



NAB-MALTA

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# NAB-MALTA


# TECHNICAL GUIDE

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ATG18 - Mandatory and Guidance Documents

Policy of the NAB-MALTA

Revision 5 February 2024

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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, maintains, and continuously develops its competence as defined in the relevant standard. This assurance is achieved through accreditation which includes regular 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) No 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 document, 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 **It is the responsibility of the** CABs and Verifiers to ensure that they have the latest revisions of the listed **and applicable** publications. If there is any doubt, the CAB should contact the NAB-MALTA **or the relevant regulator/competent authority**.
- 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 **where necessary**. **The NAB-MALTA will follow the transition periods as established by the European Co-operation for Accreditation (EA)**.
- 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 **shall apply**. 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 provide technical or scientific guidance and recommended examples on how to fulfil the criteria.**

### 2.2 Mandatory Documents

- 2.2.1 CABs shall comply with the requirements established by the NAB-MALTA, EA, ILAC, IAF mandatory publications and any other normative documents (such as those found in European **Regulations and**

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Directives and requirements issued by Competent Authorities/Regulators). These requirements will be assessed as part of the NAB-MALTA's accreditation process as necessary.

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 a 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 **regulatory requirements** 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.
- **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 <https://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 REQUIREMENTS (applicable to all Conformity Assessment Bodies)

- **RAB01** – General Regulations
- **RAB02** – The Use of the Accreditation Symbol, Text Reference to Accreditation and reference to EA MLA status.

#### 5. LABORATORIES

##### 5.1 Main accreditation standards


- |                         |   |
|-------------------------|---|
| <b>EN ISO/IEC 17025</b> | General requirements for the compliance of testing and calibration laboratories |
| <b>EN ISO 15189</b>     | Medical laboratories – Requirements for quality and competence                  |

##### 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 - Policy of the NAB-MALTA.
- **ATG16:** Policy Flexible Scopes - Implementation and Management - 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](http://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](http://www.european-accreditation.org)).
- 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

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- **EA Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website ([www.european-accreditation.org](http://www.european-accreditation.org))
- **ILAC Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website ([www.european-accreditation.org](http://www.european-accreditation.org)).
- **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 - 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 (<https://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 (<https://european-accreditation.org/>). The appropriate standards related to the calibration/testing methodologies.

### 6.3 Important guidance documents (non-mandatory)

- **ATG05:** NAB-MALTA Assessment Process for Inspection Bodies.
- **EA Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website ([www.european-accreditation.org](http://www.european-accreditation.org))
- **ILAC Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website ([www.european-accreditation.org](http://www.european-accreditation.org)).

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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 - 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 (<https://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 (<https://european-accreditation.org/>).
- **Mandatory IAF documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>)

### 7.3 Important guidance documents (non-mandatory)

- **ISO/IEC 17067** - Conformity assessment — Fundamentals of product certification and guidelines for product certification schemes
- **EA Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>)
- **ILAC Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>).
- **IAF Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>).



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## 8. VERIFICATION AND VALIDATION BODIES

### 8.1 Main accreditation standard

#### EN ISO/IEC 17029


Conformity assessment — General principles and requirements for validation and verification bodies

### 8.2 Additional criteria

- **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 - 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 (<https://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 (<https://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 (<https://european-accreditation.org/>)The appropriate standards related to the calibration/testing methodologies.

### 8.3 Important guidance documents (non-mandatory)

- **EA Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>)
- **ILAC Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>).
- **IAF Guidance documents** as listed on document EA-INF/01 (List of EA Publications and International Documents) available from the EA website (<https://european-accreditation.org/>).

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## 9. EMAS VERIFIERS

9.1 EMAS Verifiers are accredited and supervised to the requirements of **Regulation (EC) No 1221/2009** dated 25<sup>th</sup> November 2009, and according to any additional requirements as established by the Forum for Accreditation and Licensing Bodies (FALB).

