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NAB-MALTA


TECHNICAL GUIDE

ATG18 - Mandatory and Guidance Documents

Policy of the NAB-MALTA

Revision 4

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of Conformity Assessment Bodies (CABs) including laboratories, inspection bodies and certification bodies.

The National Accreditation Board - Malta (NAB-MALTA) is the sole national accreditation body appointed as per Article 4 of Regulation (EC) 765/2008 with the responsibility for accreditation in accordance with the relevant normative documents. It operates a management system compliant with the requirements of EN ISO/IEC 17011.

International trade relies on certificates and reports issued by competent bodies. Confidence in certificates and reports is achieved by accreditation. Confidence in accreditation is based on a series of confidence building steps between the accreditation bodies and accredited conformity assessment bodies and the assurance given by the accreditation body that the accredited conformity assessment body constantly implements the relevant criteria and maintains and continuously develops its competence as defined in the relevant standard. This assurance is achieved through accreditation which includes regular on-site assessments and other types of accreditation activities.


The services of the NAB-MALTA are accessible to all CABs whose requests fall within the current activities offered by the NAB-MALTA and which are in compliance with the cross-border accreditation requirements as stipulated in Article 7 of Regulation (EC) 765/2008. Access is not conditional upon the size of the applicant CAB or membership of any association or group.

For the scope of this guide, the masculine gender shall also refer to the feminine gender.

SCOPE OF PUBLICATION


This publication has been drawn up to outline the NAB-MALTA policy regarding mandatory and guidance documents for accredited and applicant Conformity Assessments Bodies (CABs).

This is a mandatory document and comes into effect with the date of publication.

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1. Introduction

- 1.1 This publication lists the main documents which are relevant to various Conformity Assessment Bodies (CABs).
- 1.2 All Conformity Assessment Bodies (CABs) and Verifiers shall ensure that they have the latest revisions of the listed publications. If there is any doubt, the CAB should contact the NAB-MALTA.
- 1.3 Standards and interpretative documents are subject to change and are updated. In case of a change or revision to documents which determine the accreditation criteria, the NAB-MALTA will establish a transition period.
- 1.4 The revision of the quoted standard is not specified in this document. Unless covered by a transition policy the latest version of the standard will be applicable. Temporary transition policies are issued by the NAB-MALTA whenever the main accreditation standards are revised. These policies will clearly indicate which version of the standard will be used during the assessment.
- 1.5 The NAB-MALTA may find it necessary to use publications not listed in this document during the assessment to ensure a proper evaluation of the CAB.
- 1.6 It is not the intention of this document to list all the available guidance documents. The websites referred to in this document provide useful resources to various types of CABs.


2. Definitions

2.1 Guidance Documents

- 2.1.1 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 guidance.

2.2 Mandatory Documents

- 2.2.1 CABs shall comply with the requirements established by NAB-MALTA, EA, ILAC, IAF mandatory publications and any other normative documents (such as European Directives). These requirements will be assessed as part of the NAB-MALTA's accreditation process.

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2.2.2 CABs shall ensure that mandatory requirements are incorporated and implemented into their quality management system.

3. General and specific requirements

3.1 The main accreditation standards listed in this publication contain **general requirements** in the scope of technical competences, organisation and management. A CAB or Verifier applying for accreditation shall demonstrate, through objective evidence, that it has a management system conforming to the relevant standard, adequate to its structure and size and the scope of activities. This shall be described in procedures, records and supporting documentation. A set of documents are to be submitted with the application form, which may vary according to the type of CAB.

3.2 **Specific requirements**, depending on the type of CAB or Verifier, are contained in other normative documents (such as those describing test methods contained in international standards), in legal provisions and in other guidelines established for bodies acting in specific fields of conformity assessment.

3.3 The NAB-MALTA adopts all publications issued by the **European Co-operation for Accreditation (EA)**, some of which are mandatory for use by the accreditation bodies and the conformity assessment bodies. EA publications may be downloaded from <http://www.european-accreditation.org>. EA-INF/01 lists all the current EA publications.


3.3.1 This also applies to:

- ILAC documents (<http://www.ilac.org>), IAF documents (<http://www.iaf.nu>) and joint ILAC-IAF documents as agreed during the EA General Assembly;
- documents issued by the EC or Notified Bodies Groups which regulate the operations of Notified Bodies;
- documents applicable to sector schemes.

3.4 In relation to **EMAS**, the NAB-MALTA adopts any publications issued by the European Commission (EC) and the Forum of Accreditation and Licensing Bodies (FALB).

3.5 NAB-MALTA also uses:

- **ILAC** (International Laboratory Accreditation Co-operation) publications. ILAC documents can be downloaded from the ILAC website <http://www.ilac.org>.

