



Evaluation of conformity assessment schemes

PS18

1) Purpose

This statement sets out the Irish National Accreditation Board (INAB) policy on its approach to assessment of conformity assessment schemes.

2) Policy

It is the policy of the Irish National Accreditation Board that all conformity assessment bodies (CABs) and conformity assessment scheme owners (SOs) adopt the measures listed in this document when addressing the requirements of the various accreditation standards.

3) Reference

- EA-1/22 A is the EA procedure and criteria for the evaluation of conformity assessment schemes by EA accreditation body members and is a normative document in the application of this policy. It is available at:
<https://european-accreditation.org/publications/ea-1-22-a/>
- IAF MD 25 is the IAF procedure setting out the criteria for evaluating conformity assessment schemes. It is available at:
https://iaf.nu/iaf_system/uploads/documents/IAF_MD_25_Criteria_for_the_Evaluation_of_CAS_Issue1_Version2_13062023.pdf

4) Definitions/abbreviations

4.1) CAS: Conformity Assessment Scheme as defined in ISO/IEC 17000 - a documented and publicly available set of requirements which establish:

- The object of conformity assessment, i.e. product, process, service, system, person to be assessed for conformity;
- The requirements against which conformity is to be assessed;
- The mechanism by which conformity is determined, e.g. testing, inspection or auditing and any other supporting activities to ensure conformity;
- Any requirements placed on CABs by the SO, and any specific applications or interpretations thereof, if applicable;
- Any specific applications or interpretations of ISO/IEC 17011, if applicable.

A document that exclusively details one of the above-mentioned aspects, such as a standard document or interpretation document, is not considered to constitute a scheme.

For the purposes of this document, an international CAS is one where CABs legally established in more than one EA member country are involved and more than one NAB is requested to provide accreditation for the CAS in question.

It should be noted that being an international CAS does not depend on the locations where the object of the conformity assessment is utilised.

Where all the requirements for a CAS are documented in one single standard (def. of ISO/IEC Guide 2) published by international, regional or national standardisation body, the evaluation of the CAS according to this document is not applicable.

4.2) CAB: Conformity Assessment Body – a laboratory, certification or inspection body.

4.3) NAB: National Accreditation Body.

4.4) SO: Scheme Owner: the organisation that has established the CAS, is responsible for its design and is legally identifiable. The SO shall have the authority to establish and change the requirements of the CAS and the mandate to co-operate with the NAB.

4.5) Scheme specific requirements for the CABs: specific requirements on accredited CABs laid down by SO. These shall not contradict or exclude any of the requirements included in the accreditation standard.

4.6) Scheme specific requirements for NABs: specific applications of any ISO/IEC 17011 requirements for a particular CAS established by the SO. These shall not contradict or exclude any requirement in ISO/IEC 17011, Regulation 765/2008, EA/ILAC/IAF mandatory documents. The final decision on acceptance of these requirements resides with the NAB.

5) Introduction

This policy statement describes INAB's method of evaluating conformity assessment schemes. The document also contains requirements that apply to scheme assessments relevant to specific accreditation standards.

This document is applicable to bodies applying for accreditation or to bodies that have been accredited. It can also apply to scheme owners/scheme managers who intend to use accredited CABs to perform the conformity assessment activity.

Applications for assessment of a scheme (or a modified scheme) must be completed on form AF-3-B and be accompanied by the extension to scope application relevant to the activity concerned (certification, inspection, testing, etc.), via the INAB CRM.

The AF-3-B form shall be completed in full and returned with applicable supporting documentation for evaluation by INAB. The INAB team shall review this form and raise findings which must be addressed prior to any assessment activity being performed.

The scheme review will be completed by a lead assessor and technical expert(s) as appropriate.

The scheme review is normally completed off-site, but an onsite evaluation may be undertaken if INAB deems it necessary. Where the scheme involves (or is intended to involve) CABs in other jurisdictions, INAB may choose to collaborate with other accreditation bodies on its review.

6) Requirements for conformity assessment schemes

Requirements applicable to schemes are based upon accreditation standards and the applicable EA, IAF and ILAC guidelines and the INAB policy documents and explanatory documents. EA-1/22 Annex 2 provides guidance on conformity assessment schemes.

In general, it is recommended that scheme owners use the guidance given in the documents of the ISO/CASCO Conformity Assessment Toolbox when designing a conformity assessment scheme.

6.1) Competence & Impartiality

All schemes must be prepared by persons demonstrably competent in that capacity. This competence should cover both the technical field of expertise and the conformity assessment procedure used.

It shall be determined what competence is required for application of the new scheme by the CAB (including management, decision making and administrative personnel in addition to those performing conformity assessment activities). Competence shall be evaluated and demonstrated prior to application for accreditation.

