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NAB-MALTA

TECHNICAL GUIDE

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

Revision 5 January 2009

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FOREWORD

Accreditation provides a structure and indicates a process to achieve reliable testing and calibration reports and certificates. Accreditation is the mechanism to assure customers of the competence of laboratories and other types of conformity assessment bodies.

The National Accreditation Board of Malta is the Maltese National Authority with responsibility for accreditation in accordance with the relevant normative documents in line with EU Regulation 765/2008, Article 4(1).


International trade relies on certificates and reports issued by competent bodies. Confidence in accreditation is based on a series of confidence building steps between the accreditation bodies and accredited organizations and the assurance given by the accreditation body that the accredited body constantly implements the relevant criteria and maintains and develops its competence continuously as defined in the relevant standard as an ongoing process. This assurance is achieved through accreditation which includes an initial assessment, regular surveillance and reassessment visits, enhance, where appropriate, by other surveillance activities.

The services of the NAB-Malta are accessible to all applicants whose requests fall within the current activities as offered by the NAB-Malta. Access is not conditional upon the size of the applicant laboratory or membership of any association or group.

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


SCOPE OF PUBLICATION

This publication has been drawn up to provide laboratories with general guidance on the conduct of assessment visits 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 laboratories to carry out defined types of test and/or calibrations, and subsequently to ensure by surveillance and reassessment that the required standards are maintained. On-site assessment plays a central part in providing the evidence on which accreditation is awarded.
- 1.2 Each applicant laboratory gives basic information on its activities, equipment and staff in the Application Form, **NABAF01** and schedule **NABAF01/L**, and on its administrative and operating procedures in its quality manual which is to be submitted to the NAB-MALTA with the application form. It is essential, however, to check the work of the laboratory by observation on site. The purpose of this on-site assessment is to determine whether a laboratory complies with the criteria of competence prescribed by the NAB-MALTA, with the NAB-MALTA regulations, policies, technical documents, EA/ILAC¹ publications and with any further requirements specified by the NAB-MALTA.
- 1.3 NAB-MALTA laboratory assessment procedures are applicable to all sizes of laboratory. The Assessment Team will take account of the size and complexity of the body when assessing the management system of a laboratory. The management system, which must have been in operation **for a minimum period of three months**, must provide assurance that a laboratory, whatever its size or complexity, or the location where work is carried out, meets the requirements of the criteria of accreditation.
- 1.4 The assessment procedure used by the NAB-MALTA must cater for medium-sized laboratories carrying out a wide range of tests, and some may therefore appear to be over-elaborate for laboratories concerned with only a few types of test. Assessors will take this into account when judging whether the quality system of such laboratories complies with the requirements of the NAB-MALTA. References to "Lead Assessor" or "meeting of the assessors" may also be inappropriate to small laboratories, where a single assessor operating for one day or less may be all that is required.
- 1.5 All information obtained before, during or after assessment, including the fact that a particular laboratory 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.
- 1.6 Experts are used to assess the competence of the laboratory to perform the tests/calibrations for which accreditation is sought. Their assessment will be confined to

¹ EA = European Co-operation for Accreditation (<http://www.european-accreditation.org>)
ILAC = International Laboratory Co-operation (<http://www.ilac.org>)

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investigating and reporting the findings that result from observation and discussion in the laboratory and through examination of documentation.

- 1.7 In addition to its own staff, NAB-MALTA also uses contracted external assessors. All NAB-MALTA assessors meet defined criteria in terms of their technical expertise and experience, are knowledgeable of NAB-MALTA assessment procedures and are bound by confidentiality agreements.
- 1.8 The procedures described in this publication apply to preliminary and assessment visits and to visits after accreditation has been granted, for the purposes of surveillance, reassessment, extension of scope, resolution of complaints or other purposes.
- 1.9 The NAB-MALTA policy is to keep its clients informed of progress and the next steps in the accreditation process. Communications will normally come from the NAB-Malta Officer in charge of the client.
- 1.10 NAB-MALTA uses standard forms to report the findings of assessment. The forms are reviewed from time to time.
- 1.11 An NAB-MALTA Officer will be present during all site visits to the laboratory.

