapsed it was noticed that such approach sometimes appears to be restrictive since it constrains new or modified methods to be added to a laboratory's scope, even where competence in this general area has already been demonstrated. Accreditation of a flexible scope places more of the responsibility onto the laboratory itself because it imposes to the laboratory to establish and maintain management system that can control its proposed approach. Flexible scope of accreditation yields benefit to all accreditation stakeholders but, on the other hand, introduces more requiring interpretations of relevant standard clauses and includes the bounds of the scope which are defined in more distinct way.*
Keywords: *accreditation, flexible scope*

1. INTRODUCTION

Accreditation is regularly regarded as third party attestation relating to conformity assessment body conveying formal demonstration of its competence to carry out conformity assessment tasks. In other words, accreditation can be explained as the process of formal recognition of organizational and technical competence in which the authoritative body on behalf of the state (the accreditation body) assesses competence, impartiality and integrity of a conformity assessment body (e.g. laboratory, inspection or certification body). Accreditation status is linked to the legal entity of conformity assessment body. However, basically accreditation does not cover every activity operated within or by the accredited body. Therefore, crucial element of each accreditation is the scope of accreditation which makes the undetachible part of the granted accreditation and the accreditation body refers to scope definition with maximum due care.

The scope of accreditation of a testing laboratory is the formal and precise statement of the activities which the laboratory is accredited for. It is as such result of a combination of information (scope parameters) concerning the testing field, the type of test (describing measuring principle), the product/object tested and the methods and procedure used for the test. This means that the assessment (and reassessment) of the scope of accreditation represents the core of the accreditation process and may be defined as the set of operations carried out by the accreditation body in order to ensure, with an adequate degree of confidence, that the laboratory has the competence to provide reliable test services within the defined scope.

2. THE DEFINITION OF THE SCOPE OF ACCREDITATION

For the convenience of accreditation end users the scopes of accreditation of laboratories

shall clearly identify the testing field. There differences in testing field classification among countries, but majority follow the profiles of persons that have developed the methods, thus having electrical, chemical, mechanical… testing. However, when products to be tested are concerned, a variety of solutions is encountered, from generic to quite specific.

Tests are regularly identified in terms of following sub-elements:

A) Materials or products tested: denoting material/product on which test method is undertaken;
B) Test type/property measured along with range of measurement: containing measured parameter or property of materials including the range of measurement the accreditation is granted for;
C) Standard specification: identifying the procedure used in tests
D) Measurement techniques used: defining the measurement techniques underpinning the performance of test
E) Associated testing and measurement uncertainties (wherever applicable)

While test procedures and methods may be classified either as generic or specific, for accreditation purposes it is more convenient to split them into standard procedures/methods or in-house ones. Standard method includes a method by a standardization body (both global and national) or other well established operations whose methods are generally accepted by the technical sector in question. On the other hand, in-house or laboratory developed method denotes a method developed by the laboratory itself (or other involved parties) or modified from standard method and validated.

Parameters of accreditation scope can be differently stressed depending on the type of laboratory activity thus affecting the way how the scope will be presented and assessed.

3. FIXED AND FLEXIBLE SCOPE

If all the sub-elements listed above used to identify are fixed and laboratory cannot change them prior to provide approval from the accreditation body such accredited scope can be regarded as fixed one. However, flexible scope of accreditation means that a laboratory may claim accreditation for changes made to its scope of accreditation without prior approval by national accreditation body, regardless the changes are permanent or may relate to a single task.

Flexibility may exert on some sub-elements. Flexibility for materials and products tested allows for changes in the specific or materials within a product group if this is conducted by using the same techniques for the test parameters (properties or analytical parameters) for which the laboratory has already been accredited. On the other hand, flexibility may influence test parameters thus to allow for changes in the testing field with respect to test parameters (properties, range) if this can be carried out by using testing techniques and test types for which laboratory already possesses accreditation. Finally, flexibility may concern the performance of the method if it allows for changes in the performance of a specific method for a test of a specific product or material and a given test parameter (property) if this can be done by the same testing technique for which laboratory has already been accredited.

To develop new or to modify existing methods, a comprehensive technical knowledge of methods or techniques planned to be implemented are needed. The question arises how to evidence such thorough understanding. Adequate answer might be participation in scientific/research or development projects, taking part in projects dealing with mere method development, possessing significant experience and practice in the particular testing field or a combination thereof. As far as general requirements for accredited testing are concerned it becomes obvious that the laboratory pretending to gain accreditation in flexible scope shall adapt and extend its management system to take into account size and complexity of the test categories. Such system shall provide sufficient reliability of laboratory technical capacity to perform test within full category thus to maintain compliance with referent standard (ISO/IEC 17025) and the regulations oh national accreditation body. Therefore, it is quite unexpected that any laboratory applying for accreditation for the first time may objectively meet above requirements. Just to stay on safe side national accreditation bodies often define in its own rules that a laboratory may not apply

for flexible scope prior its first re-assessment, i.e. four years after initial assessment for the first accreditation.

