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**EA Policy For
Conformity Assessment
Schemes
(Sector schemes)**

PURPOSE

EA recognises that the market sometimes requires accreditation of Conformity Assessment Bodies (CABs) to conform to special requirements set out in sector schemes: this is the policy for EA to develop and maintain co-operation with such sector schemes and mutual confidence.

Authorship

The publication has been prepared by the EA Executive Committee

Official language

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

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Further information

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Revision of the document

Changes are marked in **bold**

1- All references to "ISO" have been replaced by ISO/IEC where relevant.

2- Chapter 3 section 3.1.2, 2nd paragraph

The requirements established by the SO for the CABs must necessarily include the compliance with all the provisions of the **relevant** standards that are formally accepted by EA currently: ISO/IEC 17025 ISO 15189, ISO/IEC 17020, EN 45011(or its equivalent ISO), EN 45012 (or its equivalent ISO), ISO/IEC 17024, and the relevant guidance established by EA.

3- Chapter 3 section 3.3

EA will not participate if the CAS has been produced without **demonstrated market demand**.

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1 Purpose

This document has the following four objectives:

- 1) To lay down the policy established by EA regarding the conditions under which EA can establish formal relationships with Scheme Owners (Clause 3)
- 2) To set out the principles by which schemes can be considered as “covered by the MLA”. (Clause 4)
- 3) To set out the nature of the relationships between EA and the Scheme Owner (Clause 5).
- 4) To describe the decision-taking process followed by EA in these issues.

It is neither the aim of this document nor the competence of EA to determine in which conformity assessment schemes each signatory can or cannot operate at national level as long as that activity is not presented as covered by the MLA.

2 Definitions

2.1 Activity covered by the MLA: Conformity assessment activity to which, once accredited by a signatory to the MLA, the commitments agreed in the MLA apply and whose correct accreditation is assessed as part of the peer evaluation process.

2.2 Conformity assessment scheme (CAS): In this document, conformity assessment scheme is understood as the set of documents that establish:

I) The requirements / reference documents that must be used by the Conformity Assessment Bodies (CABs) (i.e. test procedures, regulatory documents against which the certification or inspection is going to be performed, etc.)

II) The requirements applicable to the CABs that specify criteria regarding their organization, mode of operation, staff, equipment, reports, etc.

III) The requirements applicable to the organizations that perform assessments of CABs (accreditation bodies or other organizations performing assessments of CABs).

2.3 Scheme owner (SO): Organization that has established a CAS. The following are examples of SOs:

- Standardization bodies
- Conformity Assessment Bodies
- Public administration bodies
- Organizations that use services provided by CABs

- Organizations that buy or sell products subject to conformity assessment activities

2.4 SO Recognition (of the CAB): Recognition means that the SO is authorizing the CABs to carry out activities within the remit of the scheme provided that they have accreditation. The SO, through such a recognition process, may authorize the CAB to, for example:

- Perform conformity assessment activities in the regulatory field
- Perform conformity assessment activities so that these can be recognized by certain organizations that make use of the reports or certificates (COI, IWTO, WADA, EFI, etc).
- Perform conformity assessment activities on products or systems so that such activities can be taken into account in their buying decisions (EUREPGAP, BRC, AECMA, GFSI, Bluetooth)

Note: Not all the CAS include recognition

2.5 Scheme Specific Requirements (for Accreditation Bodies): Specific applications of any ISO/IEC 17011 requirement for a particular scheme established by the SO.

2.6 Scheme Specific Requirements (for the CAB): Requirements laid down by the SO at the CAB level these requirements may go beyond but must not contradict, nor exclude, any of the requirements included in the standards used for accreditation (ISO/IEC 17025, ISO/IEC 17020, etc).

2.7 End User (of a CAS): The party in the market that uses the information issued by a CAB (report, certificate, mark, etc) within its decision making process. Typically, End Users are the public authorities in the regulatory field, or buyers/specifiers of tested, certified or inspected goods

3 EA prerequisites for the establishment of relations with Scheme Owners

3.1 EA will cooperate with SO only if:

3.1.1 The SO can demonstrate a clear market support for the scheme. This has to include evidence of support for the scheme coming from all interested parties. The number and nature of the “interested parties” will be different for different CAS nevertheless the acceptance of the scheme by the end user (see definitions) will always be needed.

3.1.2 The CAS must be based on the internationally recognized standards used for accreditation.

The requirements established by the SO for the CABs must necessarily include the compliance with all the provisions of the relevant standards that are **formally accepted by EA**, currently: ISO/IEC 17025, ISO 15189, ISO/IEC 17020, EN 45011(or its equivalent ISO), EN 45012 (or its equivalent ISO), ISO/IEC 17024, and the relevant guidance established by EA.

