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NAB-MALTA

TECHNICAL GUIDE

ATG01 - Guide to the NAB-MALTA Assessment Process for Laboratories

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of laboratories and other types of conformity assessment bodies.

The National Accreditation Board of 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 applicant laboratory 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 provide laboratories **with general guidance** on the assessment process with the scope of achieving and maintaining accreditation.

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1. Introduction

1.1 The main function of the NAB-MALTA is to establish the technical competence of laboratories to carry out defined test and/or calibration methods, and to ensure, through regular assessment activities, that the CAB continues to fulfil the requirements of the accreditation scheme.

1.2 The NAB-MALTA will accept applications from laboratories that are established as a legal entity in Malta. The decision to accept of applications from laboratories established in other countries will be based on the NAB-MALTA Cross Frontier Policy **ATG13** and EA Policy **EA2/13 M**.

1.3 The NAB-MALTA assessment of the competence of a laboratory is carried out:

- through an assessment of the documentation that describes the management system and procedures of the laboratory;
- on the results of one or more assessments, on-site or remote, to assess how its functions are performed in practice;
- through any other assessment activity as may be suitable.

1.3.1 The purpose of the assessment is to determine whether the laboratory complies with the accreditation scheme requirements specified in publication **ATG18** and as prescribed in the relevant normative documents including the NAB-MALTA regulations and policies, technical documents, the relevant EA/ILAC documents and with any further requirements.

1.4 The NAB-MALTA assessment process is applicable to all sizes of laboratories. The assessment team will take into account the size and complexity of the laboratory. The laboratory, whatever its size or complexity or the location where work is carried out, must provide assurance that it meets the accreditation scheme criteria.

1.5 The time required for assessment activities depends on the scope of accreditation, the complexity of the laboratory, the spread of its activities and the structure of the management system.

1.6 An assessment team having the necessary competence to be able to assess the scope of accreditation will be appointed.

1.7 All information obtained as part of the assessment process is treated as confidential by the NAB-MALTA and its assessors and/or experts.

1.8 NAB-MALTA may use external assessors/experts with the relevant specialist knowledge to judge the competence of the laboratory. The assessors and experts are required by the NAB-MALTA to sign an agreement covering impartiality, confidentiality and conflicts of interest. Activities will be confined to assessing the laboratory's activities for compliance with the accreditation scheme criteria and reporting to the NAB-MALTA.

1.9 The NAB-MALTA assessment team will seek to establish through objective evidence and through its assessment techniques that:

- the management system is appropriate and effective to the laboratory's needs, organisational arrangements and methods of operation;
- the requirements of **EN ISO/IEC 17025** and/or **EN ISO 15189** and other applicable accreditation scheme criteria have been satisfactorily addressed;
- the operational, administrative and technical procedures used to support the management system are complete, technically valid and appropriate and reflect the laboratory's activities.

1.10 Some of the assessment techniques used to establish that the accreditation scheme requirements are being met include:

- questioning of management and staff who have an involvement in or bearing upon the quality of testing and/or calibration work;
- examination of records;
- examination of the suitability, maintenance, calibration, control and use of all equipment used for laboratory work;
- witnessing of testing and/or calibration activities falling within the scope of accreditation;
- examination of the arrangements for exercising control over external suppliers.

2. Scope of accreditation

2.1 It is the policy of the NAB-MALTA to define the scope of a laboratory's accreditation as precisely as possible. Laboratories will therefore be asked to specify in detail the field, measured quantity, method and range of testing and/or calibration for which accreditation is sought and the locations at which these activities are to be carried out. This scope will be agreed as much as possible prior to the assessment in order to determine the extent of the assessment activities.

2.1.1 Scopes of calibration shall at least identify the following:

- the calibration and measurement capability (CMC) expressed in terms of:
- measurand or reference material;
- calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
- measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
- measurement uncertainty;
- location code.

2.1.2 Scopes of testing laboratories shall at least identify the following:

- the materials/product/matrix tested

- type of test, parameter/component/characteristic measured, range of measurement, equipment.
- standard specifications/in-house methods/techniques
- location code

2.2 Applicants should note that the selection of the NAB-MALTA assessment team will be based on the scope applied for and it may not be possible to amend or extend this scope once the assessment team has been appointed.

