



IAF Policy Document



Policies and Procedures for Expansion of the Scope of the IAF MLA

Issue 3

(IAF PL 3:2016)

The International Accreditation Forum, Inc. (IAF) facilitates trade and supports regulators by operating a worldwide mutual recognition arrangement among Accreditation Bodies (ABs) in order that the results issued by Conformity Assessment Bodies (CABs) accredited by IAF members are accepted globally.

Accreditation reduces risk for business and its customers by assuring them that accredited CABs are competent to carry out the work they undertake within their scope of accreditation. ABs that are members of IAF and the CABs they accredit are required to comply with appropriate international standards and the applicable IAF application documents for the consistent application of those standards.

ABs that are signatories to the IAF Multilateral Recognition Arrangement (MLA) are evaluated regularly by an appointed team of peers to provide confidence in operations of their accreditation programs. The structure and scope of the IAF MLA is detailed in IAF PR 4 – Structure of IAF MLA and Endorsed Normative Documents.

The IAF MLA is structured in five levels: Level 1 specifies mandatory criteria that apply to all ABs, ISO/IEC 17011. The combination of a Level 2 activity(ies) and the corresponding Level 3 normative document(s) is called the main scope of the MLA, and the combination of Level 4 (if applicable) and Level 5 relevant normative documents is called a sub-scope of the MLA.

- Main scope of the MLA includes activities e.g. product certification and associated mandatory documents e.g. ISO/IEC 17065. The attestations made by CABs at the main scope level are considered to be equally reliable.
- Sub scope of the MLA includes conformity assessment requirements e.g. ISO 9001 and scheme specific requirements, where applicable, e.g. ISO TS 22003. The attestations made by CABs at the sub scope level are considered to be equivalent.

The IAF MLA delivers the confidence needed for market acceptance of conformity assessment outcomes. An attestation issued, within the scope of the IAF MLA, by a body that is accredited by an IAF MLA signatory AB can be recognized worldwide, thereby facilitating international trade.

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IAF Policies and Procedures for Expansion of the Scope of the IAF MLA

1. INTRODUCTION

1.1 The IAF has established the IAF MLA. The scope of the IAF MLA includes main scopes and sub-scopes. The main scopes include accreditation activities based on international standards for conformity assessment bodies (e.g. ISO/IEC 17021-1, ISO/IEC 17024 and ISO/IEC 17065) as endorsed by IAF and associated IAF application documents to the standards. Membership of the IAF MLA for a main scope provides confidence that CABs accredited by IAF MLA accreditation body signatories under that main scope are equally reliable in the outcomes of conformity assessment activities.

1.2 A main scope of the IAF MLA may specifically define a sub-scope(s) which is(are) a conformity assessment scheme(s) (e.g. for specific product, management system and/or persons) based on relevant standards or normative documents as endorsed by IAF and associated IAF application documents, as appropriate. The membership of the IAF MLA for a sub-scope further provides confidence that the outcomes of the specific conformity assessment scheme (e.g. ISO 9001 QMS, ISO 14001 EMS etc) operated by CABs accredited by the IAF MLA accreditation body signatories under that sub-scope are equivalent.

1.3 The standards or normative documents as endorsed by IAF for the main scopes and sub-scopes of the IAF MLA are included in the list of IAF Endorsed Normative Documents, which can be found in IAF PR 4 *.

*Available on the IAF Website at www.iaf.nu under Publications, Procedures Documents

1.4 This document provides policies and procedures for the expansion of the scope of the IAF MLA.

2. GENERAL POLICY FOR EXPANSION OF THE SCOPE OF THE IAF MLA

2.1 The general criteria for evaluating suitability for inclusion of a standard or other normative documents under the IAF MLA for main scope and/or sub-scope include:

- i) Significant relevance to the accreditation of conformity assessment bodies under the scope of the IAF activities;
- ii) Sufficient substance to enhance the recognition of competence;

- iii) Fulfils appropriate needs on an international, regional or national basis;
- iv) Lack of inclusion poses threats to IAF leadership in accreditation;
- v) Complementary to or supportive of any of the other standards being currently used;
- vi) Does not contradict any existing standard(s) under the IAF MLA;
- vii) Document must be produced by a consensus process.