2. Preparing for Accreditation and Submitting the Application Form to the NAB-MALTA

- 2.1 Having decided to consider seeking NAB-MALTA accreditation, a laboratory is strongly recommended to:
 - consult the NAB-MALTA website (<http://www.nabmalta.org.mt>);
 - consult the European Co-operation for Accreditation (EA) (<http://www.european-accreditation.org>) and ILAC (<http://www.ilac.org>) websites;
 - download the applicable documents from the NAB-MALTA website, especially the application forms, regulations, guides and policies²;
 - hold a meeting with the NAB-MALTA so that the laboratory management is clear about the requirements of accreditation;
 - carry out an internal review of its management system which should include a review of its current quality manual, procedures and documentation against the requirements of MSA EN ISO/IEC 17025 and/or MSA EN ISO 15189 and the NAB-MALTA regulations, policies and other relevant normative documents.

² Hard copy versions of NAB-MALTA documentation are also available from the NAB-MALTA Office.

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- 2.1.1 If the internal review indicates the need for any modifications to existing procedures or documentation, then the laboratory should plan to have these carried out and in operation prior to the assessment visit.
- 2.2 Once this internal review is held by the laboratory, it is recommended that a meeting be held with the NAB-MALTA. During this meeting the application requirements and the accreditation process will be explained and the laboratory may also ask for any further clarifications.
- 2.3 The management system of the laboratory shall be in operation for a minimum period of **three months** prior to the assessment visit and that a full cycle of internal audits plus a management review should be carried out.
- 2.4 If an estimate of the cost of accreditation is required, the laboratory shall clearly identify the potential scope of accreditation upon which a rough estimate will be based. The estimate will be communicated to the client after the meeting.
- 2.5 The laboratory should then complete in full all the sections of the application forms for accreditation. The forms to be completed are:
- **NABAF01** : General form for application;
 - **NABAF01/L** : Schedule for Laboratories applying for accreditation;
 - Documents requested by these forms, especially by **NABAF01/L**
- 2.5.1 It is very important that the applicant laboratory takes great care in compiling the application forms and the requested documentation. If the laboratory feels that parts of the application forms are not applicable to its scope of operation, then it should clearly indicate so on the application form and, where necessary, provide reasons.
- 2.6 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 abide by all the regulations of the accreditation process as specified by NAB-Malta, including the payment of the accreditation fees within the requested time.
- 2.7 The laboratory and the NAB-MALTA shall also sign the contract of accreditation (**NABC03**) prior to the start of the accreditation process.

3. The Scope of Accreditation

- 3.1 It is the policy of NAB-Malta to define closely the scope of a laboratory's accreditation. This ensures that the laboratory's clients are provided with an accurate and unambiguous


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description of the range of calibration/tests covered by a laboratory's accreditation. Each laboratory is therefore asked to list on **NABAF01/L Section B**, the standard specifications or other methods or procedures relevant to the calibration or tests for which accreditation is sought, and the major items of laboratory equipment used to conduct those calibration/tests.


- 3.2 **For scopes of calibration**, the type of calibration, the range of measurements, the best measurement capability and the operators to be assessed will be provisionally agreed before the initial assessment. During initial assessment and after examination of the results of measurement audits, the content of the schedule, including best measurement capability, will be agreed with the laboratory.
- 3.3 **For scopes of testing**, the materials tested, type of test and method specification/equipment will be provisionally agreed before the initial assessment to enable the appropriate technical competency to be deployed at initial assessment.
- 3.4 In some cases, as the assessment proceeds, it may become clear that the laboratory is not in a position to achieve accreditation for certain areas within the proposed scope. In such cases, the Lead Assessor may be able to recommend accreditation for a suitably reduced or redefined schedule.
- 3.5 Scopes of accreditation of accredited laboratories are regarded as being in the public domain.

