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| Application Form for Extension to Scope  Testing and Calibration Laboratories |
| NABAF01/L/E |
| EN ISO/IEC 17025:2017 |



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| Logo Small | **NATIONAL ACCREDITATION BOARD**  **MALTA** |
| **APPLICATION FOR EXTENSION TO SCOPE - LABORATORY ACCREDITATION**  **SCHEDULE NABAF01/L/E** | |
| 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**     1. 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.      1. 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. 2. All information provided will be treated in confidence. 3. Additional advice or information may be obtained by contacting the NAB-MALTA at the above address or Tel: (+356) 23952510, e-mail: [info@nabmalta.org.mt](mailto:claudio.boffa@msa.org.mt) 4. 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](http://www.nabmalta.org.mt), the EA website [www.european-accreditation.org](http://www.european-accreditation.org) and the ILAC website [www.ilac.org](http://www.ilac.org). 5. Incomplete applications will result in a delay in process, therefore, ensure that all the information required is available before submitting to the NAB-MALTA. 6. The term “Conformity Assessment Body” and its abbreviation “CAB” will be used in this form to signify the applicant organisation i.e., the laboratory. 7. NAB-MALTA normally organises assessments of extensions to scope at the scheduled assessments unless a separate assessment is specifically requested by the CAB. NAB-MALTA may need to organise a separate assessment to that planned where there is an urgent need to process the extension. 8. In certain circumstances it may be possible for NAB-MALTA to process an extension remotely where the extension sought is very similar to current accredited activities. 9. Advance planning is required, and the assessment may involve additional assessor(s) time and costs. 10. All applications for extension to scope for assessment at the next scheduled on-site assessment must be submitted to NAB-MALTA at least **4 months** in advance of the first day of the planned assessment activity. | |

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| **SECTION A** |

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| 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 CAB requesting an extension to scope | |
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| Address | |
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| Current NAB-MALTA Reg. No..: | VAT No.: |
| Telephone Number: | E-Mail: |
| Website Address: | |
| ***Note****: These details will be used by the NAB-MALTA on the NAB-MALTA databases, certificates, etc.* | |

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| 2. INVOICING DETAILS *(If different to No.1 above)* | |
| Invoicing Contact Name | |
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| Address | |
| Company Registration No.: | VAT No.: |
| Telephone Number: | e-mail: |

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| **3. MANAGEMENT REPRESENTATIVE**  *Name and position (director level) of the CAB’s representative with authority to commit the CAB to the requirements for accreditation.* |
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| e-mail: |

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| 4. 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.* |
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| e-mail: |

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| 5. DEPUTY CONTACT*Name, position, and address of CAB’s deputy contact with the NAB-MALTA* |
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| e-mail: |

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| 6. DISCIPLINE/S OF REQUESTED EXTENSION TO SCOPE |
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| **7. HUMAN AND TECHNICAL RESOURCES**  *(List here the resources which will be in relation to the extension to scope being sought)* | | |
| **7.1 Total number of employees in relation to extension to scope applied for:** | | |
| **7.2 Distribution of employees in relation to extension to scope applied for:** | **Full-time** | **Others (specify relationship for e.g., individually contracted)** |
| Employees with University education |  |  |
| Employees with Technical education |  |  |
| Employees trained in quality management |  |  |
| Employees specially trained as technicians |  |  |
| Employees specially trained as laboratory assistants |  |  |
| Employees without special training |  |  |
| Other (incl. secretarial and support staff) |  |  |

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| **8. 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.)* |
| 8.1 Laboratory Manager (refer to Clause 5.2 of EN ISO/IEC 17025:2017) |
| 8.2 Deputy Laboratory Manager |
| 8.3 Person responsible for the quality management system (refer to Clause 5.6 of EN ISO/IEC 17025:2017) |
| 8.4 Deputy of the person responsible for the quality management system |

| SECTION B |
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| 9. ACCREDITATION SCOPE | | | | | | | | | | |
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| **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 the extension to scope 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 | | | | | | | | | | |
| 1. **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 12 months* |
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| *\* Testing laboratories to have available an estimate of the uncertainty of measurement and detection limits for the tests for which accreditation is sought.* | | | | | | | | | | |
| 1. **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 12 months* |
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| *(\*) 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. | | | | | | | | | | |