2.2 A precondition for IAF expanding the IAF MLA into a new main scope shall be that an international standard for accreditation of conformity assessment bodies has been developed and published which contains requirements applicable to the types of conformity assessment bodies other than those covered by the existing main scopes.

3. SPECIFIC PROCEDURE FOR EXPANSION OF THE SCOPE OF THE IAF MLA BASED ON PUBLICLY OWNED (INCLUDING REGULATORY) NORMATIVE DOCUMENTS

3.1 The evaluation of suitability for inclusion of publicly owned standards/normative documents (e.g. ISO standards and other standards/normative documents developed for public purpose) in the IAF MLA will be initiated when the Technical Committee creates a new working project proposed by any member of IAF and related to a specific scheme based on publicly owned standards/normative documents which have not been endorsed as scope of the IAF MLA. The evaluation of the suitability to demonstrate the fulfilment of the criteria as described in Clauses 2.1 and 2.2 shall be part of the task of a new project. The new project shall be approved by the Executive Committee.

3.2 A recommendation for expanding the IAF MLA to include a main scope and/or sub-scope shall be submitted to the Executive Committee by the Technical Committee based on the outcome of the evaluation from the above working project. The recommendation shall contain sufficient descriptive information which demonstrates that the criteria as described in Clauses 2.1 and 2.2 are fulfilled.

(Refer to Section 1 of Annex 1 for the information to be provided in the recommendation.)

3.3 Upon the endorsement by the Executive Committee of the recommendation, the Technical Committee shall study the need for the development of specific IAF application documents and the MLA Committee shall be responsible for the analysis of the need for additional preparation of peer evaluation based on the outputs of the Technical Committee for the proposed new scope.

(Refer to Section 2 of Annex 1 for the information to be provided.)

3.4 A Proposal for expanding the IAF MLA to cover further main scope and/or sub-scope, including the evaluation methodology to be used by the MLA MC, shall be put forward to the General Assembly by the Executive Committee based on the recommendation of the Technical Committee and MLA Committee.

(Refer to Annex 1 for the information to be provided in the proposal. Annex 3 provides a diagrammatic representation of the Section 3 procedure.)

3.5 The decision to include an additional main scope and/or sub-scope in the IAF MLA shall be made by the IAF General Assembly. Following the development of any specific IAF application documents and additional preparation of peer evaluation, the newly endorsed standards or normative documents for the main scope and/or sub-scope shall be added to the list of IAF Endorsed Normative Documents, which can be found in IAF PR 4.

4. SPECIFIC POLICY AND PROCEDURE FOR EXPANSION OF THE SCOPE OF THE IAF MLA BASED ON PRIVATELY OWNED SECTOR SCHEMES

4.1 Specific Policy for Expansion of the Scope of the IAF MLA based on Privately Owned Sector Schemes

4.1.1 IAF welcomes the opportunity to work with scheme owners which demonstrate that they represent substantial parts of the scheme's designated sector, to expand the scope of the IAF MLA. Expanding the IAF MLA is also beneficial to the scheme owner as it allows IAF accreditation body members to contribute their expertise to the ongoing development of the scheme whilst also providing access to the IAF world-wide recognition program.

4.1.2 IAF is interested in working with any scheme owner which wishes to operate a third-party sector scheme provided that the criteria as described in Clauses 2.1 and 2.2 are fulfilled and additionally the sector scheme –

- i) is based upon a publicly available normative document(s) (e.g. for product, management system and/or persons) which has (have) been developed and will be reviewed and updated as required at appropriate intervals in an open and transparent manner, through a consensus process involving participation by interested parties, and is(are) set out preferably in separate normative documents from the conformity assessment requirements, in order to assist transparency, non-discrimination and open competition among conformity assessment bodies;
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- ii) has demonstrable clear international, regional or national market support;
- iii) is operated and administered in an open, non-discriminatory and transparent manner, avoiding conflicts of interest or limitation on the acceptance of conformity assessment bodies or accreditation bodies other than relevant technical considerations;
- iv) is based on the international standards for accreditation of conformity assessment bodies without any requirements which either contradict or exclude any of the requirements of the relevant accreditation standard;
- v) will make effective use of the expertise of IAF MLA signatories and the value of the IAF world wide MLA;
- vi) will use IAF application documents, with specific requirements for accreditation bodies and conformity assessment bodies which are prepared by IAF in co-operation with the scheme owner, where such documents are required as determined by IAF;
- vii) will involve accreditation bodies which are signatories of the IAF MLA in the operation of the scheme, and
- viii) agrees to make all normative documents relevant to its sector scheme available at a fair and reasonable cost for Members of IAF and their applicants/accredited bodies to adopt into their accreditation/conformity assessment programs.