2.3 Whenever testing and/or calibration activities are carried out for regulatory purposes, a meeting will be held between the Regulator, the NAB-MALTA and the laboratory to discuss the scope of accreditation preferably prior to the initiation of the accreditation process.

2.4 Following accreditation, the scope of accreditation is considered to be in the public domain. In exceptional cases access to certain information can be limited upon the request of the laboratory (e.g. for security reasons).

3. Accreditation in regulatory areas

3.1 Laboratories may apply to be accredited in regulatory areas which are governed by European or national legislation or any other statutory requirements.

3.1.1 Applicants will be required to have engaged with the relevant Regulators and/or Competent Authorities in advance of applying in regulatory areas and, where necessary, have obtained approval for the conformity assessment standard applied for from such Regulator.

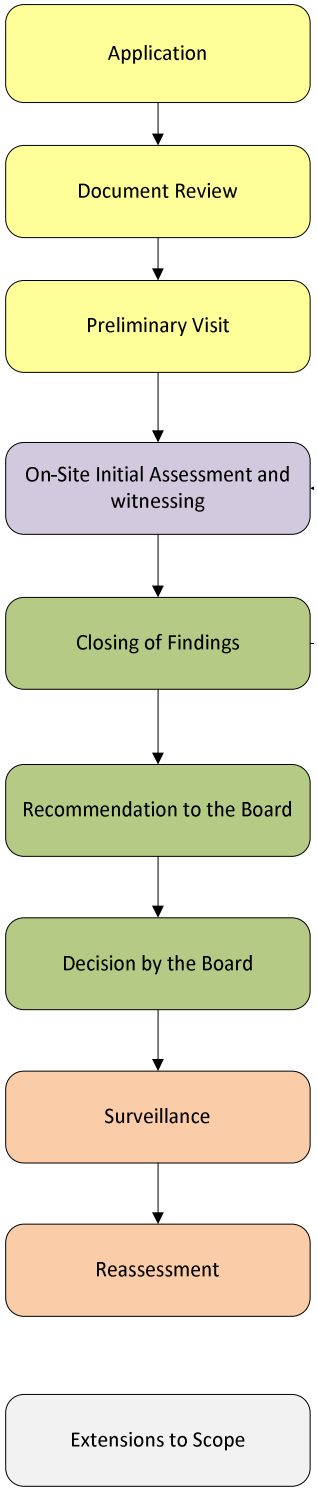
3.2 In cases where the function of the laboratory is defined by European and/or national legislation, the NAB-MALTA will follow any normative documents and guidance published by the European Commission and the relevant Regulator or Competent Authority.

3.3 The testing and/or calibration activities to be accredited will normally be defined in the applicable national or European legislation or in harmonised standards. When this is not the case, the relevant Regulator or Competent Authority should provide the necessary guidance.

3.4 In cases where the laboratory has the intention to become a Notified Body, the NAB-MALTA will follow any guidance published by the European Commission (including the **Blue Guide**), the relevant Regulator/Competent Authority and the provisions defined in **EA2/17 M**.

3.5 During such assessments, the NAB-MALTA will need to communicate with the relevant Regulator/Competent Authority as and when necessary for e.g. to check that all the pertinent issues and guidelines are checked during the assessment process.

3.6 When providing accreditation for regulatory scheme purposes, the NAB-MALTA may grant accreditation without witnessing the conformity assessment activities, on the condition that those activities are witnessed at the first opportunity after accreditation.



Stage 1

Stage 2

Stage 3

Stage 4

Stage 5

STAGE 1 – PREPARATION FOR ACCREDITATION + APPLICATION

4. Preparing for accreditation and submitting the application form

4.1 Having decided to consider seeking NAB-MALTA accreditation, it is strongly recommended that the laboratory:

- consults the NAB-MALTA website and downloads the applicable documents especially the application form, regulations, guides and policies[1];
- consults the European Co-operation for Accreditation (EA) and ILAC websites;
- carries out an internal review of its management system which should include a review of its current quality documentation, procedures and policies against the requirements of **EN ISO/IEC 17025** and/or **EN ISO 15189**, applicable EA/ILAC documents and the NAB-MALTA regulations, policies and other relevant normative documents as described in the NAB-MALTA policy **ATG18**.