| 10. APPLICATION FOR EXTENSION TO SCOPE WITH FLEXIBLE SCOPES *Note: This applies only when the laboratory is applying for a flexible scope. Prior to such an application please contact the NAB-MALTA.* | | | | |
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| 10.1 Is the laboratory applying for a flexible scope? | | | YES | NO |
| If YES to 10.1, answer the following questions: | | | | |
| 10.2 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 |
| 10.3 For Testing laboratoriesFor 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)* |
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| ***Note****: Add as many rows as necessary to cover the full scope of accreditation to be covered by this application.* | | | | |
| 10.4 Please state justification for applying for a flexible scope: | | | | |
| 10.5 Does the laboratory keep an updated list of accredited test methods**, on the form NABG34?** | | | Yes | No |
| 10.6 Are the responsibilities for the management of the flexible scope established and documented? | | | Yes | No |
| 10.7 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? | | | Yes | No |
| 10.8 Has the process of reviewing and accepting/authorising methods under a flexible scope been incorporated into the internal audit programme? | | | Yes | No |
| 10.9 Has the system covering the flexible scope been internally audited? | | | Yes | No |
| **Note:** Accreditation with a flexible scope may be not possible in some technical sectors. | | | | |

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| 11. TIMEFRAMES *.* | | |
| 11.1 Do you wish the proposed extension to scope be assessed at the next scheduled assessment activity? | YES | NO |
| OR | | |
| 11.2 Is there a special urgency for achieving accreditation for the extension which would justify a separate assessment activity? | YES | NO |
| 11.3 If you answered YES to 11.2, please state reason: | | |
| 11.4 Please indicate suitable date (month/year) for separate assessment activity: | | |

| SECTION C | | |
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| **12. 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.*  *(5) All information submitted should be in relation to the application for extension to scope. If the CAB is applying for an extension to scope in new fields or for new testing techniques, all the documents listed below must be submitted.* | | |
|  |  | In the box below, tick as necessary and write any necessary references. If not applicable, explain why. |
|  | An indexed and numbered list of the attachments *(use the folder structure provided)* |  |
|  | 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 CAB’s 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).* |  |
|  | Master list of documents controlled in the management system |  |
|  | Documentation describing the management system according to EN ISO/IEC17025, relevant to the extension to scope applied for (e.g., quality management manual, procedure instructions, work instructions, SOPs, applicable standards) - – Refer to EN ISO/IEC 17025:2017 Clause 8.2.1 |  |
|  | **General - Impartiality -** Declaration of impartiality by management |  |
|  | **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. |  |
|  | **General – Confidentiality –** Copy of legally enforceable agreements for management of customer information. |  |
|  | **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*. |  |
|  | **Structure** - Site plan to scale showing the test/calibration areas for extension to scope. This plan should include dimensions. |  |
|  | **Personnel** - Competence criteria and description of responsibilities (job descriptions) of staff members |  |
|  | **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 |  |
|  | **Personnel** - List of employees stating their qualification/professional training/responsibility at all levels as required in EN ISO/IEC 17025 |  |
|  | **Personnel –** List of personnel authorised to sign test/calibration certificates/reports for the scope of accreditation sought. |  |
|  | **Equipment -** List of equipment (including loaned equipment and used working standards, if applicable) relative to ETS applied for  **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... |  |
|  | **Equipment -** If applicable, list of reference materials in use and proof of traceability - relative to ETS applied for |  |
|  | **Process** - Method validation data and validation summary, relative to ETS applied for |  |
|  | **Process** - Uncertainty measurement budgets (for each measurand/calibration item) relative to ETS applied for |  |
|  | **Process** - Copy of at least one original version of test/calibration report/certificate for each testing/calibration field applied for the extension to scope in. |  |
|  | **Process – Proficiency Testing -** Summary report **NABG32** containing proof of participation in proficiency testing and interlaboratory comparisons (refer to ATG10)relative to ETS applied for. A copy of the updated PT/ILC plan (refer to ATG10). |  |
|  | **Management system** - Explanation of how the laboratory considers risks and opportunities associated with the laboratory activities, and the records relating to this activity. |  |
|  | **Management system -** Copy of the internal audit programme |  |
|  | **Management system** - Copy of the minutes of the latest management review |  |
|  | 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 * 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. |  |
|  | The number of tests/calibrations conducted (in relation to the applied scope of accreditation) during the preceding 12 months. Please also list the major clients (in relation to the scope of accreditation applied for). |  |

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| **SECTION D** | |
| **13. 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. | |
| **14. 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** |