4.1.3 From time to time IAF may develop supplementary policies in the application of the policy as described in Clause 4.1.2 in accordance with relevant rules of IAF.

4.2 Specific Procedure for Expansion of the Scope of the IAF MLA based on Privately Owned Sector Schemes

4.2.1 An application for a specific agreement with IAF shall be submitted to the IAF Secretary by the scheme owner, covering the proposed scheme. The application shall comprehensively explain the scope of the proposed scheme, any specific requirements, the interaction/ responsibilities to be assigned between the scheme owner and IAF and how the scheme complies with the IAF policy for endorsement of privately owned normative documents (itemized in Clause 4.1).

(Refer to Annex 2 for policy declarations, objective evidence and information on specific requirements to be provided in the application.)

4.2.2 The Executive Committee will appoint a Task Group consisting of the appointed IAF liaison sector representative, the scheme owner contact person, as well as the Chair

of the MLA Committee, Chair of the Technical Committee and Chair of the User Advisory Committee or their nominees and other persons as necessary, to review “Information covered in scheme owner Applications for Sector Schemes” with conclusion on the compliance with the specific requirements as described in Clauses 4.1 and 4.2.3 as well as the general criteria as described in Clause 2.1 and 2.2, for consideration by the Executive Committee.

(Refer to Annex 2 for comment on the compliance with the specific requirements as described in Clauses 4.1 and 4.2.3 and Section 1 of Annex 1 for the information to be provided for the conclusion on the compliance with the general criteria as described in Clause 2.1 and 2.2.)

4.2.3 An agreement with a scheme owner for a sector scheme will only be established if, in the opinion of the IAF Executive Committee, an application submitted by the scheme owner confirms that:

- i) the scheme owner’s proposed scheme meets the IAF policy for expansion of the scope of the IAF MLA based on privately owned sector schemes as set out in Clause 4.1 and it is clearly understood and accepted as to what IAF can and cannot provide;
- ii) the scheme owner agrees to contribute to the development and preparation of any requirements specific to its scheme in order to meet the scheme owner’s particular needs (if such specific requirements are needed);
- iii) the scheme owner agrees to appoint a liaison person to IAF for their scheme;
- iv) before the IAF endorsed sector scheme is changed, the scheme owner transmits the new draft version document(s) with a gap analysis and proposed transition plan for implementation of the new version document(s) to IAF in order to allow IAF to make sure, that the scheme continues to comply with the requirements of PL3.

Note: In order to ensure active participation in the sector scheme and cooperation by IAF Members, it is understood that the scheme owner would also have initiated an application for IAF membership.

4.2.4 The following actions shall be taken prior to granting of the Sector Scheme Agreement to the scheme owner:

- i) the Executive Committee will confirm that the person nominated as the representative of the scheme owner is correctly identified and that contact details are correct.

- ii) the Task Group appointed by the Executive Committee will develop an implementation plan/work program for the new sector scheme. This plan will include the identification of the needs and expectations of the sector scheme that can currently be met, and those needs and expectations that will require further scheme development.
 - iii) the Task Group will prepare and agree on any requirements of the MLA specific to the sector scheme. The analysis of the application, implementation plan/work program and draft agreement will be forwarded to the MLA Committee for review and comment.
 - iv) the Task Group will then forward the new scheme implementation plan/work program and agreement to the IAF Executive Committee for endorsement and subsequent ballot to all IAF members.
 - v) should IAF members approve the new scheme, IAF will incorporate the sector scheme into the MLA as a sub-scope by including the sector scheme in the list of IAF Endorsed Normative Documents, which can be found in IAF PR 4.
- 4.2.5 Following granting of the Sector Scheme Agreement to the scheme owner, the Executive Committee or its Task Group will meet with the representatives of each sector scheme as appropriate for a management review of the arrangements for the sector scheme. The representatives of the sector scheme will be invited to observe the relevant accreditation assessment and/or peer evaluation processes if it is defined in the relevant agreement between the scheme owner and IAF for the sector scheme.