4.1.1 If the internal review indicates the need for any modifications to existing procedures or documentation, then the laboratory should plan to have these carried out and in operation prior to the assessment.

4.2 Once this internal review is completed, it is recommended that a meeting be held with the NAB-MALTA. During this meeting the application requirements and the accreditation process will be explained, and the laboratory may also ask for any further clarifications. It is recommended that the key personnel responsible for leading the laboratory towards accreditation, including a representative of management, are present for this meeting.

4.3 The management system of the laboratory has to be in operation for a minimum period of **three months** prior to the initial assessment and that a **full cycle of internal audits plus a management review** have been carried out.

4.4 Each applicant laboratory gives basic information on its activities, equipment and staff in the Application Form, **NABAF01/L** and in the documentation, which is to be submitted to the NAB-MALTA with the application form. It is very important that the documents listed in **Section D** of **NABAF01/L** are submitted with the application form using the folder structure available on the NAB-MALTA website.

4.4.1 Special attention should be given to the scope of accreditation sought.

4.4.2 Before submitting the application form, the laboratory should contact the NAB-MALTA which will provide a template of the accreditation contract. This signed contract of accreditation (**NABC03**) should be submitted together with the application form and the other documentation.

[1] Hard copy versions of NAB-MALTA documentation are also available from the NAB-MALTA Office.

4.4.3 The application for accreditation is a formal request to the NAB-MALTA to conduct the accreditation process and is a commitment from the laboratory to abide by all the accreditation scheme requirements and to pay the **accreditation fees**.

4.4.4 If the laboratory has the intention to become a Notified Body then it should promptly inform the NAB-MALTA. In this case, the laboratory should ensure that it has taken into consideration the requirements defined in the applicable **Directive/s, European Commission Guidance (including the Blue Book)** and **EA2/17 M**. In such a case it is recommended that the Laboratory also holds a meeting with the Notification Authority (refer to Clause 3 – Accreditation in Regulatory Areas).

4.4.4.1 A tri-partite meeting between the applicant laboratory, the Regulator and the NAB-MALTA is preferably held so as to ensure that all the pertinent requirements are clear and that ultimately the scope of accreditation will satisfy the needs of both the CAB and the Regulator; refer to Clause 3 – Accreditation in Regulatory Areas).

5. Review of the application form and the preliminary visit

5.1 On receipt of the **application form** and other associated documentation, the NAB-MALTA appoints an NAB-MALTA Officer, who normally has the function of Team Leader.

5.1.1 As far as possible, NAB-MALTA ensures that the same NAB-MALTA Officer is responsible for processing that laboratory's application through to the accreditation stage and for liaising with the laboratory during its accreditation process. The appointed NAB-MALTA Officer will be present during assessments.

5.2 The NAB-MALTA will carry out an initial application review to ensure that it:

- has received all the necessary information;
- has understood the laboratory's requirements;
- identifies the members of the assessment team with the necessary expertise and competence;
- can make realistic estimates of the timescales and costs involved.

5.3 The NAB-MALTA then sends the following to the applicant:

- an acknowledgement;
- request for any missing documents, where applicable;
- an invoice covering the application fee (which can also include the costs of the preliminary visit);
- the names of the assessment team (i.e. Team Leader and Technical Assessor/s and Technical Expert/s);
- the names of any observers.

5.3.1 The laboratory may object to the chosen members of the assessment team and should inform the NAB-MALTA, in writing, with good and sufficient reason(s) for such objection/s. If these reasons are justified the laboratory will be informed that the process of finding and appointing a new assessor/s might influence the date of any potential assessment and might prolong the accreditation process. If the laboratory objects again to the composition of the newly chosen member/s of the assessment team, the issue will be raised to the Board and a decision will be taken whether to accept the application.

5.3.2 If no objection is received within the period specified in the notification, it will be assumed that the laboratory has accepted the team.

5.4 Once payment covering the preliminary visit is received from the laboratory the necessary arrangements for the assessment activity will be co-ordinated by the NAB-MALTA Officer.

5.5 On approval of the assessment team and on the receipt of the payment of the applicable fees, the NAB-MALTA will proceed to send the relevant laboratory documentation to the assessment team.

