Application Form for Testing and Calibration Laboratories

NABAF01/L

EN ISO/IEC 17025:2017

NAB-MALTA

NAB-MALTA

NATIONAL ACCREDITATION BOARD - MALTA

APPLICATION FOR LABORATORY ACCREDITATION
NABAF01/L

Instructions

1. This application should be completed in detail and returned duly signed to:

   The Director,
   National Accreditation Board Malta,
   Mizzi House,
   National Road,
   Blata l-Bajda HMR9010,
   Malta

2. This application and the requested documents shall be submitted in digital format. Documents are to be submitted in WORD, EXCEL or PDF format in the folder structure provided.

3. This application, except for original signatures, **shall be typed** and shall be submitted in WORD format either via email or in any other digital format. Handwritten applications shall not be accepted. A scanned copy of the application form with original signatures shall also be submitted.

4. All information provided will be treated in confidence.

5. Additional information may be obtained by contacting the NAB-MALTA at the above address, tel: (+356) 23952510, and/or e-mail: info@nabmalta.org.mt

6. Please ensure that you have read all the relevant standards, publications, and other normative documents (especially those listed in **ATG18**) relevant to your application. The accreditation scheme criteria, regulations and policies are available from the NAB-MALTA website www.nabmalta.org.mt, the EA website www.european-accreditation.org and the ILAC website www.ilac.org.

7. Incomplete applications will not be accepted. Should any section of this application form not be applicable, then this shall be clearly marked as “N/A” by the applicant.

8. The term “Conformity Assessment Body” and its abbreviation “CAB” will be used in this form to signify the applicant organisation i.e., the laboratory.

SECTION A

1. BASIC DETAILS CONFORMITY ASSESSMENT BODY (CAB) *(Please ensure that the specific entity seeking accreditation and the legal entity are precisely identified. Please also state legal entity and trading name if different.)*	
Name of the Conformity Assessment Body	
Main address	
Company Registration No.:	VAT No.:
Telephone Number:	E-Mail:
Website:	
***Note**: These details will be used by the NAB-MALTA on the NAB-MALTA databases, certificates, etc...*	

2. INVOICING DETAILS	
Invoicing Contact Name	
Address	
Company Registration No.:	VAT no.:
Telephone number:	e-mail:

3. LEGAL STATUS OF THE CONFORMITY ASSESSMENT BODY (CAB)

	Yes/No	Documentary evidence
3.1 Owned by an individual		
3.2 Private company or partnership		
3.3 Public limited company		
3.4 Academic institution		
3.5 Public body/authority		
3.6 Another category? If so, please specify:		

The applicant is to list here any other activities it, its parent company and/or related companies carries out and not subject to this application for accreditation.

4. CAB PART OF A LARGER ORGANISATION

If the CAB is part of a larger organisation, what is the relationship to that organisation?

Notes: *- For CABs which are part of Government please define the relationship within Government.*
- Provide the name and other contact details of the parent organisation if any

5. LOCATIONS COVERED BY THIS APPLICATION

Notes:
(1) The location details will be used by the NAB-MALTA on the NAB-MALTA database, certificates, etc.
(2) Also include any virtual sites (a virtual site is an online environment allowing persons to execute processes e.g., in a cloud environment).

5.1 Does the CAB operate from multiple sites? Yes:☐ No:☐
If yes, complete the details hereunder as appropriate. Site numbering is to start with A1.

Site no.	Site Location (Address) and total working area	Activities performed at this site	Contact details
A1			
A2			
A3			

6. OTHER EXTERNAL EVALUATIONS/AUDITS

Has your organisation been evaluated or audited (e.g., accreditations, certifications, audits by regulatory authorities) by other external organisations in the past 5 years? If so, please fill in the table below

Name and address of evaluation organisation	Type of evaluation (refer to applicable criteria)	Date of evaluation	Recognition granted if any

7. HUMAN AND TECHNICAL RESOURCES

(List here the resources which will be utilised to cover the scope of accreditation sought)

7.1 Total number of employees in relation to scope of accreditation:

7.2 Distribution of employees in relation to scope of accreditation:	Full-time	Others (specify relationship for e.g., individually contracted)
Employees with University education		
Employees with Technical education		
Employees specially trained as laboratory assistants		
Employees specially trained as technicians		
Employees without special training		
Employees trained in quality management		
Other (incl. secretarial and support staff)		

8. MANAGEMENT REPRESENTATIVE *Name and position (director level) of the CAB's representative with authority to commit the CAB to the requirements for accreditation.*
e-mail:

9. MAIN CONTACT *Name, position, and address of CAB's main contact with the NAB-MALTA* *Note: This is the person to whom all correspondence from the NAB-MALTA will be addressed.*
e-mail:

10. DEPUTY CONTACT *Name, position, and address of CAB's deputy contact with the NAB-MALTA*
e-mail:

11. INFORMATION ABOUT KEY PERSONNEL *(Please identify the following personnel and briefly describe their competence giving the technical qualifications and experience. Professional C.V. to be submitted.)*
11.1 Laboratory Manager/s (refer to Clause 5.2 of EN ISO/IEC 17025:2017)
11.2 Deputy/ies Laboratory Manager/s
11.3 Person/s responsible for the quality management system (refer to Clause 5.6 of EN ISO/IEC 17025:2017)
11.4 Deputy/ies of the person responsible for the quality management system

SECTION B

12. ACCREDITATION SCOPE

Notes:

a. Testing laboratories are to complete **Table (i),** while **Calibration** laboratories are to complete **Table (ii).**

b. A clear description of the test/calibration activities, and a list of standards, methods, or procedures, for which accreditation is being sought, including limits of capability, is to be given in this section.

c. Applicants referring to regulations/legislation in the scope of accreditation they are applying for are to clearly indicate where such regulatory documents refer to conformity assessment activities. Such conformity assessment activities shall be clearly defined and clearly related to an accreditation standard. If such information is not submitted, the accreditation for that activity cannot continue.

d. Add as many rows as necessary to cover the full scope of accreditation to be covered by this application.

e. In column "FREQ" indicate the frequency with which you perform the test/calibration by using the following codes:

d = daily one to several times
w = weekly one to several times
m = monthly one to several times
i = infrequent (one to a few times per year)

f. In column "LOC" indicate whether the test/calibration will be carried out in the laboratory or in some other location. Use the following codes:

A = Test/Calibration is carried out in the laboratory *(If the laboratory operates from multiple sites the use of A1, A2, A3, etc is to be made as per Section 5.1 of this application form*)

B = Test/Calibration is carried out at an offsite location not belonging to the laboratory

(i) For Testing Laboratories

Material/Product/ Matrix tested/	*Type of test/or property measured, range of measurement**	*Applicable EC directives or regulations, national/international standard specifications, internal procedures and works instructions (specify document numbers and revisions).*	*Loc.*	*Freq*	*No. of tests in the past 12m*

** Testing laboratories to have available an estimate of the uncertainty of measurement and detection limits for the tests for which accreditation is sought.*

12. ACCREDITATION SCOPE

(ii) For Calibration Laboratories:

Measured Quantity Instrument or Gauge	*Range*	*Calibration and Measurement Capability (CMC) Expressed as an Expanded Uncertainty (k = 2) (*) (**)*	*Calibration or measurement method or procedure*	*Remarks*	*Loc.*	*Freq*	*No. of calibrations the past 12m*

(*) The expanded uncertainty is at a confidence level of around 95%
(**) To the relative uncertainty shown in the table at least the contribution of the resolution (0.29 units) has to be summed quadratically

Reference to ILAC P14:09/2020 ILAC Policy for Measurement Uncertainty in Calibration should be made when completing the table above.

13. APPLICATION FOR FLEXIBLE SCOPE OF ACCREDITATION

Notes

(a) This applies only when the laboratory is applying for a flexible scope.
(b) Before applying for flexible scope make sure you have read NAB-MALTA Policy ATG16

13.1 Is the laboratory applying for a flexible scope?	YES ☐	NO ☐
If **YES** to 13.1, answer the following questions:		
13.2 Kindly indicate which of the below best identifies the flexible scope which the laboratory is applying for (refer to NAB-MALTA Policy **ATG16**):		
Modification of existing methods (Category 1)	YES ☐	NO ☐
Inclusion of technically equivalent standard methods (Category 2)	YES ☐	NO ☐
Inclusion of revised standard methods (Category 3)	YES ☐	NO ☐

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Notes

(a) This applies only when the laboratory is applying for a flexible scope.

(b) Before applying for flexible scope make sure you have read NAB-MALTA Policy ATG16

13.3 ***For Testing laboratories***

For the accreditation scope applied for, kindly indicate the flexible scope categories which are being requested for each test discipline:

Material/Product/ Matrix tested	*Type of test/or property measured, range of measurement*	*Applicable EC directives or regulations, national/international standard specifications, internal procedures and works instructions (specify document numbers and revisions).*	*Flexible Scope Category required (Cat 1,2,3, or n/a) **

**If Category 1 is identified, kindly provide an explanation of the flexibility boundaries which the laboratory would like to apply for (e.g., different matrix, different test method, different range of measurement, etc)*

***Note:** Add as many rows as necessary to cover the full scope of accreditation to be covered by this application.*

13.4 Please state justification for applying for a flexible scope:

Note: Accreditation with a flexible scope may be not possible in some technical sectors.

