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# NAB-MALTA

# TECHNICAL GUIDE

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## ATG05 - Guide to the NAB-MALTA Assessment of Inspection Bodies

Revision 3    December 2010


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## FOREWORD

The National Accreditation Board of the Malta (NAB-MALTA) is the Maltese National Authority with responsibility for accreditation in accordance with the relevant normative documents.


This publication has been drawn up to provide Inspection Bodies with general guidance on the conduct of assessment, surveillance and reassessment visits. Inspection is understood to include the function of bodies whose work may include the examination of materials, products, installations, plant, processes, work procedures or services and the determination of their conformity with requirements, and the subsequent reporting of the results of these activities to clients and, when required, to supervisory authorities. Inspection of a product, an installation or plant may concern all stages during the lifetime of these items, including the design stage. Such work normally requires the exercise of professional judgement in providing the service, in particular when assessing conformity.

For the scope of this guide, the masculine gender shall also refer to the feminine gender.

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## **1. Introduction**


- 1.1 The main function of the NAB-MALTA is to establish the competence of inspection bodies to carry out inspections in defined fields and to ensure by surveillance and reassessment that the requirements of accreditation are maintained.
- 1.2 The NAB-MALTA will normally accept applications from inspection bodies that are established as a legal entity in Malta, or where the assessment process is managed and controlled in Malta.
- 1.3 The NAB-MALTA assessment of the competence of an Inspection Body is carried out through an assessment of the documentation that describes the management system and procedures of the Inspection Body and on the results of one or more visits to the body in order to assess how its functions are performed in practice. The first visit is normally carried out at the Inspection Body's Head Office. Part of the assessment includes participation of the NAB-MALTA as an observer of at least one inspection carried out by the applicant, however this depends on the variety of inspections included in the scope. The purpose of the assessment is to determine whether the inspection body complies with the criteria of competence as prescribed in the relevant normative documents including the NAB-MALTA regulations, policies, technical documents, the relevant EA/IAF/ILAC interpretative guidelines on the application of ISO/IEC17020 (EA guidelines are specified in **ILAC/IAF:A4**) and with any further requirements specified by the NAB-MALTA. The main accreditation criteria are specified in publication **ATG03**.
- 1.4 NAB-MALTA assessment procedures are applicable to all sizes of inspection bodies. Assessors will take account of the size and complexity of the body when assessing the quality system. The quality system must provide assurance that the inspection body, whatever its size or complexity, or the location where work is carried out, meets the requirements of the criteria of accreditation.
- 1.5 The time required for assessment, surveillance and reassessment will depend on the complexity of the organisation, the spread of its activities, the structure of the quality system and the proposed scope of accreditation.
- 1.6 The composition of the assessment team depends on the specific application and is chosen on the basis of the applied scope of accreditation as well as the size of the applicant body. The NAB-MALTA will take into consideration the optimal size of the team and the number of assessment days.
- 1.7 The assessment procedure used by the NAB-MALTA must cater for medium-sized inspection bodies and some may therefore appear to be over-elaborate for certain Inspection Bodies. Assessors will take this into account when judging whether the quality system of such inspection bodies complies with the requirements of the NAB-MALTA.

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- 1.8 All information obtained before, during or after assessment, including the fact that a particular inspection body has applied for accreditation, or that an application for accreditation has been deferred or rejected, is treated as strictly confidential by the NAB-MALTA and its assessors.
- 1.8.1 NAB-MALTA may use external technical assessors with the relevant specialist knowledge to judge the competence of the Inspection Body to perform the inspections for which accreditation is sought. The assessors are required by NAB-MALTA to maintain confidentiality, and to sign a Confidentiality Agreement specifying the need to declare any potential for conflict of interest. Their activities will be confined to assessing the Inspection Body's activities for compliance with the requirements and reporting their findings to the NAB-MALTA.
- 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 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 MSA ISO/IEC17020 and other applicable accreditation criteria have been satisfactorily addressed ;
  - (c) the Inspection Body has implemented all the requirements of the management system effectively;
  - (d) the operational, administrative and technical procedures used to support the quality manual are complete, technically valid and appropriate and reflect the Inspection Bodies activities.
- 1.10 The following techniques will be employed to establish that procedures are being correctly and fully implemented:
- (a) questioning of management and staff who have an involvement in or bearing upon the quality of inspection work;
  - (b) examination of records;
  - (c) examination of the suitability, maintenance, calibration, control and use of all equipment used for inspection work;
  - (d) examination of the arrangements for exercising control over subcontractors and suppliers.

