

INAB Mandatory and Guidance Documents - Policy and Index

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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
Publication Sales: info@standards.ie

Tel: (01) 8576730

Fax: (01) 8576729

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.

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

4) Contact

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

Phone: +353 1 614 7000

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	GLP Programme	V/V
ISO 15189	Medical laboratories - Particular requirements for quality and competence	3	Nov 2012	√					
ISO 22870	Point -of-care Testing (POCT) - Requirements for quality and competence.	2	Nov 2016	√					
ISO 17020	Conformity assessment - Requirements for the operation of various types of bodies performing inspections.	2	Mar 2012			√			
ISO 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 17024	Conformity Assessment -General requirements for bodies operating certification schemes for persons	2	July 2012		√				
ISO 17025	General Requirements for the competence of testing and calibration laboratories	2	May 2005	√					
ISO 17025	General Requirements for the competence of testing and calibration laboratories (3 year transition period to Nov 2020).	3	Nov 2017	√					
ISO 17029	Conformity assessment – General principles and requirements for validation and verification bodies	1	Oct 2019						√
ISO 17065	Conformity Assessment - Requirements for bodies certifying products, processes and services.	1	Sep 2012		√				

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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	GLP Programme	V/V
ISO 22000:2018	Food safety management systems -- Requirements for any organization in the food chain (Transition deadline 19 June 2021)		Jun 2018		√				
ISO 50001:2018	ISO 50001:2018 Energy management systems -- Requirements with guidance for use (Transition deadline for CBs 21 February 2020)		Aug 2018		√				
ISO 17034	General requirements for the competence of reference material producers	1	Nov 2016				√		
ISO/TS 22003	Food Safety Management Systems - Requirements for bodies providing audit and certification of food safety management systems.	2	Dec 2013		√				
ISO/IEC 27006	Information technology - Security techniques-Requirements for bodies providing audit & certification of information security management systems.	3	Sep 2015		√				
ISO 50003	Energy management systems - Requirements for bodies providing audit and certification of energy management systems.	1	Oct 2014		√				

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IAF publications are available from www.iaf.nu and ILAC publications are available from https://ilac.org/									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>INTERNATIONAL MANDATORY DOCUMENTS</u>									
IAF MD 1:2018	IAF Mandatory Document for the Audit and Certification of a Management System operated by a Multi-Site organisation	2	Jan 2018		√				
IAF MD 2:2017	Transfer of Accredited Certification of Management Systems	2	Jun 2017		√				
IAF MD 3:2008	Advanced Surveillance and Recertification Procedures (ASRP) Withdrawn - This document was withdrawn 31 October 2019 in accordance with IAF Resolution 2019-16. Certification bodies will have one year following withdrawal (i.e. 31 October 2020), to transition their certified organizations away from IAF MD3.	1	Feb 2008		√				
IAF MD 4:2018	IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes	2	Jul 2018		√				√
IAF MD 5:2019	Determination of audit time of quality and environmental management systems	4	Nov 2019		√				
IAF MD 9:2017	Application of ISO/IEC 17021-1 in the Field of Medical Device Quality Management Systems (ISO 13485)	3	June 2017		√				
IAF MD 10:2013	Assessment of Certification Body Management of Competence in Accordance with ISO 17021:2011	1	Feb 2013		√				
IAF MD 11:2013	IAF Mandatory Document for Application of ISO/IEC 17021 for Audits of Integrated Management Systems (IMS)	1	Dec 2013		√				
IAF MD 11:2019	Application of ISO/IEC 17021-1 for Audits of Integrated Management Systems (application from 17 January 2021)	2	Jul 2019		√				
IAF MD 15:2014	IAF Mandatory Document for the Collection of Data to Provide Indicators of Management System Certification Bodies' Performance	1	Jul 2014		√				
IAF MD 16:2015	Application of ISO/IEC 17011 for the Accreditation of Food Safety Management Systems (FSMS) Certification Bodies	1	Jan 2015		√				
IAF MD 17:2019	IAF Mandatory Document for witnessing activities for the accreditation of management system CBs.	2	May 2019		√				

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IAF publications are available from www.iaf.nu and ILAC publications are available from https://ilac.org/									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>INTERNATIONAL MANDATORY DOCUMENTS</u>									
IAF MD 22 :2019	Application of ISO/IEC 17021-1 for the certification of occupational health and safety management systems (OH&SMS) (application from 07 May 2020)	2	May 2019		√				
IAF MD 23:2018	Control of Entities Operating on Behalf of Accredited Management Systems Certification Bodies	1	May 2018		√				
ILAC-G21	Cross Frontier Accreditation- Principles for Cooperation		Sep 2012	√		√			
ILAC-P09	ILAC Policy for Participation in National and International Proficiency Testing Activities	1	Jun 2014	√					
ILAC-P10	ILAC Policy on Traceability of Measurement Results	1-13	2013	√			√		
ILAC-P14	ILAC Policy for Uncertainty in Calibration	1-13	2013	√			√		
ILAC-P15	ILAC Policy for Application of ISO 17020:2012 for the Accreditation of Inspection Bodies The implementation date for ILAC P15:05/2020 is 18 months from the date of publication on the ILAC website (ie November 2021)	05-20	May 2020			√			