SECTION C

14. INFORMATION ABOUT THE CONFORMITY ASSESSMENT BODY		
	Yes/ No	All boxes shall be completed with the necessary information. Enter references from the CAB's quality management system (reference to a document number/s is sufficient) and any other applicable information as necessary.
14.1 Does the applicant legal entity have full control and autonomy over its quality management system?		
14.2 For how long has the quality management system been in operation? (Note: According to regulations RAB01, the system must have been in operation for at least 3 months. This means that records should be available to show that the system has been in operation).		
14.3 Has a complete cycle of internal audits been carried out? If no, please specify date by when a complete cycle will be carried out. (Note: According to regulations RAB01, a complete cycle of internal audits covering the full system of the applicant must be completed prior to the initial assessment.)		
14.4 Are there legally enforceable agreements for ensuring the management and confidentiality of all information obtained or created during performance of laboratory activities?		
14.5 What is the laboratory's policy in relation to reporting opinions and interpretations?		
14.6 What is the laboratory's policy in relation to reporting statements of conformity?		
14.7 Has the laboratory selected Option A or Option B for its management system requirements? (refer to EN ISO/IEC 17025:2017 Clause 8).		
For applicants applying for Flexible Scopes of Accreditation		
14.8 Does the laboratory keep an updated list of accredited test methods**, on the form NABG34?**		
14.9 Are the responsibilities for the management of the flexible scope established and documented?		
14.10 Does the laboratory have a procedure to ensure that all requests, tenders, and contracts are carefully reviewed to determine the requirements of the client and whether the required parameters fall within the agreed boundaries of the laboratory's flexible scope of accreditation?		
14.11 Has the process of reviewing and accepting/authorising methods under a flexible scope been incorporated into the internal audit programme?		

SECTION D

15. Documents and records to be submitted

Notes:

(1) The following documents must be submitted in electronic format with the application in the provided folder structure. NAB-MALTA will not process the application until all the items listed below have been received.

(2) If any of the documents are included as part of a quality management system manual or other documentation, please quote either the manual section or document reference number in the space provide next to the tick box.

(3) Documents submitted are to be in the English or Maltese language.

(4) If an application refers to legislation/regulations and such documentation is not in English or Maltese, then an official translation of such legislation/regulation shall be submitted

		In the box below, tick as necessary and write any necessary references. If not applicable, explain why.
1.	An index and numbered list of the attachments *(use the folder structure provided)*	☐
2.	Cross-reference table *(Note: This should allow a complete and effective identification of the correspondence between the clauses and sub-clauses of the applicable standard/other relevant accreditation criteria (Refer to **ATG18**) such as guidance documents (e.g., EA/ILAC publications) and the parts of the Applicant Laboratory documentation (QM, Procedures, etc) where such requirements are addressed; the non-applicable requirements must be properly identified and not simply omitted; (exclusions must be justified).*	☐
3.	NAB-MALTA accreditation contract, duly signed by authorised company representative *(this document is to be requested from the NAB-MALTA)*	☐
4.	Master list of documents controlled in the management system	☐
5.	All documentation describing the management system according to EN ISO/IEC17025 (e.g., quality management manual, procedure instructions, work instructions, SOPs, applicable standards) – Refer to EN ISO/IEC 17025:2017 Clause 8.2.1	☐
6.	**General - Impartiality -** Declaration of impartiality by management	☐
7.	**General - Impartiality -** Explanation of how the laboratory checks risks to impartiality on an ongoing basis and the records relating to the identification of risks to impartiality.	☐
8.	**General – Confidentiality –** Copy of legally enforceable agreements for management of customer information.	☐
9.	**Structure** - Proof of legal status of the laboratory and declaration of ownership (e.g. copy of MFSA/MBR certificate, Memorandum and Articles of Association)	☐

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		In the box below, tick as necessary and write any necessary references. If not applicable, explain why.
10.	**Structure** - Information on the structure of the laboratory (include organisation chart with names, functions, etc). *Note: Any relationships with a related organisation should be clearly showed or explained*.	☐
11.	**Structure** - Site plan to scale showing the test/calibration areas. This plan should include dimensions.	☐
12.	**Personnel** - Competence criteria and description of responsibilities (job descriptions) of staff members	☐
13.	**Personnel** - Professional C.V. and proof of the relevant qualifications* of the laboratory manager and his/her deputy, the person responsible for the quality management system and his/her deputy. *Where applicable, evidence of equivalence of relevant qualifications are to be provided against the Malta Qualifications Framework	☐
14.	**Personnel** - List of employees stating their qualification/professional training/responsibility at all levels as required in EN ISO/IEC 17025	☐
15.	**Personnel** – List of personnel authorised to sign test/calibration certificates/reports for the scope of accreditation sought.	☐
16.	**Equipment -** List of equipment (including loaned equipment and used working standards, if applicable) **Required information**: inventory number, location, measurand (for which a proof of measurement traceability must be present), indication of equipment/type of equipment/item, manufacturer, calibration interval, indication of the proof of measurement traceability, whether calibration is done in-house or by an external provider. Optional information: testing standard, serial number, responsible person for the equipment, etc...	☐

