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NAB-MALTA

TECHNICAL GUIDE

ATG06 - Guide to the NAB-MALTA
Assessment Process for Certification
Bodies and EMAS Verifiers

Revision 2 September 2019

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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 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 on-site 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. 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 provide certification bodies and EMAS Verifiers with general guidance on the NAB-MALTA assessment process with the scope of achieving and maintaining accreditation.

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Note: Unless otherwise stated, the term “Conformity Assessment Body (CAB)” shall refer to certification bodies, verifications bodies, validation bodies, EMAS Verifiers, and any other conformity assessment body covered by this guide.

1. Introduction

- 1.1 The main function of the NAB-MALTA is to establish the competence of CABs to carry out specified conformity assessment activities in defined fields 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 CAB is carried out:
- through an assessment of the documentation that describes the management system and procedures of the CAB
 - on the results of one or more on-site assessments in order 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 CAB complies with the accreditation scheme requirements specified in publication **ATG18** and as prescribed in the relevant normative documents including the NAB-MALTA regulations, policies, technical documents, the relevant EA/IAF documents and with any further requirements.
- 1.4 NAB-MALTA assessment procedures are applicable to all sizes of CABs. The assessment team will take into account of the size and complexity of the CAB during the assessment. The CAB, 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 CAB, the spread of its activities and the structure of the management system.

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- 1.6 The composition of the assessment team depends on the scope of accreditation and the size of the CAB and will have the necessary competence to assess the accreditation scope the CAB has applied for.
- 1.7 All information obtained as part of the assessment process is treated as confidential by the NAB-MALTA and its assessors/experts.
- 1.8 NAB-MALTA may use external technical assessors/experts with the relevant specialist knowledge to judge the competence of the CAB. The assessors and experts are required by the NAB-MALTA to sign a sign an agreement covering impartiality, confidentiality and conflicts of interest. Activities will be confined to assessing the CAB'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 CAB's needs, organisational arrangements and methods of operation; including multiple location operations and number of auditors/verifiers;
 - the requirements of the applicable accreditation scheme criteria have been satisfactorily addressed;
 - the requirements of the certification 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 CAB'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 are involved in the conformity assessment activities;
 - examination of records;
 - examination of the suitability, maintenance, calibration, control and use of all equipment, where necessary;
 - witnessing of conformity assessment activities falling within the scope of accreditation;
 - examination of the arrangements for exercising control over external providers.

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2. Scope of accreditation

- 2.1 It is policy of the NAB-MALTA to define the scope of accreditation as precisely as possible. CABs will be asked to provide the necessary details about the activities for which accreditation is sought and the locations at which these activities are to be carried out; this scope will be agreed as far as possible before the assessment in order to determine the extent of the assessment activities.
- 2.2 CABs 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 assessment team has been appointed.
- 2.3 **Whenever conformity assessment activities are carried out for regulatory purposes**, a meeting will be held between the Regulator, the NAB-MALTA and the CAB 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 unless otherwise requested by the CAB for legitimate reasons.

