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NAB-MALTA

TECHNICAL GUIDE

ATG05 - Guide to the NAB-MALTA Assessment Process for Inspection Bodies

Revision 9

February 2024

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of conformity assessment bodies (laboratories, inspection bodies, certification 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. Access is not conditional upon the size of the 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 inspection bodies (referred to as CABs (conformity assessment bodies)) 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 competence of inspection bodies (referred to as CABs (Conformity Assessment Body) in this document) and to ensure, through regular assessment activities, that CABs continue to fulfil the requirements of the accreditation scheme.
- 1.2 The NAB-MALTA will accept applications from CABs that are established as a legal entity in Malta. Additional factors will be taken into consideration prior to the acceptance of an application. The decision to accept of applications from CABs 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 and capability 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 assessments, on-site or remote, to assess how its functions are performed in practice;
 - through any other accreditation 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 as 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 any further requirements.
- 1.4 The NAB-MALTA assessment process is applicable to all sizes of CABs. The assessment team will take account of the size and complexity of the body 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 requirements.
- 1.5 The time required for assessment activities will depend on the complexity of the organisation, the spread of its activities, the structure of the management system and the scope of accreditation.
- 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 technical experts.

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- 1.8 The NAB-MALTA may use external technical assessors/experts with the relevant specialist knowledge to judge the competence of the CAB. The assessors and technical experts are required by the NAB-MALTA to sign an agreement covering impartiality, confidentiality, and conflicts of interest.
- 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 inspectors;
 - all of the requirements of **EN ISO/IEC 17020** 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 CAB’s activities.
- 1.10 Some of the techniques used to establish that the accreditation scheme requirements are being met include:
- questioning of management and staff who are involved in inspection activities;
 - examination of records;
 - examination of the suitability, maintenance, calibration, control, and use of equipment used for the inspection activities;
 - witnessing of inspection activities;
 - examination of the arrangements for exercising control over external providers.

2. Scope of accreditation


- 2.1 It is policy of the NAB-MALTA to define the scope of an CAB’s accreditation as precisely as possible. CABs will therefore be asked to specify in detail the field, type, and range of inspections 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 Applicants should note that the selection of the NAB-MALTA Assessment Team will reflect the scope applied for and it may not be impossible to amend or extend this scope after the Assessment Team has been appointed.

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- 2.3 Following successful assessment, the scope of accreditation will include:
- the type of CAB (as defined in ISO/IEC 17020);
 - inspection schemes, where relevant;
 - the field and range of inspection for which accreditation has been granted;
 - the regulations, inspection methods, standards and/or specifications containing the requirements against which the inspection is to be performed, as applicable.
- 2.4 Whenever inspections 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.
- 2.5 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 CAB (e.g., for security reasons).

