

INAB Mandatory and Guidance Documents - Policy and Index

DC1

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

ISO/IEC standards are available only from:

ILI

42-44 Northumberland Road, Dublin 4

Tel: (01) 8576730 Fax: (01) 8576729 Web: <http://www.standards.ie>

1) EA Guideline Documents are available from the EA website

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

2) ILAC publications are available from

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

3) IAF publications are available from

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

4) All other documents are available on the INAB website at

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

Or in hard copy by request to INAB Offices:

Tel: (01) 6073003 Fax: (01) 6073109

5) Copies of EU Legislation and Directives are available at

Web: http://eur-lex.europa.eu/RECH_legislation.do?ihmlang=en

Organisations are also required to hold copies of current EA, ILAC and IAF publications relevant to their areas of activity. These are available on the appropriate websites.

Please ensure that you pay careful attention to what documents are mandatory and which are guidance as the classification is not always obvious (e.g.: Category 2 documents are EA MLA documents that support the application of standards used for accreditation and must be implemented by INAB for use in its accreditation systems).

INAB Policy on Mandatory and Guidance Documents

1) Purpose

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

2) Documents

2.1) The INAB Publications Index lists the INAB accreditation publications by: document, title and issue date, under the headings mandatory, guidance, directories and publicity.

2.2) The EA Publications Document (EA-1/01), available from the EA website, www.european-accreditation.org lists EA publications by: document, title and issue date and identify the requirement documents for accredited organisations.

3) Guidance Documents

Guidance documents represent preferred practice in applying relevant standards. The approaches taken are not mandatory and are for the guidance of the national accreditation bodies and their clients.

The guidance documents are produced as a means of promoting a consistent approach to accreditation.

4) Mandatory Documents

4.1) Accredited organisations shall comply with the INAB and EA Mandatory requirement publications as listed in the documents referred to in 2.1 and 2.2 above. EA Category 3 Sector Specific Documents are **mandatory** for INAB applicant and accredited CABs and will be assessed as part of INAB's accreditation process.

4.2) Accredited organisations shall have controlled copies of the INAB and EA Mandatory and Guidance publications relevant to their activity and scope of accreditation.

5) Contact

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

Phone: +353 1 6073003

Fax: +353 1 6073109

E-mail: inab@inab.ie

Website: www.inab.ie

INAB Publications Index

	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme	
ISO/IEC standards are available from www.standards.ie										
INTERNATIONAL MANDATORY DOCUMENTS	ISO 17025: 2005	General Requirements for the competence of testing and calibration laboratories	2	May 2005	√					
	ISO 15189: 2007	Medical laboratories - Particular requirements for quality and competence	2	April 2007	√					
	ISO 17020	General Criteria for the operation of various types of bodies performing inspection	1	Nov 98			√			
	ISO 17021	Conformity Assessment - Requirements for bodies providing audit and certification of management systems	1	Sep 2006		√				
	ISO Guide 65/ (EN45011)	General guidelines for bodies operating product certification systems		1996		√				
	ISO 17024	General requirements for bodies operating certification schemes for persons	1	2003		√				
	ISO/IEC 27006:2007	Information technology - Security techniques- Requirements for bodies providing audit and certification of information security management systems	1	March 2007		√				
	IAF publications are available from www.iaf.nu									
	IAF/ILAC-A4:2004	IAF/ILAC Guidance on the application of ISO/IEC 17020	1	Jan 2005				√		
	IAF MD 1: 2007	Certification of Multiple Sites Based on Sampling	1	Nov 2007		√				
IAF MD 2: 2007	Transfer of Accredited Certification of Management Systems	1	Dec 2007		√					
IAF MD 3: 2008	Advanced Surveillance and Recertification Procedures (ASRP)	1	Feb 2008		√					

