



*Publication
Reference*

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EA Requirements for the Accreditation of Flexible Scopes

PURPOSE

The purpose of this document is to establish overall requirements within EA to enable an accredited CAB to assume responsibility for the management of all or part of its scope of accreditation without the necessity of a preliminary evaluation by the NAB for each new or modified activity.

EA may supplement these requirements with specific requirements relevant to the particular sector being considered. Where additional requirements are considered necessary, these will be published as separate supplements to this document.

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The publication may be translated into other languages as required. The English language version remains the definitive version.

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1 INTRODUCTION

- 1.1** Accreditation is the third-party attestation related to a conformity assessment body (CAB) conveying formal demonstration of its competence, impartiality and consistent operation in performing specific conformity assessment activities (ISO/IEC 17000:2020).
- 1.2** It follows that a description of the competence of a CAB must be clearly visible to all interested parties. This is currently done through the scope of accreditation. It is important to define the scopes in such a way that it is possible to establish accurately and unambiguously the range of activities covered by a CAB's accreditation.
- 1.3** Historically, accreditation has been based on so called fixed scopes of accreditation, published by the national accreditation body (NAB). This system for defining the scope permits on one hand, an accurate description of the accredited activities of the CAB and on the other ensures that an appropriate evaluation of its competence is carried out each time an additional or modified activity is included in the scope.
- 1.4** However, this method of describing a scope can be considered as restrictive by some CABs for the following reasons:
- There is a difference between listing specific activities that a CAB is competent to carry out, and defining its competence to apply its knowledge, skills, and experience to different activities. It is important not to let the limitations of describing the scope determine what is accredited, instead of determining what a CAB is competent to do and then describing that.
 - The fixed scope does not readily enable additional or modified activities to be added to a body's scope without further assessment, even where competence in this general area has already been demonstrated. Although existing CABs may apply for an extension to scope at any time throughout the assessment cycle, the timescales involved may prevent tenders or contracts being met within their customer's timeframe.
 - In practice, end-users are not always experienced in the conformity assessment standards. They are often faced with significant difficulties to understand the content of very long, detailed and technical scopes of activities. A more generic approach might help to promote the use of the scope of accreditation by the end-users.
- 1.5** NABs therefore need to establish mechanisms that permit, in defined circumstances, CABs to include additional or modified activities in their scope of accreditation on the basis that their competence has been evaluated not only to carry out activities in accordance with previously evaluated procedures, but also for the development and validation of their procedures in accordance with a pre-established system. This kind of scope is called "flexible scope".

2 TERMINOLOGY

- 2.1** The terms and definitions given in ISO/IEC 17011:2017 “Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies” apply.
- 2.2** ISO/IEC 17011:2017 defines a scope of accreditation as specific conformity assessment activities for which accreditation is sought or has been granted.
- 2.3** ISO/IEC 17011:2017 defines a flexible scope as an expression “to allow conformity assessment bodies to make changes in methodology and other parameters which fall within the competence of the conformity assessment body as confirmed by the accreditation body”.
- 2.4** The term “flexible scope” is not restricted solely to scopes that are flexible in their entirety. It is also relevant to scopes that include a combination of fixed and flexible activities, or even for primarily fixed scopes that, for example include one or two flexible elements. In some cases, it may be best to define the scope by defined activities; in other cases, it may be better to use the techniques applied and the (technical) field covered by the body. Sometimes different ways may be combined.
- 2.5** The term “fixed scope” means a clearly defined description of the specific conformity assessment activities for which the body holds accreditations.

3 PURPOSE

- 3.1** The purpose of this document is to establish requirements to enable an accredited CAB to manage all or part of its scope of accreditation without a preliminary evaluation by the NAB for each new or modified activity. This will enable the description of the competence of a CAB to be clearly visible to all parties interested in accredited services.
- 3.2** The following requirements are mandatory for EA members who offer “flexible scopes” accreditation.