5.6 The assessment team carries out an initial desk review audit. Unless major deficiencies are encountered during this review, it is preferable to discuss the outcome of such a review during the preliminary visit. The NAB-MALTA may recommend to the laboratory to take the necessary actions on the deficiencies reported in the desk review and report back to the NAB-MALTA, especially if no preliminary visit will be carried out.

5.7 A preliminary visit is always recommended. The final decision as to whether such a visit will be carried out will be taken by the NAB-MALTA.

5.7.1 The preliminary visit allows discussions with the laboratory on the extent to which the management system and operating procedures appear to fulfil the accreditation scheme requirements.

5.7.2 The benefits of a preliminary visit include:

- better preparation for the initial assessment;
- clarification with the laboratory of the applied scope of accreditation;
- the laboratory can understand better the assessment process;
- the assessment team can form a general idea of the level of implementation of the management system described in the submitted documentation and its compliance with the accreditation scheme criteria. This will be taken into consideration during the preparation of the visit plan for the initial assessment.

5.8 The preliminary visit is conducted by the Team Leader who is, where necessary, accompanied by other members of the assessment team. This visit is usually completed in one day and it is a one-off activity.

5.8.1 During the preliminary visit, the assessment team will identify any deficiencies in order to fulfil the accreditation scheme requirements. The Team Leader will also remind the laboratory that the preliminary visit is not a full assessment and will describe the nature of the initial assessment.

5.8.2 The assessment team will discuss the proposed scope of accreditation and will carry out a brief examination of the laboratory's technical capabilities.

5.8.3 A preliminary visit report will be prepared by the assessment team.

5.9 Depending on the outcome of the preliminary desk study and the result of the preliminary visit, the NAB-MALTA will decide whether to proceed with the accreditation process.

5.10 If the accreditation process can continue, the Team Leader, in liaison with the rest of the assessment team, will determine the composition of the assessment team, and the effort (in man days) required for the initial assessment including time for preparation and standard post assessment activities. This will be a risk-based approach and will consider all factors necessary to enable a reliable assessment of the competence of the laboratory to perform the full range of test or calibration activities proposed for inclusion in its scope of accreditation, including,

- the need either to assess all calibration/test activities, or a representative sample thereof;
- the need to assess all key activities;
- the identification of laboratory technical personnel to be observed;
- the identification of sites/locations in the case of multi-location activities including on-site calibrations/tests.

Note: Key activities include: policy formulation, process and/or procedure development and, as appropriate, contract review, approval and decision on the results of calibrations/tests.

STAGE 2 – INITIAL ASSESSMENT

6. Preparation for the initial assessment

6.1 Should the preliminary visit report indicate that the assessment process can continue, the NAB-MALTA will start preparing for the initial assessment by:

- finalising the selection of the assessment team;
- preparing the assessment plan taking into consideration the risks associated with the activities, locations and personnel covered by its scope of accreditation.
- issuing the assessment plan to the CAB;
- issuing an invoice to cover the assessment effort.

6.1.1 The laboratory shall inform the NAB-MALTA with any changes and actions which may have been taken following the preliminary visit. The laboratory has to submit any revised documentation **not later than 30 days prior to the date of the scheduled assessment.**

6.2 The NAB-MALTA will only proceed with the accreditation process when:

- a formal reply that the assessment team and any observers are acceptable, is received from the laboratory (this formal reply will only be required if the assessment team has been changed from that of the preliminary visit or if any observers have been added);
- full payment of the assessment fee has been settled.

6.2.1 Invoices shall remain valid for a period of **one (1) month** from the date of the invoice.

6.3 The NAB-MALTA adopts a formal selection procedure to ensure that the assessment team has:

- appropriate knowledge of the specific scope for which accreditation is sought;
- sufficient understanding to make a reliable assessment of the competence of the laboratory to operate within its scope.

6.4 An assessment plan will be prepared by the Team Leader in liaison with the other members of the assessment team. This plan will:

- indicate the section/activities/location(s) to be assessed by each assessor;
- specify the tests/calibrations that each assessor will witness during the visit, including any on-site activities and in-house calibrations, as necessary.

6.4.1 The NAB-MALTA Officer will distribute copies of the assessment plan to the laboratory and to the assessment team. All parties are given the opportunity to raise any queries related to the assessment plan.