4. Review of the Application Form and the Preliminary Visit

- 4.1 On receipt of the application form, schedule, quality manual and other associated documentation, the NAB-MALTA appoints an NAB-MALTA Officer, who normally carries out the function of Lead Assessor.
- 4.1.1 As far as possible, NAB-MALTA ensures that the same NAB-MALTA Officer is responsible for processing that laboratory's application through to the accreditation stage and for liaising with the laboratory during its accreditation. This NAB-MALTA Officer will be present during all site visits to the laboratory.
- 4.2 The NAB-MALTA will carry out an initial application review to ensure that the NAB-MALTA:
- has received all the necessary information;
 - has understood the client's requirements;
 - identifies the members of the assessment team with all the necessary expertise and competence; and
 - can make realistic estimates of the timescales and costs involved.

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- 4.3 The NAB-MALTA then sends the following to the applicant:
- an acknowledgement;
 - request for any missing documents, where applicable;
 - an invoice covering the application fee;
 - the names of the Assessment Team (i.e. Lead Assessor and Technical Assessor/s).
- 4.3.1 The laboratory may object to the chosen members of the Assessment Team and should inform the NAB-MALTA, in writing, with good and sufficient reason(s) for such objection/s.
- 4.4 On approval of the Assessment Team and on the receipt of the payment of the applicable fees, the NAB-MALTA will proceed to send to the Assessors the Quality Manual and any supporting documentation received from the applicant laboratory. The Assessment Team carries out an initial desk review audit
- 4.5 A report of this desk review identifying any deficiencies and the need for any further documentation is sent to the laboratory. The NAB-MALTA will also recommend to the client to take the necessary actions on these findings and preferably to report back to NAB-MALTA, especially if no preliminary visit will be carried out.
- 4.6 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, depending on the level of preparedness of the laboratory.
- 4.6.1 The preliminary visit allows discussions with the laboratory management on the extent to which the laboratory's management system, quality manual and operating procedures appear to fulfil the requirements for accreditation to the Standard.
- 4.6.2 The benefits of a preliminary visit include: -
- proper preparation for the initial assessment including preparation of visit plan, determination of approximate duration of assessment and type of assessors required;
 - clarification with the applicant of the applied scope of accreditation;
 - the Assessment Team can form a general idea of the level of implementation of the quality system described in the submitted documentation and its compliance with the standard.
- 4.7 Following this desk review, the NAB-MALTA will send the invoice covering the preliminary visit fee. Once payment covering the preliminary visit is received from the laboratory the necessary arrangements for the site visit will be co-ordinated by the NAB-MALTA Officer.

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- 4.7.1 *Note:* Depending on the outcome of meetings held with the laboratory, this step of the accreditation process might be integrated with Cl. 4.3 above.
- 4.8 The **preliminary visit** is conducted by the Lead Assessor who is, where necessary, accompanied by the Technical Assessor/s. This visit is usually completed in one day.
- 4.8.1 The visit should be structured so that the Lead Assessor can ascertain that the essential components of the management system of the laboratory have been addressed and are being implemented. In particular, the Lead Assessor needs to establish whether the laboratory has a stated policy for defined responsibilities and a means of meeting each of the requirements of the Standard.
- 4.8.2 The Assessment Team will discuss the proposed scope of accreditation and to carry out a brief examination of the laboratory's testing/calibration facilities.
- 4.8.3 Normally the Technical Assessor will discuss with the laboratory any documented in-house methods used for calibration/testing that form part of the scope of accreditation and any in-house calibrations used in support of accredited measurement activities. This will allow the Technical Assessor to be satisfied that such methods have been validated and to permit any necessary changes to be made before the initial assessment. The discussion will cover the laboratory's policy and procedures for estimating uncertainty of measurement.
- 4.8.4 The Technical Assessors will review the participation of the laboratory in proficiency testing schemes.
- 4.8.5 During the preliminary visit, the Assessment Team will advise the laboratory of any areas that appear to require attention in order to fulfil the requirements of accreditation. The Lead Assessor will also remind the laboratory that the preliminary visit is not a full assessment and will describe the nature of the full assessment visit.
- 4.8.6 The preliminary visit report prepared by the Assessment Team shall include:
- if a further preliminary visit is required;
 - whether plans for initial assessment of the laboratory can proceed;
 - specific reasons why plans cannot proceed;
 - whether an interlaboratory comparison (e.g. measurement audit) is needed.
- 4.9 Depending on the outcome of the preliminary desk study and the result of the preliminary visit, the NAB-MALTA will decide whether or not to proceed with the assessment process.

