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NAB-MALTA

TECHNICAL GUIDE

ATG12- Submission of documentation in
preparation for an assessment
Policy of the NAB-MALTA

Revision 11 November 2021

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of conformity assessment bodies including testing and calibration laboratories, inspection bodies and various types of certification bodies.

The National Accreditation Board of the Malta (NAB-MALTA) is the single national accreditation body appointed as per Article 4 of Regulation (EC) 765/2008 with responsibility for accreditation in accordance with the relevant normative documents. It operates a management system which complies with the requirements established in 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 assessments and other types of accreditation activities.


The services of the NAB-MALTA are accessible to all applicants whose requests fall within the current activities as 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 conformity assessment body 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 describes the policy of the NAB-MALTA with regards to documentation which needs to be submitted to the NAB-MALTA prior to an assessment. This policy applies to all conformity assessment bodies.

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

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1. Purpose

- 1.1 This publication outlines the policy of the NAB-MALTA on the submission of documents by a conformity assessment body (CAB) to the NAB-MALTA, prior to an assessment, a scheduled witnessed activity or any other accreditation activity where the submission of documents is necessary.
- 1.2 This documentation will enable **the assessment team** to prepare effectively for the accreditation activity.
- 1.3 For the scope of this procedure, the term CAB shall also apply for Environmental Verifiers for EMAS as per Regulation (EU) 1221/2009.

2. NAB-MALTA Policy


- 2.1 It is the policy of the NAB-MALTA that all CABs provide the information specified in the relevant clause of this document, to the NAB-MALTA **30 days prior to an assessment or a scheduled witnessed activity**.
 - 2.1.1 Non-adherence with this timeframe may cause difficulties in the planning of the assessment which could lead to the postponement of the accreditation activity and which may eventually lead to the suspension of accreditation.
- 2.2 All accredited CABs shall send all the requested and complete information in one batch and using the appropriate folder structure within the “ZIP” file provided by the NAB-MALTA.
- 2.3 In case of a new application or extension to scope, the CAB shall submit the documentation as requested by the applicable application forms, **4 months prior to the assessment**.
- 2.4 **30-days prior to the reassessment**, the CAB shall submit all the management system and technical procedures related to the current scope of accreditation. As a reassessment closes an accreditation cycle and covers all of the requirements of the standard(s) for which the CAB is accredited, additional preparatory work will be necessary by the Team.
- 2.5 CABs are reminded that they are obliged to immediately inform the NAB-MALTA of any changes to their operations which would impact their ability to meet the applicable accreditation scheme criteria including NAB-MALTA policies and regulations (refer to **ATG18**) by completing form **NABG11**. This is an obligation set out in **RAB01 clause 5**. It is recommended to contact the NAB-MALTA where there is a doubt about the impact of any change.

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- 2.6 Accredited inspection and certification bodies shall contact the NAB-MALTA at the start of each year to allow for adequate planning of witnessed inspections/certifications for the coming year.
- 2.7 Accredited CABs performing work in the regulated sector shall review relevant legislation and any other mandatory requirements at the appropriate frequency to ensure continuing compliance. Such reviews shall be available to the NAB-MALTA assessment teams.
- 2.8 The NAB-MALTA may, at any time, request documentation and information as and when necessary.


3. Laboratories

- 3.1 Documentation describing the management system and list of amendments, clearly identifying the changes and confirming that they are based on the most recent standards. Notice shall be taken of Clause 2.4 of the documentation to be submitted in case of a reassessment.
- 3.2 Master list of documents (as specified also in **RAB01**) clearly identifying the documents which have been updated since the last accreditation activity.
- 3.3 Any new or revised management system documentation, including revised procedures (including SOPs) and forms, which have either been introduced or updated since the last accreditation activity.
- 3.4 Internal audit programme, identifying planned and completed audits since the last accreditation activity.
- 3.5 Minutes of last management review meeting(s) as per Clause 8.9 of ISO/IEC17025:2017.
- 3.6 The most recent documented analysis of the laboratory's risks and opportunities. This shall include potential risks to impartiality, including those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. A relationship that threatens the impartiality of the laboratory can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc. Such analysis shall clearly show how the laboratory is addressing these risks and opportunities.
- 3.7 Latest revision of organization chart including the names of the key personnel, highlighting changes to the structure and changes to involvement with related bodies.
- 3.8 Summary Report of performance in proficiency testing schemes (PT) and interlaboratory comparisons (ILC) where applicable (as specified also in **ATG10**) by using the Proficiency Testing and

