



INAB Mandatory and Guidance Documents - Policy and Index

DC1

This publication is aimed at assisting in determining what documents are relevant to various organisations and at providing contact points for accessing such documents.

- 1) ISO/IEC standards are available only from SAI Global.

SAI Global are the official distributor of NSAI Standards contact details:

SAI Global, c/o NSAI, 1 Swift Square, Northwood, Santry, Dublin 9
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Web: <http://www.standards.ie>

- 2) European Co-operation for Accreditation (EA) publications are available from

Web: <http://www.european-accreditation.org>

EA-INF/01 lists all current EA publications.

- 3) International Laboratory Co-operation (ILAC) ILAC publications are available from

Web: <http://ilac.org/>

- 4) International Accreditation Forum (IAF) publications are available from

Web: <http://www.iaf.nu>

- 5) Notified Bodies - useful link for information

https://ec.europa.eu/commission/index_en

- 6) All other documents are available on the INAB website at

Web: <http://www.inab.ie>

Organisations are required to ensure that they keep informed of relevant INAB notifications maintained on the INAB Website (<http://www.inab.ie/Documents-Forms/>). Organisations are also required to ensure that they keep informed of EA, ILAC and IAF publications relevant to their areas of activity. CABs are not required to keep controlled copies of INAB documents; all that is required is that the CAB needs to identify if any changes were needed, and to have evidence that appropriate changes were made to the CAB's management system.

INAB Policy on Mandatory and Guidance Documents

1) Purpose

This statement outlines the Irish National Accreditation Board's policy regarding mandatory and guidance documents for accredited and applicant organisations.

2) Guidance Documents

Guidance documents represent preferred practice in applying relevant standards and are produced as a means of promoting a consistent approach to accreditation. The approaches taken are not mandatory and are for the guidance of the national accreditation bodies and their clients. Please note that some INAB and international publications entitled 'guidance' do contain mandatory requirements and are identified as such in this document.

3) Mandatory Documents

- a. Applicant and accredited organisations shall comply with the INAB, EA, ILAC and IAF mandatory requirement publications as listed in this document. These documents specify **mandatory** requirements for INAB applicant and accredited CABs and will be assessed as part of INAB's accreditation process.
- b. Applicant and accredited organisations shall ensure that mandatory requirements are incorporated and implemented into the quality system.
- c. New documents or revisions are applicable from date of publication, unless otherwise noted.

Glossary - INAB Publications

LA = Laboratory Accreditation

CB = Certification Body Accreditation

IB = Inspection Body Accreditation

RM = Reference Material Producers

NB = Notified Body

CRM = Client Relationship Management

GLP = Good Laboratory Practice

V/V = Validation/Verification Bodies

BB = Biobanking

4) Contact

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

Phone: +353 1 614 7182

E-mail: inab@inab.ie Website: www.inab.ie

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ISO/IEC standards are available from www.standards.ie

INTERNATIONAL MANDATORY DOCUMENTS

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
ISO 15189	Medical laboratories - Particular requirements for quality and competence	3	Nov 2012	√						
ISO 15189	Medical laboratories – Requirements for quality and competence (Implementation deadline 06/12/2025. This new revision also replaces ISO 22870:2016)	4	Dec 2022	√						
ISO 22870	Point -of-care Testing (POCT) - Requirements for quality and competence. (Replaced by ISO 15189:2022)	2	Nov 2016	√						
ISO 20387	Biotechnology - Biobank - general requirements for biobanking	1	Aug 2018					√		
ISO/IEC 17020	Conformity assessment - Requirements for the operation of various types of bodies performing inspection	2	Mar 2012			√				
ISO/IEC 17021-1	Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements	3	Jun 2015		√					
ISO/IEC TS 17021-2	Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 2: Competence requirements for auditing and certification of environmental management systems	1	Dec 2016		√					
ISO/IEC TS 17021-3	Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 3: Competence requirements for auditing and certification of quality management systems	1	Mar 2017		√					
ISO/IEC TS 17021-10	Conformity assessment -- Requirements for bodies providing audit and certification of management systems -- Part 10: Competence requirements for auditing and certification of occupational health and safety management systems	1	Mar 2018		√					
ISO/IEC 17024	Conformity assessment – General requirements for bodies operating certification of persons	2	July 2012		√					
ISO/IEC 17025	General Requirements for the competence of testing and calibration laboratories	3	Nov 2017	√						

