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NAB-MALTA

TECHNICAL GUIDE

ATG16 - Flexible Scopes –
Implementation and Management
The Policy of the NAB-MALTA

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FOREWORD

Accreditation is the process which gives assurance to customers that Conformity Assessment Bodies (CABs) including laboratories, inspection bodies, certification bodies, validation and verification bodies, reference materials producers and providers of proficiency testing schemes, are competent to perform specific conformity assessment activities.

The National Accreditation Board - 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. Accreditation is based upon a series of confidence building steps between accreditation bodies and CAB's, and the subsequent assurance given by NABs that the CABs continuously maintain and enhance their competence. This assurance is achieved through on-site assessments and regular accreditation activities.


The services of the NAB-MALTA are accessible to all applicants whose requests fall within the current activities offered by the NAB-MALTA. 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 on flexible scopes of accreditation for laboratories. It is based on the requirements of EN ISO/IEC17011:2017 and EA-2/15.

This is a mandatory document.

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1. Purpose


- 1.1 This publication outlines the policy of the NAB-MALTA on the accreditation of testing laboratories wishing to implement and maintain a management system capable of controlling a [flexible scope of accreditation](#).
- 1.2 This policy is not restricted solely to scopes that are entirely flexible but is also relevant to scopes which include a combination of fixed and flexible methods.
- 1.3 This policy enables an accredited testing laboratory to assume responsibility for the management of all or part of its scope of accreditation without the necessity of a preliminary evaluation of the NAB-MALTA for each new activity.

2. Definitions

- 2.1 **Fixed Scope:** defines a scope of accreditation as specific conformity assessment activities for which accreditation is sought or has been granted. This scope of accreditation can only be changed by the NAB-MALTA following a formal request by the laboratory which may necessitate the completion of an application for an extension to its scope, and an assessment by the NAB-MALTA.
- 2.2 **Flexible scope of accreditation:** scope of accreditation expressed to allow laboratories to make changes in methodology and other parameters which fall within the competence of the laboratory as confirmed by the NAB-MALTA (from EN ISO/IEC17011:2017).
- 2.3 **Design Process:** refers to the process the laboratory must have in order to expand into additional areas covered by the flexible scope, but not previously undertaken. A design process will need to determine the input requirements, develop the conformity assessment service, validate that the activities meet the requirements, and verify it against the requirements.

3. Introduction

- 3.1 [Flexible scopes of accreditation](#) can allow a laboratory to undertake certain activities, and to report the results as accredited, even though they may not be explicitly stated on their accreditation scope. This may involve:


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- a) the inclusion of new or amended tests in accordance with a method that requires the same competences for which the laboratory is already accredited for;
 - b) the modification of existing methods to broaden their applicability (for e.g. to deal with new materials tested or properties measured);
 - c) the inclusion of newly revised or technically equivalent standard methods that are already covered by accreditation.
- 3.2 Accreditation of a flexible scope places more responsibility onto the laboratory itself for demonstrating that valid, fit-for-purpose activities are undertaken competently, impartially and consistently. However, this does not mean that a laboratory can undertake any test that is requested of it by a client. The boundaries within which the scope is flexible must be clearly defined, with the laboratory demonstrating to NAB-MALTA that it has the knowledge, experience, resources and competence to work within the full range of its flexible scope, as well as possessing suitable environments and equipment at all the applicable sites as declared on the application form and/or through the notification of changes form **NABG11**.
- 3.2.1 These boundaries should be set with respect to the range of:
- a) the materials/products tested
 - b) type of test (e.g. chemical, physical, mechanical, etc...)
 - c) properties measured
 - d) measurements made
 - e) equipment/techniques used
- 3.3 The NAB-MALTA shall monitor and assess the laboratory's system for the management of flexible scopes through regular accreditation activities.
- 3.4 Guidance on the manner in which flexible scopes will be assessed may be found in **ATG01**.

4. Applicability of flexible scopes

4.1 Modification of existing methods (Category 1)

- 4.1.1 A fixed scope of accreditation is generally sufficient in meeting the needs of laboratories that perform routine analysis of specified test items. The methods covered in the scope of accreditation will have been validated to cover the range of items which fall within the scope.

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4.1.2 However, fixed scopes of accreditation might be considered as restrictive by some laboratories as these do not enable additional or modified activities to be added without prior assessment by the NAB-MALTA even where competence in this general area has already been demonstrated.

4.1.3 In these circumstances, provided that the request falls within the agreed boundaries of a flexible scope, a laboratory can implement a process of review and validation of an existing accredited method. This shall follow a predefined protocol in order to demonstrate that the method is fit for purpose for the new application.

4.1.4 Examples of this type of approach include:

- a chemistry laboratory that may have a standard method for analysing a range of pesticides in soil but is requested to analyse a new pesticide, for which the method has not previously been validated;
- a physical testing laboratory accredited for testing the temperature and pressure resistance of pipes might be requested to carry out similar tests on the fittings that connect the sections of the pipe together.