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4.10 If the accreditation process can continue, the Lead Assessor in liaison with the Technical Assessor will determine the composition of the assessment team, and the effort (in mandays) required for the visit including time for preparation and standard post visit activities. This will take into account all factors necessary to enable a reliable assessment of the competence of the laboratory to perform the full range of measurements/tests/techniques proposed for inclusion in its scope of accreditation, including,

- whether it is necessary to assess all calibration/test activities, or if a representative sample can be selected
- the need to assess all key activities
- in the case of multi-location activities including on-site calibrations/tests, the need to ensure that all locations where key activities are performed are assessed.

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

5. Preparation for the Initial Assessment Visit

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


- finalise the selection of the assessment team;
- prepare and issuing a visit plan;
- issuing an invoice.

5.1.1 The laboratory shall inform the NAB-MALTA with any corrective actions which may have been taken following the preliminary visit. The laboratory shall submit any revised documentation **not later than 6 weeks** prior to the date of the scheduled assessment visit.

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

- a formal reply that the assessment team is acceptable is received from the applicant laboratory;
- full payment of the assessment fee has been settled.


5.2.1 Should no reply be received the invoice will become invalid. Invoices shall remain valid for a period of **one (1) month** from the date of the invoice.

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- 5.3 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;
 - have understanding sufficient to make a reliable assessment of the competence of the laboratory to operate within its scope.
- 5.4 A **visit plan** will be prepared by the NAB-MALTA in liaison with the other members of the assessment team. This plan will:
- indicate the section/activities/location(s) to be assessed by each assessor
 - specify the tests/calibrations that each assessor must witness during the visit, including any on-site activities and in-house calibrations, as necessary.
- 5.4.1 NAB-MALTA will distribute copies of the visit plan to the laboratory and to all the assessment team. All parties are given the opportunity to raise any queries related to the visit plan.
- 5.4.2 When the date and plan for the assessment have been settled, the laboratory should ensure that:
- a) key members of the laboratory 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;
 - 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 overalls, for use by the assessors.
- 5.5 Before the on-site visit, each Assessment Team member shall carry out a final detailed review of the relevant documents and records supplied by the laboratory.

6. Overview of Assessment Visit


- 6.1 The assessment visit begins with an **opening meeting** between the NAB-MALTA assessment team and representatives of the laboratory.
- 6.2 Each member of the assessment team then departs to his respective areas to begin the assessment. The assessors will examine procedures and records and witness the relevant calibration and testing activities included in the scope.

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- 6.2.1 The Lead Assessor will manage the Assessment Team to ensure that the relevant activities are assessed and provide support and advice as necessary.
- 6.2.2 A member of the laboratory staff nominated by the management should accompany each assessor.
- 6.3 The visit ends with a **closing meeting** between the assessment team and laboratory representatives, at which each assessor presents a summary of the areas examined and the findings (this may include more detailed reporting of the individual observations as appropriate). Each Assessor will give his findings of the team in the Assessment Summary Report form.
- 6.4 Interim meetings with the laboratory management may be held during a visit, particularly if a number of assessors are present over a number of days.
- 6.5 Private meetings between assessors may be held, as appropriate.