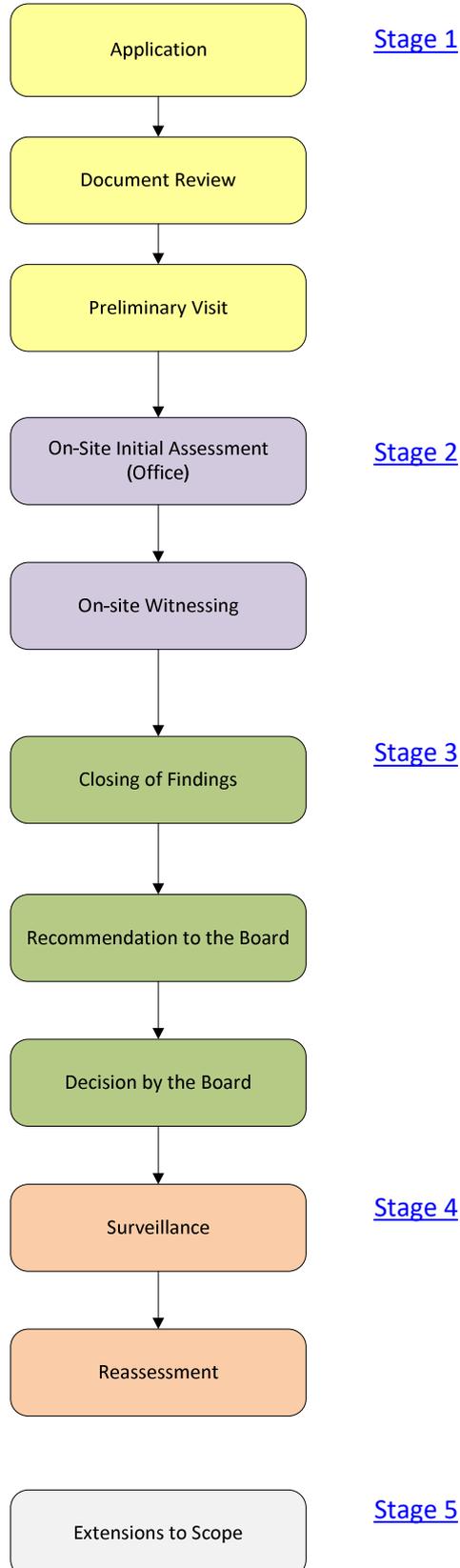
3. Accreditation in regulatory areas

- 3.1 CABs may apply to be accredited in areas which are governed by European or national legislation or any other statutory requirements.
- 3.1.1 CABs shall 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 CABs is defined by European and/or national legislation, the NAB-MALTA will follow any guidance published by the European Commission and the relevant Regulator or Competent Authority.
- 3.3 The conformity assessment activities to be accredited will normally be defined in the applicable national or European legislation or in harmonised standards. Where this is not the case, the relevant Regulator or Competent Authority shall provide the necessary guidance.

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- 3.4 In cases where the CABs have the intention to become Notified Bodies, the NAB-MALTA will follow any guidance published by the European Commission (including the **Blue Book**), 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 on an ongoing basis and as necessary, especially to ensure the publication of a correct scope of accreditation and 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.

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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 CAB:
- consults the [NAB-MALTA](#) website and downloads the applicable documents especially the application form, regulations, guides and policies¹;
 - consults the [European Co-operation for Accreditation](#) (EA), and [IAF](#) websites and other relevant websites (e.g. for EMAS – the EC EMAS Web Portal);
 - carry out an internal review of its management system which should include a review of its current quality documentation against the requirements of the applicable accreditation schemes 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 CAB should plan to have these carried out and in operation prior to the on-site assessment visit.
- 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 CAB may also ask for any further clarifications. It is recommended that the key persons responsible for leading the CAB towards accreditation, including a representative of management, are present for this meeting.
- 4.3 The management system of the CAB shall 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** shall have been carried out.
- 4.4 Each applicant CAB gives basic information on its activities, equipment and staff on the appropriate application form (**NABAF01**) and in the documentation which are to be submitted to the NAB-MALTA with the application form. It is very important that the documents listed in Section D of **NABAF01** are submitted with the application form using the folder structure available on the NAB-MALTA website.

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

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

4.4.2 Before submitting the application form, the CAB 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.

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

4.5.1 If the CAB has the intention to become a Notified Body then it should promptly inform the NAB-MALTA. In this case the CAB 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 CAB also holds a meeting with the Malta Competition and Consumer Affairs Authority (MCCAA), which is the Authority responsible for the notification of such bodies to the European Commission (refer to [Clause 3 – Accreditation in Regulatory Areas](#)).

4.5.2 A tri-partite meeting between the applicant CAB, 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 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 CAB's application through to the accreditation stage and for liaising with the CAB during its accreditation process. This NAB-MALTA Officer will be present during on-site assessments.

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

- has received all the necessary information;
- has understood the CAB's requirements;

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- identifies the members of the assessment team with all the necessary expertise and competence; and
- can make realistic estimates of the timescales and costs involved.

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

- 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 CAB 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 CAB will be informed that the process of finding and appointing a new assessor/s **and/or experts** might have an effect on the date of any potential on-site assessments and might prolong the accreditation process. If the CAB objects to the assessment team once again, 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 this period it will be assumed that the CAB has accepted the team

5.4 Once payment covering the preliminary visit is received from the CAB the necessary arrangements for the on-site 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 CAB 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 CAB to take the necessary actions on the deficiencies reported in the desk review and preferably to report back to NAB-MALTA, especially if no preliminary visit will be carried out.

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

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5.7.1 The preliminary visit allows discussions with the CAB 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 CAB of the applied scope of accreditation;
- 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 the Technical Assessor/s and/or Technical Expert(s). This visit is usually completed in one day and it is a one-off activity. It is preferable to witness an inspection during such a visit.

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 CAB that the preliminary visit is not a full assessment and will describe the nature of the initial on-site assessment.