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EA publications are available from www.european-accreditation.org									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
INTERNATIONAL MANDATORY DOCUMENTS									
EA-1/22	EA Procedure and Criteria for the Evaluation of Conformity Assessment Schemes by EA Accreditation Body Members	4	Apr 2020		√				
EA 2/13 M	EA Cross Border Accreditation Policy and Procedure for Cross Border Cooperation between EA Members	2	May 2019	√	√	√	√		√
EA 2/13 M S1:2013	Supplement 1 to EA 2/13		Aug 2013	√	√	√	√		√
EA 2/15 M	EA Requirements for the Accreditation of Flexible Scopes	1	Apr 2019	√	√	√	√		√
EA 2/17 M	EA Document on Accreditation for Notification Purposes	3	Nov 2016	√	√	√			
EA 2/17 M	EA Document on Accreditation for Notification Purposes Date of Implementation: April 2021, see transition period below Within one year from publication, all NABs shall have procedures in place to implement the requirements of this document. Within three years from publication, all CABs accredited for the purpose of notification shall comply with this document.	4	Apr 2020	√	√	√			
EA-2/20 G	EA Guidance on Consultancy, and the Independence of Conformity Assessment Bodies Date of implementation: April 2021 (one year from publication)	0	Apr 2020	√	√	√			
EA 3/12 M	EA Policy for the Accreditation of Organic Production Certification	0	Jun 2013		√				
EA 3/13 M	EA Document on the Application of ISO/IEC 17021-1 for the certification for occupational health and safety management systems (Application from 20 th June 2019).	0	Jun 2016		√				
EA 4/02 M	Expressions of the Uncertainty of Measurement in Calibration	1	Sep 2013	√			√		
EA 4/17 M	EA Position Paper on the description of scopes of accreditation of medical laboratories	0	Dec 2008	√					
EA 6/02 M	EA Guidelines on the Use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834	1	Jun 2013		√				
EA 6/03 M	EA Guidance for Recognition of Verification Bodies under EU ETS Directive	4	Nov 2013						√

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EA publications are available from www.european-accreditation.org									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>INTERNATIONAL MANDATORY DOCUMENTS</u>									
EA 6/04 M	EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites	1	Jul 2011		√				
EA 7/04 M	EA Legal Compliance as a part of Accredited ISO 14001:2015 certification	3	May 2017		√				

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
MANDATORY									
DC1	INAB Mandatory and Guidance Documents - Policy and Index	79	Jul 2020	√	√	√	√	√	√
R1	R1 INAB Regulations	21	Jul 2020	√	√	√	√		√
TC	INAB Terms and Conditions	8	Jul 2020	√	√	√	√		√
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	3	Dec 2018	√					
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	Form to Capture Certificate Activities for all CBs	6	Oct 2019		√				√
PS10F1	CAB Checklist for PS 10 Submission	7	Jul 2020	√	√	√	√	√	√
AG 4	Template Agreement between INAB and National Authorities	5	Jan 2020	√	√	√			
RM-IB	Risk Management Inspection Body Form	2	Nov 2017			√			

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INAB publications are available from www.inab.ie									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>POLICY</u>									
Policy Statement No. 1	Proficiency Testing	11	Sep 2018	√					
Policy Statement No. 3	Policy for Laboratories Performing Tests on Biological Agents	7	Nov 2018	√					
Policy Statement No. 4	Performance Reports	5	Mar 2017	√					
Policy Statement No. 5	Traceability of Measurement	8	Jul 2020	√		√	√		
Policy Statement No. 6	INAB Policy on Unannounced Visits to INAB Accredited Organisations	8	Oct 2019	√	√	√	√		√
Policy Statement No. 7	INAB policy on annual reporting and cross frontier accreditation	12	Oct 2019		√				√
Policy Statement No. 8	Code of Conduct for Assessment Visits	8	Oct 2017	√	√	√	√	√	√
Policy Statement No. 10	Submission of Documentation to INAB in preparation for INAB assessment.	19	Jul 2020	√	√	√	√		√
Policy Statement No. 11	Flexible Scope of Accreditation for ISO 17025 and ISO 15189 testing laboratories.	5	Oct 2019	√					
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	5	Jul 2020	√	√	√	√		√
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	4	Oct 2018	√		√			
Policy Statement No. 18	Policy on the evaluation of conformity assessment schemes	3	Jun 2018		√	√			√
Policy Statement No. 19	Policy on the accreditation and assessment of multisite Conformity Assessment Bodies (CABs)	7	Jul 2020	√	√	√	√		√
Policy Statement No. 21	Accreditation of Reference Material Producers	3	Aug 2018				√		