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Interlaboratory Comparison Summary form **NABG32**. The laboratory is not expected to submit the full data reports, unless otherwise requested.


- 3.9 A copy of the latest Proficiency Testing schemes (PT) and Inter Laboratory Comparisons (ILC) plan, in line with **ATG10**.
- 3.10 A list detailing all instruments calibrated in-house which support measurements related to the accredited test/calibration methods e.g. balances, pipettes, thermometers. For in-house calibrations, the laboratory shall:
- submit any revised in-house calibration procedures;
 - submit procedures, including calibration reports, for any instrument which started to be calibrated in-house since the last assessment. (**Note:** The laboratory shall ensure that all the requirements of **ATG15** are followed)
- 3.11 A list of the personnel authorised to carry out the test/calibration methods within the scope of accreditation. Such list shall:
- clearly highlight newly authorised personnel since the **last assessment**
 - relate personnel against each test/calibration activity for which he/she is authorised.
 - include the names of the personnel authorised to carry out in-house calibrations.
- 3.12 A review of the relevant legislation, if any, affecting the laboratory's scope of accreditation. Please include all regulator specified testing/calibration requirements as they relate to your scope of accreditation.
- 3.13 Number of "accredited" tests/calibrations carried in the preceding year since the last submission of documents.
- 3.14 For testing laboratories adopting a **flexible scope**, the following shall be submitted:
- Updated **NABG34** – Flexible Scope Master list, clearly indicating recently added tests since the last assessment;
 - Relevant records related to the changes in the flexible scope master list (e.g. validations / verifications performed).
- 3.15 Any other information which the laboratory deems necessary.
- 3.16 The NAB-MALTA may, at any time, request any other documentation, as necessary for e.g. tests methods for test(s) to be witnessed during the next assessment.

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4. Inspection Bodies

4.1 Inspection Bodies – Head Office


- 4.1.1 Documentation describing the management system and list of amendments, clearly identifying the changes and confirming they are based on the most recent standards. Notice shall be taken of Clause 2.4 of the documentation to be submitted in case of a reassessment.
- 4.1.2 Master list of documents (as specified also in **RAB01**) clearly identifying the documents which have been updated since the last assessment.
- 4.1.3 Any new or revised management system documentation, including revised procedures and forms, which have either been introduced or update since the last assessment.
- 4.1.4 Schedule of internal audits, identifying planned and completed audits since the last assessment.
- 4.1.5 Minutes of last management review meeting(s) as per Clause 8.5 of ISO/IEC 17020:2012.
- 4.1.6 The most recent documented analysis of the inspection body's risks to impartiality and independence status, including those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. A relationship that threatens the impartiality and independence status of the inspection body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc. Such analysis shall clearly show how the inspection body is addressing these risks and opportunities.
- 4.1.7 Latest revision of organization chart including the names of the key personnel, highlighting changes to the structure and changes to involvement with related bodies.
- 4.1.8 Documented procedure for management of conflicts of interest. (Ref. to EN ISO/IEC 17020 Cl. 4.1)
- 4.1.9 Details of changes to legislation, if any, that have an impact on the scope of accreditation
- 4.1.10 Details of activity related to the scope of accreditation clearly stating the number of inspections carried out (in relation to the scope of accreditation) since the last assessment. This data is to include the number and type of inspections per inspector. If the inspector is also involved in other activities within the Inspection Body, then this will have to be stated. For area of the scope where there has been no activity, the inspection body shall provide details how it manages the maintenance of competence in these areas.