5.8.2 The assessment team will discuss the proposed scope of accreditation and will carry out a brief examination of the CAB'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 or not to proceed with the accreditation process.

5.10 If the accreditation process can continue, the Team leader in liaison with the Technical Assessor/s and or Technical Expert(s) will determine the composition of the assessment team, and the effort (in man days) required for the initial assessment including time for preparation and post on-site assessment activities. This will be a risk-based approach and will take into account all factors necessary to enable a reliable assessment of the competence of the CAB to perform the full range of conformity assessment activities proposed for inclusion in its scope of accreditation, including,

- the need either to assess all conformity assessment activities, or a representative sample thereof;
- the need to assess all key activities

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- the identification of technical personnel to be observed;
- the identification of sites/locations in the case of multi-location activities including on-site conformity assessment activities.

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

STAGE 2 – INITIAL ASSESSMENT

6. Preparation for the initial on-site 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 on-site assessment effort.

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

6.2 The NAB-MALTA will only proceed with the processing of the application process when:

- a formal reply that the assessment team is acceptable is received from the CAB (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 as a whole has:

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

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- 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/expert;
 - specify the conformity assessment activities that each assessor/expert will witness either on the same day of the Head Office visit or during another day when such activities are available for witnessing.
- 6.4.1 The NAB-MALTA Officer will distribute copies of the assessment plan to the CAB 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 CAB should ensure that:
- key members of the CAB's staff will be available on the date(s) of the on-site 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 on-site assessment, each assessment team member carries out a final detailed review of the relevant documents and records supplied by the CAB.
- 6.6 The nature of the initial assessment will depend upon the scope of accreditation required by the CAB and the complexity of the management system that is being operated. The following elements will be covered:
- assessment of all elements of the management system;
 - witnessing of a sufficiently representative sample of conformity assessment activities covering the various competencies;
 - assessment of multiple locations (where applicable);

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7. Initial assessment

- 7.1 All type of conformity assessment activities will be subject to an office assessment and technical review. The assessment team will assess the technical competence for each conformity assessment activity covered by the application. This will be done through different assessment techniques including but not limited to:
- the examination of documents and records;
 - interviewing and discussion with CAB personnel;
 - assessment of the performance of the staff whilst conducting conformity assessment activities as per the agreed assessment plan or as selected by the assessment team during any day of the on-site assessment activity.
- 7.1.2 The main purpose of the on-site assessment is for the assessment team to gather objective evidence that, for the applicable scope, the CAB conforms to the relevant accreditation scheme criteria.
- 7.2 The on-site assessment begins with an opening meeting between the NAB-MALTA assessment team and CAB representatives.
- 7.3 Each member of the assessment team then departs to his respective areas to begin the assessment. The assessors will examine procedures and records and witness the relevant conformity assessment 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 Staff members of the CAB should be nominated by the management to accompany each assessor.
- 7.3.3 Normally, the Team Leader will examine the CAB's quality management system with the appropriate staff, to verify that it meets the applicable accreditation scheme requirements.
- 7.3.4 Technical Assessors/Experts will proceed according to the agreed assessment plan and examine the technical competence of the CAB and the supporting management system. Technical Assessors/Experts will witness the CAB's conformity assessment activities and examine the documentation and records.

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7.3.4.1 When deciding on the conformity assessment activities to be witnessed, the following will be taken into account:

- the variety of the activities and the variety of products, services, processes and plant covered by the activities;
- the CAB'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 CAB's staff;
- the various locations from which the CAB will operate;
- statutory requirements.

7.3.4.2 When deciding on which CAB 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 CAB management may be held during the on-site assessment, particularly if a number of assessors are present over a number of days.

7.4 Findings will be based on objective evidence and may 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 **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 CAB'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 conformance of the CAB with the accreditation scheme requirements.

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- 7.5.1 During this meeting the preliminary list of findings NABG10 are carefully considered to determine whether nonconformities with the applicable accreditation scheme criteria are to be issued.
- 7.6 When the list of findings is finalised, the Team Leader shall give it to the CAB so that this can be internally discussed prior to the closing meeting. The various CAB representatives present during the assessment process should facilitate this process by providing details to their management.
- 7.7 The on-site assessment ends with a closing meeting between the assessment team and the CAB's 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 CAB's representatives shall be given the opportunity to ask questions.
- 7.8 After the on-site 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. Witnessed conformity assessment activities

- 8.1 The purpose of witnessed activities, such as certifications and verifications, is to observe the procedures in practice and to ensure that the level of sector competence displayed by the CAB is such that results, and conclusions are credible and reliable.
- 8.2 There will be situations where planning for the witnessing of activities may only be finalised either during the Office assessment or after. There will be a maximum of 3 months between the Office assessment and the conformity assessment activities to be witnessed. In cases where witnessing is not carried out during the same week of assessment of the Office, separate reporting with a separate set of findings, may be necessary.
- 8.3 The minimum number of on-site witnessing at initial assessment will normally be one for each type of conformity assessment activity.

