

Publication Reference

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# **Procedure for**

# development and approval of EA documents

## and

# adoption of ILAC/IAF documents

#### **PURPOSE**

This document describes the various stages of development and approval of EA documents and adoption of ILAC/IAF documents as EA publications.

### EA-1/14 • Procedure for development and approval of EA documents and adoption of ILAC/IAF documents

#### Authorship

The publication was written by the Secretariat.

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

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#### **CONTENTS**

1	PRINCIPLES AND DEFINITIONS	.4
1.1	POLICY FOR DEVELOPMENT OF DOCUMENTS	.4
1.2	ABBREVIATIONS	.4
1.3	CLASSIFICATION AND STATUS OF EA DOCUMENTS	.5
1.4	GENERAL RULES FOR APPROVAL AND IMPLEMENTATION OF EA DOCUMENTS	.6
2	PROCESS FOR THE PROPOSAL FOR NEW EA DOCUMENTS OR REVISION OF EXISTING DOCUMENTS – NEW WORK ITEM (NWI)	
2.1	NWI PROPOSAL (NWIP)	.7
2.2	COMMENTS	.8
3	DEVELOPMENT AND CIRCULATION OF DOCUMENTS FOR COMMENTS	.8
4	APPROVAL OF MANDATORY DOCUMENTS	.9
5	APPROVAL OF GUIDANCE AND INFORMATIVE DOCUMENTS	10
6	SECRETARIAT OPERATIONAL AND MANAGEMENT SYSTEM DOCUMENTS	10
7	ADOPTION OF ILAC/IAF MANDATORY DOCUMENTS AS EA DOCUMENTS	10
8	PUBLICATION AND NOTIFICATION	11
9	WITHDRAWAL OF EA DOCUMENTS	12
10	REVIEW OF EA DOCUMENTS AND INTERNATIONAL DOCUMENTS	12
GENER	PAL SUMMARY TABLE FOR ALL EA DOCUMENTS	13
A DDENI	DIY - PROPOSAL FOR THE PREPARATION OF FA DOCUMENTS	1 1

#### 1 PRINCIPLES AND DEFINITIONS

#### 1.1 Policy for development of documents

The EA policy is to develop Members' Procedural and CAB Application documents to ensure implementation of harmonised practices, particularly in cases when the document is essential to achieve EA objectives.

In compliance with EA-1/15: *Policy for Relations with Stakeholders*, EA shall consult all stakeholders and interested parties when considering the need for a new document or the revision of existing EA documents, and involve relevant stakeholders and interested parties in the development process as required.

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#### EA publishes:

- documents which define organisational policies and procedures to be followed by EA and its Members and the Secretariat;
- other process, procedural and application documents which are mandatory or not for both Members and signatories to the EA MLA; and
- Information documents.

The process described in this document applies to EA documents based on their classification as defined below.

#### 1.2 Abbreviations

NWI	New Work Item
NAB	National Accreditation Body
N/A	Not applicable
MAC MLA	MLA Council Multilateral Agreement
LC	Laboratory Committee
IC	Inspection Committee
HHC	Horizontal Harmonization Committee
GA	General Assembly
EXB	Executive Board
EAAB	EA Advisory Board
CPC	Communications and Publications Committee
CC	Certification Committee
CAB	Conformity Assessment Body

19<sup>th</sup> April 2022\_rev03 Page 4 of 15

#### 1.3 Classification and status of EA documents

#### 1.3.1 Status of EA documents

EA documents may have the following status:

Mandatory

Documents with mandatory status are documents that shall be applied by those concerned.

Guidance

Documents with guidance status are those documents that provide technical or scientific guidance and recommended examples on how to fulfil the criteria.

Informative

Documents with informative status are those documents that are published for pure information purposes.

#### 1.3.2 Classification of EA documents

Governance and Policy documents

EA Governance and Policy documents include documents such as the Articles of Association, Rules of Procedure and other documents relating to the operation of EA.

Note: They don't include documents published by Committees<sup>1</sup>, such as the EA Strategic Plan. Terms of Reference for EA Committees and Council.