Any other requirements laid down by the SO at the CAB level must not contradict, nor exclude, any of the requirements included in the above documents (see definition of scheme specific requirements) – process and/or service certification schemes according to EN 45011 may define slightly different requirements (e.g. the possibility of minor non compliances remaining for a defined time but the certificate could be granted).

- 3.2 The EA cooperation in the development of a CAS will be limited to aspects related to assessment.
- 3.3 EA will not participate if the CAS has been produced without demonstrated market demand.

4. Conformity Assessment Schemes (CAS) covered by the EA-MLA

Schemes are covered by the EA-MLA in those cases where the SO does not:

- a) establish requirements other than those established in ISO/IEC 17011 for the AB and the different standards used by EA to establish its MLAs for the CAB, and
- b) have any role in the assessment/recognition of the CAB.

Notes: the following are the activities covered by the EA MLA at the time of approval of this document:

- Accreditation according to ISO/IEC 17025
- Accreditation according to ISO/IEC 15189
- Accreditation according to ISO/IEC 17020
- Accreditation according to ISO/IEC 17024
- Accreditation according to EN 45011
- Accreditation according to EN 45012 for the certification of ISO 9001 Quality Management Systems
- Accreditation according to ISO/IEC Guide 66 for the certification of ISO 14001 Environmental Management Systems

When the SO does establish scheme specific requirements for the CAB/AB or has some role in the assessment/recognition of the CABs, the following principles have to be fulfilled in order for the accreditation

activities performed by a signatory to an EA-MLA to be considered as covered by the EA-MLA for a given CAS.

4.1 First principle: the SO does not exclude any member of the relevant MLA

4.2 Second principle: The assessment processes must fulfill all the requirements established in ISO/IEC 17011.

Notes: Some SOs (particularly in the case of laboratories) have their own assessment processes and seek the AB recognition of the output of such assessment in order for it to be used by the AB in its assessment procedure. This situation may lead to organizations outside EA benefiting from bilateral agreements with EA MLA signatories as *de facto-signatories*.

Thus, when an AB enters into an agreement with a SO for any part of the accreditation process (including the assessment), the SO as a subcontractor has to demonstrate the fulfillment of the subcontracting requirements laid down in ISO/IEC 17011, and the MAC has to be notified for the purpose of peer evaluation.

In no case can the AB (see the third principle) conclude agreements for the recognition of the assessment processes, or base its decisions on information supplied by organizations, that do not fulfill the paragraph above.

This principle does not prevent the AB using assessors or experts supplied by the SO since such activity is not considered to be subcontracting.

4.3 Third principle: The accreditation body is the only body responsible for the decisions taken in respect of accreditation.

Notes: By definition, accreditation bodies must take the final decision regarding the grant or denial of accreditation, as this must be a third-party activity.

If the SO has established a recognition process (see definitions 2.4), this must be clearly distinct from accreditation. If the SO has laid down scheme specific requirements for the CAB and requires the AB to assess them, the AB will be responsible for the decisions taken regarding the fulfillment of those requirements.

In no circumstances will it be acceptable for accreditation decisions to be changed or influenced by any type of revision of the CAS by the SO. The MLA will not cover activities in which the accreditation decision is not fully taken by the signatory to the MLA.

4.4 Fourth principle: The EA-MLA is based on signatory ABs fulfilling the requirements of ISO/IEC 17011 and the requirements and procedures of the MLA. Decisions regarding the maintenance of an AB in the MLA can only be taken within EA and on the basis of such requirements.

Notes: In order to ensure the independence and credibility of the evaluation process, decisions regarding the maintenance of an AB in the MLA can only be taken within EA.

Where a SO has laid down additional requirements for the AB which are over and above but do not contravene those of ISO/IEC 17011, so long as there is no breach of compliance with ISO/IEC 17011, a breach of the additional requirements shall not be a reason for EA to impose sanctions against the AB. As these additional requirements should be addressed through a bilateral agreement between the SO and the AB, they shall not be assessed during EA peer evaluations.

However, EA may agree to the request from a SO to address the fulfillment by an AB of a SO's **scheme specific requirements** (for the AB) (see definitions) during the peer evaluation process. This shall be granted only where such scheme specific requirements are specific applications of ISO/IEC 17011 to the scheme, for example, specific qualification criteria for assessors, more precise content of reports, etc. Only these can be considered as covered by the MLA; any other activities for which the SO has laid down additional requirements for the AB cannot be considered as covered by the MLA.