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	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
INTERNATIONAL MANDATORY DOCUMENTS	IAF publications are available from www.iaf.nu								
	IAF MD 4: 2008	Use of Computer Assisted Auditing Techniques ("CAAT") for Accredited Certification of Management Systems	1	May 2008		√			
	IAF Guidance GD5	Guidance on the application of Guide 65:1996	2	Dec 2006		√			
	IAF Guidance GD24	Guidance on the application of ISO/IEC 17024:2004	1	2004		√			
	IAF MD 5: 2009	Duration of QMS and EMS Audits	1	Feb 2009		√			
	IAF MD 9:2011	Application of ISO/IEC 17021 in Medical Device Quality Management Systems (ISO 13485)	1	July 2011		√			
	EA Guideline documents are available from www.european-accreditation.org								
	EA Guideline EA-7/04	EA Legal Compliance as a part of Accredited ISO 14001:2004 certification	1	Mar 2007		√			
	EA 7/05	EA Guidance on the Application of ISO/IEC 17021: 2006 for Combined Audits		Oct 2008		√			
	EA-6/02	EA Guidelines in the use of EN 45011 and ISO/IEC 17021 for Certification to EN ISO 3834	1	July 2007		√			
	EA-6/03	EA Guidance for Recognition of verification Bodies under EU ETS Directive		2010		√			
	EA-4/02	Expressions of the uncertainty of measurement in Calibration		1999	√				
	EA- 4/07	Traceability of Measuring and Test Equipment to National Standards - http://www.european-accreditation.org/	1	Nov 1995	√				
	EA- 4/16	EA Guidelines on the Expression of Uncertainty in Quantitative Testing	0	Dec 2003	√				

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EA Guideline documents are available from www.european-accreditation.org									
INTERNATIONAL MANDATORY DOCUMENTS	EA- 2/15	EA Requirements for the Accreditation of Flexible Scopes	0	July 2008	√				
	EA- 2/17	EA Guidance on the horizontal requirements for the accreditation of conformity assessment bodies for notification purposes	1	June 2009	√	√	√		
	EA- 4/17	EA Position Paper on the description of scopes of accreditation of medical laboratories		Dec 2008	√				
	EA - 6/04	EA Guidelines on the Accreditation of Certification of Primary Sector Products by Means of Sampling of Sites	0	July 2011		√			
EU Legislation and Directives are available from www.europa.eu									
	EMAS Regulation 1221/2009	Regulation allowing voluntary participation by organizations in a Community eco-management and audit scheme (EMAS) available from http://europa.eu/		2009		√		√	
	EU Electronic Signatures Directive	Electronic signatures directive and associated guidance for certification bodies certifying Certification service providers issuing qualified certificates		1999/93/EC		√			

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Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
INAB publications are available from www.inab.ie								
DC1	INAB Mandatory and Guidance Documents - Policy and Index	55	Nov 2011	√	√	√	√	√
R1	R1 INAB Regulations	8	April 2011	√	√	√		
TC	INAB Terms and Conditions	3	Dec 2007	√	√	√		
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	2	Sept 2009	√				
AIC - Protocol	National Protocol for the Implementation of Reporting Mechanism in line with the requirements of S.I. 543 of 2002 (Implementation of the Solvents Emissions Directive in Ireland)	2	Dec 2004			√		
RM-IB	Risk Management - Inspection Body Form	1	July 2010			√		
PS7F1	Form to Capture Certificate Activities for all CBs	2	March 2011		√			
PS19F1	Multisite Report Form	1	July 2010	√	√	√		

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	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
<u>POLICY</u>	Policy Statement No. 1	Proficiency Testing	6	Aug 2008	√				
	Policy Statement No. 3	Policy on the Laboratory Testing for Group 3 Organisms	5	Sep 2008	√				
	Policy Statement No. 4	Performance Reports	4	Mar 2007	√				
	Policy Statement No. 5	Traceability of Measurement	4	Mar 2007	√		√		
	Policy Statement No. 6	INAB Policy on Unannounced Visits to INAB Accredited Organisations	6	June 2009	√	√	√		
	Policy Statement No. 7	INAB policy on issuing accredited certificates outside Ireland	8	July 2010		√			
	Policy Statement No. 8	Code of Conduct for Assessment Teams (Assessors) conducting assessments for INAB	5	Sep 2011	√	√	√	√	√
	Policy Statement No.9	INAB Guidance on the use of Stubbs and More method for reporting "Apparent Total Meat Content"	3	Mar 2007	√				
	Policy Statement No. 10	Submission of Documentation to INAB in preparation for an INAB visit.	10	June 2011	√	√	√		
	Policy Statement No. 11	Flexible Scope of Accreditation for Chemical Testing Laboratories	2	Mar 2007	√				
	Policy Statement No. 12	Policy for accredited organisations undertaking work in an area which is regulated by legislation	2	Mar 2007	√	√	√		
	Policy Statement No. 13	Policy on the Performance of In-house Calibrations	2	Mar 2007	√		√		
	Policy Statement No. 14	Policy on assessment of quality system documentation and data in an electronic environment	2	Mar 2007	√	√	√		