6.2) Market Support

The SO shall be able to demonstrate that there is a need in the market for the CAS. This may include demonstration of added value, the involvement of interested parties, government initiatives or regulatory needs. The SO shall be able to provide evidence of market need for the CAS coming from relevant interested parties.

6.3) CAS Validation

The scheme owner shall demonstrate that the CAS has been validated. Validation requires the scheme to have successfully completed a test period, demonstrating that the scheme is practicable and in line with the intentions and expectations of the scheme owner. The validation documentation shall include:

- A description of the purpose of the scheme;
- A description of the requirements of the scheme;
- An analysis of the appropriateness of the established requirements for fulfilling the defined purpose of the scheme;
- A description of the methods to be used for determining fulfilment of the requirements;
- In case of an ISO/IEC 17065 scheme, and as mentioned in Clause 6.2 of that standard, the identification of the applicable requirements of the relevant International Standards. The same applies to an ISO/IEC 17020 scheme where reference is made to testing;
- An analysis of the appropriateness of the described methods to be used for determining fulfilment of the requirements;
- A decision on the conformity assessment activity to be used (including identification of the applicable conformity assessment standard);
- An analysis of the appropriateness of the selected conformity assessment activity.

7) Evaluation of conformity assessment schemes

In the evaluation of schemes for conformity assessment, there are two scenarios:

- 7.1) The scheme is the property of a body that is accredited or is applying for accreditation; in this instance, the CAB is the SO;
- 7.2) The scheme is the property of a body (scheme owner) that is applying for scheme acceptance.

Scenario 1: CAB-owned schemes

The evaluation of the scheme takes place prior to either initial assessment or assessment for extension of the scope of accreditation. Prior to such an assessment, which in most cases will include witnessing the conformity assessment activity, the body must submit all scheme documentation, accompanied by AF-3-B, the relevant application form via the INAB CRM, and self-assessment documentation if appropriate. INAB will not evaluate CAB schemes unless they are submitted as part of an assessment for accreditation.

Scenario 2: application by scheme owner for acceptance of scheme

Scheme owners may apply for acceptance of their conformity assessment scheme. The evaluation of a scheme prepared by an accepted scheme owner consists of the following steps:

1. SO makes an enquiry about having a scheme reviewed and is advised of the process and relevant procedures and forms: PS18, AF-3-B, and EA 1/22. If it is likely to be an international scheme, then the SO is informed of the involvement of other ABs and the concept of being a home AB.
2. INAB offers to have a meeting with the SO at an early stage to examine the feasibility of the proposed scheme and to discuss the process.
3. SO owner contacts INAB to request a review of their scheme.
4. INAB will provide a number of forms for completion and return:
 - a. Form AF-3-B, scheme details
 - b. Financial information form
 - c. Application form and contract agreement
5. INAB reviews the application and the Manager allocates an assessment manager to review the application and interact with the SO and engage a technical assessor/expert as required.
6. The assessment manager advises the SO of the cost and requests a PO number; work will not proceed unless a PO is provided. Fees for scheme reviews are charged at the daily rate for assessment, per assessor required. The assessment manager may also request further documentation at this point before beginning the review.
7. The INAB assessment manager conducts a review of the scheme and if there are queries or areas which do not meet accreditation criteria these are itemised in a report which is forwarded to the SO for attention.
8. Once the SO has responded and re-submitted the scheme (if amended) the assessment manager will review the response received and this may involve the technical assessor/expert again, depending on the issue.
9. Once all issues have been satisfactorily resolved the completed report is given to the INAB Manager for final review and sign-off.
10. Following sign-off by the INAB Manager, the outcome of the review is communicated to the SO. This will not occur until all INAB invoices have been issued and paid.
11. The assessment manager enters the details of the review including version number and date in the register of approved schemes and this is made publicly available on the INAB website.
12. The scheme is now eligible to be used by CABs applying for accreditation.

13. In the event that the scheme changes and approval is sought, a new application shall be made by the SO.
14. All schemes approved shall be reviewed for continued validity every 12 months or as information becomes known to INAB.
15. During the time of assessment of the conformity assessment body for accreditation for the new scheme, non-conformities related to the scheme may arise that were undetected during scheme evaluation. Witnessed activities are most likely to identify such issues. In such cases, nonconformities will be issued to the conformity assessment body, which will be expected to liaise with the scheme owner for resolution and amendment of the scheme where appropriate.

8) Status and implementation

Mandatory implementation from date of issue.

9) Contact

For further information about this statement please contact an INAB assessment manager at the **Irish National Accreditation Board**.

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