4.2 Inclusion of technically equivalent standard methods (Category 2)


4.2.1 In some sectors, laboratories specialise in certain tests in accordance with standard methods specified by the client. Under a fixed scope of accreditation, the laboratory would need to demonstrate competence to undertake each specific standard method. However, in some cases the client may request the test to be conducted to a national, or similar, standard that has not been specifically accredited by NAB-MALTA although, with the possible exception of one or more minor differences in parameters such as time, temperature, pressure, etc..., it may be regarded as technically equivalent to one for which the laboratory has been accredited.

4.2.2 Where such occurrences arise, provided that the laboratory has undertaken a formal and documented review of the new standard method against their existing accredited method to determine the key differences and to ensure that these are within the boundaries of its flexible scope, then these can be authorised by the laboratory for use.

4.3 Inclusion of revised standard methods (Category 3)

4.3.1 This approach is similar to 4.2 above, although it is more concerned with laboratories working within a sector (e.g. fuel testing) where standard methods are frequently updated.


4.3.2 In order for laboratories operating within such environments to demonstrate ongoing competence to NAB-MALTA, they need to be able to demonstrate that the revisions for standard methods

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remain within their specified competence and capabilities. Therefore, laboratories shall have a formal process in place to review the revised standard, determine the changes and, if they fall within the boundaries of their flexible scope, authorise the revised standard for use.

5. General requirements

- 5.1 This policy document is aligned with **EA-2/15**, *EA Requirements for the Accreditation of Flexible Scopes*. The requirements of this policy document and EA-2/15 shall apply equally to all accredited testing laboratories.
- 5.2 The laboratory shall keep an **updated list of accredited test methods**, including newly modified or introduced methods, available for review by NAB-MALTA. The purpose of this list is to provide transparency of the application of the flexible scope and shall be made readily available to the NAB-MALTA and shall be publicly available. The laboratory shall make use of the NAB-MALTA form **NABG34 – Flexible Scope Master List**.
- 5.2.1 This list shall only be updated after that the appropriate and defined technical activities have been properly performed.
- 5.3 The laboratory's documented quality management system shall clearly state whether it maintains a flexible scope of accreditation and if so, specify the areas of activity and the limits within which it operates. The process of modifying, adding, reviewing, validating/verifying and authorizing methods shall be documented.
- 5.4 Accredited laboratories may be allowed to modify their in-house methods or use revised methods/standards they are accredited for and to introduce similar new methods without prior approval from NAB-MALTA, **provided that these modifications and updated versions of standards/methods do not incorporate new measurement principles that are not covered by the assessed scope**. For such an addition, the laboratory shall apply with NAB-MALTA for an extension to scope.
- 5.5 Laboratories applying for a flexible scope of accreditation shall demonstrate their technical capability to validate modified methods in accordance with clause 7.2.2.2 of EN ISO/IEC 17025.
- 5.6 Successful participation in proficiency testing (PT) scheme(s) is normally required during verification of a change in method, test parameter, etc. The laboratory shall document when it would/would not consider it necessary to demonstrate successful participation in an appropriate PT scheme before reporting a result as accredited.

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- 5.7 Laboratory management shall formally authorise appropriate personnel as competent to take responsibility for key tasks including the review, validation and the authorisation of modified or new methods for inclusion within the system. Any changes to these key posts shall be formally and immediately notified to the NAB-MALTA in writing via **NABG11**.
- 5.8 The responsibilities for the management of the flexible scope shall be established and documented.
- 5.9 The process for review and accepting/authorising methods under a flexible scope shall be incorporated into the internal audit programme. The application and implementation of the flexible scope process shall be discussed during the management reviews.
- 5.10 The laboratory shall maintain a record system that can demonstrate how a method was modified and accepted, the justification for any modifications, and who was responsible for each key activity. The information recorded shall be sufficient to allow audits to clearly trace the events leading to the introduction of each new and/or modified method.
- 5.11 The laboratory shall 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.
- 5.11.1 Prior to accepting work which falls under the flexible scope, the laboratory shall ensure that:
- a) access to all the necessary resources and other means required for the completion of the specific requested activity are available to the laboratory;
 - b) suitably qualified personnel for the completion of the specific activity and its validation or verification are available to the laboratory;
 - c) responsibilities for each of the set activities are assigned;
 - d) the necessary validation or verification according to the procedures established by the laboratory are carried out;
 - e) the relevant procedure is approved;
 - f) prior to updating the master list (**NABG34**), the laboratory shall ensure that the technical activities have been properly performed and duly authorised;
 - g) all premises of the laboratory involved in the testing activity have been previously declared to and assessed by the NAB-MALTA. Moreover, an additional testing activity shall not be included in the list if it involves premises of the laboratory that have not been previously assessed by the NAB-MALTA.
- 5.11.2 The client shall be clearly informed whether the laboratory is capable of undertaking the work within its flexible scope, and whether the results can be reported as accredited.