6.4.2 When the date and plan for the assessment have been settled, the laboratory should ensure that:

- key members of the laboratory staff will be available on the date(s) of the assessment;
- these staff members are aware of the procedures which will be followed during the assessment process;
- a suitable room will be available for the assessors to meet from time to time, in order to discuss the progress of the assessment, to evaluate the observations made and to complete their paperwork;
- prepare any necessary health and safety equipment, including personal protective equipment, for use by the assessment team and any observers.

6.5 Before the assessment, each assessment team member carries out a final detailed review of the relevant documents and records supplied by the laboratory.

6.6 The nature of the initial assessment will depend upon the scope of accreditation required by the laboratory and the complexity of the management system. The following elements will be covered:

- assessment of all elements of the management system;
- witnessing of a sufficiently representative sample covering all the various competencies for the different types of tests/calibrations activities at the laboratory;
- assessment of multiple locations (where applicable).

7. The initial assessment

7.1 All testing and/or calibration activities will be subject to an assessment. The assessment team will assess the technical competence of the staff in each testing and/or calibration activity covered by the scope. This will be done through different assessment techniques including but not limited to:

- the examination of the records outlined above;
- interviewing and discussion with laboratory personnel;
- assessment of the performance of the staff whilst conducting testing and/or calibration activities as per the agreed assessment plan or as selected by the assessment team during any day of the assessment.

7.1.2 The main purpose of the assessment is for the assessment team to gather objective evidence that, for the applicable scope, the laboratory conforms to the relevant accreditation scheme criteria.

7.2 The assessment begins with an **opening meeting** between the NAB-MALTA assessment team and representatives of the laboratory.

7.3 Each member of the assessment team then starts assessing his respective areas. The assessors will examine procedures and records and witness the relevant testing and/or calibration activities included in the scope.

7.3.1 The Team Leader will manage the assessment team to ensure that the assessment plan is completed, relevant activities are assessed and provide support and advice as necessary.

7.3.2 Members of the laboratory staff nominated by the management should accompany each assessor respectively.

7.3.3 Normally, the Team Leader will examine the laboratory's management system requirements to verify that it meets the applicable accreditation scheme requirements.

7.3.4 Assessors/Experts will proceed according to the agreed assessment plan and examine the technical competence of the laboratory and the supporting management system. Assessors will witness testing and/or calibration activities and examine documentation and records.

7.3.4.1 When deciding on the testing and/or calibration activities to be witnessed, the following will be taken into account:

- the variety of the testing and/or calibration activities;
- the laboratory's procedures for selecting, training, authorising and monitoring its personnel, having regard to the qualifications and experience required for different fields and types of activities;
- the skills and competence needed by laboratory staff;
- the various locations from which the CAB will operate;
- statutory requirements, where applicable.

7.3.4.2 When deciding on which laboratory staff will be assessed, account will be taken of:

- new recruits or newly/recently authorised personnel;
- qualifications and experience;
- location;
- roles and responsibilities;
- statutory requirements.

7.3.5 Interim meetings with the laboratory management may be held during the assessment, particularly if a number of assessors/experts are present over a number of days.

7.4 Findings will be based on objective evidence and will be recorded and verified before assessors/experts leave the area under assessment. To secure agreement on the facts, and to avoid subsequent dispute, assessors/experts explain the finding to confirm that it is factually correct.

7.4.1 The findings are recorded on form **NABG10** "List of Findings".

7.4.2 No attempt is made at the time of recording a finding to classify its significance. Interpretation of all the recorded facts, in the context of the NAB-MALTA requirements, is carried out in conjunction with the Team Leader, prior to the closing meeting.

7.5 After the assessors have completed their individual assignments, they hold a private meeting during which each will summarise his own findings and contribute to a co-ordinated view of the laboratory's work. This meeting will help the assessment team to analyse all the relevant information and evidence gathered. This analysis should be sufficient to allow the team to determine the extent of conformity of the laboratory with the accreditation scheme requirements.

7.5.1 During this meeting the preliminary list of findings as listed in **NABG10** is carefully considered to determine whether nonconformities with **EN ISO/IEC 17025** and/or **EN ISO 15189** and/or other accreditation scheme criteria are to be raised.

7.6 When the list of findings is finalised, the Team Leader passes it to the laboratory so that this can be internally discussed prior to the closing meeting. The various laboratory representatives present during the assessment process should facilitate this process by providing details to their management.