Peer Evaluation Process documents, including policies and procedures

Peer evaluation process documents include policy and procedural documents for the operation of the EA peer evaluation system and documents relating to the management of the peer evaluation process and training of EA evaluators.

Members' Procedural documents

Members' procedural documents include procedures and requirements applying to EA members including application documents for National Accreditation Bodies (NABs).

The purpose of issuing such EA documents is to ensure consistency and to support harmonisation of accreditation practices by all EA MLA signatories when working with international standards, harmonised standards and other applicable requirements.

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<sup>&</sup>lt;sup>1</sup> In this document, the term "committee" includes General Assembly, Executive Board, Technical Management Board, Councils and/or Technical Committees.

#### Application documents for CABs

Application documents are documents to be used by CABs for the application of harmonized standards and other accreditation requirements.

• Secretariat operational and management system documents

Documents used by the Secretariat for its operations and the management system. These documents are controlled by the Secretariat.

Information documents

This category includes general information about EA and its members as well as specific EA activities.

#### 1.4 General rules for Approval and Implementation of EA documents

#### 1.4.1 Approval of EA Documents and Date of Publication

The rules and process for approval are laid down in chapter 4. When approval is carried out by electronic ballot the date of approval is the closing date for the ballot plus one day. When approval is done by voting at a GA or committee meeting, the date of approval will be the last day of the meeting.

How to approve a document is based on the status of the document.

The date of publication is the date on which the document is published on the website of EA and members are officially notified about the publication according to chapter 8.

#### 1.4.2 Transition period

The transition period is the period of time between the publication date and the implementation date.

#### 1.4.3 Implementation of EA Documents

As a general rule, the date of implementation of an EA published document shall be the date of publication plus one year, unless otherwise agreed.

While it is expected that every NAB will apply the procedures set out in a new EA document and, where relevant, require its accredited and applicant bodies to apply the procedure from the implementation date, this does not mean that the NAB has confirmed through an assessment of the accredited CAB the implementation of a new document by that date.

The implementation of the requirements or procedures set out in a new EA document, by accredited CABs, must however be confirmed through assessment on or before the next scheduled assessment date for the accredited body following the implementation date. The implementation of the new document by the NAB will be covered by the next peer evaluation if not defined otherwise.

# 2 PROCESS FOR THE PROPOSAL FOR NEW EA DOCUMENTS OR REVISION OF EXISTING DOCUMENTS – NEW WORK ITEM (NWI)

#### 2.1 NWI proposal (NWIP)

A proposal for drafting a new document or revising an existing EA document, whether originating from EA or international work, shall be supplemented by information on those EA documents, where relevant, that will be superseded by the new document and will therefore have to be withdrawn. Any EA member/body can make a proposal for a new work item (NWIP).

A NWI shall be proposed for the following documents:

- Governance and Policy documents
- Peer Evaluation Process documents, including policies and procedures
- Members' Procedural documents
- Application documents for CABs

The NWIP process shall not be applied for the following documents:

- Secretariat Management System and operational documents
- Information documents
- Templates / Form sheets

Proposals shall be submitted in writing to the Secretariat of the Committee involved using the Appendix of this procedure. The Committee Secretariat shall then consult the relevant EA Committee(s) for comments and endorsement of the proposal.

The NWIP shall be endorsed by the following EA committee:

	Mandatory documents	Guidance documents	Informative documents
Governance and Policy documents	GA	N/A	N/A
Peer Evaluation Process documents, including policies and procedures	GA	MAC	MAC
Members' Procedural documents	GA	TMB	TMB
Application documents for CABs	TMB	TC	TC

Before the NWIP is endorsed by the relevant EA Committee, the EAAB shall be invited to provide its advice to the NWIP, but for mandatory and guidance documents only. The endorsement of the NWIP is done either by electronic ballot or voting in a meeting.

In urgent cases, the NWIP may also take the form of a resolution presented for approval at an EA GA meeting under the EXB or TMB responsibility. Representatives of stakeholders and the EA Advisory Board have then the opportunity to react and comment.