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- 4.1.11 An updated list of authorised inspectors related to the inspection methods listed in the scope of accreditation, clearly highlighting any new inspectors. This list shall include the names of the personnel authorised to carry out in-house calibrations.
- 4.1.12 A list detailing all instruments calibrated in-house which support measurements e.g. balances, gauges, etc. For in-house calibration, the inspection body shall:
- submit any revised in-house calibration procedures;
 - submit procedures, including calibration reports, for any instrument which started to be calibrated in-house since the last assessment (**Note:** The inspection body shall ensure that all the requirements of **ATG15** are followed).
- 4.1.13 Details of all critical and foreign locations where offices are located.
- 4.1.14 Details of adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations. Where provision is through an insurance, a copy of the latest liability insurance certificates and policies
- 4.1.15 Number of “accredited” inspections by each inspector carried in the preceding year since the last submission of documents.
- 4.1.16 Any other information which the inspection body deems necessary.
- 4.1.17 The NAB-MALTA may request any other documentation, as necessary for e.g. inspection methods for inspections to be witnessed during the **next assessment**.

4.2 Inspection Bodies - Witnessed activities


- 4.2.1 Copy of the inspection plan, where applicable;
- 4.2.2 Location of, and directions to, the witnessed activity, with contact details for on-site personnel;
- 4.2.3 Records clearly showing that the competence of all personnel involved in the activity has been assessed and demonstrated;
- 4.2.4 Details of inspection duration determination/calculation, where appropriate;
- 4.2.5 A copy of the inspection procedure and the working documents used by the inspector.

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5. Certification Bodies

5.1 Certification Bodies – Head Office


- 5.1.1. Documentation describing the management system and list of amendments, clearly identifying the changes and confirming they are based on the most recent standards. Notice shall be taken of Clause 2.4 of the documentation to be submitted in case of a reassessment.
- 5.1.2 Master list of documents (as specified also in **RAB01**) clearly identifying the documents which have been updated since the last assessment.
- 5.1.3 Any new or revised management system documentation, including revised procedures and associated forms which have either been introduced or update since the last assessment.
- 5.1.4 Schedule of internal audits, identifying planned and completed audits since the last assessment.
- 5.1.5 Minutes of last management review meeting(s).
- 5.1.6 The most recent documented analysis of the certification body's risks to impartiality, including those risks that arise from its activities, or from its relationships, or from the relationships of its personnel. A relationship that threatens the impartiality of the inspection body can be based on ownership, governance, management, personnel, shared resources, finances, contracts, marketing (including branding), and payment of a sales commission or other inducement for the referral of new clients, etc. Such analysis shall clearly show how the certification body has eliminated or minimized such risks.
- 5.1.7 Latest revision of organization chart including the names of the key personnel, highlighting changes to the structure and changes to involvement with related bodies.
- 5.1.8 Details of any changes to the mechanism for safeguarding impartiality, for e.g. changes to the composition of an impartiality committee.
- 5.1.9 Details of any new certificates issued since the last Head Office visit, with associated EA sector or technical area.
- 5.1.10 Details of changes to legislation or certification schemes that have an impact on the scope of accreditation.
- 5.1.11 Details of all critical and foreign locations where audits are carried out or where offices are located.

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- 5.1.12 Details of activity related to scope of accreditation, in particular, related to areas of the scope where there has been no activity, and details of how the certification body manages the maintenance of competence in these areas.
- 5.1.13 An updated list of auditors authorised to carry out the certifications listed in the scope of accreditation, clearly highlighting any new auditors.
- 5.1.14 An updated list of external resources used during the evaluation process.
- 5.1.15 Records indicating the effectiveness of the corrective actions implemented in response to the findings raised at the previous NAB-MALTA assessment.
- 5.1.16 Details of adequate provision (e.g. insurance or reserves) to cover liabilities arising from its operations. Where provision is through an insurance, a copy of the latest liability insurance certificates and policies.
- 5.1.17 Any other information which the certification body deems necessary.
- 5.1.18 The NAB-MALTA may request any other documentation, as necessary.

