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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 AB for each new 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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1 INTRODUCTION

- 1.1 Accreditation is the third party attestation related to a conformity assessment body (CAB) conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO/IEC 17000:2004).
- 1.2 It follows that a description of the competence of a CAB must be clearly visible to prospective customers, other interested parties, and the marketplace in general. 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 body's accreditation.
- 1.3 Historically, accreditation has been based on so called fixed scopes of accreditation, published by the accreditation body (AB). 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 activity is added to the scope.
- 1.4 However, this method of describing a scope can be considered as restrictive by some CABs.
- There is a difference between listing specific activities that an organisation 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 an organisation 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 client'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 ABs therefore need to establish mechanisms that permit, in defined circumstances, CABs to include additional 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".

1.6 Terminology

- 1.6.1 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 methods, or even for primarily fixed scopes that, for example include one or two flexible or generic activities. 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 PURPOSE

- 2.1 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 AB for each new activity. In doing so, it will enable the description of the competence of a CAB to be clearly visible to prospective customers, other interested parties, and the marketplace in general, and not only serve the needs of ABs and CABs, but also end-users of accredited services.
- 2.2 EA may supplement these requirements on the recommendation of its technical committees with specific requirements relevant to the particular sector being considered. Where specific requirements are considered necessary, these will be published as separate supplements to this document.
- 2.3 The following requirements are mandatory for EA members willing to offer “flexible scopes”.

3 CONSTRAINTS

- 3.1 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 organisations accredited with a flexible scope in accordance with this document, as those with traditional fixed scopes. The following requirements only apply where the EA member chooses to provide the service to customers.
- 3.2 ABs shall retain the right to decide how to define the scope and whether or not to grant a flexible scope to a particular CAB.
- 3.3 ABs 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 normal full assessment by the AB.

4 GENERAL POINTS FOR CONSIDERATION

- 4.1 The differing needs of CABs means that there is no single way of implementing flexible scopes. Instead, it is the responsibility of each CAB to determine exactly what its requirements are, how it can approach this within the framework of the standard used for accreditation, and how it can demonstrate to its AB that this approach is fit for its intended use and capable of being maintained within control.
- 4.2 The technical capability for a CAB to manage itself within a flexible scope becomes the key to introducing flexible scopes. 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 conformity assessment or to expand into additional areas covered by the flexible scope, but not previously undertaken.

- 4.3 The CAB's design process needs to address how the body determines the input requirements, how it develops the conformity assessment service, how it will verify that it meets the requirements, and how it validates that it has met the requirements.
- 4.4 Without a demonstrated design process, even the existing scopes are questionable and it would not be possible to extend flexibility beyond the current fixed scope position.
- 4.5 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 competently and consistently.
- 4.6 CABs will have to devote adequate time to explain to potential customers the boundaries of their accredited scopes, and this may require ABs to spend more time examining contract reviews during assessments. On the other hand, even though it is not the intent of flexible scopes, a CAB may see holding a flexible scope as a overt sign that it is perhaps more competent than a body that operates with a fixed scope.
- 4.7 ABs may, therefore, need to discourage CABs from implying or claiming that a flexible scope implies a greater level of confidence for an accredited activity as there should be no difference in the outcomes of activities specified individually in a scope of accreditation, and the same activities conducted within a flexible scope.
- 4.8 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 REQUIREMENTS

5.1 Requirements for CABs

- 5.1.1 CABs shall maintain a List of activities conducted under their flexible scope. This List should contain similar information to that required for 'classic' fixed accreditation schedules, but the AB may further define the detail.
- 5.1.2 The purpose of the List is to provide up-to-date transparency of the application of the flexible scope and shall be made available to the AB and other interested parties on request.
- 5.1.3 The CAB shall maintain a fully documented system for the proper management of the flexible scope and the subsequent updating of the List. Such a system shall ensure that:
 - Responsibilities for the management of the flexible scope have been established
 - Updating of the List is made only after appropriate technical activities have been properly performed
 - Information on what is/can be covered by accreditation is transparent and accurate
 - A procedure exists and is followed for receipt of an application for activities that are under the flexible scope that have not been carried out before. Such procedures must ensure the CAB complies with the following minimum requirements before it accepts the work:

- Access to all the necessary resources and other means required for the completion of the specific requested activity are available to the CAB
 - Suitably qualified personnel for the completion of the specific activity and its validation or verification are available to the CAB
 - Responsibilities for each of the set activities are assigned
 - The necessary validation or verification according to the procedures established by the CAB are carried out
 - The relevant procedure is approved
 - The addition of the additional activity to the List has been duly authorised by the CAB management
 - All new premises of the CAB involved in the additional conformity assessment activity have been previously declared to the AB. Moreover, an additional conformity assessment activity shall not be included in the List if it involves new premises of the CAB that have not been previously visited by the AB and from which one or more key activities are performed
- The procedure for contract review contains the features applicable to this type of accreditation scope, especially in those cases where the CAB has not yet included a requested activity in its List. In these cases, the CAB shall inform the client of the following:
 - That it will not be able to issue a report/certificate under accreditation unless the activities established in its system are satisfactorily accomplished
 - The appropriate implications (e.g. turnaround time, price, etc)

5.1.4 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 client 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 AB in order to review whether the way that the accreditation scope is described must be modified

5.2 Requirements for ABs

5.2.1 ABs shall establish procedures to regulate their assessment and accreditation of flexible scopes where they provide such a service to customers. These should include controls for managing these accreditations, including what records are needed, how they will plan assessments depending upon complexity and changeability of the scope, how the CABs will update the AB 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.

5.2.2 ABs shall verify that CABs are competent to manage a flexible scope, including through the examination of real examples where a CAB has implemented a flexible scope. In surveillance visits and re-accreditation, emphasis should be given to the control of:

- All additional/modified activities
 - Validation
 - Metrology assessment
 - Competence and training of personnel involved with the additional activity
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- Availability of working instructions, legal requirements, Directives etc
 - Comparisons with other activities
 - Risk assessment
- 5.2.3 The accreditation certificate/schedule issued by the AB shall make reference to the List.
- 5.2.4 ABs shall have procedures to be able to respond to enquiries from end users to confirm whether or not a particular accreditation covers a specific activity that is required by the user.
- 5.2.5 Should the CAB have issued any reports/certificates under accreditation that do not comply with the requirements of this document, the AB shall take the measures it deems appropriate.
- 5.2.6 In the same way, depending upon the nature, implications and severity of the possible non-compliance identified in terms of the management of a flexible scope, and without prejudice to other actions (for example, suspension of accreditation), the AB may decide to revise the scope such as to reduce or even withdraw the flexibility, thus limiting the specific activities included in the List.