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## FOREWORD

The National Accreditation Body of the Malta Standards Authority (NAB-MSA) is the Maltese National Authority with responsibility for accreditation in accordance with the relevant national, international and European standards and guides, and the applicable national, international and European requirements.

Activities conducted by the NAB-MSA include:

- the accreditation of Laboratories for calibration and testing;
- the accreditation of Certification Bodies providing certification of products, services, management systems and personnel;
- the accreditation of Inspection Bodies;
- the accreditation of Attestation Bodies for public procurement;
- the accreditation of EMAS Verifiers;
- the accreditation of CSPs providing E-Signatures;
- the assessment of Conformity Assessment Bodies.

This publication has been drawn up to provide Certification Bodies with general guidance on the conduct of assessment, surveillance and reassessment visits.

The services of the NAB-MSA are accessible to all applicants whose requests fall within the activities of the NAB-MSA. Access is not conditional upon the size of the applicant 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.

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### **1. Introduction**

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- 1.1 The main function of the NAB-MSA is to establish the competence of Certification Bodies to carry out certification in defined fields and to ensure by surveillance and re-assessment that the requirements of accreditation are maintained.
  
- 1.2 Each applicant Certification Body gives basic information on its activities, equipment and staff in the Application Form, **NABAF01** and schedule **NABAF01/C**, and in the administrative and operating procedures in its quality manual which is to be submitted to the NAB-MSA with the application form.
  
- 1.3 The NAB-MSA assessment of the competence of a Certification Body is carried out through an assessment of the documentation that describes the quality system and procedures of the Certification 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 Certification Body's central Head Office. Part of the assessment includes participation of the NAB-MSA as an observer of at least two certifications carried out by the applicant in the various fields applied for (e.g. ISO9001, ISO14001). The purpose of the assessment is to determine whether the Certification Body complies with the criteria of competence prescribed by the NAB-MSA, with the NAB-MSA regulations, policies, technical documents, the relevant EA/IAF interpretative guidelines on the application of the applicable standards and guides and with any further requirements specified by the NAB-MSA. The main accreditation criteria are specified in publication **ATG03**.
  
- 1.4 NAB-MSA assessment procedures are applicable to all sizes of certification 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 Certification Body, whatever its size or complexity, or the location where work is carried out, meets the requirements of the criteria of accreditation.
  
- 1.5 NAB-MSA uses assessors with the relevant specialist knowledge to judge the competence of the Certification Body to perform the certifications for which accreditation is sought. The assessors are required 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 Certification Body's activities for compliance with the requirements and reporting their findings to the Certification Body and to the NAB-MSA.
  
- 1.7 All information obtained before, during or after assessment, including the fact that a Certification Body has applied for accreditation, or that an application for accreditation has been deferred or rejected, is treated as strictly confidential by the NAB-MSA and its assessors.

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## **2. Preparing for Accreditation and Submitting the Application Form to the NAB-MSA**

- 2.1 Having decided to consider seeking NAB-MSA accreditation, the Certification Body is strongly recommended to review its current quality manual, procedures and documentation against the requirements of the applicable accreditation criteria as defined in **ATG03**. If the review indicates the need for any modifications to existing procedures or documentation, then the Certification Body should plan to have these carried out and in operation prior to the visit by the NAB-MSA.
- 2.2 The Certification Body must carry out an evaluation of risk and determine the amount and type of insurance that they should have in place.
- 2.3 The Certification Body should then complete the Application Form for Accreditation, **NABAF01** and the corresponding schedule **NABAF01/C**. This formal application should include:
- the general features of the Certification Body, including corporate entity, addresses, legal status and human and technical resources;
  - general information concerning the Certification Body such as its functions, its relationship in a larger corporate entity if any, and addresses of all its physical location(s);
  - a clearly defined, requested, scope of accreditation;
  - a description of the conformity assessment services which the Certification Body undertakes, and a list of standards, methods and procedures for which the Certification Body seeks accreditation, including limits of capability where applicable;
  - an agreement to fulfil the requirements for accreditation and the other obligations as specified in the NAB-MSA regulations and policies;
  - a copy of the Certification Body's quality manual, and relevant associated documents and records,
  - a copy of the insurance certificate covering the scope of activities.