Annex 4 provides a diagrammatic representation of the Section 4 procedure.

ANNEX 1**Proposal for inclusion of standards/normative documents in the IAF MLA**

General description/explanation of the proposed standards/normative documents (including the scope of the MLA for the standards/normative documents):

IAF Requirement		
1. General Criteria	Relevant PL 3 Clause	Descriptive information of how requirement is met or to be met*
a) Significant relevance to the accreditation of conformity assessment bodies under the scope of the IAF activities.	Clause 2.1 (i)	
b) Sufficient substance to enhance the recognition of professional competence.	Clause 2.1 (ii)	
c) Fulfils appropriate needs on an international, regional or national basis.	Clause 2.1 (iii)	
d) Lack of inclusion poses threats to IAF leadership in accreditation.	Clause 2.1 (iv)	
e) Complementary to or supportive of any of the other standards being currently used.	Clause 2.1 (v)	
f) Does not contradict any existing standard under the MLA.	Clause 2.1 (vi)	
g) Document must be produced by a consensus process.	Clause 2.1 (vii)	
h) A precondition for IAF expanding the IAF MLA into a new main scope shall be met, i.e. an international standard for accreditation of conformity	Clause 2.2 (Applicable for main scope only)	

assessment bodies has been developed and published which contains requirements applicable to the types of conformity assessment bodies other than those covered by the existing main scopes.		
2. Further Actions Required		Plan**
a) Need for the development of specific IAF application documents for inclusion of publicly owned standards/normative documents in the MLA.	Clause 3.3	
b) Need for additional preparation of peer evaluation.	Clause 3.3	

* Sufficient descriptive information as how the IAF requirement is met, or will be met by the publicly owned normative documents for inclusion in the MLA, is provided by the Technical Committee as per Clause 3.2. For the privately-owned sector schemes, the information is provided by the Task Group appointed by the Executive Committee as per Clause 4.2.2.

** The need for the development of specific IAF application documents for inclusion of publicly owned standards/normative documents in the MLA is proposed by the Technical Committee and the need for additional preparation of peer evaluation by the MLA Committee as per Clause 3.3.

ANNEX 2

Information covered in scheme owner's applications for Sector Scheme Endorsement

General description/explanation of the proposed sector scheme (please provide information on its scope, any specific requirements for the relevant scope of the MLA, the interaction/responsibilities to be assigned between the scheme owner and IAF and any other information relevant to the scheme's operation):

IAF Requirement	Relevant PL 3 Clause	Results	Comment**
1. Objective Evidence		Explanation/evidence of how requirement is met or to be met*	
a) Evidence of the scheme owner representing a substantial part of the affected sector and market impact of the sector scheme.	Clause 4.1.1		
b) Evidence that normative document(s) of the sector scheme (e.g. for specific product, management system and/or persons) has(have) been developed and will be reviewed and updated as required at appropriate intervals in an open and transparent manner, through a consensus process involving participation by interested parties and is publicly available.	Clause 4.1.2 (i)		

c) Evidence that the sector scheme has clear international, regional or national market support.	Clause 4.1.2 (ii)		
d) Evidence of operating and administrating in an open, non-discriminatory and transparent manner, avoiding conflicts of interest or limitation on the acceptance of conformity assessment bodies or accreditation bodies other than relevant technical considerations.	Clause 4.1.2 (iii)		
e) Evidence that the sector scheme is based on the international standards for accreditation of conformity assessment bodies without any requirements which either contradict or exclude any of the requirements of the relevant accreditation standard.	Clause 4.1.2 (iv)		
2. Policy Declarations		Scheme owner to declare how the IAF Policy requirements will be met	
a) Intends to make effective use of the expertise of IAF MLA signatories and the value of the IAF world-wide MLA.	Clause 4.1.2 (v)		
b) Intends to use IAF application documents, with specific requirements for	Clause 4.1.2 (vi)		