4 CONSTRAINTS

- 4.1** Throughout the following, it should be noted that it is not mandatory for EA members to accredit flexible scopes, although EA encourages EA members to provide this as a service to their customers. However, all EA Members are required to recognise as being equally reliable the certificates and/or reports from CABs accredited with a flexible scope in accordance with this document, as those with traditional fixed scopes.
- 4.2** NABs shall retain the right to decide how to define the scope and whether or not to grant a flexible scope to a particular CAB.

- 4.3** NABs shall not allow the principle of flexibility to enable a CAB to move, under accreditation, into a new field of accreditation covered by a different accreditation standard or outside the defined boundaries of the flexible scope without going through the assessment process as per any fixed scope assessment by the NAB.
- 4.4** This document applies to the scope of accreditation as described in clause 7.8.3 of ISO/IEC 17011. It does not apply to other accreditation information referenced in clause 7.8.1 of ISO/IEC 17011.

5 GENERAL POINTS FOR CONSIDERATION

- 5.1** It is the responsibility of each CAB to determine how it will implement flexible scope (i.e. what its requirements are) in the framework of the standard used for accreditation, and how it can demonstrate that this approach is fit for its intended use and capable of being maintained and controlled.
- 5.2** A flexible scope can only be awarded when the CAB has demonstrated it has a design/development process that it can apply for any additional or modified conformity assessment activity or to expand into new areas (within defined boundaries) covered by the flexible scope, but not previously undertaken.
- 5.3** The design process shall determine the requirements, develop the conformity assessment service, validate that the planned activities will meet the requirements, and verify that the activities have met the requirements.
- 5.4** Without a demonstrated design process it would not be possible to extend flexibility beyond the current fixed scope position.
- 5.5** Accreditation of a flexible scope places more of the responsibility onto the CAB itself for demonstrating that the way that it operates is valid, fit-for-purpose, and is undertaken impartially, competently and consistently.
- 5.6** A flexible scope is a reflection of the competence of the CAB, not just technically to carry out activities covered under the accreditation, but also its ability to manage the process of having a flexible scope and its commitment to offer accredited activities within this scope.
- 5.7** CABs shall explain to (potential) customers the boundaries of their accredited scope.
- 5.8** An NAB or CAB shall not imply in any communication that holding a flexible scope is an overt sign that it is more competent than a CAB holding a fixed scope.

6 REQUIREMENTS

6.1 Requirements for CABs

6.1.1 The CAB shall have a documented design and implementation process which needs to ensure the following:

- How it determines its requirements
- How it takes into account the boundaries of flexibility
- How it develops the conformity assessment activity
- How it validates that the planned activity will meet the requirements
- How it verifies that the activity has met the requirements
- The responsibilities for the management of the flexible scope and for each set of activities
- The contract review process confirms and informs the customer/enquirer that a request is within the boundaries of its flexible scope
- Information on what is covered by accreditation is transparent and accurate (see 6.1.2 – 6.1.3)

6.1.2 CABs shall maintain a List of accredited activities conducted under their flexible scope. This List should contain information as a minimum to that detailed in section 7.8.3 a-h of ISO/IEC 17011:2017, but the NAB may further define the detail.

6.1.3 The purpose of the List is to provide up-to-date transparency of the application of the flexible scope and shall be made publicly available on request unless there is a good reason not to do so (e.g. regulatory requirements).

6.1.4 The CABs contract review procedure shall detail how it processes a request which is within the boundaries of its flexible scope, but where the activity has not been undertaken before (i.e. not on the List). In such cases the CAB needs to ensure the following:

- It informs the customer that it will not be able to issue a report/certificate under accreditation until the activities have been established and authorised within its system under its flexible scope process
- It informs the customer of the appropriate implications (e.g. turnaround time, price, etc)
- It has access to all necessary resources and other means required for the completion of the specific requested activity
- It has suitably qualified personnel for the completion of the specific activity and its validation or verification.
- The necessary validation or verification has been carried out
- Updating of the List is made only after appropriate technical activities have been properly performed as per the design and implementation process and duly authorised by the CAB
- All locations of the CAB involved in the additional or modified conformity assessment activity have been previously declared to the NAB. Moreover, an additional or modified conformity assessment activity shall not be included in the

List if it involves new locations of the CAB until the NAB has added the locations to the accreditation information referenced in clause 7.8.1 of ISO/IEC 17011.