It is very important that all the documents listed in Annex 2 of **NABAF01/C** are submitted with the application form.

- 2.3 The application for accreditation is a formal request to the NAB-MSA to conduct the accreditation process and is a commitment from the applicant to pay the accreditation fees.

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### **3. Scope of Accreditation**

- 3.1 It is policy of the NAB-MSA to define the scope of a Certification Body's accreditation as precisely as possible.
- 3.2 Following accreditation, the Schedule is considered to be in the public domain unless otherwise requested by the Certification Body for legitimate reasons.

### **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-MSA will make a 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.

It will also contact the Certification Body to confirm the type of certification for which the body is seeking accreditation;

- 4.2 On completion of this review, the NAB-MSA selects a Lead Assessor bearing in mind the sectors in which Certification Body will be operating and will prepare an invoice to cover the costs of the application. These will be sent to the client for approval.

- 4.2.1 The Certification Body may object to the chosen Lead Assessor and should inform the NAB-MSA with good and sufficient reason(s) for such objection.

- 4.3 On approval of the Lead Assessor and the payment of part of the application fee, the NAB-MSA will proceed to send the Quality Manual and any supporting documentation received from the applicant Certification Body to the Lead Assessor. The Lead Assessor carries out a desk audit and will identify:

- the need for further documentation;
- the need for a preliminary visit;
- potential nonconformities;
- proposed composition of the assessment team.

- 4.4 A preliminary visit by the Lead Assessor is normally recommended where the application indicates that additional information is required, or where advice to the Certification Body on preparation for the assessment visit seems necessary. The preliminary visit also helps

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the NAB-MSA in determining whether the body appears to be sufficiently prepared for an initial assessment. The preliminary visit normally takes no longer than one day.

4.5 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 technical assessors required, where necessary (e.g. for product certification bodies);
- selection of the certifications to be witnessed;
- clarification with the applicant of the applied scope of accreditation;
- the Lead Assessor can briefly examine the systems which have been established and implemented. In this manner he 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 and discuss any findings related to the documentation.

4.6 The visit should be structured so that the Lead Assessor can ascertain that the essential components of a quality system have been put in place or have been addressed. In particular, the Lead Assessor needs to establish whether the Certification Body has a stated policy for defined responsibilities and a means of meeting each of the requirements of the standard.

4.7 In addition to examining the documented quality system prepared by the Certification Body, the Lead Assessor will discuss the proposed scope of accreditation.

4.8 Normally the Lead Assessor will discuss with the Certification Body any specific sector schemes that form part of the scope of accreditation, especially in the field of product certification.

4.9 During the preliminary visit, the Lead Assessor will advise the Certification Body of any areas that appear to require attention in order to comply with the accreditation criteria. The Lead Assessor will also remind the Certification Body that the preliminary visit is not a full assessment.

4.10 The preliminary visit report prepared by the Lead Assessor shall include:

- if a further preliminary visit is required;
- whether plans for initial assessment of the Certification Body can proceed;
- type of technical assessors or technical experts that are required;
- a draft of the assessment visit plan;
- specific reasons why plans cannot proceed.