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5.11.3 The procedure for contract review of the laboratory shall include the features of flexible accreditation scope, especially in those cases where the laboratory has not yet included a requested activity in its list. In these cases, the laboratory shall inform the client of the following:

- a) that it will not be able to issue a report/certificate under accreditation unless the activities established in its system are satisfactorily accomplished;
- b) the appropriate implications. (e.g. turnaround time, price, etc)

5.11.4 Should the validation process of an activity result in the conclusion that the laboratory is not capable of issuing valid reports/certificates, the laboratory shall ensure that an analysis of the cause is carried out and that adequate corrective action is taken. Such actions will include:

- to inform its client that while the analysis and any consequent actions are being progressed, the laboratory will not be able to issue accredited reports/certificates and the reasons for this;
- the revision of the relevant procedures or methods should the reason be specific technical problems for this particular activity, in order to resolve the problem identified and to ensure it does not happen again in the future;
- redefinition of the boundaries within which the scope is flexible. In this case, the laboratory shall inform the NAB-MALTA to review whether the way that the accreditation scope is described must be modified.


5.12 Reports and certificates that bear results derived from a flexible scope of accreditation shall clearly indicate the method used, and whether this falls within the boundaries of the flexible scope of accreditation. Laboratories need to adhere to the regulations stipulated in **RAB02** on the use of the NAB-MALTA accreditation symbol, text reference to accreditation and reference to EA MLA signatory status.

5.13 The laboratory shall inform the NAB-MALTA about all modified methods falling under the flexible scope boundaries, prior to each scheduled assessment or any other accreditation activity, as specified in **ATG12**.

6. Assessment process requirements

6.1 Applying for flexible scopes

6.1.1 All laboratories seeking accreditation for a flexible scope of accreditation shall have at least completed one accreditation cycle. This requirement may be waived in exceptional cases, such as when the flexible scope is immediately required by a laboratory to comply with EU legislation, national legislation or other statutory requirements.

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6.1.2 Testing laboratories, applying for flexible scopes of accreditation shall clearly state in the application form if they would like their management system to be assessed for the purposes of controlling a flexible scope of accreditation. The application form shall clearly define the testing activities and areas that are proposed for inclusion within the boundaries of the flexible scope. Such applications shall be processed by the NAB-MALTA following the normal route for extensions of scope.

6.1.3 Where there is an application for flexible scope then this shall include:


- a) A description of the reason and justification for applying for a flexible scope.
- b) A completed **NABG34 – Flexible Scope Master List**.
- c) A list of the person(s) responsible for the flexible scope system within the laboratory and a brief description of their competence, qualifications and experience.
- d) 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.
- e) 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.
- f) The documented process that the laboratory will follow on receipt of applications for tests within the flexible scope.
- g) The documented verification process that the laboratory will follow on receipt of applications for tests within the flexible scope.
- h) Records related to a practical example of a completed flexible scope design process, for each area the laboratory has applied for.
- i) Evidence of the laboratory's own internal audit completed as evidence of conformity with this policy document.

6.2 Maintenance of Accreditation and Monitoring

6.2.1 The laboratory shall submit all relevant documentation to NAB-MALTA prior to each scheduled assessment as indicated in **ATG12** within the requested timeframes. The NAB-MALTA may also request laboratories to submit specific information on the use of the flexible scope prior to the timeframes as established by **ATG12**.

6.3 Suspension, reduction or withdrawal of flexibility

6.3.1 If it is discovered that a laboratory has not maintained its quality management system, and that the controls have not been effectively implemented resulting in the inappropriate authorisation of modified or new methods, then appropriate measures shall be taken by the NAB-MALTA. The severity of the measures will depend upon the nature, implications and severity of the possible

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non-compliance, in terms of the management of a flexible scope and without prejudice to other actions, the NAB-MALTA may decide to revise the scope such as to reduce or even withdraw the flexibility, thus limiting the specific activities included in the list.

- 6.3.2 The laboratory shall be required to formally inform, in writing, all clients that would have been directly affected by any tests in question and to notify them that the previous reports were outside the laboratory's scope of accreditation. This notification shall clearly state the reason why this has occurred and include any further actions that may be necessary as a result.
- 6.3.3 The implementation and effectiveness of a laboratory's management system in controlling its flexible scope of accreditation shall be monitored as part of the normal assessment cycle. Sufficient time shall be allowed at surveillance and reassessment visits to assess the continuing effectiveness of the management system. This shall include the examination of laboratory records relating to decisions on new and/or modified methods since the last assessment visit, on a sampling basis as appropriate. The time required for these surveillance activities will depend upon the approach taken, the technical area(s) involved, and the number and complexity of new/modified methods included. In some circumstances this may require an additional visit, or visits, to be made to a laboratory's premises.

END