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- 8.4 When deciding on the activities to be witnessed, the aspects listed in [7.3.4.1](#) will be considered by the NAB-MALTA.
- 8.5 When deciding on which CAB personnel will be assessed, the aspects listed in [7.3.4.2](#) will be considered.
- 8.6 During the witnessed activity, the Assessment Team will need to see that as a minimum:
- The CAB's member of staff has the competence for the activity performed;
 - The CAB's member of staff competence is consistent with records;
 - The CAB's member of staff has been supplied with all the necessary documentation.
- 8.7 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If a CAB's member of staff operates from home, this examination will be arranged at a mutually acceptable location.
- 8.8 The CAB will be required to pay the costs of an independent interpreter, as necessary, where a witnessed activity is not conducted in English or Maltese.
- 8.9 The NAB-MALTA assessors will ensure that their role during on-site assessment is one of observer and they will not influence the outcome of the conformity assessment activity being performed.
- 8.9.1 Where applicable at the opening meeting the CAB representative may be required to allow the NAB-MALTA assessor to explain his role and the purpose to the CAB's client.
- 8.10 At the end of the witnessing of the activity, a meeting shall be held during which the NAB-MALTA team will provide their feedback. The NAB-MALTA assessor will prepare a witness report and, where necessary, a list of findings. This report and the findings may form part of the overall summary report or may be considered as a separate report.

9. Multi-site CAB (including temporary sites)

- 9.1 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**.

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- 9.2 On application, the CAB must indicate the number and range of locations being operated. At the assessment the NAB-MALTA will visit selected locations taking into account:
- the results of internal audits from the 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 **conformity assessment** activities undertaken.
- 9.3 It will normally not be necessary to witness the full range of activities for each selected location.
- 9.4 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.
- 9.5 **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.
- 9.6 During the assessment the NAB-MALTA may need to see records of certain conformity assessment activities which are being carried out at different locations.
- 9.7 If the NAB-MALTA observes nonconformities at any one of the locations of the CAB 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.
- 9.8 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.

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

9.10 The NAB-MALTA must be advised of any changes to location addresses and activities **through the use of form NABG11**. The establishment of any new locations from which the CAB 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

10. Post-assessment process

10.1 The CAB 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.

10.1.1 The CAB will complete the List of Findings **NABG10**. The CAB should complete the relevant columns of the List of Findings NABG10. Cross-referencing of the evidence of individual actions taken to the finding number should be very clear.

10.1.2 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.

10.1.3 The time for the provision of the evidence is specified in **RAB1**. 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).

10.1.4 The NAB-MALTA Officer will acknowledge receipt of the evidence. The assessment team will assess this evidence.

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- 10.1.5 A follow-up visit to the CAB may be necessary to assess the implementation of corrective actions taken. This will be directed specifically to the confirmation of clearance of findings. **If the assessment team observes a new finding, this will be brought to the attention** of the CAB and to the Director of the NAB-MALTA and will also report it in writing. The cost of such visits will be charged to the CAB.
- 10.2 Once the Assessment Team is satisfied that all findings have been satisfactorily cleared, **or after that the review process is repeated for three times, whichever comes first,** the Team Leader (NAB-MALTA Officer) will submit a report to the Board which shall include the final recommendation on accreditation.
- 10.3 The Board will review the recommendation 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.
- 10.4 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.