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ISO/IEC standards are available from www.standards.ie

INTERNATIONAL MANDATORY DOCUMENTS

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
ISO/IEC 17029	Conformity assessment – General principles and requirements for validation and verification bodies	1	Oct 2019							√
ISO/IEC 17065	Conformity Assessment - Requirements for bodies certifying products, processes and services.	1	Sep 2012		√					
ISO 17034	General requirements for the competence of reference material producers	1	Nov 2016				√			
ISO 22003-1	Food Safety Management Systems - Requirements for bodies providing audit and certification of food safety management systems.	1	June 2022		√					
ISO/IEC 27006	Information technology - Security techniques-Requirements for bodies providing audit & certification of information security management systems. (Withdrawn)	3	Sep 2015		√					
ISO/IEC 27006-1:2024	Information security, cybersecurity and privacy protection – Requirements for bodies providing audit and certification of information security management systems	1	Mar 2024		√					
ISO 50003	Energy management systems – Requirements for bodies providing audit and certification of energy management systems	2	May 2021		√					

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IAF publications are available from www.iaf.nu and ILAC publications are available from <https://ilac.org/>

INTERNATIONAL MANDATORY DOCUMENTS

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
IAF MD 1	IAF Mandatory Document for the Audit and Certification of a Management System operated by a Multi-Site organisation (Application date 18 th October 2023)	Issue 3 Version 1	Oct 2023		√					
IAF MD 2	IAF Mandatory Document for the Transfer of Accredited Certification of Management Systems	Issue 2 Version 2	Jun 2023		√					
IAF MD 4	IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes	Issue 2 Version 4	Jun 2023		√					√
IAF MD 4	Mandatory Document for the Use of Information and Communication Technology (ICT) for Conformity Assessment Purposes (Application date 30 th Jan 2026)	Issue 3 Version 1	Jan 2025		√					√
IAF MD 5	Determination of Audit Time of Quality, Environmental, and Occupational Health & Safety Management Systems	Issue 4 Version 3	Jun 2023		√					
IAF MD 6	IAF Mandatory Document for the Application of ISO 14065:2020	Issue 3 Version 2	Sep 2024							√
IAF MD 9	IAF MD 9:2022 Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)	Issue 5 Version 1	Nov 2023		√					
IAF MD 11	IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS) (Application date 12 th September 2023)	Issue 3 Version 1	Sep 2023		√					
IAF MD 15	IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance	Issue 1 Version 2	Jun 2023		√					
IAF MD 17	Witnessing Activities for the Accreditation of Management Systems Certification Bodies	Issue 2 Version 2	Jun 2023		√					
IAF MD 22	Application of ISO/IEC 17021-1 for the certification of occupational health and safety management systems (OH&SMS)	Issue 2 Version 2	Jun 2023		√					

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IAF publications are available from www.iaf.nu and ILAC publications are available from <https://ilac.org/>

INTERNATIONAL MANDATORY DOCUMENTS

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
IAF MD 23	Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies	Issue 2 Version 1	Dec 2023		√					
IAF MD 24	Transition Requirements for ISO 50003:2021	Issue 1 Version 2	Jun 2023		√					
IAF MD 25	Criteria for Evaluation of Conformity Assessment Schemes	Issue 1 Version 2	Jun 2023		√					√
IAF MD 26	Transition Requirements for ISO/IEC 27001:2022	Issue 2 Version 1	Feb 2023		√					
IAF MD 28	Mandatory Document for the Upload and Maintenance of Data on IAF Database	Issue 1 Version 1	Oct 2023		√					
IAF MD 29	Transition Requirements for ISO/IEC 27006-1:2024	Issue 1 Version 1	May 2024		√					
ILAC-G21	Cross Frontier Accreditation- Principles for Cooperation		Sep 2012	√		√		√		
ILAC-P09	ILAC Policy for Proficiency Testing and/or Interlaboratory comparisons other than Proficiency Testing	2	Jan 2024	√						
ILAC-P10	ILAC Policy on Metrological Traceability of Measurement Results	07-20	Jul 2020	√			√	√		
ILAC-P14	ILAC Policy for Measurement Uncertainty in Calibration	09-20	Sep 2020	√			√	√		
ILAC-P15	ILAC Policy for Application of ISO 17020:2012 for the Accreditation of Inspection Bodies	05-20	May 2020			√				