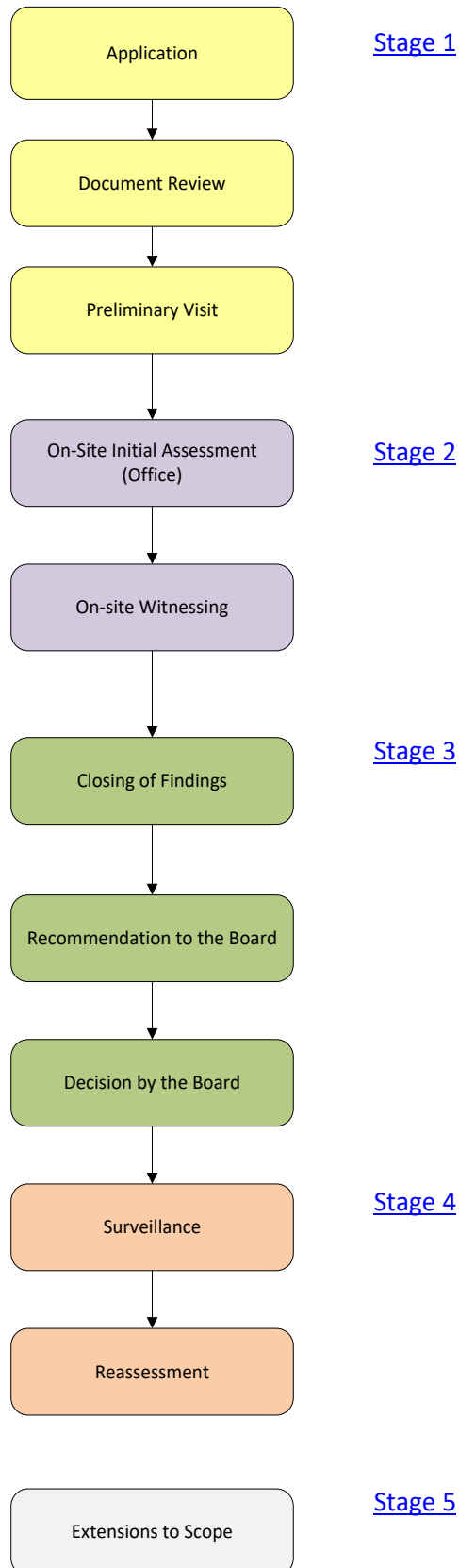
3. Accreditation in regulatory areas


- 3.1 CABs 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 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 standard to be applied for accreditation from such Regulator/Competent Authority.
- 3.2 In cases where the function of CABs is defined by European and/or national legislation, the NAB-MALTA will follow any normative documents and guidance including that published by the European Commission, the relevant Regulator or Competent Authority and the European Co-operation for Accreditation.
- 3.3 The conformity assessment activities to be accredited will normally be defined in the applicable national or European legislation or in harmonised standards or in other similar documents (for e.g., regulator-approved certification schemes). When this is not the case, the CAB shall obtain the necessary guidance from the relevant Regulator or Competent Authority.
- 3.3.1 The applicant CAB will clearly identify the conformity assessment requirements for the regulatory scheme they are applying for, by cross referencing the application with the applicable regulatory requirements.

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- 3.4 In cases where the CAB has the intention to become a Notified Body, the NAB-MALTA will follow any guidance published by the European Commission (including the **Blue Book**), the relevant Regulator/Competent Authority and the requirements in **EA2/17 M**.
- 3.5 During such assessments, the NAB-MALTA will need to communicate with the relevant Regulatory/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. **Such communication may result in the exchange of the CAB documents with the Regulator/Competent authority.**
- 3.6 When providing accreditation for regulatory scheme purposes, the NAB-MALTA may grant accreditation without witnessing the conformity assessment activities conditional that those activities are witnessed at the first opportunity after accreditation. **This will be in line with the requirements as established in EA-2/17 and the relevant EA resolutions.**
- 3.7 **Where a CAB applies for accreditation which makes reference to a legislation from another country, the NAB-MALTA may need to consult with the national accreditation body of that country in line with the requirements of EA-2/13. Communication with the regulator/competent authority of that country may also be necessary and this may result in the exchange of information about the CAB and its documents.**

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STAGE 1 – PREPARATION FOR ACCREDITATION + APPLICATION

4. Preparing for accreditation and submitting the application form


- 4.1 When an applicant CAB have decided to consider seeking accreditation from the NAB-MALTA, it is strongly recommended that the CAB:
- consults the [NAB-MALTA](#) website and downloads the applicable documents especially the application form, regulations, guides, and policies;
 - 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 documentation (policies, procedures, definition of responsibilities, etc.) against the requirements of **EN ISO/IEC 17020**, 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 CAB 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 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. A **full cycle of internal audits and a management review** shall have been carried out prior to the submission of application.
- 4.4 Each applicant CAB shall give information on its activities, equipment, and staff in the Application Form, **NABAF01/I** and in the documentation, which is to be submitted with the application form. It is very important that the documents listed in Section D of **NABAF01/I** are submitted with the application form using the folder structure available on the NAB-MALTA website.
- 4.4.1 Special attention should be given when defining the scope of accreditation sought.

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- 4.4.2 Before submitting the application form, the CAB should contact the NAB-MALTA which will provide a template of the accreditation agreement. This signed agreement (**NABC03**) should be submitted together with the application form and the other documentation.
- 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 CAB to abide by all the accreditation scheme requirements and to pay the **accreditation fees**.
- 4.4.4 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 **complies with the requirements defined in the applicable Directive/s and EA2/17 M and** has taken into consideration **European Commission guidance (including the Blue Book)**. In such a case it is recommended that the CAB 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 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 will normally also carry out the function of Team Leader.
- 5.1.1 As far as possible, the same NAB-MALTA Officer will be responsible for processing that CAB's application through to the accreditation stage and for liaising with the CAB 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:
- all the necessary information has been received;
 - the client's requirements have been understood;
 - the members of the assessment team with all the necessary expertise and competence are identified; and
 - estimates of the timescales and costs are calculated.
- 5.3 The NAB-MALTA then sends the following documents to the applicant:

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- 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, 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 acceptable, the CAB will be informed that the process of finding and appointing new assessors and/or experts might have an effect on the date of any potential assessments and might prolong the accreditation process. If the client 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 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.