7.7 The assessment ends with a **closing meeting** between the assessment team and laboratory representatives, during which each assessor presents a summary of the areas assessed. It is not the intention of the closing meeting to re-run the assessment and to hold detailed discussions about all the nonconformities raised, as establishment and agreement of facts should be carried out during the assessment.

7.7.1 During the closing meeting, the laboratory's representatives shall have the opportunity to ask questions.

7.8 After the assessment, the Team Leader, with the contribution of the assessment team, will prepare an "Assessment Summary Report" **NABG08** which will provide more details on the outcome of the assessment.

8. Multi-site organization (including temporary sites)

8.1 An applicant that operates from a central office through a number of locations may seek a single accreditation. This application will be treated according to EA policy **EA-2/13 M**.

8.2 On application, the laboratory must indicate the number and range of locations being operated. At the on-site assessment the NAB-MALTA will visit selected locations taking into account:

- the results of internal audits from office and other locations;
- the results of management reviews;
- variations in the size of locations;

- complexity of the quality system;
- complexity of the operations carried out at the various locations;
- variations in working practices including, where applicable, equipment used;
- variations in activities undertaken e.g. types of testing and /or calibration.

8.3 It will normally not be necessary to witness the full range of activities for each selected location.

8.4 The NAB-MALTA will seek to establish through objective evidence and by using various techniques that:

- all locations are operating under the same management system;
- all locations are included in the internal audit programme and central review process.

8.5 **Temporary locations** must be working to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process, to provide evidence of the operation and effectiveness of the system.

8.6 During the initial assessment the NAB-MALTA may need to see records of certain activities which are being carried out at different locations.

8.7 If the NAB-MALTA observes nonconformities at any one of the locations of the laboratory with multiple locations, the corrective action procedure shall apply to all locations where applicable. If the results of any of the assessments of sample locations reveal that there is a significant weakness or inconsistency in the application of the quality management system, the NAB-MALTA will review the assessment programme and may increase the number of locations to be assessed.

8.8 Failure by one location to comply with the NAB-MALTA requirements may lead to removal of the location from the scope of accreditation. If the cause of nonconformity is the lack of central control, then the corporate accreditation will be the subject of review by the NAB-MALTA and may lead to suspension or withdrawal of accreditation from all locations.

8.9 Generally, each location from which the laboratory is operating will be visited at least once during the accreditation cycle.

8.10 The NAB-MALTA must be advised of any changes to location, address, ownership, key personnel, scope, equipment, use of accreditation symbol and other significant changes through the use of form **NABG11**. The establishment of any new locations from which the laboratory proposes to offer accredited services must be notified to the NAB-MALTA before these can be included in the scope of accreditation; the need for assessment of the new location will be reviewed, the scope of accreditation will be amended as appropriate and the location will be included in the programme of surveillance and reassessment.

STAGE 3 – CLOSING OF ASSESSMENT

9. Post-assessment process

9.1 The laboratory submits a description of its root cause analysis and extent of the findings and the appropriate corrective actions implemented together with the necessary evidence of such implementation to address any findings to the NAB-MALTA.

9.1.1 The laboratory will carefully complete the List of Findings **NABG10** with such information. Cross-referencing of the evidence of individual actions taken to the finding number should be very clear.

9.1.2 Evidence should be presented to NAB-MALTA identified by the finding number. Evidence submitted should be sent in separate electronic folders clearly identified by the finding number. All evidence is to be submitted in one whole package.

9.1.3 The time for the provision of the evidence is specified in **RAB01**. In many cases it will be possible to provide the evidence electronically, via e-mail or electronic transfer, to the NAB-MALTA (e.g. revised procedure documents, up-to-date calibration certificates, photos).

9.1.4 The assessment team assesses this evidence.

9.1.5 An additional assessment may be necessary to assess the implementation of corrective actions taken. This will be directed specifically to the confirmation of clearance of findings. If an assessor observes a new finding, he will bring the matter to the attention of the laboratory management and to the Director of the NAB-MALTA and will also report it in writing. The cost of such assessments will be charged to the laboratory.

9.2 Once the assessment team is satisfied that all findings have been satisfactorily closed or once the laboratory has exhausted its three chances to close off findings the Team Leader (NAB-MALTA Officer) will prepare a report which will be presented to the Board.