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EA publications are available from www.european-accreditation.org

INTERNATIONAL MANDATORY DOCUMENTS

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
EA-1/22A	EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members	5	May 2023		✓					
EA 2/13 M	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members	2	May 2019	✓	✓	✓	✓	✓		✓
EA 2/15 M	EA Requirements for the Accreditation of Flexible Scopes	2	Nov 2023	✓	✓	✓	✓			✓
EA 2/17 M	EA Document on Accreditation for Notification Purposes	4	Apr 2020	✓	✓	✓				
EA-3/01 M	EA Conditions for the use of Accreditation Symbols, Logos and other claims of accreditation and reference to the EA MLA Signatory status	8	Jun 2025	✓	✓	✓	✓	✓		✓
EA 3/12 M	EA Policy for the Accreditation of Organic Production Certification	2	Mar 2022		✓					
EA 4/02 M	Evaluation of the Uncertainty of Measurement In Calibration	3	Apr 2022	✓			✓	✓		
EA 4/17 M	Description of scopes of accreditation for medical laboratories	1	Feb 2022	✓						
EA 6/02 M	EA Guidelines on the use of ISO/IEC 17065 and ISO/IEC 17021-1 for Certification to EN ISO 3834	3	Jan 2022		✓					
EA 6/03 M	EA document for accreditation of Verification Bodies for the purpose of EU ETS Directive	5	Jun 2022							✓
EA 7/04 M	EA Legal Compliance as a part of Accredited ISO 14001:2015 certification	3	May 2017		✓					

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INAB publications are available from www.inab.ie

MANDATORY

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
DC1	INAB Mandatory and Guidance Documents - Policy and Index	87	Jun 2025	√	√	√	√	√	√	√
R1	INAB Regulations	28	May 2025	√	√	√	√	√		√
TC	INAB Terms and Conditions	11	May 2025	√	√	√	√	√		√
TC-SO	INAB Terms and Conditions for Scheme Owners	1	Jan 2022		√					√
AML-BB	Minimum Requirements for Blood Bank Compliance with Article 14 (Traceability) and Article 15 (Notification of Serious Adverse Reactions and Events) of EU Directive 2002/98/EC	7	May 2025	√						
COMMISSION REGULATION (EU) No 600/2012	Commission Regulation 600/2012 on the verification of greenhouse gas emission reports and tonne-kilometre reports and the accreditation of verifiers pursuant to Directive 2003/87/EC of the European Parliament and of the Council Text with EEA relevance Associated EU Commission guidance documents are available from http://ec.europa.eu/clima/policies/ets/monitoring/documentation_en.htm		Jun 2012							√
PS7F1	Annual reporting - Annual metrics for certification, inspection and validation/verification bodies	8	Nov 2024		√					√
PS10F1	CAB Checklist for PS 10 Submission	9	Jun 2024	√	√	√	√	√	√	√
AG 4	Template Agreement between INAB and National Authorities	8	Dec 2024	√	√	√				