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

- 5.1 Should the preliminary visit report and the advice received from the Lead Assessor indicate that the assessment procedure can continue the NAB-MSA will proceed to prepare a quotation and to select the assessors for the assessment of the Head Office and the witness certifications.
- 5.1.1 The Certification Body shall inform the NAB-MSA with any corrective actions which may need to be taken following the preliminary visit. This may involve the Certification Body to submit revised documentation.
- 5.2 The NAB-MSA will only proceed with the processing of the application when a formal written reply that the assessment plan and the assessment team are acceptable and when payment is received from the applicant Inspection Body. Should no reply be received the invoice will become invalid.
- 5.2.1 The assessment plan will indicate the section/activities to be assessed by each assessor, and specify the on-site certifications that each assessor must witness during the visit.
- 5.3 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.
- 5.4 The nature of the initial assessment will depend upon the schedule of accreditation required by the Certification Body and the complexity of the quality system that is being operated. However, the following elements will need to be covered:
- (a) Head Office assessment;
  - (b) assessment of multiple locations (where applicable);
  - (c) observation of on-site certifications for each certification scheme offered by the Certification Body.
- 5.5 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-MSA will take into consideration the optimal size of the team and the number of assessment days.
- 5.5.1 The NAB-MSA adopts a formal selection procedure to ensure that the assessment team as a whole shall:

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- 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 Certification Body to operate within its scope.

5.6 The NAB-MSA shall agree with the assessment team and the Certification Body on the date and schedule of the assessment visits.

5.7 Before any onsite visit, the assessment team members shall carry out a detailed review of the relevant documents and records supplied by the Certification Body. This is the final review which the NAB-MSA 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 Certification Body should ensure that:

- a) key representative of the personnel will be available on the date(s) of the visit;
- b) the personnel are aware of the procedures which will be followed during the assessment process;
- 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 The NAB-MSA assessment team will seek to establish through objective evidence and by using various techniques that:

- (a) the quality system is appropriate to the Certification Body's needs, organisational arrangements and methods of operation, including multiple location operations and number of assessors;
- (b) all of the requirements of the applicable accreditation criteria have been satisfactorily addressed ;
- (c) the Certification Body has implemented all the requirements of the quality system effectively;
- (d) the operational, administrative and technical procedures used to support the quality manual are complete, technically valid and appropriate.

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- 6.2 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 work related to the certification activities;
  - (b) examination of records;
  - (c) examination of the arrangements for exercising control over subcontractors and suppliers.
- 6.3 All types of certification will be subject to an office assessment and technical review. 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 certifications.
- 6.4 The assessment begins with an opening meeting between the NAB-MSA assessment team and representatives of the Certification Body. It is intended to enable the assessors and the representatives of the Certification Body to become acquainted, and to clear up any difficulties about the purpose of the assessment and what is expected of the Certification Body during the visit.

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 certification covered by the application;
- (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 management of the Certification Body, and any late changes;
- (d) methods and procedures to be used to conduct the assessment, including advising the certification body 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;
- (e) confirmation of formal communication channels between the assessment team and the certification body representatives;

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- (f) confirmation of the language to be used during the assessment;
  - (g) confirmation that, during the assessment, the certification body representatives will be kept informed of the assessment progress;
  - (h) confirmation that the resources and facilities needed by the assessment team are available;
  - (i) confirmation of matters relating to confidentiality;
  - (j) confirmation of relevant work safety, emergency and security procedures for the assessment team;
  - (k) confirmation of the availability, roles and identities of guides;
  - (l) an explanation of the role of the Certification Body's representatives in the assessment, particularly in agreeing statements of fact concerning observations made by assessors which might indicate a nonconformity with the applicable accreditation criteria.
  - (m) the method of reporting, including the grading of nonconformities;
  - (n) information about conditions under which the assessment may be terminated;
  - (o) information about the method of appeal regarding the conduct and conclusions of the assessment;
  - (p) an opportunity for the Certification Body representatives to ask relevant questions.
- 6.5 The Head Office assessment ends with a meeting between the NAB-MSA assessment team and the Certification Body representatives at which the Lead Assessor sums up the findings of the team as a whole.

## **7. On-site Assessment of Certification**

- 7.1 On-site assessment of certification activities is an essential part of the NAB-MSA assessment of certification bodies.