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	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
POLICY	Policy Statement No. 15	Guide to Method Validation for Quantitative Analysis in Chemical Testing Laboratories	2	Mar 2007	√				
	Policy Statement No. 16	Development of certification schemes and extensions to scopes of accreditation	2	Dec 2007		√	√		
	Policy Statement No. 17	The Principles for the assessment of sampling methods to ISO 17025 and ISO 17020	1	July 2010	√		√		
	Policy Statement No. 19	Policy on the accreditation and assessment of multisite Conformity Assessment Bodies (CABs)	1	July 2010	√	√	√		
	Policy Statement No. 20	Policy on Accredited Inspection Contractors (AIC)	1	July 2010			√		
GUIDANCE	P7	Guide to INAB assessment Procedures	13	July 2010	√	√	√	√	√
	P9	Classification system for testing and calibration laboratories	9	Apr 2007	√				
	P10	Classification System for Inspections	2	May 2007			√		
	ES4	EMAS Graphic and Statement	6	June 2010				√	
	GLP Manual	INAB GLP Compliance Monitoring Programme	8	June 2011					√
	ISO/TR 22869	Medical laboratories-guidance on laboratory implementation of ISO15189:2003	1	Feb 2005	√				
	R-PT	Register of PT Providers	8	July 2011	√		√		
	GD01	Guidance on Consultants Contracts for ISO 15189 laboratories and assessors	1	Nov 2011	√				

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	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
SCHEDULE OF FEES	IR-04-A10	Schedule of Fees - Laboratories, and Inspection Bodies	1-2011	Jan 2011	√		√		
	IR-04-A15	Schedule of Fees for Medical Laboratories	1-2011	Jan 2011	√				
	IR-04-A11	Schedule of Fees - Certification Bodies and Verifiers	1-2011	Jan 2011		√			
	IR-04-A12	Schedule of Fees - Registration as an EMAS site	1-2011	Jan 2011				√	
	IR-04-A13	Schedule of Fees - Supervision of EMAS Verifiers	1-2011	Jan 2011				√	
	IR-04-A14	Schedule of Fees - GLP Facilities	1-2011	Jan 2011					√
DIRECTORIES	D1	Directory of INAB Registered Organisations		Current Edition	√	√	√	√	√

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	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
APPLICATION FORMS	AF-1-A	Application for Laboratory accreditation to ISO 17025	8	July 2010	√				
	AF-1-B	Application for Certification Body and Verifier Accreditation	17	June 2011		√			
	AF-1-C	Application for Inspection Body Accreditation to ISO 17020	8	July 2010			√		
	AF-1-D	Application for Laboratory accreditation to ISO 15189	9	June 2011	√				
	AF-1-E	Application for registration as an EMAS site	3	April 2011				√	
	AF-2-A	Application for Amendment or Extension to scope of Accreditation for ISO 17025	5	June 2009	√				
	AF-2-B	Application for extension to scope for Certification Bodies	12	Jan 2011		√			
	AF-2-C	Application for extension to scope for Inspection Bodies	6	July 2010			√		
	AF-2-D	Application for extension to scope for Laboratory accreditation to ISO 15189	6	June 2011	√				
	AF-1-D-BB	Annex to AF-1-D for Blood Banks for compliance with Article 14 & 15 of EU Directive 2002/98/EC	2	Oct 2007	√				
	AF-1-F	Organisation Change Information Form	1	July 2009	√	√	√		
	AF-1-NB	Application form for approved or notified body under SI or EC Directive	2	July 2010	√	√	√		

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	Document	Title	Issue No.	Issue Date	Laboratory Accreditation	Certification Body / Verifier Accreditation	Inspection Body Accreditation	EMAS Sites	GLP Programme
PUBLICITY		The Irish National Accreditation Board Brochure		Current Edition	√	√	√	√	√
		INAB Newsletter		Current Edition	√	√	√	√	√
		EA Brochure		Current Edition	√	√	√		