EA recognizes that SOs may seek assurance of the effectiveness of the peer evaluation process for the particular scheme concerned. To this end, EA will consider requests from SOs to observe the process of peer evaluation of sector schemes on a sample basis.

4.5 Fifth principle: The information supplied to the market must always be transparent and not create barriers to competition.

Notes: If the SO has laid down Scheme specific requirements for the CAB, these must be clearly defined and documented by the SO and made available to anyone that requests it. If the accreditation body has assessed the Scheme specific requirements, reference to such document and to the CAS will be included in the certificate or scope of accreditation.

5 Scheme Owners and EA relationships

5.1 EA is an organization open to collaboration with any SO that operates at the European or international level, provided the CAS fulfills the principles set down in Clause 3 above. The depth and nature of such

collaboration will depend on the SO and EA needs and expectations. Nevertheless the next conditions must be respected:

5.2 When a SO fulfills the principles set down in Clauses 3 and 4 above and wishes to control its CAS through the EA MLA, the agreements between EA and the SO should include:

- The commitment of EA to include the SO in some of the EA committees so as to improve the required multilateral communication or, if appropriate, to create a specific task force for that SO.
- The possibility of receiving assistance and support (excluding financial support) from EA in issues related to the conformity assessment in its scheme and the possibility of nominating a single interlocutor.
- The commitment of EA members to preferably consider the use of assessors supplied by the SO (provided the fourth principle below is fulfilled).
- Definition of any activities performed by the SO **prior** to the accreditation that must be taken into account by the AB.

Even without an explicit agreement between SO and EA , if the SO asks for accreditation to the CABs operating in the scheme, EA will ensure the commitment of the ABs that operate under the scheme to:

- Evaluate the Scheme specific requirements laid down by the SO in their assessment processes.
- Make reference to the CAS documents established by the SO in the scope of accreditation.
- Operate accordingly to the guidelines or recommendations provided by the SO.

In any event, the steps described in Clause 5 must be followed before reaching this type of agreement.

5.3 In the case of CASs fulfilling only the requirements on Clause 3 **but not those in Clause 4**, EA can only act as an organization that facilitates the access of the SO to different national ABs with whom it wants to enter agreements.

In this case, EA may reach agreements with the SO in order to, for example:

- Create a specific task force for that SO within which scheme-related issues can be discussed.
- Develop, if appropriate, a list of assessors recognized by the SO to be used by the ABs in their assessments conducted under the scheme.
- Agree other commitments between the participating ABs and the SO.

These agreements must make clear that EA will not include in its peer evaluations the assessment of such schemes.

In any event, the steps described in Clause 6 must be followed before reaching this type of agreement.

- 5.4** One of EA's objectives is to reduce the number of assessments required to CABs. Therefore, EA will be especially careful with those CASs in which the SO acts or has acted *de facto* as an AB under its scheme. EA will not conclude any type of agreement if the SO does not accept that the AB may plan the assessments in such a way that, while ensuring an appropriate technical assessment, the costs of the assessment process are minimized, both in terms of money and time.

6. Implementation

The national ABs are responsible for analyzing if the CASs in which they participate at the national level fulfill the requirements laid down in Clauses 3.1 and 4.

If the CAS does not meet such requirements it is the AB's responsibility to make it clear to the SO, the CABs, and the general market.

Hence, the AB should have procedures to assure, both in the accreditation certificate and in the accredited certificates/reports issued by the CAB, differentiate between the activities covered and those not covered by the MLA. These procedures should include the use of a disclaimer in the accreditation certificates and in the reports/certificates issued by the CABs in schemes not covered by the MLA stating "This report/certificate is not covered by any EA MLA" or similar. These procedures and their implementation must be open to assessment during peer evaluations.

If an AB, cooperating with a SO at the national level, believes that the CAS also has an impact on the European market, the AB should inform EA and also recommend to the SO that it gets in touch with EA.

An SO seeking to sign an agreement with EA must contact any member of EA or the chairman of any of its committees. The agreements must be approved by the EA General Assembly following a proposal by the Executive Committee, which itself should follow receipt of a favorable opinion from the relevant EA Committee (after assessing the fulfillment of the requirements established in this procedure and the identification of any scheme specific requirements or additional requirements as mentioned in 4.4).

In those cases where a CAS exists to meet the requirements of public authorities, EA may choose to participate even if the CAS does not meet completely the conditions defined in this document.