9.2.1 Although three rounds for closing off findings are provided, laboratories should strive to submit all the necessary information and evidence to enable findings to be closed off after the first round of review of such information by the Assessment Team. The second and third rounds should be kept for clarification of only some of the findings. A need for the majority of the findings needing to be closed after the second or third round will normally indicate some deficiencies in the laboratory's process for treating corrective actions.

9.3 The Board will review the report and any other information relevant to the case. The Board may accept the request for accreditation either conditionally or unconditionally, may request further information, or may reject it.

9.4 The NAB-MALTA will inform the CAB about the decision of the Board. If the CAB disagrees with the accreditation decision taken by the Board, it may appeal. The appeal must be in writing and must be received by NAB-MALTA within 30 working days from the date of when the decision was notified to the CAB by e-mail.

STAGE 4 – ACCREDITATION CYCLE

10. Accreditation cycle

10.1 The accreditation cycle beings at or after the date of the decision for granting the initial accreditation or decision after reassessment and will not be longer than **5 years**.

10.2 The NAB-MALTA shall apply an assessment programme for assessing the laboratory's activities during the accreditation cycle to ensure that the laboratory activities representative of the scope of accreditation at the relevant locations are assessed during the accreditation cycle. Factors such as knowledge obtained by the NAB-MALTA about the laboratory's management system and activities and the performance of the laboratory shall be considered by the NAB-MALTA when establishing the assessment programme.

10.3 The assessment programme shall ensure that the requirements of the accreditation scheme and the scope of accreditation will be assessed taking risk into consideration.

10.4 The laboratory will be assessed through regular assessment activities, either on-site or remotely.

10.5 The first scheduled assessment will normally take place **not more than 12 months** after the initial accreditation decision. The NAB-MALTA reserves the right to make extraordinary and unannounced random assessments. This may be the result of complaints or changes, or other matters that may affect the ability of the laboratory to fulfil requirements of accreditation. It may also be a simple random check.

10.6 Before the end of the accreditation cycle, a reassessment is planned and performed taking into consideration the information gathered from the assessments performed over the accreditation cycle. The reassessment's objective is to confirm the laboratory's competence and will cover all the requirements of EN ISO/IEC 17025 or EN ISO 15189.

10.7 The laboratory shall ensure that all the information requested by **ATG12** is submitted to the NAB-MALTA within **30 days** prior to a scheduled assessment. Non-receipt of these documents within this timeframe might lead to the cancellation of the scheduled assessment which might result in the suspension of accreditation. Cancellation costs will normally be charged accordingly.

10.8 At the opening meeting of assessments visits the Team Leader will ask whether all significant changes in the laboratory status or operation have been notified to the NAB-MALTA as per **RAB01** requirements and that any other changes have been specified within the documents submitted as per **ATG12** requirements.

10.8.1 If an assessment reveals that there have been significant changes, for example, of personnel, equipment or the range of services available, these matters shall be recorded by the Team Leader. Assessors shall check that the changes are not such as to diminish the laboratory's capabilities as described in the scope of accreditation, and that they have already been fully notified to NAB-MALTA.

10.8.2 Non-notification of significant changes may cause either the postponement of a scheduled assessment or have an effect on the assessment plan. This may lead to a suspension of accreditation or additional charges being imposed, as additional time to that planned may be needed.

10.9 For the management system, the internal audit and management review are evaluated during each scheduled assessment. Other elements of the management system to be assessed are selected following a risk-based approach. Factors taken into consideration include findings from previous accreditation activities, changes in personnel and other changes. All elements of the management system are assessed at least once during the accreditation cycle.

10.10 At the conclusion of a scheduled assessment, the Team Leader will make a recommendation to the Board on the continuing accreditation of the laboratory.

10.11 Suspension or withdrawal of accreditation will be recommended where the number and seriousness of the nonconformities is such that the laboratory's management system has failed, and the accreditation scheme requirements can no longer be met.

10.12 Changes to scope, suspensions and withdrawals, unless not voluntarily requested by the laboratory, will need to be sanctioned by the Board. The Director of the NAB-MALTA has the authority to immediately reduce or suspend an accreditation and then present his reasons to the Board.