5.5 The assessment team carries out an initial desk review. Unless major deficiencies are encountered during the desk review, it is normally preferable to discuss the outcome of such a review during the preliminary visit. The NAB-MALTA may recommend to the client 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.

5.6 A preliminary visit is always recommended.

5.6.1 The preliminary visit allows discussions with the CAB's management on the extent to which the management system and related documentation appear to fulfil the requirements for accreditation to EN ISO/IEC17020.

5.6.2 The benefits of a preliminary visit include:

- better preparation for the initial assessment;
- clarification with the applicant of the applied scope of accreditation;
- the CAB can understand better the assessment process;

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- the assessment team can form a general idea of the level of implementation of the management system described in the submitted documentation and its conformity with the accreditation scheme criteria. This will be taken into consideration during the preparation of the plan for the initial assessment.

5.7.3 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. It is preferable to witness an inspection during such a visit.

5.7.4 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 an assessment and will describe the nature of the initial assessment.

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


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

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

5.9 If the accreditation process can continue, the Team Leader in liaison with the rest of the assessment team, will determine the final composition of the assessment team, and the effort (in man days) required for the initial assessment including time for preparation and post-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 inspections proposed for inclusion in its scope of accreditation, including:

- whether it is necessary to assess all inspection activities, or if a representative sample can be selected;
- the need to assess all key activities;
- the identification of CAB technical personnel to be observed;
- the identification of sites/locations in the case of multi-location activities including on-site inspections.


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

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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 CAB shall inform the NAB-MALTA with any changes and 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 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 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 as a whole the assessment team shall have:
- appropriate knowledge of the specific scope for which accreditation is sought
 - sufficient understanding to make a reliable assessment of the competence of the CAB 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 inspection methods that each assessor must witness either on the same days of the Head Office visit or during other days when inspections are available for witnessing.

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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 will ensure that:

- a) key members of the CAB staff will be available on the date(s) of the assessment;
- b) these staff members are aware of the procedures which will be followed during the assessment process;
- c) 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;
- d) prepare any necessary health and safety equipment, including personal protective equipment, for use by the assessment team and any observers. **The CAB should ensure to inform the NAB-MALTA about specific health and safety requirements prior to the assessment.**

6.5 Each assessment team member prepares for the assessment through a detailed review of the relevant documents 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. However, the following elements will be covered:

- assessment of all elements of the management system;
- assessment of multiple locations (where applicable);
- witnessing of a sample of inspection methods in different fields and types of inspection and carried out by different inspectors, where applicable.

7. Initial assessment

7.1 The assessment team will assess the technical competence of the CAB in each field or type of inspection 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 inspections as per the agreed assessment plan or as selected by the assessment team during any day of the assessment activity.

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7.1.2 The main purpose of the 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 assessment begins with an opening meeting between the assessment team and representatives of the CAB.

7.3 Each member of the assessment team then departs to his/her respective areas to begin the assessment. The assessors/experts will examine procedures and records and witness the relevant inspection activities included in the scope.

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

7.3.2 Members of the CAB staff nominated by the management should accompany each assessor/expert.

7.3.3 Normally, the Team Leader will examine the CAB's 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 inspection activities and examine documentation and records.

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

- the variety of the inspection 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, where applicable.

7.3.4.2 When deciding on which CAB's staff will be assessed, account will be taken of:

- new recruits or newly/recently authorised personnel;
- qualifications and experience;
- location;
- roles and responsibilities;
- the extent to which inspectors are required to exercise professional judgement.

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- statutory requirements.

7.3.5 Interim meetings with the CAB management may be held during an 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 may be recorded and verified before assessors 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/her 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 conformity of the CAB 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 or not nonconformities with **EN ISO/IEC 17020** or other accreditation scheme criteria are to be raised.

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

7.7.1 During the closing meeting, the CAB shall be given the opportunity to ask questions.

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

8. Witnessed inspections

8.1 The purpose of a witnessed inspection is to observe the inspection procedures in practice and to ensure that the level of sector competence displayed by the inspectors is such that results are credible and reliable.

8.2 **By default, witnessing of inspection activities shall be carried out either before or during the Head Office assessment. However,** there will be situations where planning of witness inspections may only be finalised either during the Head Office assessment or after.

8.2.1. There will be a **maximum of 4 months between the Head Office assessment and a witnessed inspection.**

8.2.2 Witnessed inspections may also be organised as standalone assessment activities, with separate reporting and a separate set of findings, if any.


8.3 The minimum number of witnessing of inspections at initial assessment will normally be one for each type of inspection.