5.2 Certification Bodies - Witnessed activities


- 5.2.1 Copy of the audit plan, where applicable.
- 5.2.2 Previous client audit report completed by the certification body, as applicable.
- 5.2.3 Location of, and directions to, the witnessed activity, with contact details for on-site personnel;
- 5.2.4 Records clearly showing that the competence of all personnel involved in the activity has been assessed and demonstrated;
- 5.2.5 Details of audit duration determination/calculation, where appropriate;
- 5.2.6 A copy of the audit procedure and the working documents used by the auditor.

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6. Notified Bodies (Conformity Assessment Bodies for the purposes of notification) - Head Office

In addition to the information listed in Sections 3 – 5, the CAB shall submit the following:

- 6.1 Procedure for management of impartiality
- 6.2 Summary evidence of ongoing involvement in Notified Body groups on the European level.
- 6.3 List of approved subcontractors with identified tasks.
- 6.4 Notified body (NB) identification number.
- 6.5 List of personnel authorised as competent in the conformity assessment activities.
- 6.6 Summary log of communications with the Notifying Authority (e.g. Malta Competition and Consumer Affairs Authority – MCCA).
- 6.7 Summary of activity levels of certificates issued/suspended/withdrawn.

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7. Environmental Verifiers accredited by the NAB-MALTA in line with Regulation (EC) 1221/2009

7.1 Head Office

All the information listed in Clause 5.1

7.2 Documentation to be submitted at least four weeks in advance of each verification, in line with Regulation (EU) 1221/2009 Art.23

7.2.1 Accreditation or license details. This shall include but shall not be limited to the date and scope of accreditation/license and a copy of the accreditation/license certificate.

7.2.2 Time and place of the verification and copy of the audit plan.

8. Environmental Verifiers active in Malta and accredited or licensed by another Accreditation/Licensing Body - Documentation to be submitted at least four weeks before performing verification and validation activities in Malta, in line with Regulation (EU) 1221/2009 Art.24 and Commission Decision (EU) 2016/1621


8.1 accreditation or license details, with evidence that the accreditation or licence is still valid and not affected by suspension or withdrawal and that it is adequate for the specific activities of the organisation under verification or validation;

8.2 team composition and competencies, in particular knowledge of legal requirements relating to the environment and knowledge of English and/or Maltese;

8.3 arrangements to ensure competence in Maltese environmental law and the Maltese environmental legislative framework including environmental permitting system;

8.4 personnel records, where necessary, such as records of relevant qualifications, training and experience specific to the economic sector being verified


8.5 time and place of the verification and validation, including the environmental verifiers visit at the organisation and all stages before and after that visit, as set out in Article 25 of Regulation (EC) No. 1221/2209;

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- 8.6 address and contact details of the organisation that is subject to verification or validation including all sites and activities under the scope of verification or validation, and the number of employees;
- 8.7 a copy of the Environmental Statement for the site to be verified and any supporting documentation
- 8.8 Any other relevant background information received by the Verifier

9. Health and Safety

- 9.1 As per accreditation contract, CABs are reminded that they shall advise the NAB-MALTA at the time of submission of the above documentation of any requirements with respect to site health and safety and to inform the NAB-MALTA if any personal protective equipment (PPE) is required for scheduled on-site assessment activities, and whether this will be provided on-site.

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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>.

EA (European Co-operation for Accreditation) publications are available for download from <http://www.european-accreditation.org>.

ILAC publications are available for download from <https://ilac.org/publications-and-resources/>

IAF publications are available for download from <https://www.iaf.nu/articles/Publications/6>

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