## **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

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before the assessment in order to determine the extent of the assessment activities. Applicants should note that the NAB-MALTA assessment team will reflect the scope applied for and it may be impossible to amend or extend this scope after the assessment team has been appointed. Following successful assessment, the scope, including standard specifications, methods and procedures relevant to the inspections concerned will be identified on the accreditation scope.

- 2.2 Following accreditation, the scope of accreditation is considered to be in the public domain unless otherwise requested by the Inspection Body for legitimate reasons.

## STAGE 1 – PREPARATION FOR ACCREDITATION + APPLICATION

### **3. Preparing for Accreditation and submitting the Application Form to the NAB-MALTA**


- 3.1 Having decided to consider seeking NAB-MALTA accreditation, the Inspection Body is strongly recommended to review its current quality manual, procedures and documentation against the requirements of MSA ISO/IEC 17020, ILAC/IAF:A4 and the NAB-MALTA regulations, policies and other relevant technical documentation. If the 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 visit by the NAB-MALTA.
- 3.2 The Inspection Body must carry out an evaluation of risk arising to it and to its staff under all categories and determine the amount and types of insurance that it should have in place in each risk category.
- 3.3 Prior to submitting the application form, it is recommended that the Inspection Body contacts the NAB-MALTA for any clarifications and to ensure that the adequate information is provided within the application form.
- 3.4 Each applicant inspection body gives basic information on its activities, equipment and staff in the Application Form, **NABAF01** and schedule **NABAF01/I**, and in the administrative and operating procedures in its quality manual which are to be submitted to the NAB-MALTA with the application form. It is very important that the documents listed in Annex 2 of **NABAF01/I** are submitted with the application form.
- 3.4.1 Particular attention should be given to the scope of accreditation sought. Applicants should note that the NAB-MALTA assessment team will reflect the scope applied for and it may be impossible to amend or extend this scope after the assessment team has been appointed.

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- 3.5 On receipt of the application form the Inspection Body and the NAB-MALTA shall sign a contract of accreditation.
- 3.6 The application for accreditation is a formal request to the NAB-MALTA to conduct the accreditation process and is a commitment from the applicant to pay the accreditation fees.
- 3.7 If the Inspection Body has the intention to become a Notified Body then it should inform the NAB-MALTA accordingly.

#### **4. Review of the Application Form and the Preliminary Visit**

- 4.1 On receipt of the application form, scope, quality manual and other associated documentation, the NAB-MALTA will make a resource review to ensure that:
- it has fully understood the client's requirements;
  - it has the ability to carry out the assessment, in terms of its own policy, its competence and availability of suitable assessors and experts.
- 4.2 On completion of this review, the NAB-MALTA chooses an Assessment Team bearing in mind the fields of inspection and other factors involved and will send the invoice of application and the name of the Assessment Team members to the client.
- 4.2.1 The Inspection Body may object to any chosen members of the Assessment Team and should inform the NAB-MALTA in writing with good and sufficient reason(s) for such objection within 3 days from the receipt of this communication or within any other timeframes as established by the NAB-MALTA.
- 4.3 On approval of the Assessment Team and payment of the application fees, the NAB-MALTA will proceed to send the Quality Manual and any supporting documentation received from the applicant Inspection Body to the Assessment Team. The Assessment Team carries out a desk audit and will identify:
- any deficiencies in the system
  - the need for a preliminary visit.
- 4.4 A preliminary visit is normally carried out where the application indicates that additional information is required, or where the Assessment Team considers that the applicant is not ready to proceed directly to the initial assessment. The preliminary visit normally takes no longer than one day.
- 4.4.1 The final decision for a preliminary visit will be taken by the NAB-MALTA.

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4.5 The preliminary visit report, a copy of which will be submitted to the Inspection Body, prepared by the Lead Assessor shall:

- identify any areas that appear to require attention in order to comply with the accreditation criteria;
- potentially, planning for the initial assessment visit including the inspections to be witnessed;
- identify if a further preliminary visit is required or whether plans for initial assessment of the Inspection Body can proceed.