- 6.1.5 Should the validation process of an activity result in the conclusion that the CAB is not capable of issuing valid reports/certificates, the CAB must ensure that an analysis of the cause is carried out and that adequate corrective action is taken. Such actions will include:
- To inform its customer that while the analysis and any consequent actions are being progressed, the CAB will not be able to issue accredited reports/certificates and the reasons for this
 - The revision of the relevant procedures or methods should the reason be specific technical problems for this particular activity, in order to resolve the problem identified and to ensure it does not happen again in the future
 - Redefinition of the boundaries within which the scope is flexible. In this case, the CAB shall inform the NAB in order to review whether the way that the accreditation scope is described must be modified

6.2 Requirements for NABs

- 6.2.1 A NAB shall have a flexible scope policy on whether it will accredit flexible scopes (as per 4.1)
- 6.2.2 If the NAB policy is to accredit flexible scope it shall consider applications for flexible scope based on the level of risks associated with the activity.
- 6.2.3 In determining the level of risks associated with the activities, to accept the application of a CAB for a flexible scope and design a suitable assessment process, the NAB shall consider, in addition to the usual risks associated with accreditation processes and operation of NABs (see EA-2/19 INF:2022), the following aspects:
- Extent of flexibility requested by the CAB
 - Robustness of the process (including extent of controls) designed by the CAB for managing its flexible scope
 - Stability of technical personnel within CAB, responsible for the management of flexible scope and for the different activities relating to flexible scope
 - Complexity and level of familiarity of the NAB with the conformity assessment activities. For example, with new and emerging activities, the competency requirements may not yet be fully known
 - Ability of the CAB to demonstrate that the way that it operates is suitable and valid, and is undertaken impartially, competently and consistently
 - Stakeholders/regulatory expectations
 - Reputational risks for NABs
- 6.2.4 NABs shall establish procedures to regulate their assessment and accreditation of flexible scopes where they provide such a service to CABs. These should include controls for managing these accreditations, including what records are needed, how they will plan assessments depending upon risk, complexity and changeability of the scope, how the CABs will update the NAB on changes or

additional work, what changes will be required in assessment reports to be able to justify decisions made to grant flexible scopes etc.

6.2.5 NABs shall verify that CABs are competent to manage a flexible scope and compliant with the requirements of section 6.1. The verification process should include the examination of real examples where a CAB has implemented a flexible scope. In the assessment programme for the CAB, the NAB should take a risk-based approach and justify its approach and ongoing effort for each CAB. This risk based approach should take into account factors detailed in 6.2.3 to determine the appropriate level of sampling to confirm ongoing controls and effective implementation are in place in areas such as:

- All additional/modified activities
- Validation
- Metrology assessment (where applicable) / Quality assurance mechanisms
- Competence and training of personnel involved with the additional/modified activity
- Availability of working instructions, legal requirements, Directives etc
- Comparisons with other activities
- Risk assessment

6.2.6 The NAB shall consider the following aspects during the assessment and decision-making process:

- Degree of understanding of the CAB in the rules and procedures for implementing and managing a flexible scope
- Performance and robustness of the CAB's management system for the defined boundaries
- Knowledge of the CAB and its compliance to the relevant standards and activities
- The planned frequency with which the CAB intends to update the List of activities relating to the flexible scope
- Proofs of the performance of the full process including the extent of controls implemented by the CAB for managing a flexible scope
- Extent of flexibility given to CAB

6.2.7 The scope of accreditation in accordance with clause 7.8.3 of ISO/IEC 17011 issued by the NAB shall make clear the extent of flexibility given and make reference to the List.

6.2.8 Should the CAB have issued any reports/certificates under accreditation that do not comply with the requirements of this document, the NAB shall take the measures it deems appropriate.

6.2.9 In the same way, depending upon the nature, implications and severity of the possible non-conformity identified in terms of the management of a flexible scope, and without prejudice to other actions (for example, suspension of accreditation), the NAB may decide to revise the scope such as to reduce or even withdraw the flexibility, thus limiting the specific activities included in the List.