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- **IAF** (International Accreditation Forum) publications. IAF documents can be downloaded from the IAF website <http://www.iaf.nu>.

4. GENERAL CRITERIA (applicable to all Conformity Assessment Bodies)

- **RAB1** – General Regulations
- **RAB2** – The Use of the Accreditation Symbol, Text Reference to Accreditation and reference to EA MLA status.


5. LABORATORIES

5.1 Main accreditation standards

EN ISO/IEC 17025	General requirements for the compliance of testing and calibration laboratories
EN ISO 15189	Medical laboratories – Requirements for quality and competence
EN ISO 22870	Point-of-care testing (POCT) – Requirements for quality and competence (has to be used with ISO 15189)
CEN/TS 15675	Air quality. Measurement of stationary source emissions. Application of EN ISO/IEC17025:2005 to periodic measurements (has to be used with EN ISO/IEC 17025). (Note: CEN/TS 15675 has been withdrawn with a transition period until November 2020).

5.2 Additional criteria

- **ATG10:** Proficiency Testing and Interlaboratory Comparisons – Policy of the NAB-MALTA.
- **ATG11:** Traceability of Measurement – Policy of the NAB-MALTA.
- **ATG12 :** Submission of documentation in preparation for NAB-MALTA surveillance activity
- **ATG15 :** Performance of in-house calibrations - The Policy of the NAB-MALTA
- **ATG16 : Policy Flexible Scopes - Implementation and Management - The Policy of the NAB-MALTA**
- **Mandatory EA documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)

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- **Mandatory ILAC documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)The appropriate standards related to the calibration/testing methodologies.
- Any other criteria as may be established in European or national legislation for e.g. Water Framework Directive

5.3 Important guidance (non-mandatory)

- **ATG01:** NAB-MALTA Assessment Process for Laboratories
- **EA-4/16:** EA Guidelines on the Expression of Uncertainty in Quantitative testing
- **GUM:** Guide to the Uncertainty of Measurement (<http://www.iso.org/sites/JCGM/GUM-JCGM100.htm>)

6. INSPECTION BODIES

6.1 Main accreditation standard


EN ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

6.2 Additional criteria

- **ILAC P15** - Application of ISO/IEC 17020:2012 for the Accreditation of Inspection Bodies
- **ATG10:** Proficiency Testing and Interlaboratory Comparisons – Policy of the NAB-MALTA.
- **ATG11:** Traceability of measurements – Policy of the NAB-MALTA.
- **ATG12** : Submission of documentation in preparation for NAB-MALTA surveillance activity
- **ATG15** : Performance of in-house calibrations - The Policy of the NAB-MALTA
- **Mandatory EA documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)
- **Mandatory ILAC documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org). The appropriate standards related to the calibration/testing methodologies.

6.3 Important guidance (non-mandatory)

- **ATG05:** NAB-MALTA Assessment Process for Inspection Bodies.
- **ILAC G27:** Guidance on measurement performed as part of the inspection process.

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7. CERTIFICATION BODIES (Products, Process, Services)

7.1 Main accreditation standard


EN ISO/IEC 17065 Conformity assessment – Requirements for bodies certifying products, processes and services

7.2 Additional criteria

- As defined by the Certification Scheme.
- **ATG10:** Proficiency Testing and Interlaboratory Comparisons – Policy of the NAB-MALTA.
- **ATG11:** Traceability of Measurements – Policy of the NAB-MALTA.
- **ATG12 :** Submission of documentation in preparation for NAB-MALTA surveillance activity
- **ATG15 :** Performance of in-house calibrations - The Policy of the NAB-MALTA
- **Mandatory EA documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)
- **Mandatory ILAC documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)The appropriate standards related to the calibration/testing methodologies.
- **Mandatory IAF documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)The appropriate standards related to the calibration/testing methodologies.

7.3 Important guidance (non-mandatory)

- **ISO/IEC 17067** - Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes

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8. EMAS VERIFIERS

8.1 EMAS Verifiers are accredited and supervised to the requirements of **EC Council Regulation 1221/2009** dated 25th November 2009 and according to any additional requirements as established by the Forum for Accreditation and Licensing Bodies (FALB).

9. NOTIFIED BODIES (CABs applying with the scope of notification)

9.1 Main accreditation documents

Applicable Accreditation Standards

As defined by the Regulator and depending on the applicable modules and legislation. The standards as defined in EA2/17 shall be the preferred standards.

Decision No. 768/2008/EC

Legal Notice 136 of 2003

Methods for Designating Conformity Assessment Body Regulations

Applicable EU Legislation

(Directive/Regulation)


Applicable National Legislation transposing the specific EU Directive

EA2/17M

EA Document on Accreditation for Notification purposes.