7. The Opening Meeting

- 7.1 The **opening meeting** is held before the assessment commences. It is intended to enable the assessors and the laboratory's representatives to become acquainted, and to clear up any difficulties about the purpose of the assessment and what is expected of the laboratory during the visit. All participants to the opening meeting will be asked to sign the attendance list.
- 7.2 The meeting is chaired by the Lead Assessor and covers the following points:
- a) introduction of the participants, including an outline of their roles;
 - b) confirmation of the assessment objectives, scope and criteria and discussion of the scope of testing/calibration covered by the laboratory's application and the terms in which the laboratory's accreditation should be defined;
 - c) confirmation of the assessment visit plan and other relevant arrangements with the laboratory, such as the date and time for the closing meeting, any interim meetings between the assessment team and the laboratory's management, and any late changes;
 - d) methods and procedures to be used to conduct the assessment, including advising the laboratory that the assessment evidence will only be used on a sample of the information available and that therefore there is an element of uncertainty in auditing;

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- e) confirmation of formal communication channels between the assessment team and the laboratory representatives;
 - f) confirmation that, during the assessment, the laboratory representatives will be kept informed of the assessment progress;
 - g) confirmation that the resources, organisation personnel and facilities needed by the assessment team are available;
 - h) an assurance that all findings will be treated in confidence;
 - i) confirmation of relevant work safety, emergency and security procedures for the assessment team;
 - j) confirmation of the availability, roles and identities of guides;
 - k) an explanation of the role of the laboratory representatives in the assessment, particularly in agreeing statements of fact concerning observations made by assessors which might indicate a nonconformity with MSA EN ISO/IEC 17025 or MSA EN ISO 15189, the NAB-MALTA regulations and policies and other normative documents.
 - l) the method of reporting;
 - m) information about conditions under which the assessment may be terminated;
 - n) information about the method of appeal regarding the conduct and conclusions of the assessment;
 - o) an opportunity for the laboratory representatives to ask relevant questions.
- 7.3 Each person present for the opening meeting shall sign the attendance form circulated by the NAB-MALTA.

8. The Assessment - Examination of Laboratory Operations

- 8.1 The main purpose of the on-site visit is for the assessment team to gather objective evidence that for the applicable scope the laboratory conforms to the relevant standard(s) and other requirements for accreditation.
- 8.2 The most important part of the assessment consists of on-the-spot observations of the laboratory going about its normal business. Although the assessment should as far as possible make use of normal on-going work, it may be necessary for NAB-MALTA to ask the laboratory to provide a demonstration of some activities that are not on-going, in order to cover the range of tests or calibrations for which accreditation is sought. This should normally be evident from the visit plan. Assessors need to establish the laboratory's overall competence in all aspects required by the Standard.
- 8.3 Assessors need:
- to form a general impression of the laboratory's capability,

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- to assess the suitability of the equipment for the work for which accreditation is sought and its state of maintenance and calibration;
- to evaluate that the laboratory has sufficient number of staff to provide assurance of the competence across the scope of accreditation;
- to evaluate the effectiveness of the management system in ensuring that errors are not allowed to appear in recording, analysing and reporting results.

8.4 Normally, the Lead Assessor will examine the laboratory's management system and quality documentation with the Quality Manager and any other appropriate staff, to verify that it meets the requirements of the Standard.

8.5 Technical Assessors will proceed according to the agreed visit plan and examine the management system in operation and the competence of the laboratory staff to perform specific calibrations/tests. All components of the management system involved will be assessed.

8.5.1 Technical Assessors will examine the test/calibration procedures and their implementation in the laboratory. They will determine whether the treatment of measurement uncertainty is in accordance with international criteria. It may not always be necessary to examine every procedure in operation because of the similarities between some tests/calibrations, but assessors will verify the implementation of the procedures for the tests/calibrations listed in the visit plan. The assessors will ask to see the equipment involved, the manufacturer's manuals, and establish the state of calibration of the equipment.

8.5.2 Technical Assessors will witness tests/measurements and examine documentation concerning tests/ calibrations in progress, and will review associated records and certificates/reports.

