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NAB-MALTA

TECHNICAL GUIDE

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

Revision 8 June 2021

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of inspection bodies 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. Access is not conditional upon the size of the Inspection Body 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 **with general guidance** on the NAB-MALTA 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 and to ensure, through regular assessment activities, that inspection bodies continue to fulfil the requirements of the accreditation scheme.
- 1.2 The NAB-MALTA will accept applications from inspection bodies 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 inspection bodies 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 an inspection body is carried out:
- through an assessment of the documentation that describes the management system and procedures of the Inspection Body;
 - **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 inspection body 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 inspection bodies. The assessment team will take account of the size and complexity of the body during the assessment. The inspection body, 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 NAB-MALTA may use external technical assessors/experts with the relevant specialist knowledge to judge the competence of the inspection body. 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:
- (a) the management system is appropriate and effective to the Inspection Body's needs, organisational arrangements and methods of operation, including multiple location operations and number of inspectors;
 - (b) all of the requirements of **EN ISO/IEC 17020** and other applicable accreditation scheme criteria have been satisfactorily addressed;
 - (c) the operational, administrative and technical procedures used to support the management system are complete, technically valid and appropriate and reflect the Inspection Body'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 inspection body's accreditation as precisely as possible. Inspection bodies 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.
- 2.3 Following successful assessment, **the scope of accreditation will include:**

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- the type of inspection body (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 inspection body 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 unless otherwise requested by the inspection body for legitimate reasons.

3. Accreditation in regulatory areas


3.1 Inspection bodies 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 conformity assessment standard applied for from such Regulator.


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

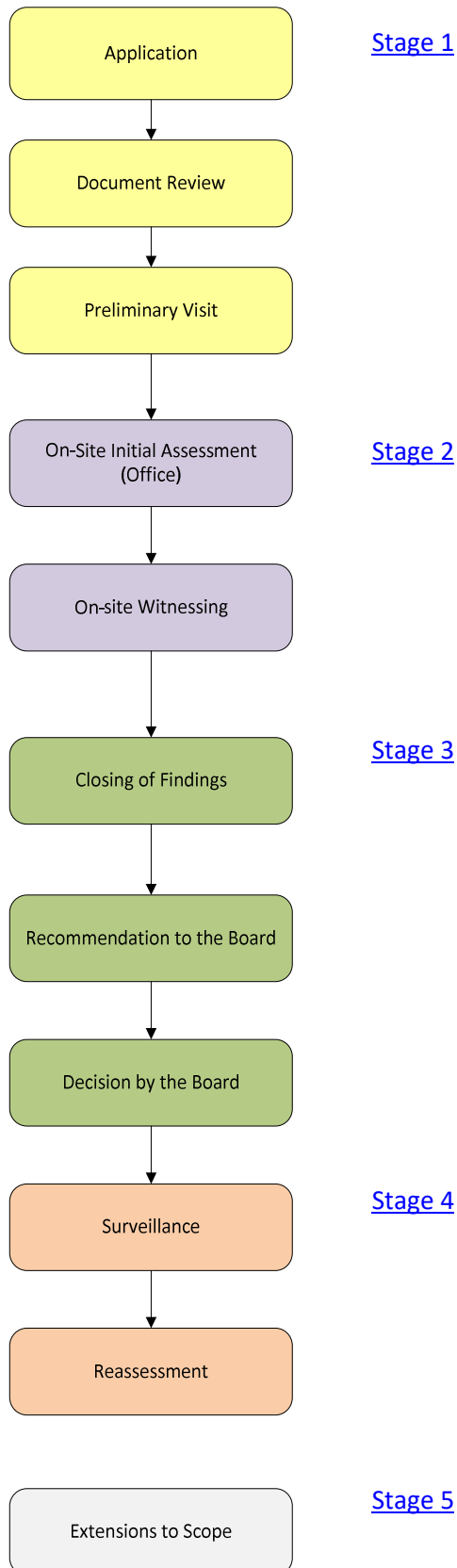
3.3 Normally the inspection methods shall be defined in the applicable national or European legislation or in harmonised standards. Where this is not the case, the relevant Regulator or Competent Authority shall provide the necessary guidance.


3.4 In cases where the inspection body 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**.

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- 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.
- 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.

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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 inspection body:
- consults the NAB-MALTA website (<http://www.nabmalta.org.mt>) and downloads the applicable documents especially the application form, regulations, guides and policies;
 - consults the European Co-operation for Accreditation (EA) (<http://www.european-accreditation.org>) and ILAC (<http://www.ilac.org>) 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 inspection body 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 inspection body may also ask for any further clarifications. It is recommended that the key persons responsible for leading the inspection body towards accreditation, including a representative of management, are present for this meeting.
- 4.3 The management system of the inspection body shall be in operation for a minimum period of **three months** prior to the initial assessment visit and that a **full cycle of internal audits plus a management review** shall have been carried out.
- 4.4 Each applicant inspection body gives 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 inspection body 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 inspection body to abide by all the accreditation scheme requirements and to pay the **accreditation fees**.
- 4.4.4 If the inspection body has the intention to become a Notified Body then it should promptly inform the NAB-MALTA. In this case the inspection body 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 inspection body 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 inspection body's application through to the accreditation stage and for liaising with the inspection body 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 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 and technical assessor/s and technical expert/s);
- the names of any observers.