The approved NWIP should normally be reflected in the relevant work programme(s).

#### 2.2 Comments

The NWIP shall identify the owner Committee responsible for the document and specify the comment procedure to be applied according to the table below:

	Owner Committee	Stage 1: Committee comments	Stage 2: EA GA comments	
Governance and Policy documents	EXB, HHC	<b>✓</b>	✓	
Peer Evaluation Process documents, including policies and procedures	MAC	<b>~</b>	N/A	
Members' Procedural documents	ннс	<b>√</b>	N/A	
with a mandatory status	LC, IC, CC	✓	✓	
Members' Procedural documents with a guidance or informative status	HHC, LC, IC, CC	<b>~</b>	N/A	
Application documents for CABs with a mandatory status	LC, IC, CC	<b>√</b>	✓	
Application documents for CABs with a guidance or informative status	LC, IC, CC	<b>&gt;</b>	N/A	
Secretariat Management System and operational documents	SECR	N/A	N/A	
Information documents	SECR, EXB, TMB	N/A	N/A	

#### 3 DEVELOPMENT AND CIRCULATION OF DOCUMENTS FOR COMMENTS

- 3.1 The responsible Committee shall complete the work. Where relevant, the Committee is encouraged to consult with other regional accreditation body co-operations.
- **3.2** When a draft is complete, it shall be circulated for comments in compliance with the agreed comment process.

Normally the Committee comment period is 60 days. Any other proposals shall be indicated in the proposed new work item with proper justification. Furthermore, during the development process, specific circumstances may require a quick response from EA and a shorter comment period may be applied. The owner Committee retains responsibility for recommending adjusting the duration of the comment period, to be confirmed by the Committee responsible for the endorsement of the NWIP.

- 3.3 Comments received shall be considered. The Committee shall respond to each comment and set out the rationale for not accepting a comment. A revised draft is then produced and submitted to the Committee for endorsement. Should the Committee decide to circulate the revised draft to members of the Committee/Council for a new comment period, clauses 3.2 3.3 shall be repeated but with a comment period of 30 days, unless otherwise agreed in the Committee.
- Where applicable, the revised draft is circulated for EA GA comments. When an EA GA comment period is required, the process as described in 3.3 shall apply.
  - Note: EA GA means Members as well as recognized stakeholders.
- 3.5 Comments received shall be consolidated by the Secretariat and then sent to the responsible Committee for consideration. The responsible Committee shall consider every comment and give a response and revise the document as necessary. The final revised draft shall be endorsed by the Committee before circulation for voting.
- 3.6 The Secretariat shall arrange the ballot for approval of documents. Before circulation for ballots, the Secretariat shall review the document for compliance with the applicable requirements as set out in EA-0/06: Format and Layout of EA documents.

#### 4 APPROVAL OF MANDATORY DOCUMENTS

- 4.1 Mandatory documents will be approved either during an EA General Assembly session or, more generally, through electronic ballots. The rules for decisions and votes by the EA General Assembly apply as set out in the Articles of Association. Results of electronic ballots shall be ratified at a General Assembly meeting.
- 4.2 When EA documents are presented for approval during an EA General Assembly session or by electronic ballot, the following documents and information shall be circulated to the contact point of voting members:
  - the final draft of the document.
  - a track change version from the previous document provided it remains legible,
  - the template with comments and responses considered during the EA comments phase,
  - information on the implementation date and proposed transition period shall be given in the draft submitted for voting.
- 4.3 If the adoption of a document is to be completed by electronic ballot, voting members will normally have 30 days to vote from the time of posting the document for voting. Fast track process can be used in urgent cases, with the EXB or TMB deciding on the most appropriate voting period.
- **4.5** During the voting period, the EA Secretariat will follow up and remind voting members to vote, notably when the quorum is not reached.

- **4.6** The EA Secretariat will advise voting members and the recognized stakeholders of the voting result within two weeks of the close of voting.
- **4.7** If the outcome of the vote on the document is negative, the EXB or the TMB will decide on the future process to be followed.