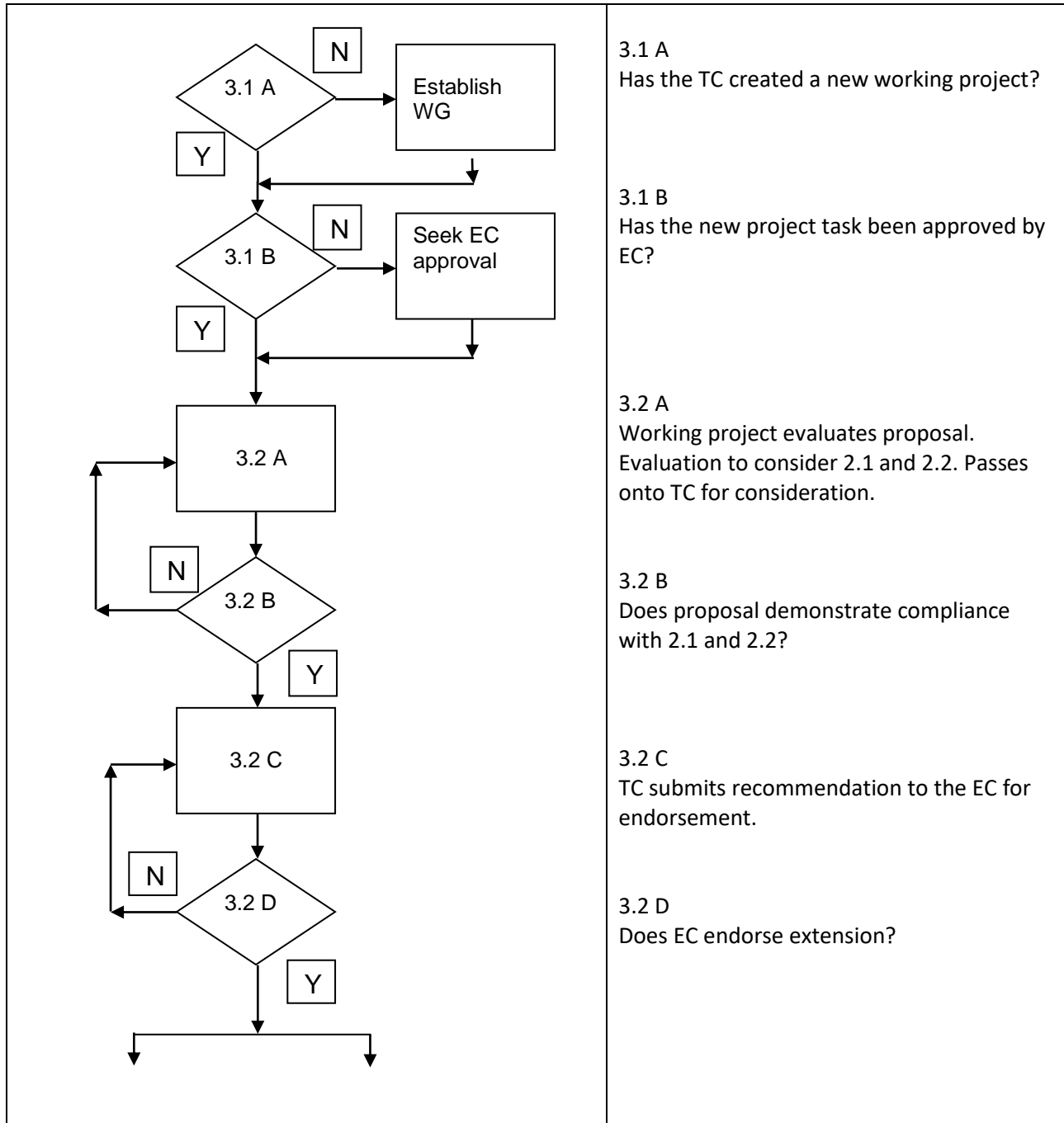
accreditation bodies and conformity assessment bodies which are prepared by IAF in co-operation with the scheme owner, where such documents are required as determined by IAF.			
c) Intends to involve the accreditation bodies which are signatories of the IAF MLA in the operation of the scheme.	Clause 4.1.2 (vii)		
d) Agrees to make all normative documents relevant to its sector scheme available at a fair and reasonable cost for Members of IAF and their applicants/accredited bodies to adopt into their accreditation/conformity assessment programs.	Clause 4.1.2 (viii)		
e) Understands what IAF can and can not provide	Clause 4.2.3 (i)		
f) Agrees to contribute to the development of specific requirements for accreditation bodies and conformity assessment bodies for the sector scheme if needed.	Clause 4.2.3 (ii)		
3. Specific Requirements		Information to be provided by scheme owner	
a) Specific requirements for accreditation bodies and	Clause 4.2.3 (ii)		