9.2 Additional criteria

- **ATG10:** Proficiency Testing – Policy of the NAB-MALTA.
- **ATG11:** Traceability – Policy of the NAB-MALTA.
- **ATG12 :** Submission of documentation in preparation for NAB-MALTA visits
- **ATG15 :** Performance of in-house calibrations - The Policy of the NAB-MALTA
- **Mandatory EA documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)
- **Mandatory ILAC documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)The appropriate standards related to the calibration/testing methodologies.

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- **Mandatory IAF documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (www.european-accreditation.org)The appropriate standards related to the calibration/testing methodologies.

Note: If a CAB is applying for accreditation with the intention of becoming a Notified Body then it should inform the NAB-MALTA immediately. This will normally be followed up with a meeting with the regulator.

10. AUTHORISED CABs (ACABs) - Lifts


10.1 Main accreditation standard

EN ISO/IEC 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection

10.2 Additional criteria


- All criteria as listed in Clause 7.2
- **Legal Notice 231 of 2007:** Inspections of Lifts Regulations
- **Legal Notice 136 of 2003 :** Methods for Designating Conformity Assessment Body Regulations
- **Regulatory Affairs Directorate Requirements:** Any other requirements as established by the Regulatory Affairs Directorate within the Malta Competition and Consumer Affairs Authority (available from MCCA).

Note: If a CAB is applying for accreditation with the intention of becoming an ACAB then it shall immediately inform the NAB-MALTA. A meeting with the regulator is normally necessary.

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Appendix 1: Summary of NAB-MALTA Applicable Documents


Document	Laboratories Testing	Laboratories Calibration	Laboratories Medical	Inspection	Certification Bodies	EMAS Verifiers
	EN ISO/IEC 17025	EN ISO/IEC 17025	EN ISO 15189	EN ISO/IEC 17020	EN ISO/IEC 17065	(EC) 1221/2009
Regulations (Mandatory)						
RAB1	X	X	X	X	X	X
RAB2	X	X	X	X	X	X
Policies (Mandatory)						
ATG10	X	X	X		X	
ATG11	X	X	X	X	X	
ATG12	X	X	X	X	X	
ATG13	X	X	X	X	X	X
ATG15	X	X	X	X	X	
ATG16	X					
ATG18	X	X	X	X	X	X
Application forms (Mandatory)						
NABAF01/L	X	X	X			
NABAF01/L/E	X	X	X			
NABAF01/I				X		
NABAF01/I/E				X		
NABAF01/C					X	X
NABAF01/C/E					X	X
Guidelines (Not Mandatory)						
ATG01	X	X	X			
ATG05				X		
ATG06					X	X

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Appendix 2: Summary of Mandatory EA, ILAC, IAF Applicable Documents and Level 4 Standards – For Reference Only

(Note: The complete comprehensive list is available for reference from the EA, ILAC and IAF websites)

Document	Laboratories Testing	Laboratories Calibration	Laboratories Medical	Inspection	Certification Bodies			EMAS Verifiers
	EN ISO/IEC 17025	EN ISO/IEC 17025	EN ISO 15189	EN ISO/IEC 17020	EN ISO/IEC 17065			(EC) 1221/2009
EA Mandatory Documents (http://www.european-accreditation.org)								
EA-2/15	X							
EA-2/17 (only for Notified Bodies)	X	X	X	X	X			
EA-3/01	X	X	X	X	X			
EA-4/02	X	X	X					
EA-4/17			X					
EA-6/02					X			
EA-6/04					X			
IAF Mandatory Documents (http://www.iaf.nu)								
IAF MD 4					X			X
IAF MD 12					X			
ILAC Mandatory Documents (http://www.ilac.org)								
ILAC-P9	X	X	X	X				
ILAC-P10	X	X	X	X	X			
ILAC-P14	X	X	X	X	X			
ILAC-P15				X				
Applicable standards								
EN ISO 22870			X (POCT)					
CEN/TS 15675	X (for Stack Emissions)							

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Note - All CABs are expected to make regular and frequent reference to the EA, ILAC and IAF websites (and where necessary other websites such as Euramet) to ensure that they have the latest revisions and that any new documents issued by these respective organisations are integrated within their management system, as necessary and within the timeframes defined in the document.

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Do you need further information?

This publication, application forms and other information about accreditation including this document, are available for download from the NAB-MALTA website at <http://www.nab.gov.mt>.

The EA (European Co-operation for Accreditation) publications referred to in this document are available for free download from <http://www.european-accreditation.org>.

Should you need any further information we advise you to contact us.

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