4. MANAGEMENT SYSTEM FEATURES FOR LABORATORIES SEEKING FLEXIBLE SCOPE

Management of the laboratory seeking flexible scope of accreditation shall define and authorize persons possessing comprehensive (sufficient) technical competence and also assign key responsibilities in the management of the system. Such assignment is to include the issues of development/revision of testing methods. Unlike remaining assignments in a laboratory which do not require notification of the accreditation body about changes, national accreditation bodies regularly impose to accredited laboratories with flexible scope the obligation to seek the approval for the new assigned persons.

Particular stress is given to validation issues. Usually laboratories with flexible scope are required to define a sort of validation strategy that corresponds to the extent and technical nature of the category for which flexible accreditation scope is sought. The strategy will include but will not be limited to:

- Definition of the acceptance criteria of validation results,
- Modes of confirmation that method is suitable for the intended purpose,
- Demonstration to the clients about the results of validation.

If laboratory decides to define different test categories, it may introduce different degrees of validation. In such an approach validation appears to be rather extensive at the beginning since it is necessary to determine the characteristics of the method but further it may require different degrees of partial validation if a new product is to be simply to a group of products that have already been validated. Also, when extension of parameters range is concerned it will require less extensive validation than was primarily done.

Flexible scope of accreditation requires clear responsibility assigned to a single person for each individual validation job. The person with delegated responsibility shall have an evidenced experience in method development within the relevant area and possess theoretical/practical competence to be able:

- To create a validation plan,
- To assess the suitability of the method (including meeting the client's needs),
- To evaluate or to assess measurement uncertainties,
- To assess the performance of the method.

Validation plans are to be drawn whenever the method falling into the flexible scope is subject to change or modification while results coming from validation and verification shall make part of the report. Laboratory with accredited flexible scope is to maintain a sort of a logbook in which any change within the flexible scope is recorded. The records shall demonstrate that all the actions required by the laboratory prior to approval have effectively been completed prior the issue of test report.

Flexible scope requires particular care in the relation with clients. The procedure for the processing of clients' requests, tenders and contracts shall include the features proper to flexible scope of accreditation. If the laboratory has not established yet the routine for a requested test the laboratory is to inform the client about the key service data (time-to-delivery, price,…) related to the requested test and to make the client acquainted with the fact that there is a possibility the laboratory will not be able to issue accredited test result depending on the outcome of the validation.

Unlike accreditation for fixed scope accreditation for a flexible scope within a particular category implies a certain commitment by the laboratory to offer accredited tests within the laboratory scope. Therefore, issue of unaccredited test reports within its scope undermines the ability of the laboratory to provide such kind of service.

Due to the fact that some application may contain tests that have not been carried out previously in the laboratory but still falling into laboratory's flexible scope, the laboratory have to establish a protocol describing the procedures to be followed upon receipt. Such procedure serves to ensure that the laboratory meets a minimum set of requirement before it claims that it is accredited for the test and should provide the set of following answers:

A) All necessary equipment and reference materials for completion of

the specified test is available and ready for use,

B) Adequate, qualified and experienced personnel are available to carry out the task,
C) Responsibilities are adequately assigned for each of the set activities,
D) The necessary validation activities are conducted pursuant to the procedure established by the laboratory,
E) The relevant test procedure are approved,
F) The implementation of the new test is authorized.

However, validation process may lead to conclusion that laboratory is not capable to issue accredited test report. If so, the laboratory should conduct an analysis and provide adequate corrective action. Such action will include but not limit to: informing the client that while corrective action are in progress the laboratory will not be able to issue the requested test report, revision of the relevant procedures/method if the cause has been identified as a specific technical problem associated with particular test, maintaining the records on problem occurrence and corrective actions taken.

The quality assurance program for the test has to include activities that represent all individual tests from the flexible scope of accreditation. Procedures and plans of action for method development, revision and new development of test methods and associated responsibilities and risks have to be continuously incorporated in internal audit of the laboratory. However, management reviews shall confirm the existing suitability and effectiveness of management system to control flexible scope.

5. THE ASSESSMENT OF FLEXIBLE ACCREDITATION SCOPE

Assessment operations may be classified into two practical elements which are very interrelated but whose complexity and importance depend on the extent of the scope, namely:

1. Assessment of the management system,
2. Assessment of the technical competence.

Accreditation body is to ensure that it assesses crucial methods in the scope and the associated personnel, that it selects tests that can be witnessed during the assessment or surveillance and finally that selected methods are suitable to provide confidence in laboratory work. The key issue is how to select the tests both from quantitative and qualitative point of view. Some of relevant items are:

- Evidence of the implementation of management system, experience, capability of modification or development of testing methods,
- Technical complexity,
- Possible risks
- Balance between standard methods and non-standard methods (client specification, in-house methods),
- Balance between complete observations of the test performance and checks of test reports and/or validation records and/or MS records and/or inspection of test facilities.