## STAGE 2 – INITIAL ASSESSMENT

### **5. Preparation for the Initial Assessment Visit**

5.1 The NAB-MALTA will only proceed with the processing of the application when the fee covering the costs of the initial assessment have been paid in full and when a formal written reply indicating that the assessment visit plan and the assessment team are acceptable is received from the applicant Inspection Body.

5.1.1 The Inspection Body may need to submit revised documentation following changes carried out subsequent to the preliminary visit.


5.4 The nature of the initial assessment will depend upon the scope of accreditation required by the Inspection Body and the complexity of the quality system that is being operated. However, the following elements must be covered:

- (a) Head Office assessment;
- (b) assessment of multiple locations (where applicable);
- (c) observation of on-site inspections for different fields and types of inspection and inspectors.

5.7 Before any on-site visit, the assessment team members carry out a desk review of the relevant documents and records supplied by the Inspection Body. This is the final review which the NAB-MALTA will consider before deciding whether or not to proceed with on-site assessments of the Head Office and the witnessing of inspections.

5.8 When the date and plan for the assessment visits have been settled, the Inspection Body should ensure that:


- a) key members of staff will be available on the date(s) of the visit;
- b) these staff members are aware of the procedures which will be followed during the assessment process;

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- c) during the Head Office visit 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.

## **6. Head Office Assessment**


- 6.1 All fields and types of inspection will be subject to an office assessment and technical review. The team will assess the technical competence of inspectors in each field or type of inspection covered by the schedule. This will be done through:
- (a) the examination of the records outlined above;
  - (b) discussions with supervisors;
  - (c) assessment of the performance of the staff whilst conducting scheduled inspections (see Cl.6).
- 6.2 The assessment begins with an opening meeting between the NAB-MALTA assessment team and representatives of the Inspection Body. It is intended to enable the assessors and the representatives of the Inspection Body to become acquainted, and to clear up any difficulties about the purpose of the assessment and what is expected of the Inspection Body during the visit.
- 6.3 After the assessors have completed their individual assignments, they will communicate together and each will summarise his own findings and contribute to a co-ordinated view of the work of the Inspection Body. The assessment team will 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 Inspection Body with the requirements for accreditation and to establish any nonconformities.
- 6.4 The Head Office assessment ends with a closing meeting between the NAB-MALTA assessment team and the Inspection Body representatives at which the Assessment Team present their findings, including any nonconformities and opportunities for improvement. During this meeting, the Inspection Body representatives shall be given the opportunity to ask questions about the findings.
- 6.5 The Assessment Team will prepare a summary report together with a list of the findings. The list of findings is normally given at the end of the closing meeting whilst the full summary report is sent to the client up to a maximum of five days after the visit.
- 6.5.1 The Summary Report will record the assessors' findings, the assessment team's recommendations to the NAB-MALTA concerning acceptance of the Inspection Body into accreditation, and the scope in which the accreditation should be defined.

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## **7. Witnessed Inspections**

- 7.1 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.
- 7.2 There will be situations where planning of witness inspections may only be finalised either during the Head Office assessment or after. However there will be a maximum of 3 months between the Head Office assessment and the witnessed inspection.
- 7.3 When deciding on the number of on-site assessments of inspections needed the following aspects will be considered by the NAB-MALTA:
- (a) the fields and types of inspection on the accreditation scope;
  - (b) the inspection body's procedures for selecting, training, authorising and monitoring inspectors, having regard to the qualifications and experience required for different fields and types of inspection;
  - (c) the results of internal audits of the inspection body;
  - (d) the locations from which inspectors operate;
  - (e) any statutory requirements;
  - (f) the extent to which inspectors are required to exercise professional judgement.
- 7.4 The minimum number of on-site witnessing of inspections at initial assessment will normally be one for each type of inspection.
- 7.5 When deciding on the activities to be witnessed, account will be taken of the following:
- The variety of products, services, processes and plant covered by the activities;
  - Skills needed by auditor/inspector;
  - Statutory requirements; and
  - The extent to which auditors/inspectors are required to exercise professional judgement.
- 7.6 When deciding on which auditors/inspectors will be assessed, account will be taken of:
- New recruits or new authorisations;
  - Qualifications and experience;
  - Location;
  - Statutory requirements; and
  - The extent to which auditors/inspectors are required to exercise professional judgement.