STAGE 5 – EXTENSIONS, CHANGES TO SCOPE, FLEXIBLE SCOPES

11. Extensions to scope

11.1 Following receipt of an application for extension to scope, NAB-MALTA will determine whether there is a need for an on-site assessment to take place. Factors which will be taken into consideration include:

- existing scope of accreditation;
- staff competences within the scopes;
- difference in the competences and variations in the scope sought, from the scope the laboratory is currently accredited for;
- the location at which the extension to scope is sought.

11.2 The NAB-Malta Officer will seek advice from the Team Leader and, normally, the Technical Assessor(s)/Expert(s) on how to proceed. The NAB-Malta Officer may need to arrange an extra on-site assessment or may suggest combining this request with the next scheduled on-site assessment.

11.3 If the extension is assessed during a scheduled on-site assessment, additional time will normally be required.

11.4 In line with **RAB01**, the application for extension of scope shall be submitted to NAB-Malta **at least 4 months before** the next scheduled assessment.

12. Changes to scope

12.1 Laboratories may, from time to time, request changes to the scope of accreditation for e.g. following the publication of a revised standard method. When such changes occur, these shall be communicated using the form **NABG11** "Notification of Changes" and the laboratory shall provide all the necessary relevant documentation.

12.2 Where a detailed document review is necessary, the related costs will be charged to the laboratory accordingly.

12.3 Changes to scope will be approved by the Board and then communicated to the laboratory.

13. Flexible scopes

13.1 A laboratory that is already accredited for testing can apply with the NAB-MALTA:

a) to modify any part of its accreditation from a fixed to a flexible scope;
b) to extend its scope to include testing activities that require a flexible scope.

13.2 Laboratories wishing to implement and maintain a management system capable of controlling a flexible scope of accreditation shall follow the NAB-MALTA policy **ATG16**.

13.3 All laboratories seeking accreditation for a flexible scope of accreditation should have at least completed one accreditation cycle. This requirement may be waivered 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.

13.4 The assessment of a laboratory which applies for a flexible scope, includes:

a) the competence and capability to perform each technique included within the bounds of the flexible scope of accreditation;
b) the management system and controls implemented by the laboratory for the purpose of maintaining a flexible scope of accreditation;
c) the process of reviewing, validating, approving and authorising new and/or modified methods for use within the bounds of the flexible scope of accreditation.

13.5 Between scheduled visits the NAB-MALTA may select a method introduced via the flexible scope process and request that the laboratory submits for assessment the relevant records relating to its validation/authorisation for review. The NAB-MALTA may select to include in the plan of the on-site assessment any test which has been introduced via flexible scope.

Appendix 1 Timeframes

Stage	Activity	Timeframe	Doc. Ref.
AS1	Initial assessment and/or extensions to scope: The maximum allowed timeframe for clearance of nonconformities	3 months	IMSP202
AS#; S##	The maximum allowable timeframe for completion date for the clearance of the nonconformities	30 working days **Stricter time limits or immediate corrective action may need to be taken depending on the type of finding**.	RAB01 IMSP202
AS#, S##	Submission of additional information and/or evidence for the closure of the nonconformity	5 working days from the request of the assessor for further evidence	RAB01
AS#, S##	Submission of information requested by ATG12	at least 30 days prior to the scheduled visit	IMSP202
ETS	Submission of NABAF01/L/E "Application form for Extension to Scope of Accreditation"	at least 120 working days in advance of the next scheduled visit.	IMSP202 RAB01 Cl.4.16 ATG01 Cl.11.3
AS#	Minimum period of operation of the CAB's management system according to the accreditation scheme requirements	3 months	ATG01 Cl. 4.3
S##	First assessment following initial assessment.	Not more than 12 months after the initial accreditation decision, unless there is a reason for such an assessment to take place later	RAB01 Cl.2.7
S##	Surveillance (except first on-site assessment following initial assessment, as above) – scheduled assessments	Normally every year	RAB01 Cl.2.7
AS#	Reassessment	Every 5 years since the date of initial accreditation decision or the date of the last reassessment	RAB01 Cl.2.7
AV#	Additional assessment activities	As required	RAB01 Cl.2.7

Do you need further information?

This publication, application forms (**NABAF01/L, NABAF01/L/E)** 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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