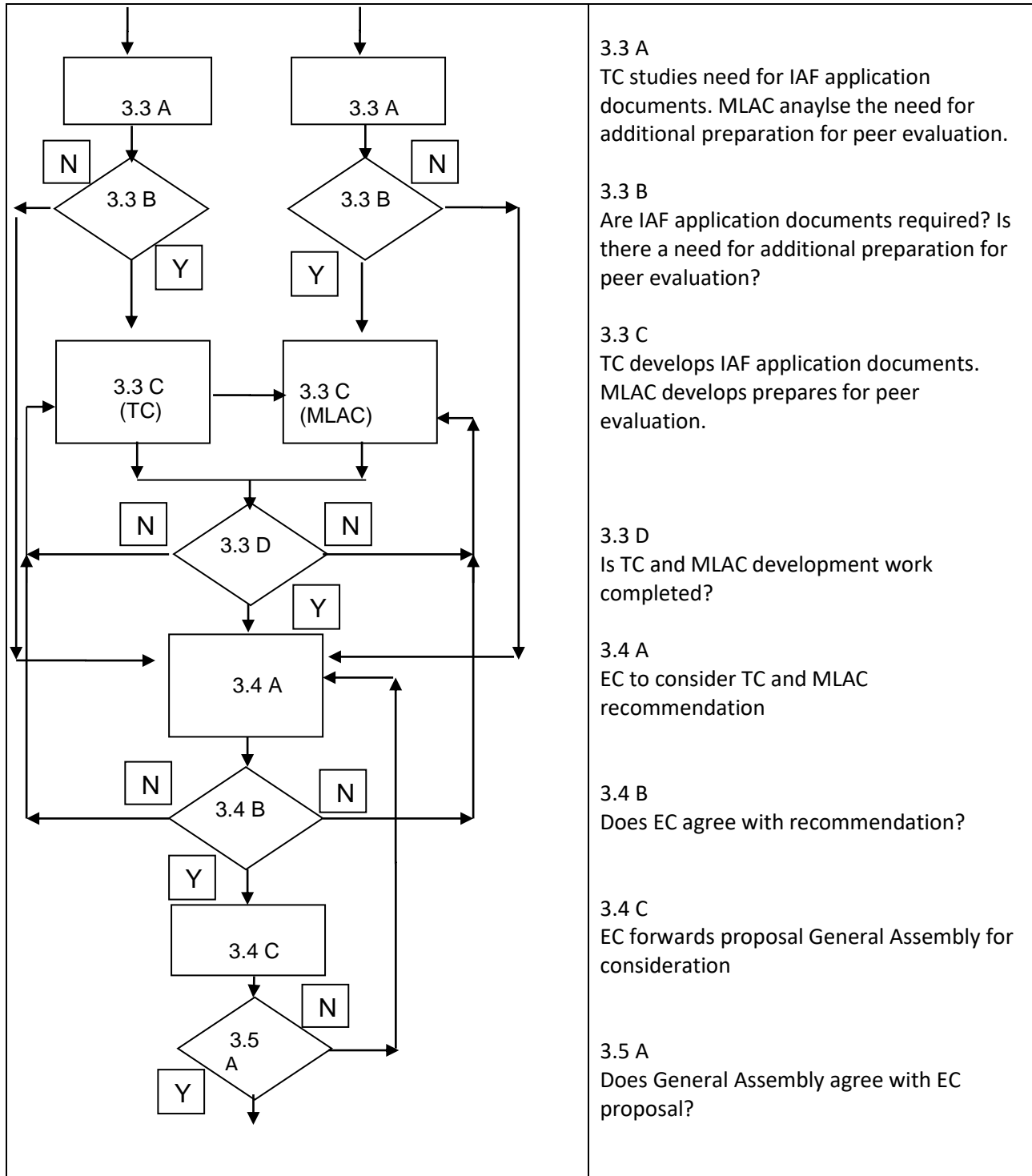
conformity assessment bodies prescribed by the sector scheme (if any).			
b) Need for IAF to develop specific requirements for accreditation bodies and conformity assessment bodies for the sector scheme.	Clause 4.2.3 (ii)		
c) scheme owner liaison representative's name and contact details.	Clause 4.2.3 (iii)		
d) scheme owner agrees to provides new draft version document(s) with a gap analysis <u>and proposed transition plan for implementation of the new version</u> document(s) to IAF in order to allow IAF to make sure, that the scheme continues to comply with the requirements in PL3.	Clause 4.2.3 (iv)		