If none of the inspectors can cover the entire scope of a specific field then more than one inspector will be assessed for that field. Where there is any evidence which casts doubt

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on the competence of inspection staff, the sample size of inspectors assessed on site may be increased.

7.7 During the witnessed activity, the assessment team will need to see that as a minimum:


- The auditor/inspector has the competence for the activity performed;
- The auditor/inspector's competence is consistent with records;
- The auditor/inspector has been supplied with all necessary documented inspection methods and procedures;
- The procedures are up-to-date;
- The auditor/inspector implements the procedure fully and correctly, i.e. no short-cuts, no personalised application where it is not permissible to do so;
- Records of all observations are made while on site as required by procedure;
- For inspection bodies, records clearly identify what has been inspected, using what method/procedure, and when;
- All records are signed/initialled, as applicable;
- All findings that indicate immediate or urgent action are reported as required to the client whilst on site;
- Reports comply with the inspection body requirements, to the relevant accreditation standard, to EA/IAF/ILAC guidance as appropriate and to relevant statutory requirements; and
- Facilities and equipment as appropriate are fit for purpose

7.8 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.

7.9 Where a witnessed inspection is not conducted in English, the applicant body may be required to pay the costs of an independent interpreter.

7.10 The NAB-MALTA assessors will ensure that their role during on-site assessment of inspections is one of observer and they will not influence the outcome of the inspection being performed.


7.10.1 Where applicable at the opening meeting the Inspection Body representative may be required to allow the NAB-MALTA assessor to explain his role and the purpose to the organisation being inspected.

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- 7.11 At the end of the witnessing of the inspection, a closing meeting shall be held during which the NAB-MALTA team will provide their feedback on the witnessed activity. The NAB-MALTA assessor will also prepare a witness report and a list of findings to the NAB-MALTA which will also be submitted to the Inspection Body about five days after the witnessing. This report and the findings will form part of the overall summary report and will be used during the preparation of the eventual recommendation to the Board.
- 7.12 During witnessed visits, the NAB-MALTA findings will be categorised as major or minor nonconformity or observation in line with the definitions listed in **RAB1**.

## **8. Multi-site Organisations**

- 8.1 An applicant that operates from a central Head Office through a number of locations may seek a single accreditation.
- 8.2 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:
- (a) the results of internal audits from Head Office and locations;
  - (b) the results of management reviews;
  - (c) variations in the size of locations;
  - (d) complexity of the quality system;
  - (e) complexity of the locations;
  - (f) variations in working practices including, where applicable, equipment used;
  - (g) variations in activities undertaken e.g. fields of inspection, types of inspection.
- 8.3 It will normally not be necessary to witness the full range of scopes for each selected location.
- 8.4 The NAB-MALTA will seek to establish through objective evidence and by using various techniques that:
- (a) all locations are operating under the same quality system;
  - (b) all locations are included in the internal audit programme and central review process.
- 8.5 Temporary locations must be working to the same requirements and may be subject to assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.
- 8.6 During the Head Office assessment the NAB-MALTA may need to see records of certain activities which are being carried out at different locations.


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- 8.7 If the NAB-MALTA observes nonconformities at the Head Office or at any one of the locations of the Inspection Body with multiple locations, the corrective action procedure shall apply to all locations where applicable. In the event that 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 system, the NAB-MALTA will review the assessment programme and may increase the number of locations to be assessed.
- 8.8 Failure by one location to comply with the NAB-MALTA requirements may lead to removal of the location from the schedule of accreditation. If the cause of nonconformity is the lack of central control then the corporate accreditation will be the subject of review by the NAB-MALTA and may lead to suspension or withdrawal of accreditation from all locations.
- 8.9 Generally, each location from which the Inspection Body is operating will be visited at least once during the four year assessment cycle.
- 8.10 The NAB-MALTA must be advised of any changes to location addresses and activities. The establishment of any new locations from which the Inspection Body proposes to offer an 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 schedule of accreditation will be amended as appropriate and the location will be included in the programme of surveillance and reassessment.