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
Policy Statement No. 1	Policy on proficiency testing	15	Jun 2024	✓		✓		✓		
Policy Statement No. 3	Policy for laboratories performing tests on biological agents	10	Nov 2023	✓				✓		
Policy Statement No. 4	Performance reports	6	Jun 2021	✓						
Policy Statement No. 5	Policy on measurement traceability	10	Jun 2024	✓		✓	✓	✓		
Policy Statement No. 6	INAB policy on unannounced visits to INAB accredited organisations	10	Jan 2023	✓	✓	✓	✓	✓		✓
Policy Statement No. 7	INAB policy on annual reporting by certification and validation/verification bodies for risk-based assessment planning	14	May 2025		✓			✓		✓
Policy Statement No. 8	Code of conduct for assessment visits	9	Jan 2021	✓	✓	✓	✓	✓	✓	✓
Policy Statement No. 10	Submission of documentation in advance of an INAB assessment visit	24	Jun 2024	✓	✓	✓	✓	✓		✓
Policy Statement No. 11	Flexible scope of accreditation for ISO 17025 and ISO 15189 testing laboratories.	9	Jun 2024	✓						
Policy Statement No. 12	Policy for accredited organisations undertaking work in an area which is regulated by legislation	4	Oct 2018	✓	✓	✓	✓			✓
Policy Statement No. 14	Policy on assessment of quality system documentation and data in an electronic environment	6	Jun 2021	✓	✓	✓	✓	✓		✓
Policy Statement No. 15	Guide to method validation for quantitative analysis in chemical testing laboratories	6	Mar 2019	✓			✓	✓		
Policy Statement No. 17	Principles for the assessment and accreditation for sampling methods	5	May 2025	✓		✓				
Policy Statement No. 18	Policy on the evaluation of conformity assessment schemes	6	May 2025		✓	✓				✓
Policy Statement No. 19	Policy on the accreditation and assessment of multisite Conformity Assessment Bodies (CABs)	8	Jan 2022	✓	✓	✓	✓	✓		✓
Policy Statement No. 21	Accreditation of Reference Material Producers	4	Jan 2023				✓			

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
Policy Statement No. 22	Policy on witnessing activities and scope management for Certification and Verification Bodies	9	May 2025		✓	✓				✓
Policy Statement No. 23	INAB policy on the provision of accredited services	5	Oct 2022	✓	✓	✓		✓		✓
Policy Statement No. 24	Minimum verification requirements for ISO 17025 & ISO 15189 testing laboratories	3	May 2025	✓						
Policy Statement No. 25	Policy on stakeholder feedback to INAB	5	May 2025	✓	✓	✓	✓	✓	✓	✓
Policy Statement No. 26	INAB policy on impartiality	4	Jun 2024	✓	✓	✓	✓	✓	✓	✓
Policy Statement No. 27	INAB policy statement on scope format for calibration laboratories	3	Nov 2023	✓	✓	✓	✓		✓	
Policy Statement No. 28	Assessment and accreditation of Opinions and Interpretations using ISO 17025:2017.	2	Jun 2021	✓						
Policy Statement No. 29	Policy for the accreditation of Whole Genome Sequencing (WGS) and Next Generation Sequencing (NGS) techniques.	1	Oct 2019	✓				✓		
Policy Statement No. 30	Policy on legal entities	1	Jul 2020	✓	✓	✓	✓	✓	✓	✓
Policy Statement No. 31	Policy for accreditation of Point of Care testing (POCT)	3	Nov 2023	✓						
Policy Statement No. 32	Policy on laboratory refurbishments/renovations/relocations and the movement of new and existing laboratory equipment (ISO/IEC 17025 & ISO 15189)	4	May 2025	✓				✓		
Policy Statement No. 34	Policy statement on scope format for testing laboratories accredited to ISO 17025	3	May 2025	✓						
Policy Statement No. 35	Policy statement on scope format for testing laboratories accredited to ISO 15189	2	Jan 2022	✓						
Policy Statement No. 36	Policy statement on calculated methods	1	Jan 2022	✓						
Policy Statement No. 37	INAB Policy on Fraudulent Behaviour	1	May 2025	✓	✓	✓	✓	✓	✓	✓

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GUIDANCE

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
ES04	EMAS Graphic and Statement	7	Dec 2016							
GD01	Guidance on consultants contracts for ISO 15189 laboratories and assessors	3	May 2018	✓						
GD03	INAB guidance on the establishment of CABs in Ireland for the purposes of accreditation.	4	Jul 2022	✓	✓	✓	✓	✓	✓	✓
GD04	INAB guidance on assessment planning	9	May 2025	✓	✓	✓	✓	✓	✓	✓
GD05	INAB Notice on Accreditation to ISO/IEC 17029:2019	4	May 2025		✓					✓
GLP Manual	INAB GLP Compliance Monitoring Programme	14	Nov 2023						✓	
P7	INAB assessment procedures	23	Jun 2024	✓	✓	✓	✓	✓	✓	✓
<u>SCHEDULE OF FEES</u>										
Fee-Sched-1	INAB Fee Schedule	7	Jan 2025	✓	✓	✓	✓	✓	✓	✓
<u>DIRECTORIES</u>										
D1	Directory of INAB Registered Organisations		Current Edition	✓	✓	✓	✓	✓	✓	✓

