

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 adopt the measures listed in this document when addressing the requirements of the various accreditation standards.

3) Reference

- 3.1) EA-1/22 A: 2016 *EA procedure and criteria for the evaluation of conformity assessment schemes by EA accreditation body members*. Available at www.european-accreditation.org

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.

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.

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.
- Determines 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

There must be evidence of market acceptance of the scheme. The SO shall be able to provide evidence of market support for the CAS coming from relevant interested parties, particular end-users (e.g. consumers or industry). All interested parties must be consulted and evidence of this consultation provided.

6.3) CAS Validation

Schemes must be validated by the scheme owner prior to application to INAB for evaluation. 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;
- 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:

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
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.

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. The scheme owner must forward the scheme documentation to INAB, accompanied by information demonstrating that:
 - a. Interested parties have approved the contents of the scheme (this also applies to scheme changes);
 - b. The scheme owner has protected any marks associated with the scheme;
 - c. At least one conformity assessment body has applied to INAB for accreditation of its conformity assessment activities against the requirements of this scheme.
2. INAB will assess the application for scheme evaluation, determine the method for the evaluation and prepare a cost estimate to be provided to the scheme owner.
3. After acceptance of the budget, the evaluation is conducted and results are reported to the applicant. After any nonconformities are resolved, a positive decision may be made regarding acceptance of the scheme. Accreditation of conformity assessment bodies for the scheme may then proceed.
4. During the 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.

8) INAB related documents

- 8.1) Form AF-3-B, current version