### 9.2 Main accreditation documents

#### **Regulation (EC) No 1221/2009**

Regulation (EC) No 1221/2009 of the European Parliament and of the Council of 25 November 2009 on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS), repealing Regulation (EC) No 761/2001 and Commission Decisions 2001/681/EC and 2006/193/EC

#### **Decision (EU) 2016/1621**

Commission Decision (EU) 2016/1621 of 7 September 2016 adopting a guidance document on notification to accreditation and licensing bodies by environmental verifiers active in a Member State other than that where the accreditation or licence was granted under Regulation (EC) No 1221/2009 of the European Parliament and of the Council

#### **Regulation (EU) 2017/1505**

Commission Regulation (EU) 2017/1505 of 28 August 2017 amending Annexes I, II and III to Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

#### **Decision (EU) 2017/2285**


Commission Decision (EU) 2017/2285 of 6 December 2017 Amending the user's guide setting out the steps needed to participate in EMAS, under Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

#### **Regulation (EU) 2018/2026**

Commission Regulation (EU) 2018/2026 of 19 December 2018 amending Annex IV to Regulation (EC) No 1221/2009 of the European Parliament and of the Council on the voluntary participation by organisations in a Community eco-management and audit scheme (EMAS)

#### **ISO/IEC 17021-1**

Requirements for bodies providing audit and certification of management system.  
Part 1: Requirements

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### 9.3 Additional criteria

#### - Mandatory FALB documents

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

### 10.1 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 unless as otherwise stated by the Regulator/Competent Authority.

#### 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.

### 10.2 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 - 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 (<https://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 (<https://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](http://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.

## 11. AUTHORISED CABs (ACABs) - Lifts


### 11.1 Main accreditation standard

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

### 11.2 Additional criteria


- All criteria as listed in Clause 6
- **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 (MCCAA) (available from MCCAA).

**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	Validation and Verification Bodies	EMAS Verifiers
	EN ISO/IEC 17025	EN ISO/IEC 17025	EN ISO 15189	EN ISO/IEC 17020	EN ISO/IEC 17065	EN ISO/IEC 17029	(EC) 1221/2009
<b>Regulations (Mandatory)</b>							
RAB01	X	X	X	X	X	X	X
RAB02	X	X	X	X	X	X	X
<b>Policies (Mandatory)</b>							
ATG10	X	X	X		X	X	
ATG11	X	X	X	X	X	X	
ATG12	X	X	X	X	X	X	
ATG13	X	X	X	X	X	X	X
ATG15	X	X	X	X	X	X	
ATG16	X						
ATG18	X	X	X	X	X	X	X
<b>Application forms (Mandatory)</b>							
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
<b>Guidelines (Not Mandatory)</b>							
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	Validation and Verification Bodies	EMAS Verifiers
	EN ISO/IEC 17025	EN ISO/IEC 17025	EN ISO 15189	EN ISO/IEC 17020	EN ISO/IEC 17065	EN ISO/IEC 17029	(EC) 1221/2009
<b>EA Mandatory Documents (<a href="http://www.european-accreditation.org">http://www.european-accreditation.org</a>)</b>							
EA-2/15	X						
EA-2/17 (only for Notified Bodies)	X	X	X	X	X		
EA-3/01	X	X	X	X	X	X	
EA-3/02					X		
EA-3/12					X		
EA-4/02	X	X	X	X	X	X	
EA-4/17			X				
EA-6/02					X		
EA-6/03						X	
<b>IAF Mandatory Documents (<a href="http://www.iaf.nu">http://www.iaf.nu</a>)</b>							
IAF MD4					X		X
IAF MD6						X	
IAF MD12					X		
IAF MD14						X	
<b>ILAC Mandatory Documents (<a href="http://www.ilac.org">http://www.ilac.org</a>)</b>							
ILAC-P8	X	X	X	X	X	X	X
ILAC-P9	X	X	X	X	X		
ILAC-P10	X	X	X	X	X		
ILAC-P14	X	X	X	X	X		
ILAC-P15				X			
<b>Applicable standards</b>							

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<b>Other</b>							
Decision (EU) 2016/1621							X

**Note** - All CABs are expected to make regular and frequent reference to the EA, ILAC, IAF and ISO 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.nabmalta.org.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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**END**