8.5.3 During assessments of calibration laboratories, Technical Assessors will establish the laboratory's capability to make measurements that are traceable to national/international standards and according to the uncertainty claimed for each parameter for which accreditation is being sought.

8.5.3.1 This will include the examination of calibration certificates and the results of any in-house calibrations to ensure that imported uncertainty and drift contributions can be substantiated. Assessors will also examine the results obtained by the laboratory in measurement audits. If calibration personnel are to be confirmed as approved operators, it will be necessary for assessors to observe the performance of operators on specific calibrations at locations chosen by NAB-Malta.

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- 8.5.4 During assessment of testing laboratories, Technical Assessors will examine the laboratory's processes for establishing traceability of measurements including any in-house calibrations and the results from participation in appropriate proficiency testing schemes and other QC/QA procedures. Technical Assessors will also assess procedures used to establish the validity of methods used.
- 8.6 The object of assessment is to establish by observation whether the work of the laboratory meets the requirements of the Standard.
- 8.6.1 Observations made will be based on objective evidence and will normally be recorded and verified before assessors leave the area under assessment. To secure agreement on the facts, and to avoid subsequent dispute, assessors normally detail observations in an Observation/Nonconformity Report and, to confirm that it is factually correct obtain countersignature from the accompanying laboratory representative.

9. Assessment Findings

- 9.1 The Assessment Trail Report Details **NABG06** and List of Findings **NABG10**, used to record possible nonconformities with the requirements of MSA EN ISO/IEC 17025 and/or MSA EN ISO 15189 or other applicable accreditation criteria, provide the objective evidence on which the Lead Assessor's recommendation on accreditation to the NAB-MALTA will be based.
- 9.2 It is important to recognise that **NABG10** is intended solely for recording factual observations, such as: "three samples being prepared for test X had no labels or other form of identification" or "no calibration certificate could be provided for equipment Y".
- 9.3 No attempt is made at the time of recording an observation 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 Lead Assessor, prior to the closing meeting with the laboratory representatives. Thus, whilst there could be disagreement regarding the Lead Assessor's recommendations to the NAB-MALTA, there should be no doubts concerning the observations on which these are based.

10. The Summary Report

- 10.1 After the assessors have completed their individual assignments, they hold a private meeting during which each will summarise his own findings and contribute to a co-ordinated view of the laboratory's work. This meeting will therefore help the assessment team to analyse all the relevant information and evidence gathered. This analysis should


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be sufficient to allow the team to determine the extent of conformance of the laboratory with the requirements for accreditation and to establish any nonconformities.

- 10.2 At this stage the Lead Assessor completes the Summary Report Form (**NABG08**), taking into account his own findings and those of the other assessors involved.
- 10.3 During this meeting the List of Findings **NABG10** are carefully considered to determine whether or not nonconformities with MSA EN ISO/IEC 17025, MSA EN ISO 15189 or other accreditation criteria are involved. Any nonconformity is then classified into one of two types, major or minor as defined in the Regulations for NAB-MALTA Accredited Bodies (**RAB1**).
- 10.4 The Summary Report will:
- record the assessors' findings, indicate key areas needing corrective action,
 - the assessment team's recommendations to the NAB-MALTA concerning acceptance of the laboratory into accreditation, and
 - the scope in which the accreditation should be defined. Recommendations may be for unconditional acceptance, for acceptance subject to an undertaking to remedy specified nonconformities by a certain date, for postponement until the nonconformities have been remedied, or for rejection. The Summary Report will make it clear which of these recommendations is to be made. The Summary Report will also indicate that an additional visit to the laboratory may be required.