5.3.1 The inspection body 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 inspection body 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 assessment visits 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 inspection body has accepted the team.


5.4 Once payment covering the preliminary visit is received from the inspection body the necessary arrangements 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 inspection body documentation to the assessment team.

5.6 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.

5.7 A preliminary 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.

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

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5.7.2 The benefits of a preliminary visit include:

- better preparation for the initial assessment;
- clarification with the applicant of the applied scope of accreditation;
- **the inspection body 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 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. 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 inspection body that the preliminary visit is not an 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 inspection body'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 review 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 **final** composition of the assessment team, and the effort (in mandays) 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 Inspection Body 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 inspection body technical personnel to be observed;

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- 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.

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 inspection body shall inform the NAB-MALTA with any **changes and actions** which may have been taken following the preliminary visit. The inspection body 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 inspection body (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 shall have:
- appropriate knowledge of the specific scope for which accreditation is sought;

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- sufficient understanding to make a reliable assessment of the competence of the Inspection Body 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.

6.4.1 The NAB-MALTA Officer will distribute copies of the assessment plan to the inspection body 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 inspection body will ensure that:

- a) key members of the inspection body staff will be available on the date(s) of the assessments;
- 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.

6.5 **Each assessment team member prepares for the assessment through a detailed review of the relevant documents supplied by the inspection body.**


6.6 The nature of the initial assessment will depend upon the scope of accreditation required by the inspection body 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.

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7. Initial assessment

- 7.1 The assessment team will assess the technical competence **of the inspection body** 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 inspection body 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.
- 7.1.2 The main purpose of the assessment is for the assessment team to gather objective evidence that, for the applicable scope, the inspection body conforms to the relevant accreditation scheme criteria.
- 7.2 The assessment begins with an opening meeting between the assessment team and representatives of the inspection body.
- 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 inspection body staff nominated by the management should accompany each assessor/expert.
- 7.3.3 Normally, the Team Leader will examine the inspection body'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 inspection body 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;

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- 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.
- statutory requirements.

7.3.5 Interim meetings with the inspection body 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 own findings and contribute to a co-ordinated view of the inspection body’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 inspection body 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.

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- 7.6 When the list of findings is finalised, the Team Leader shall give it to the inspection body so that this can be internally discussed prior to the closing meeting. The various inspection body 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 inspection body, 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 inspection body shall be given the opportunity to ask questions.
- 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 There will be situations where planning of witness inspections may only be finalised either during the Head Office assessment or after. There will be **a maximum of 4 months between the Head Office assessment and the witnessed inspection**. In cases where witnessing is not carried out during the same week of assessment of the Head Office, separate reporting with a separate set of findings, may be necessary.
- 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.

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- 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.
- 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 inspection body 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 inspection body 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 witness report and a list of findings, where necessary. This report and the findings may form part of the overall summary report or may be considered as a separate report.

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 inspection body 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;

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- 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:

- 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 inspection body 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 Inspection Body 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


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form, **NABG11**. The establishment of any new locations from which the inspection body 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.

STAGE 3 – CLOSING OF ASSESSMENT

10. Post-assessment process

- 10.1 The inspection body 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 inspection body will **carefully** 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 **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 documents, calibration certificates, photos, etc...).
- 10.1.4 **The assessment team assesses this evidence.**
- 10.1.5 A follow-up **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 inspection body and to the Director of the NAB-MALTA and will also report it in writing. **Cost of follow-up assessments** will be charged to the inspection body.
- 10.2 Once the Assessment Team is satisfied that all findings have been satisfactorily cleared, or **once the inspection body has exhausted its three chances to close off findings, the Team Leader (NAB-MALTA**


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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, inspection bodies 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 inspection body's process for treating corrective actions.

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, 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 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 inspection body'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 inspection body's management system and activities and the performance of the inspection body 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 inspection body 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 inspection body 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 requirements of EN ISO/IEC 17020.
- 11.7 The inspection body 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.

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- 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.
- 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 have an effect on 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 continuing accreditation of the inspection body.
- 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 inspection body, 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, 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 inspection body 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 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 Inspection bodies 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 inspection body shall provide all the necessary relevant documentation.


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

13.3 Changes to scope will be approved by the Board and then communicated to the inspection body.

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Appendix 1: Timeframes

Stage	Activity	Timeframes	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/I/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 ATG05 Cl.12.3
AS#	Minimum period of operation of the CAB’s management system according to the accreditation scheme requirements	3 months	ATG05 Cl. 4.3
S##	First assessment following initial assessment	Not more than 12 months after the initial accreditation decision.	RAB01 Cl.2.7
S##	Surveillance (except first assessment following initial assessment) – 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 visits or other assessment activities	As required	RAB01 Cl.2.7

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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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