The number of selected methods must be sufficient to allow drawing reliable conclusions grounded on assessment of each field but without causing unreasonable cost to laboratory being accredited. Laboratories given the possibility to continuously develop some aspects of their accreditation scope are obliged to develop specific approach in this regard which should be claimed in quality policy. The laboratories are to demonstrate to the accreditation body that they are capable to judge the suitability of the methods the use and validity of results trying to meet expectation of their clients.

Once a method is modified, changed or introduced as a new one within the given scope, it must be validated before it is to be included under the scope of accreditation unless it is a standard method. Procedures/responsibilities to develop, implement and validate such methods are to elaborate in details in MS documentation. The responsible individuals shall determine minimum quality requirements before starting the process of validation and implementation. An experienced person should be authorized by the management for each relevant technical sector in order to take the overall responsibility for modification, development and implementation of new or revised method.

Modifications and updates of test methods

or development activities including all the underlying results and other relevant validation data must be maintained on record. Accreditation bodies regularly request from laboratory to put these data on disposal. However, the assessment of the method validation process established by applicant seeking accreditation appears as one of the most difficult tasks in laboratory assessment. Accreditation body assessors must be able to judge whether the applied procedures can provide results needed to define the quality of an individual method regarding the field of application and a sort of products tested.

Finally, overall assessment program must be explained to and discussed with the applicant laboratory because the laboratory must be clearly aware of the criteria used for program establishment.

6. CONCLUSION

Historically, accreditation started off as an activity established within and by national authorities in order to allow them to accept conformity assessment results in order to back up public authority approvals. Taking into account EU present needs the conformity of accreditation simply to horizontal and generic standards such as the EN 45000 or ISO/IEC 17000 series can no longer be sufficient. The competence of conformity assessment bodies operating in the area of the New Approach directives is no longer limited to their capacity to understand and implement standards, but also to be able to test and certify to essential requirements in the absence of standards. With ostensibly changed role of accreditation these conformity assessment bodies are to answer to the needs of marketplace in a way to be capable of managing different conformity assessment procedures much more so than before.

On the other hand, accreditation function must therefore adapt itself to the new developments to remain at the position of the final level of control in the implementation of the New Approach. In other words, national accreditation bodies have to adapt their scopes of accreditation to allow room for modifications and adaptations to the scopes of the activities of the conformity assessment bodies on one side, but laboratories and certification bodies should be able to adapt their test methods and measurement programs to the needs of products, manufacturers and conformity procedures as well as technology involved, on the other.

Both the conformity assessment bodies and the national accreditors must fully document their processes thus making them clear to both parties. However, it includes that national accreditation bodies shall become capable of evaluating the capacities of the laboratories and bodies, and technical and technological competencies of the personnel concerned, but with a distinct margin not to become personnel qualification certifiers. Also, both the accreditor and the accredited shall have the capacity to validate newly developed or modified test methods. This in turn means that national accreditation bodies must have at their disposal that are both technically and technologically competent, possessing a broad but profound knowledge of the necessities of the industrial sector concerned.

However, it should be stressed that the accreditation scope must remain clearly identified even if it is broad, but without crossing the boarder to become vague and open-ended. For that reason it is particularly important that the information exchange between the accredited and the accreditor remain constant and fully documented.

To conclude, flexible conformity assessment introduced by the New Approach does require flexible accreditation, but flexibility may not serve as an excuse for vagueness or uncertainty.

REFERENCES:

[1] AKREDITACIA LABOATORII, Časť I, Oblasť a rozsas akreditacie, MSA-L/01, CAI, Bratislava, 2003
[2] H.Ischi, EA-ILAC views on flexible scopes, EL/08_08_06_254, EA LC, Oslo, 2003
[3] ISO/IEC 17011, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies, 2004

[4] J. McMillan, The need for flexible accreditation scopes for the support of conformity assessment in the EU, EA Workshop, Boras, SE, May 2006
[5] LAB39, UKAS Guidance on the Implementation and Management of Flexible Scopes of Accreditation within Laboratories, UKAS, August 2004
[6] ILAC-G18:2002, The Scope of Accreditation & Consideration of Methods and Criteria for the Assessment of the Scope in Testing
[7] EA-2/05, The Scope of Accreditation and Consideration of Methods and Criteria for the Assessment of the Scope of Testing
[8] K. Berner, R. Zimmermann, DAP, Flexible Scope of Accreditation in Non-destructive Testing Laboratories, http://www.ndt.net/article
[9] G. Boisson, Flexible scope – Accreditation of calibration laboratories, EA LC, September 2003

Recived: 19.06.2007 Accepted: 30.08.2007 Open for discussion: 1 Year