*Information and/or documented evidence as to how the IAF requirements are met, or will be met by the sector scheme, are to be submitted to the IAF Secretary by the scheme owner.

**Comment is filled in by the Task Group appointed by the Executive Committee as per Clause 4.2.2.

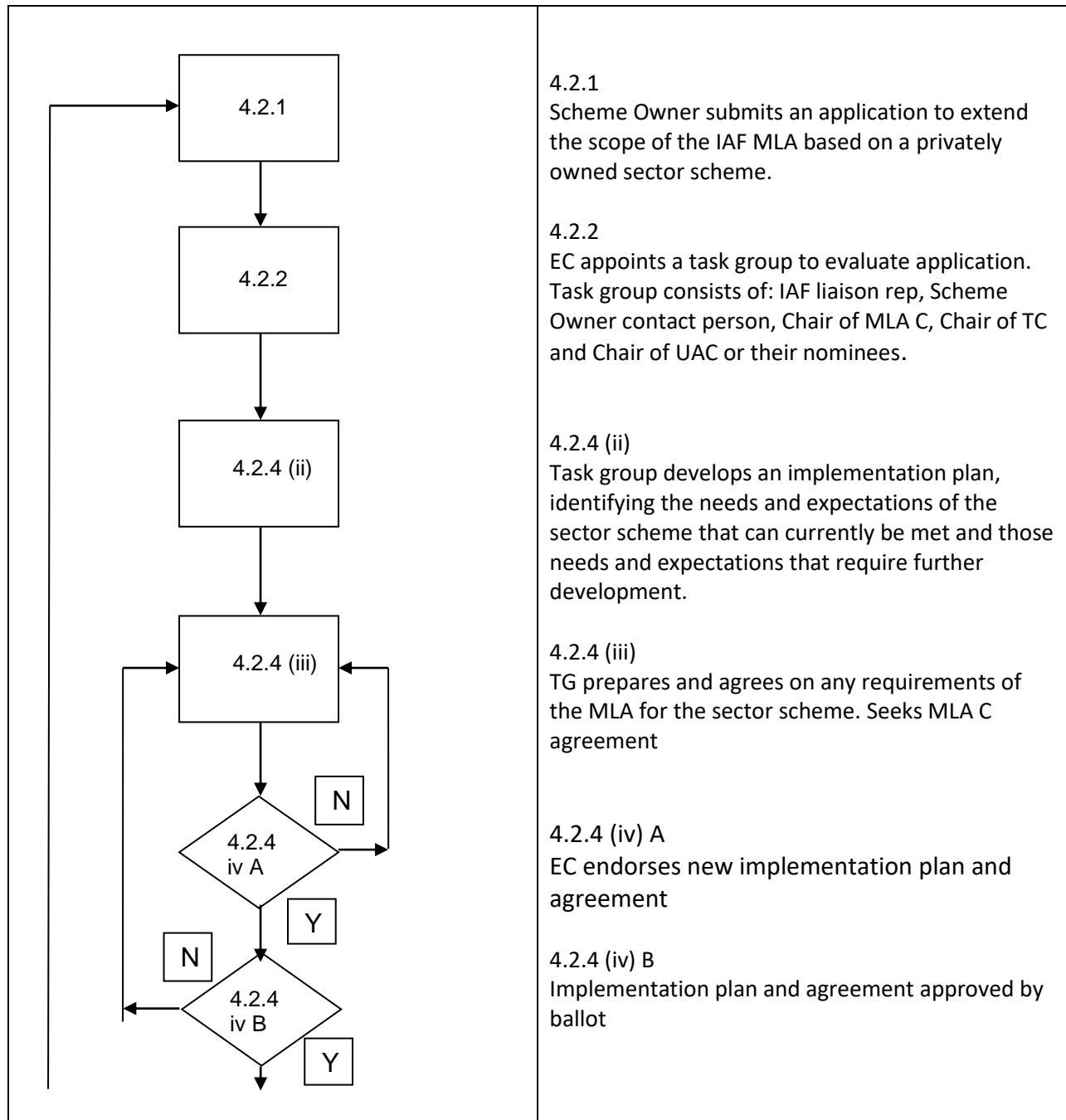