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		In the box below, tick as necessary and write any necessary references. If not applicable, explain why.
17.	**Equipment -** If applicable, list of reference materials in use and proof of traceability.	☐
18.	**Process** - Method validation data and validation summary	☐
19.	**Process** - Uncertainty measurement budgets (for each measurand/calibration item)	☐
20.	**Process** - Copy of at least one original version of test/calibration report/certificate for each testing/calibration field applied for accreditation.	☐
21.	**Process – Proficiency Testing -** Summary report containing proof of participation in proficiency testing and interlaboratory comparisons **(NABG32 to be completed and returned with this application form***)*	☐
22.	**Management system** - Explanation of how the laboratory considers risks and opportunities associated with the laboratory activities, and the records relating to this activity.	☐
23.	**Management system -** Copy of the internal audit programme	☐
24.	**Management system** - Copy of the minutes of the latest management review	☐
25.	**Flexible scope -** If this application includes a flexible scope, submit: • Flexible Scope Master List form - **NABG34** • Responsibilities for the management of the flexible scope established and documented	☐

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		In the box below, tick as necessary and write any necessary references. If not applicable, explain why.
	• Criteria for defining the competence of laboratory personnel for the purposes of developing, reviewing, validating, and authorising new and/or modified methods within the boundaries of the flexible scope. • Records of qualifications, experience and training of laboratory personnel authorised to review and authorise new and/or modified methods within the boundaries of the flexible scope. • The documented process that the laboratory will follow on receipt of applications for tests within the flexible scope. • The documented verification process that the laboratory will follow on receipt of applications for tests within the flexible scope. • Records related to a practical example of a completed flexible scope design process, for each area the laboratory has applied for. • Evidence of the laboratory's own internal audit completed as evidence of conformity with this policy document.	

SECTION E

16. STATEMENT BY APPLICANT CONFORMITY ASSESSMENT BODY (the "CAB")

The CAB identified below (details of which are set out on paragraphs 1 and 2 of Section A of this application form) hereby applies to the NAB-MALTA to assess the CAB for its eligibility to be accredited as competent to provide the services specified in this application, having regards to relevant accreditation criteria and any other normative documents, conditions or factors that the NAB-MALTA considers to be relevant to or to affect the CAB's competence for the specified services.

The CAB acknowledges that it has read and signed the NAB-MALTA terms and conditions and the relevant NAB-MALTA policies and regulations and agrees to always comply, during the currency of the application made herein and any resulting accreditation, with the NAB-MALTA terms and conditions as the same may be substituted, amended, supplemented or varied by the NAB-MALTA after the date of this application.

The CAB undertakes to pay all fees due to the NAB-MALTA. The CAB declares that it has the necessary resources to undertake accreditation for the scopes requested.

The CAB hereby confirms that it has a right to supply the data and information contained in this application or which it otherwise gives to the NAB-MALTA, and gives its own consent and confirms that it has obtained all properly informed consents from any individuals in respect of whom the Organisation is giving data or information to the NAB-MALTA to enable the NAB-MALTA to lawfully receive such data and information and make use thereof for the purposes of its functions (having particular regard to, but not limited to, applicable data protection legislation) and also confirms that all such data and information is complete, accurate and correct and that it will promptly provide any such further information and data as may be required by the NAB-MALTA to assess and process this application.

The CAB also accepts that the NAB-MALTA might consult with the appropriate regulator and/or other national accreditation bodies should an application be according to the requirements of European or national legislation or any other regulatory instrument. The CAB also accepts that the NAB-MALTA assessment team may be accompanied either by representatives from the European Co-operation for Accreditation (EA) or any other representative from specific regulators or competent authorities.

17. Data Protection Declaration

The NAB-MALTA ("the Controller") will process your personal data in accordance with the relevant provisions of the General Data Protection Regulation (GDPR), the Data Protection Act (Chapter 586 of the Laws of Malta) and other regulations made thereunder. The Controller will process your personal data for assessment and administrative purposes and to comply with its legal obligations. For further information on how your personal data will be processed refer to the Controller's privacy policy.

I, the data subject, hereby consent to having the NAB-MALTA collect and process my personal information from this application.

Signed for and on behalf of
(enter name of organisation and preferably a rubber stamp)

Company Representative

Position:

Signature	**Date**