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>POLICY</u>									
Policy Statement No. 22	Policy on Witnessing Activities and Scope Management for Certification and Verification Bodies	4	Apr 2019		√	√			√
Policy Statement No. 23	INAB Policy on the provision of accredited testing and calibration in INAB accredited laboratories.	3	Apr 2019	√					
Policy Statement No. 24	Minimum verification requirements for ISO 17025 & ISO 15189 testing laboratories	1	Feb 2016	□√					
Policy Statement No. 25	INAB Stakeholder feedback mechanisms	3	Apr 2020	√	√	√	√	√	√
Policy Statement No. 26	INAB Policy on Impartiality	2	Jan 2020	√	√	√	√	√	√
Policy Statement No. 27	INAB Policy Statement on Scope Format for Calibration Laboratories	1	Jun 2018	√	√	√	√	√	
Policy Statement No. 28	Assessment and accreditation of Opinions and Interpretations using ISO 17025:2017.	1	Jan 2019	√					
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)	1	Apr 2020	√					
Policy Statement No. 32	Policy on laboratory refurbishments/renovations, the movement of accredited testing equipment, and new laboratory equipment (ISO17025 & ISO15189)	1	To be issued late 2020						
Policy Statement No. 33	Policy for Externally Contracted Personnel Services	1	To be issued late 2020						
Policy Statement No. 34	Policy Statement on Scope Format for Testing Laboratories accredited to ISO 17025	1	Jul 2020	√					

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>GUIDANCE</u>									
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.	3	Sep 2019	√	√	√	√	√	√
GD04	INAB Guidance on assessment planning	2	Apr 2020	√	√	√	√	√	√
GD05	INAB Notice on Accreditation to ISO14065	1	Feb 2019		√				√
GLP Manual	INAB GLP Compliance Monitoring Programme	11	Mar 2020					√	
P7	Guide to INAB assessment Procedures	18	Oct 2019	√	√	√	√	√	√
R-PT	Register of PT Providers	11	Dec 2016	√		√			
<u>SCHEDULE OF FEES</u>									
Fee-Sched-1	INAB Fee Schedule	3	Dec 2018	√	√	√	√	√	√
<u>DIRECTORIES</u>									
D1	Directory of INAB Registered Organisations		Current Edition	√	√	√	√	√	√

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INAB publications are available from www.inab.ie									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>APPLICATION FORMS</u>									
AF-1-E	Application for registration as an EMAS site	5	Jun 2015						
AF-1-F	Organisation Change Information Form	6	Mar 2019	√	√	√	√		√
AF-1-G	Information Requirements for EMAS Registration	2	Dec 2016						
AF-3-B	Application for review of new conformity assessment schemes	6	Sept 2015		√	√			√
AF-3-E	Application for Foreign Verifiers operating in Ireland	1	Feb 2016		√				√
AF108	CAB Self-Assessment Record & INAB Contract review	2	Jun 2019	√	√	√	√	√	√

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Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
CRM 2	INAB CAB Portal User Guide	5	Jun 2020	√	√	√	√		
CRM FS-14	Interpreting INAB Scopes of Accreditation	4	Jun 2020	√	√	√	√		
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	3	Sep 2019	√					
ST3CRM	Chemical testing classification	2	Sep 2019	√					
ST4CRM	Construction testing classification	5	Sep 2019	√					
ST5CRM	Mechanical testing classification	4	Sep 2019	√					
ST6CRM	Medical testing classification	4	May 2020	√					
ST7CRM	Management systems certification bodies classification	2	May 2020		√				
ST8CRM	Metrology -Calibration classification	2	Sep 2019	√					
ST9CRM	Inspection Bodies classification	2	Sep 2019			√			
ST10CRM	Heat Temperature & Humidity classification	2	Sep 2019	√					
ST12CRM	Product certification classification	4	Sep 2019		√				
ST13CRM	Personnel certification classification	3	Sep 2019						
ST14CRM	Forensic science classification	2	Sep 2019	√					
ST15CRM	Reference Material Producers classification	3	Sep 2019				√		
ST16CRM	Optical testing classification	2	Sep 2019	√					
ST17CRM	Electrical testing classification	2	Sep 2019	√					
ST18CRM	NDT testing classification	2	Sep 2019	√					

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INAB publications are available from www.inab.ie

Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	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	4	Sep 2019		√				
ST24CRM	Persons Certification Notified Body classification	4	Sep 2019		√				

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INAB publications are available from www.inab.ie									
Document	Title	Issue No.	Issue Date	LA	CB	IB	RM	GLP Programme	V/V
<u>PUBLICITY</u>									
	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 2:2016 General Principles for Use of the IAF MLA Mark	3	May 2016	√	√	√	√		
	ILAC-R7:05/2015 Rules for the Use of the ILAC MRA Mark		May 2015	√	√	√	√		
	EA 3/01 EA conditions for the use of accreditation symbols, text reference to accreditation and MLA signatory status		Current Edition	√	√	√	√		