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 inspector has the competence for the activity performed;
- the inspector's competence is consistent with records;
- the inspector has been supplied with all necessary documented inspection methods and procedures.

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- 8.7 It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports, and planning arrangements. If an inspector 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 inspection is not conducted in English or Maltese.
- 8.9 The NAB-MALTA assessors will ensure that their role during witnessing of inspections is one of observer and they will not influence the outcome of the inspection being performed.
- 8.9.1 Where applicable, at the opening meeting the CAB representative may be required to allow the NAB-MALTA assessor/expert to explain his role and the purpose to the organisation being inspected.
- 8.10 At the end of the witnessing of the inspection, a meeting shall be held during which the NAB-MALTA team will provide their feedback on the witnessed activity. The NAB-MALTA assessment team will also prepare a list of findings, where necessary. **Where the witness activity is held as a separate activity from the Head Office assessment, a separate report will be prepared.**


9. Multi-site organisation (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**.
- 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 activities undertaken e.g., fields of inspection, types of inspection.
- 9.3 It will normally not be necessary to witness the full range of scopes for each selected location.
- 9.4 The NAB-MALTA will seek to establish through objective evidence and by using various techniques that:

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- 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 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 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.
- 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, address, ownership, key personnel, scope, equipment, use of accreditation symbol and other significant changes through the use of form **NABG11**.
- 9.11 The establishment of any new locations from which the CAB proposes to offer an accredited service 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.

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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 raised by the assessment team, to the NAB-MALTA.
- 10.1.1 The CAB will carefully 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 the 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 **RAB01**. In **most** cases it will be possible to provide the evidence electronically, via e-mail or electronic transfer, to the NAB-MALTA (e.g., revised documents, calibration certificates, photos, etc...).
- 10.1.4 The assessment team assesses this evidence.
- 10.1.5 **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 the assessment team observes a new finding, this will be brought to the attention of the CAB and will also report it in writing. The cost of such assessments will be charged to the CAB.
- 10.2 Once the assessment team is satisfied that all findings have been satisfactorily cleared, or once the CAB has exhausted its three chances to close off findings, the Team Leader (NAB-MALTA Officer) will submit a report to the Board which shall include the final recommendation on accreditation.
- 10.2.1 Although three rounds for closing off findings are provided, CABs 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. In the case, where the majority of the findings shall need to be closed after the second or third round, will normally indicate some deficiencies in the CAB's process for treating corrective actions. **Additional fees will be charged if additional time is necessary to close off the findings.**

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- 10.3 The Board will review the report and any other information relevant to the case. The Board may accept the recommendation by the team either conditionally or unconditionally and 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 the 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 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 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, either on-site or remotely.
- 11.5 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 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 throughout the accreditation cycle. The reassessment’s objective is to confirm the CAB’s competence and will cover all the requirements of EN ISO/IEC 17020.
- 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 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.
- 11.8 At the opening meeting the Team Leader will ask whether all significant changes in the CAB’s status or operation have been notified to the NAB-MALTA as per **RAB01** requirements and that any other changes have been specified within the document submitted as per **ATG12** requirements.

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- 11.8.1 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 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 assessment or impact the assessment plan. This may lead to a suspension of accreditation or additional charges being imposed, as either the assessment cannot be carried out or additional time to that planned may be needed.
- 11.9 For the management system, the internal audit and management review shall be 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 shall be assessed at least once during the accreditation cycle.
- 11.10 At the conclusion of a scheduled assessment, the Team Leader will make a recommendation to the Board on the continuation or otherwise, of the 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, CHANGES TO SCOPE

12. Extensions to scope

12.1 Following receipt of an application for extension to scope, the NAB-MALTA will determine whether or not there is a need for an office and/or location assessment and/or on-site assessments of inspection to take place. Factors which will be taken into consideration will be the:

- existing scope of accreditation;
- inspector 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, from the Technical Assessor(s)/Expert(s) on how to proceed. The NAB-MALTA Officer may need to arrange an extra assessment or may suggest combining this assessment activity with the next scheduled assessment activity.

12.2.1 If the extension is assessed during a scheduled assessment, additional time will normally be required.


12.3 In line with **RAB01**, the application for extension of scope shall be submitted **at least 4 months before** the next scheduled 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.

13.1.1 Where such a change to scope result in the need for the CAB to have additional technical competence, then the CAB may need to apply for an extension to scope.

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

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13.3 Changes to scope have to be approved by the Board and then communicated the decision to the CAB.

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Do you need further information?

This publication, application forms (NABAF01/I, NABAF01/I/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>.

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