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STAGE 4 – ACCREDITATION CYCLE

11. Accreditation cycle

- 11.1 The accreditation cycle begins 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**.
- 11.2 The NAB-MALTA shall apply an assessment programme for assessing the CAB's activities during the accreditation cycle to ensure that the CAB's 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 CAB's management system and activities and the performance of the CAB shall be considered by the NAB-MALTA when establishing the assessment programme.
- 11.3 The assessment programme shall ensure that the requirements of the accreditation scheme and the scope of accreditation will be assessed taking risk into consideration.
- 11.4 The CAB will be assessed through regular assessment activities including on-site assessments. Similar procedures to those described in the previous sections will be followed for the conduct of on-site assessments. The NAB-MALTA may use other assessment techniques to achieve the same objective as an on-site assessment.
- 11.5 The first scheduled on-site assessment will normally take place **six (6) months** after accreditation has been granted. The NAB-MALTA reserves the right to make extraordinary and unannounced random assessments at any time. This may be the result of complaints or changes, or other matters that may affect the ability of the CAB to fulfil requirements of accreditation. It may also be a simple random check.
- 11.6 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 CAB's competence and will cover all the relevant accreditation scheme requirements.
- 11.7 The CAB shall ensure that all the information requested by **ATG12** is submitted to the NAB-MALTA within 30 days prior to a scheduled on-site assessment. Non-receipt of these documents within this timeframe might lead to the suspension of the scheduled on-site assessment which might result in the suspension of accreditation. Cancellation costs will normally be charged accordingly.

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- 11.8 At the opening meeting of **on-site assessments** visits the Team Leader will ask whether all significant changes in the CAB status or operation have been notified to the NAB-MALTA as per **RAB1** requirements and that any other changes have been specified within the document submitted as per **ATG12** requirements.
- 11.8.1 If an on-site 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 CAB's capabilities as described in the scope of accreditation, and that they have already been fully notified to NAB-MALTA.
- 11.8.2 Non-notification of significant changes may cause either the postponement of a **scheduled on-site 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 on-site may be needed.
- 11.9 For the management system, the internal audit and management review shall be evaluated during each **scheduled** on-site 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 shall be assessed at least once during the accreditation cycle.
- 11.10 At the conclusion of **a scheduled on-site assessment**, the Team Leader will make a recommendation to the Board on the continuing accreditation of the CAB.
- 11.11 Suspension or withdrawal of accreditation will be recommended where the number and seriousness of the nonconformities is such that the CAB's management system has failed, and the accreditation scheme requirements can no longer be met.
- 11.12 Changes to scope, suspensions and withdrawals, unless not voluntarily requested by the CAB, 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.

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STAGE 5 – EXTENSIONS AND CHANGES TO SCOPE

12. Extensions to scope

- 12.1 Following receipt of an application for extension to scope, NAB-MALTA will determine whether there is a need for an office and/or location assessment and/or on-site assessments of the activity to take place. Factors which will be taken into consideration will be the:
- existing scope of accreditation;
 - CAB’s personnel competences within the scopes;
 - difference in the competences and variations in the scope sought, from the scope the CAB is currently accredited for;
 - the location at which the extension to scope is sought.
- 12.2 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 in the normal way or may suggest combining this this request with the next scheduled on-site assessment.
- 12.3 If the extension is assessed during a scheduled on-site assessment additional time will normally be required.
- 12.4 In line with **RAB1**, the application for extension of scope shall be submitted to NAB-Malta **at least 4 months before the next scheduled on-site assessment.**

13. Changes to scope

- 13.1 CABs 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 CAB shall provide all the necessary relevant documentation.
- 13.2 Where a detailed document review is necessary, the related costs will be charged to the CAB accordingly.
- 13.3 Changes to scope will be approved by the Board and then communicated to the CAB.

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Appendix 1 Time Related Activities – Accreditation Process

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.	RAB1 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	RAB1
AS#, S##	Submission of information requested by ATG12	at least 30 days prior to the scheduled visit	IMSP202
ETS	Submission of NABAF01/E “Application form for Extension to Scope of Accreditation”	at least 120 working days in advance of the next scheduled visit.	IMSP202 RAB1 Cl.4.16 ATG06 Cl.12.4
AS#	Minimum period of operation of the CAB’s management system according to the accreditation scheme requirements	3 months	ATG06 Cl. 4.3
S##	First on-site assessment following initial assessment	Not more than 12 months after the initial on-site assessment date, unless there is a reason for such an on-site assessment to take place later	RAB1 Cl.2.7
S##	On-site surveillance visits (except first on-site assessment following initial assessment, as above)	Normally every year	RAB1 Cl.2.7
AS#	Reassessment	Every 5 years since the date of initial	RAB1 Cl.2.7

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Stage	Activity	Timeframe	Doc. Ref.
		accreditation decision or the date of the last on-site re-assessment	
AV#	Additional visits or other assessment activities	As required	RAB1 Cl.2.7

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Do you need further information?

This publication, application forms and other information about accreditation including this document, are available for download from the NAB-MALTA website at <http://www.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>.

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