## STAGE 3 – CLOSING OF ASSESSMENT

### **9. POST-ASSESSMENT PROCEDURES**


- 9.1 The NAB-MALTA Officer who shall have formed part of the assessment team will collect all the documentation and information relevant to the case. He shall also ensure that he has received the formal clearance of all the nonconformities raised during the assessment from the Assessment Team.
- 9.2 He will then proceed to prepare a complete accreditation proposal report to the Director of the NAB-MALTA who, after checking the report, will proceed to present the report to the Board. The proposal report will only be prepared when all evidence of corrective actions has been received.
- 9.3 The Board will consider the proposal report and any other information relevant to the case. The Board may accept the application for accreditation either conditionally or unconditionally, or may reject it. The Board may also ask for further information to be provided.
- 9.4 The NAB-MALTA will inform the applicant Inspection Body of the outcome of the decision.

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## STAGE 4 – SURVEILLANCE AND REASSESSMENT

### 10. SURVEILLANCE AND REASSESSMENT VISITS

- 10.1 Following the granting of the NAB-MALTA accreditation after successful completion of the procedures described above, the Inspection Body will receive regular surveillance and reassessment visits.
- 10.2 The purpose of surveillance and reassessment visits is to determine whether the Inspection Body is continuing to comply with all the accreditation criteria. Similar procedures to those described in the previous sections will be followed for the conduct of surveillance and reassessment visits.
- 10.2 The first surveillance visit normally takes place six (6) months after the decision on accreditation and annually thereafter.
- 10.3 A reassessment visit generally occurs every 5 years.
- 10.4 The level of sampling of locations and inspectors will depend on performance over the five year cycle, the extent of any changes which have taken place and the level of confidence which can be placed in the performance measures and control systems of the inspection body.
- 10.5 At the Opening Meeting of surveillance and reassessment visits the Lead Assessor will ask whether all significant changes in the Inspection Body status or operation have been notified to the NAB-MALTA and will confirm that there are no outstanding corrective actions from the previous visit.
- 10.6 At ordinary surveillance visits the surveillance team shall have the competence to assess both the management system components and the operational activities. If the surveillance is conducted by only one person, this person should have the ability to assess both the management system components and the competence in at least one of the accredited areas.
- 10.6.1 For the quality system, the internal audit and management review shall be evaluated during each surveillance visit. What other elements of the quality system are to be checked depends on various factors such as findings at previous visits, personnel changes and other changes. All elements of the quality system shall be assessed at least once between the initial assessment and reassessment.
- 10.6.2 On-site assessment of inspections will be carried out at each surveillance visit. The minimum number of on-site assessments of inspections at surveillance is one per year

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and the same criteria used for assessment will be considered when determining the number and type of inspections, and the inspectors to be witnessed.

- 10.7 In contrast to surveillance, reassessment is nearly as comprehensive as the initial accreditation and has the function of a check of the compliance with all the accreditation criteria and of the coherence of the Inspection Body's quality system. The same criteria as those used during the initial assessment will be used to determine the number and type of inspections, and the inspectors to be assessed.


## STAGE 5 – EXTENSIONS TO SCOPE

### 11. Extensions to Scope

- 11.1 Following receipt of an application for extension to scope, NAB-MALTA will determine whether or not there is a need for a central 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:
- (a) existing scope of accreditation;
  - (b) inspector competences within scopes;
  - (c) the range of scopes;
  - (d) the location at which the extension to scope is sought.
- 11.2 Where possible and desirable, any additional work will be carried out at the next surveillance or reassessment visit; where necessary, additional visits will be arranged. The estimated effort required for subsequent surveillance and reassessment will be reviewed and may be revised.

## ACCREDITATION FOR THE PURPOSES OF NOTIFICATION

- 12.1 NAB-MALTA will accredit Inspection Bodies for the purposes of notification in relation to EC legal provisions.
- 12.2 Applicants shall be required to have engaged with the relevant Maltese notifying authority in advance of submitting an application and have obtained approval for the conformity assessment standard applied for.
- 12.3 Applicants will be required to demonstrate their active participation in notified body groups on the European level.
- 12.4 NAB-MALTA shall communicate decisions and other issues to the relevant Maltese notifying authority on an ongoing basis and as necessary.

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## DO YOU NEED FURTHER INFORMATION?

This publication, application forms (NABAF01, NABAF01/I, NABAF01/E) and other information about accreditation, is available for download from the NAB-MALTA website at <http://www.nabmalta.org.mt>.

Should you need any further information we advise you to contact us.

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