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- 7.2 When deciding on the number of on-site assessments of certification needed the following aspects will be considered by the NAB-MSA:
- (a) the sectors in which the certification body will be operating;
  - (b) the certification body's procedures for selecting, training, authorising and monitoring assessors, having regard to the qualifications and experience required;
- 7.3 The minimum number of on-site assessments of certifications at initial assessment will normally be two.
- 7.4 When deciding on the certification to be witnessed account will be taken of the following:
- (a) the type of certification;
  - (b) any statutory requirements.
- 7.9 The NAB-MSA personnel will ensure that their role during on-site assessment of certification is one of observer and they will not influence the certification being performed. The NAB-MSA observer will be looking to see that, as a minimum, the team selected by the Certification Body:
- (a) has the right competence for the type of organisation being certified;
  - (b) has been supplied with all the necessary forms and procedures and that these documents are up-date;
  - (c) is familiar with the certification procedure;
  - (d) implements the procedure in full and correctly i.e. no short-cuts, no personalised application where it is not permissible to do so;
  - (e) records all observations made while on site as required by the procedure;
  - (f) ensures that all findings that indicate immediate or urgent action are reported as required to the client whilst on site;
  - (g) prepares an assessment report which complies with the Certification Body requirements, relevant NAB-MSA documents and relevant statutory requirements;
  - (h) facilities and equipment are fit for the inspection purpose.
- 7.10 At the end of the witnessing of the certification, the NAB-MSA observer will prepare a report to the NAB-MSA.

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## **8. The Assessment Trail Form NABG06**

- 8.1 During the course of the assessment, the assessors will use form number **NABG06** on which they will record their full assessment trail.
- 8.2 The information of particular observations which may indicate a nonconformity or an opportunity for improvement will be transferred to **NABG07**.

## **9. Assessment Observation/Nonconformity Form, NABG07**

- 9.1 The Assessment Observation/Nonconformity Form, **NABG07**, recording possible failures of the Certification Body's arrangements to comply with the applicable accreditation criteria, provides the objective evidence on which the Lead Assessor's recommendation to the NAB-MSA will be based. A form will be completed by an assessor as soon as possible after any incident or observation which might indicate nonconformity or afterwards is noticed. Apparent nonconformity will be discussed with the Certification Body's representative who may be able to point to an acceptable explanation. The staff of the Certification Body will always be allowed to see what is being recorded.
- 9.1.1 During on-site witness certification, any nonconformities raised will be discussed with the Certification Body assessor after the latter has completed his job.
- 9.2 On each **NABG07** form the following information is recorded:
- a) where the observation was made;
  - b) the procedure or inspection under discussion;
  - c) any documents involved;
  - d) the observed feature which might not comply with the accreditation criteria;
  - e) the relevant clauses in the Criteria of Competence;
  - f) the name(s) of the person(s) with whom the matter was discussed;
  - g) the signatures of the assessor and the representative of the Inspection Body accompanying him.
- 9.3 It is important to recognise that **NABG07** is intended solely for recording factual observations, such as: "no calibration certificate could be provided for equipment Y". 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-MSA requirements, is carried out in conjunction with the Lead Assessor, prior to the final overall meeting with the representatives of the Certification Body. Thus, whilst there could be disagreement

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regarding the Lead Assessor's recommendations to the NAB-MSA, there should be no doubts concerning the observations on which these are based.

## **10. The Summary Report Form, NABG08**

- 10.1 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 Certification 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 Certification Body with the requirements for accreditation and to establish any nonconformities.
- 10.2 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 **NABG07** Forms are carefully considered to determine whether or not nonconformities with the applicable accreditation criteria are involved. Any nonconformity is then classified into one of two types, major or minor as defined in **RAB1** – Regulations for NAB-MSA Accredited Bodies.
- 10.4 The Summary Report will record the assessors' findings, any matters needing corrective action, the assessment team's recommendations to the NAB-MSA concerning acceptance of the Certification Body 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.

## **11. Closing of Assessment**

- 11.1 When the on-site witness certifications have been carried out, a closing meeting is held between the NAB-MSA assessment team and the Certification Body representatives at which each assessor presents his observations and the Lead Assessor sums up the findings of the team as a whole. The final overall report is at this stage presented to the Certification Body.
- 11.2 The closing meeting between the assessment team and the representatives of the Certification Body is held after the assessment team has completed the Summary Report Form, **NABG08**, and decided on the recommendation which he will make to the NAB-MSA.