**ANNEX 3
Section 3 Flow Chart**

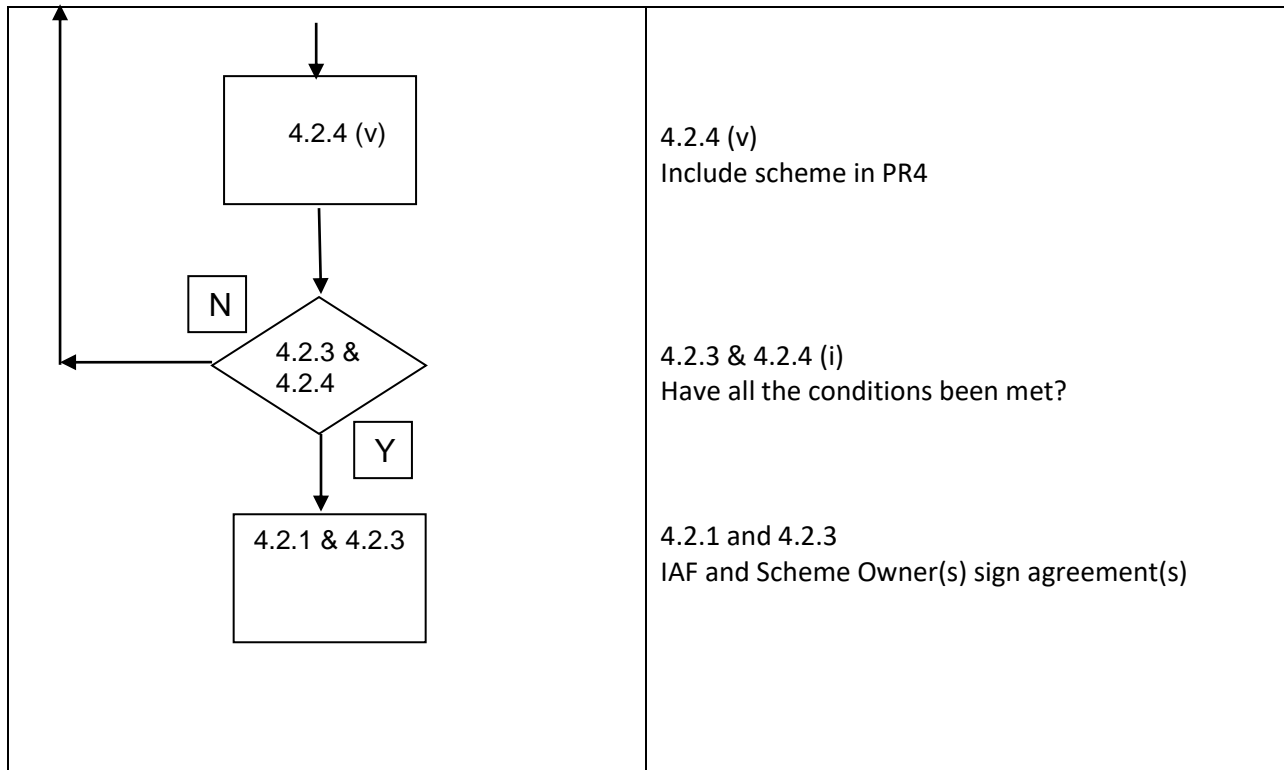




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ANNEX 4 Section 4 Flow Chart





End of IAF Policies and Procedures for Expansion of the scope of the IAF MLA.