11. Factors Affecting Recommendations on Accreditation

- 11.1 In agreeing on its recommendation the Assessment Team will take into account the extent of competence and conformity to the standard found during the assessment.
- 11.2 Where there are no findings requiring corrective action, the Lead Assessor normally recommends that accreditation be offered.
- 11.3 Where there are findings that require corrective action, the recommendation will usually be that accreditation is offered subject to satisfactory action being taken by the laboratory.
- 11.4 Where there are one or more areas of calibration or testing where the extent of competence or conformity is not acceptable, but there are no overall major systems failures, the Lead Assessor may recommend accreditation for an appropriately reduced scope.
- 11.5 Where the number and seriousness of the findings are such that the laboratory's management system and organisation fails to demonstrate competence or conformity with


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the requirements of the Standard, the Lead Assessor's recommendation will be that accreditation is refused and that the laboratory is advised to discuss future actions with NAB-MALTA.

- 11.6 For laboratories in some areas of activity, accreditation may also require satisfactory completion of a proficiency test.

12. The Closing Meeting

- 12.1 The Closing Meeting between the assessment team and the laboratory's representatives is held after the assessment team has completed the Summary Report Form, **NABG08**, and decided on the recommendation which will be made to the NAB-MALTA.
- 12.2 The Lead Assessor chairs the Closing Meeting. The following items will be addressed, normally in the order listed and as specified in Form no. **NABG17**:
- a) reminder of the purpose of the visit and reiteration of confidentiality;
 - b) the assessment team members will give a brief verbal presentation of the findings;
 - c) the summary, confirmation of scope, conclusions and recommendation will be presented;
 - d) discussion and decision of possible modifications to the statement of scope of accreditation, which might be appropriate in the light of the assessment findings;
 - e) completion of the List of Findings **NABG10** to record the proposed corrective actions (some of these may have been completed during the assessment and before the Closing meeting).
 - f) a date by which any required corrective actions will be implemented will be agreed in consultation with the laboratory. The method of verification will also be agreed;
 - g) remind the laboratory representatives that deadlines for responses to nonconformities should be strictly adhered to, in line with NAB-MALTA **RAB1** regulations.
 - h) explanation of the surveillance and reassessment process as well as payment requirements;
 - i) explanation potential sanctions if the requirements of accreditation are not adhered to;
 - j) explanation of the appeals process;
- 12.2 During this closing meeting, the laboratory representatives shall be given the opportunity to ask questions about the findings.

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- 12.3 The laboratory will be given a copy of Assessment Summary Report (**NABG08**) plus List of Findings (**NABG10**) during the closing meeting. The Lead Auditor may find it necessary to provide the Assessment Summary Report (**NABG08**) after the on-site visit, normally within a period not exceeding three days.
- 12.4 All the persons present for the Closing Meeting will be asked to sign the attendance sheet distributed by the NAB-MALTA.

13. Post-Assessment Procedures

- 13.1 The laboratory supplies NAB-MALTA with evidence of the corrective action to be taken to address any findings. Evidence should be presented to NAB-MALTA grouped by assessor. All the information should be summarised on Form No. List of Findings **NABG10**. Cross-referencing of the evidence of individual actions taken to close the finding should be made very clear.
- 13.1.1 The time for the provision of the evidence is specified in **RAB1**.
- 13.2 NAB-MALTA will acknowledge receipt of the evidence. The Assessment Team assesses this evidence.
- 13.3 In cases where accreditation is conditional on specific corrective actions being implemented by the laboratory, the NAB-MALTA will require evidence that the required measures have been taken before finalisation of the proposal report to the Board.
- 13.3.1 In many cases it will be possible to provide the evidence by post to the NAB-MALTA (e.g. revised procedure documents, up-to-date calibration certificates, photos).
- 13.3.2 Sometimes a follow-up visit to the laboratory may be necessary to assess the corrective actions taken. Assessment of such a visit will be directed specifically to the confirmation of clearance of findings. If an assessor observes a new finding, he will bring the matter to the attention to the laboratory management and to the Director of the NAB-MALTA and will also report it in writing. The cost of such visits will be charged to the laboratory.
- 13.4 Once the assessment team is satisfied that all findings have been satisfactorily actioned, the "*Accreditation Summary and Recommendation Report*" is finalised. This is forwarded to the Director of the NAB-MALTA who, after checking the report, will proceed to distribute and then present the report to the Board.