#### 5 APPROVAL OF GUIDANCE AND INFORMATIVE DOCUMENTS

Documents with guidance and informative status shall be approved by the committee itself, who is responsible for the document in question.

For the decision-making, the rules as set out in EA-1/17 *EA Rules of Procedure* shall be applied.

Documents under the category EA information documents shall be approved by the Executive Secretary or the EXB or the TMB, depending on the nature of the document.

The Secretariat will inform the EA (Committee) members and stakeholders on the approval of these documents.

Application documents for CABs published by an outside organisation, in general a Recognised Stakeholder organisation which provides useful advice on matters relating to accreditation, are endorsed by the relevant Committee of EA and listed in INF/01 and/or on the website.

# 6 SECRETARIAT OPERATIONAL AND MANAGEMENT SYSTEM DOCUMENTS

Secretariat operational and management system documents as well as information documents are prepared by the Secretariat under the management of the Executive Secretary. They are approved by the Executive Secretary, unless the EXB defines that a specific document shall be approved by the EXB.

# 7 ADOPTION OF ILAC/IAF MANDATORY DOCUMENTS AS EA DOCUMENTS

7.1 ILAC or IAF documents that are mandatory for EA MLA signatories as well as for EA (as the regional cooperation body that administers and manages the ILAC and IAF Arrangements) shall be submitted to EA Members for endorsement. EA shall formally and automatically adopt mandatory documents approved and published by ILAC and IAF.

It is assumed that ILAC or IAF documents do not contain policies or principles which conflict with EU legislation that support the European system for accreditation as decided by EA and the European Commission, because EA is part of the developing process of IAF and ILAC mandatory documents (see 7.2./7.3.)

However, in any specific case where IAF or ILAC endorses a mandatory document which contradicts European legislation or EA requirements; IAF or ILAC shall be notified that it is not possible for EA to approve the respective document, and to strive to find a solution. If no solution is possible EA will need to cancel its status as a recognized region.

7.2 EA Committee Chairs are responsible for evaluating whether ILAC/IAF documents contain provisions or requirements that may conflict with the policy and principles for the European accreditation system as decided by the European Commission. If such conflict or potential conflicts are identified during the ILAC/IAF development process, EA Committee Chairs, after consultation with the EA Committee, shall notify the EXB or the TMB depending on the owner of the document and recommend action to be taken by EA. This can be carried out by email consultations.

The Executive Secretary will inform EA ILAC/IAF Members of its considerations with the proposed recommendation for action to ILAC/IAF.

If such conflict or potential conflicts are identified during the ILAC/IAF voting process, after consultation with the EA Committee, the EXB or TMB will issue a recommendation to the EA ILAC/IAF Members. The EXB or TMB may recommend voting against the proposed ILAC/IAF document. This should only arise if the potential conflicts cannot be resolved during implementation of the document in EA.

The EXB or TMB will seek advice of the EAAB in resolving the identified conflict, if appropriate.

- 7.3 When EA Committee Chairs have not notified the EXB or TMB any conflicting principles or policies, ILAC or IAF documents will be automatically submitted to the relevant Committee for formal adoption as EA documents (see clause 7.1) after their publication by ILAC or IAF, with the relevant EA classification and status. In case that the EA Committee Chairs notified that ILAC or IAF documents contain provisions, principles or policies conflicting with those adopted for the European accreditation system, the proposal presented to the relevant Committee shall be supplemented by a recommendation, approved by the EXB or TMB, to resolve the conflict identified.
- **7.4** ILAC and IAF documents adopted as EA documents shall be available from the EA website as adopted ILAC/IAF documents and published according to the endorsed classification and status.

#### 8 PUBLICATION AND NOTIFICATION

When an EA document is approved by the General Assembly or by the relevant Committee, the Secretariat will publish the document on the EA website.