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APPLICATION FORMS

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
AF-1-F	Organisation Change Information Form	10	May 2025	✓	✓	✓	✓	✓		✓
AF-3-B	Application for review of new conformity assessment schemes	9	Jun 2024		✓	✓				✓
AF-3-E	Application for Foreign Verifiers operating in Ireland	2	May 2023		✓					✓
AF108	CAB Self-Assessment Record & INAB Contract review	6	Nov 2023	✓	✓	✓	✓	✓	✓	✓

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
CRM 2	INAB CAB Portal User Guide (Available in INAB CAB Portal Library)	7	May 2022	✓	✓	✓	✓	✓		
CRM FS-14	Interpreting INAB Scopes of Accreditation	8	May 2025	✓	✓	✓	✓	✓		
CRM FS-20	How do I apply for a flexible scope on my existing accredited scope?	1	Apr 2018							
ST1CRM	Acoustic and vibration testing classification	2	Sep 2019	✓						
ST2CRM	Biological and veterinary testing classification	4	Jun 2021	✓						
ST3CRM	Chemical testing classification	3	Jun 2021	✓						
ST4CRM	Construction testing classification	6	Jun 2021	✓						
ST5CRM	Mechanical testing classification	4	Sep 2019	✓						
ST6CRM	Medical testing classification	7	Jan 2023	✓						
ST7CRM	Management systems certification bodies classification	7	May 2025		✓					
ST8CRM	Metrology -Calibration classification	3	Nov 2023	✓						
ST9CRM	Inspection Bodies classification	4	Jan 2023			✓				
ST10CRM	Heat Temperature & Humidity classification	2	Sep 2019	✓						
ST11CRM	Verification GHG Body	3	Jan 2022							✓
ST12CRM	Product certification classification	6	Jan 2023		✓					
ST13CRM	Personnel certification classification	5	Jan 2023		✓					
ST14CRM	Forensic science classification	3	May 2025	✓						
ST15CRM	Reference Material Producers classification	4	Jan 2023				✓			
ST16CRM	Optical testing classification	2	Sep 2019	✓						

ST17CRM	Electrical testing classification	3	Feb 2022	√						
ST18CRM	NDT testing classification	2	Sep 2019	√						

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
ST19CRM	Radiometry testing classification	2	Sep 2019	√						
ST20CRM	Inspection Body Notified Body classification	4	Sep 2019			√				
ST21CRM	Management System Notified Body classification	4	Sep 2019		√					
ST22CRM	Laboratory Notified Body classification	3	Oct 2019	√						
ST23CRM	Product Certification Notified Body classification	5	Jul 2024		√					
ST24CRM	Persons Certification Notified Body classification	6	Jun 2021		√					
ST25CRM	Biobanking classification	1	Jan 2022					√		
ST26CRM	Validation and verification bodies scope classification	1	Apr 2021							√

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PUBLICITY

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	BB	GLP	V/V
	The Irish National Accreditation Board Brochure		Current Edition	✓	✓	✓	✓	✓	✓	
	INAB Newsletter		Current Edition	✓	✓	✓	✓	✓	✓	
	EA Brochure		Current Edition	✓	✓	✓	✓	✓		
	ILAC Promotional Documents https://ilac.org/publicationslist.html		Current Editions	✓	✓	✓	✓	✓		
	IAF Promotional Documents http://www.iaf.nu/articles/Promotional_Documents/25		Current Editions	✓	✓	✓	✓	✓		
	IAF ML 2: 2023 General Principles on the Use of the IAF MLA Mark	4	May 2023		✓	✓				
	ILAC-R7:05/2015 Rules for the Use of the ILAC MRA Mark		May 2015	✓	✓	✓	✓	✓		