



International Organization for Standardization



International Accreditation Forum

Date: 19 January 2007

Accreditation Auditing Practices Group **Guidance on:**

Auditing Accreditation Scopes

This paper provides guidance on how Accreditation Bodies (ABs) should assess the competence of conformity assessment bodies (CABs) in view of granting a given accreditation scope, in order to promote the adoption of an effective and uniform approach and reduce the discrepancies among different ABs.

A key element of the accreditation process aims to assure that an accredited CAB is able to operate properly within its scope of accreditation, i.e. the types and fields of conformity assessment activities for which accreditation is sought by the CAB or has already been granted to it. (*Note: for formal definition of these terms, refer to ISO/IEC 17011*).

This type of assessment is based on two fundamental kinds of evaluation:

- the analysis of the documentation of the CAB, and
- the observation of its practical behaviour.

The **documental analysis** should include, at least:

- a review of the documentation of the CAB that specifies the criteria for the competence of auditors and the selection of competent audit teams, including records of the conduct of competence analysis;
- a review of specific procedures, guidelines, check-lists, instructions etc. addressing specific requirements for the different conformity assessment activities included in the accreditation scope (if any);
- an examination of the procedures followed and the personnel available for the contract reviews, the allocation of resources and decisions concerning the issuance of applicable attestations of conformity (e.g. certifications);
- an analysis of records showing that the CAB has processes in place for the maintenance and review of the above criteria, on a periodic basis;
- an examination of documented evidence supporting the CAB's auditor competence.

The documental review should evaluate whether the criteria established by the CAB for auditor, or audit team, competence and selection have been based on analyses of the competence required to perform the applicable tasks.

The CABs auditor, or audit team, qualification process should be based on defined competence criteria and should, at least, take into consideration the following elements:

- Educational levels and study specialization;
- Work experience in the business sectors related to the scope, in order that the auditors are able to understand the characteristics of the relevant processes and products and applicable regulatory requirements;
- Demonstrated knowledge and skills acquired through audit activities, as a complement or an alternative to direct work experience, provided such audits have been conducted in cooperation with an expert/auditor competent for the scope and that supporting evidence of this is available (e.g. from the certification files and records and evaluation report).

The review should also evaluate whether the documentation supporting individual auditor's competence – as indicated by their professional history – is consistent with the competence requirements established by the CAB.

Moreover, the review should determine whether the CAB has developed specific guidance (e.g. dedicated procedures or instructions) to aid the audit team in the specific fields falling within the accreditation scope and whether such guidance is effective in enhancing the competence of the audit team. The characteristics (type and extent) of such guidance should be based on the assessment of relevant risk factors by the CAB.

The **observation of the behavior** of the CAB in actual operation, should aim at:

- confirming that the procedures and criteria established by the CAB – for ensuring the competence of the auditors and for the assignment of competent teams – have been effectively and consistently implemented;
- determining whether the required competence is actually displayed during the assessments, both in conducting them and in reporting their results.

An audit at the offices of a CAB can only produce part of the evidence needed. This will require the AB to conduct accreditation witness audits to complete the assessment of a CAB's accreditation scope.

Accreditation witness audits are an effective tool to confirm the competence of a CAB and assist significantly in deciding whether or not to grant or maintain a requested scope of accreditation.

The choice of the number of witness audits to be undertaken before deciding on granting, or maintaining, accreditation depends on a number of factors which are left to the judgment of the AB; these need to be based on risk considerations.

Due attention should be given by the AB to the fact that the CAB may be displaying its best audit teams on the occasion of witness audits, which may be not indicative of the average competence level of the CAB. It is therefore recommended that the selection of the CAB auditors (and/or audit location) be made by the AB.

If, for any reason, the AB chooses to limit its witness activity, then the assessments at the CAB premises should be more extensive, e.g. they should include interviews with CAB's auditors to obtain at least "theoretical" confirmation of their ability to properly operate in the specific conformity assessment fields. Moreover, the examination of records (e.g. audit reports) should be as comprehensive and detailed as possible, since reading in and between the lines might help to judge the real competence of the compiler.

For further information on the Accreditation Auditing Practices Group, please refer to the paper: *Introduction to the Accreditation Auditing Practices Group*

Feedback from users will be used by the *Accreditation Auditing Practices Group* to determine whether additional guidance documents should be developed, or if these current ones should be revised.

Comments on the papers or presentations can be sent to the following email address: charles.corrie@bsigroup.com.

The other papers and presentations may be downloaded from the web site:

www.iso.org/tc176/AccreditationAuditingPracticesGroup

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