- **8.2** The Secretariat shall also inform all EA Members and Stakeholders of the publication of the document.
- **8.3** When an EA document is under revision, the existing version remains the applicable version until the revised document is published. During the transition period, both versions of the documents remain valid unless otherwise agreed.

#### 9 WITHDRAWAL OF EA DOCUMENTS

- **9.1** The decision to withdraw a document shall be made by the Owner Committee, following the approval by the same Committee/GA who approved the document according to the status and the category of the document.
- **9.2** The Secretariat shall notify the EA Members and Recognized Stakeholders, when a document is withdrawn, and shall update EA-INF/01 *List of EA Publications and International Documents* and the EA website.

#### 10 REVIEW OF EA DOCUMENTS AND INTERNATIONAL DOCUMENTS

- 10.1 At least every five years or whenever it is identified as necessary, Committees will review the documents they are responsible for. The Committees secretariats will check and update the documents list regularly.
- 10.2 It is EA Committees responsibility to follow on changes on European legislation and consequences on EA publications, including European and International standards and ILAC/IAF endorsed documents.
- **10.3** All inquiries regarding the documents should be sent at first instance to the EA Secretariat.

#### GENERAL SUMMARY TABLE FOR ALL EA DOCUMENTS

Classification	Governance and Policy documents		tion process ments	Members' procedural documents		Application documents for CABs		Secretariat documents	Information documents
Status	Mandatory	Mandatory	Guidance, Informative	Mandatory	Guidance, Informative	Mandatory	Guidance, Informative		
Owner Committee	EXB or HHC	MAC	MAC	HHC, CC, IC, or LC	HHC, CC, IC, or LC	CC, IC, or LC	CC, IC, or LC	SECR, EXB	SECR, EXB, or TMB
Endorsement NWIP	GA	GA	MAC	GA	ТМВ	ТМВ	CC, IC, or LC	N/A	N/A
Committee comments	Yes	Yes	Yes	Yes	Yes	Yes	Yes	N/A	N/A
GA comments	Yes	No	No	Yes, except HHC documents	No	Yes	No	N/A	N/A
Approval by	GA	GA	MAC	GA	HHC, CC, IC, or LC	GA	CC, IC, or LC	Executive Secretary or EXB	Executive Secretary, EXB or TMB

#### APPENDIX - PROPOSAL FOR THE PREPARATION OF EA DOCUMENTS

1. PROF	POSAL MADE	BY:						
on beha	If of:				I	Date:		
EA Member								
EA Adv	risory Board:_			(name of the National Accreditation Body)				
Individu	ıal stakeholde	er or Observe	r:		/lember + Colleg	e)		
FA Boa	ard/Committee	e/Council:						
L/\ Boo	ira/Committee	,, oouricii		(name of the E	Board/Committee	e/Council)		
2								
	f the documer	nt to be prepa	ared:					
Area of	application:							
3								
	tion for the pr	oposal: ident	ification of the r	need and tard	et aroup:			
Benefit:	от тог што рт	op 00a., 1a0			, o t g. o u.p.			
4								
-	ed classification	on and status:	:					
· .								
	Governance and Policy		ation process uments		f procedural iments	Application de CA		
	documents Mandatory	Mandatory	Guidance, Informative	Mandatory	Guidance, Informative	Mandatory	Guidance, Informative	
luotific -	tion:							
Justilica	Justification:							
5								
	Is the subject matter being addressed either with EA or elsewhere (ILAC or IAF for example):							
	No, it is not (please make reference to this circumstance in the previous question) Yes (please provide information)							
6								
	•	• •	ne proposed do	cument:				
Alterna	ative solution	avaliable:						

19<sup>th</sup> April 2022\_rev03 Page 14 of 15

7
Comment procedure to be applied for the document:
A. To be circulated to <b>Committee members including relevant stakeholders</b> for comments:
Number of days  If less than 60 days, please justify:
B. To be circulated to <b>EA General Assembly Members and stakeholders</b> for a 60-day comment period, if relevant:
YES
NO
If less than 60 days, please justify:

19<sup>th</sup> April 2022\_rev03 Page 15 of 15