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- 13.5 The Board will review 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.
- 13.6 The NAB-MALTA will inform the applicant laboratory about the decision of the Board. If the laboratory 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 one-month of the decision.

14. Surveillance And Reassessment


- 14.1 Following the granting of the NAB-MALTA accreditation the laboratory will receive regular surveillance and reassessments. Their purpose is to determine whether a laboratory is continuing to comply with MSA EN ISO/IEC 17025 and/or MSA EN ISO 15189, the NAB-MALTA regulations, policies and other applicable accreditation criteria. Similar procedures to those described in the previous sections will be followed for the conduct of surveillance and reassessment visits.
- 14.2 The first surveillance visit takes place **six (6) months** after accreditation has been awarded and annually thereafter. However, NAB-MALTA reserves the right to make unannounced visits at any time.
- 14.3 A reassessment generally occurs **every 5 years**.
- 14.4 The purpose of surveillance/reassessment visits is to determine whether or not a laboratory is continuing to fulfil the requirements for accreditation. The general approach described in this publication will apply to all these visits. The surveillance team shall have the competence to assess both the management and technical requirements.
- 14.5 At the **Opening Meeting** of surveillance and reassessment visits the Lead Assessor will ask whether all significant changes in the laboratory status or operation have been notified to the NAB-MALTA and will confirm that there are no outstanding corrective actions from the previous visit.
- 14.6 If a surveillance or reassessment visit reveals that there have been significant changes, e.g., of staff, equipment or the range of services available, these matters shall be recorded by the Lead Assessor. Assessors shall check that the changes are not such as to diminish the laboratory's capabilities as described in the schedule of accreditation, and that they have already been fully notified to NAB-MALTA.

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- 14.7 Normally, during a single surveillance visit, assessors will not be expected to check the whole of the testing/calibration work for which a laboratory is accredited. The range of calibrations or tests for which the laboratory is accredited will be assessed at least once between full assessment and reassessment. Equally, not all areas of the Management system need to be covered at each surveillance visit. The assessment team will take into account the outcome of previous audits to plan the activities to be covered. The Lead Assessor will normally look at Management Review, Audits and Complaint Records at each surveillance visit.
- 14.8 In contrast to surveillance, a reassessment is similar in format and detail to an initial assessment.
- 14.9 At the conclusion of a surveillance or reassessment visit, the Lead Assessor will (as with an initial assessment) make a recommendation to the NAB-MALTA on the continuing accreditation of the laboratory. Suspension or withdrawal of accreditation will be recommended where the number and seriousness of the findings is such that the laboratory's management system has broken down, and the requirements of the Standard can no longer be met.
- 14.10 Changes to scope, suspensions and withdrawals, unless not voluntarily requested by the laboratory, will need to be sanctioned by the Board. The Director of the NAB-Malta has the authority to immediately suspend an accreditation and then present his reasons for suspension to the Board.

15. Extension Of Scope Of Accreditation

- 15.1 When a laboratory applies for an extension to its Scope of Accreditation, including the addition of new specified staff, the NAB-Malta will seek advice from the Lead Assessor and, if relevant, the technical assessor(s) on whether, after examination of documentation provided by the laboratory, accreditation can be granted without further action by the laboratory, or whether further documentation or an assessment visit is required. The NAB-Malta Officer may arrange an extra visit in the normal way or may suggest combining this visit with an imminent scheduled visit.
- 15.2 In line with **RAB1**, the application for extension of scope shall be submitted to NAB-Malta **at least 3 months before** the next scheduled visit. Applications shall be supported by validation data for any new methods.
- 15.2 If the extension is assessed during a scheduled visit it will not be allowed to reduce the effectiveness of the normal surveillance/reassessment visits so additional time will normally be required.

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DO YOU NEED FURTHER INFORMATION?

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

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

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