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11.3 At this meeting the Lead Assessor will:

- (a) give, with the assistance of other assessment team members, a brief verbal presentation on the findings of the assessment of the laboratory;
- (b) discuss, if necessary, possible modifications to the statement of scope of accreditation, which might be appropriate in the light of the assessment findings;
- (c) inform the Certification Body of his intended recommendations to the NAB-MSA
- (d) point out any corrective action that may be called for as a condition of recommendation of accreditation, and try to reach agreement on a timetable for its implementation and on the method of verification to be used;
- (e) ask the Certification Body representatives to read and sign the Summary Report Form (**NABG08**) and Assessment Observation/Nonconformity Report forms (**NABG07**).

11.4 During this closing meeting, the Certification Body representatives shall be given the opportunity to ask questions about the findings and the written list of nonconformities, if any.

## **12. Factors Affecting Assessors Recommendations**

- 12.1 In agreeing on its recommendation the assessment team will take into account the number and importance of the individual nonconformities brought to light during the assessment, as well as the general performance of the Certification Body.
- 12.2 Where there are only a relatively small number of minor nonconformities, the Lead Assessor may, under certain circumstances, recommend accreditation. However, all recommendations for accreditation, which include outstanding nonconformities, will be conditional upon them being corrected within a specified period as agreed between the Certification Body, the Lead Assessor and the NAB-MSA This type of information will be included, where appropriate, in the Summary Report Form **NABG08**, which the Head of the Certification Body will be asked to countersign, to emphasise the conditional nature of the agreement and recommendation.

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### **13. Post-Assessment Procedures**

- 13.1 The NAB-MSA 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 non-conformances raised during the assessment from the Lead Assessors.
- 13.2 He will then proceed to prepare a complete accreditation proposal report to the Head of the NAB-MSA who, after checking the report, will proceed to present the report to the Accreditation Advisory Board.
- 13.3 The Accreditation Advisory Board will consider the proposal report and any other information relevant to the case. The Accreditation Advisory Board may accept the application for accreditation either conditionally or unconditionally, or may reject it.
- 13.4 In cases where accreditation is conditional on specific corrective actions being implemented by the Inspection Body, the NAB-MSA will require evidence that the required measures have been taken before issuing the Certificate of Accreditation. In many cases it will be possible to provide the evidence by post to the NAB-MSA (e.g. revised procedure documents, up-to-date calibration certificates). Sometimes, however, an additional short visit to the Certification Body may be necessary, and the cost of such visits will be charged to the Certification Body.
- 13.5 The NAB-MSA will inform the applicant Certification Body of the outcome of the decision.
- 13.6 Following the successful outcome of an assessment, the Inspection Body shall agree to sign a contract of accreditation with the NAB-MSA.

### **14. SURVEILLANCE AND REASSESSMENT VISITS**

- 14.1 Following the granting of the NAB-MSA accreditation after successful completion of the procedures described above, the Certification Body will receive regular surveillance and re-assessment visits. Their purpose is to determine whether the Certification Body is continuing to comply with the 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.

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- 14.3 A reassessment visit generally occurs every 4-5 years.
- 14.5 At the Opening Meeting of surveillance and re-assessment visits the Lead Assessor will ask whether all significant changes in the Certification Body status or operation have been notified to the NAB-MSA and will confirm that there are no outstanding corrective actions from the previous visit.
- 14.6 At ordinary surveillance visits the surveillance team shall have the competence to assess both the quality 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 quality system components and the competence in at least one of the accredited areas.
- 14.6.1 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 checked depends on various factors such as findings at previous visits, outstanding corrections, personnel changes and other changes. All elements of the quality system shall be assessed at least once between the initial assessment and reassessment or two consecutive reassessments.
- 14.6.2 On-site assessment of certification will be carried out as part of the surveillance visit. The minimum number of on-site witness of certifications at surveillance is one per year and the same criteria used for assessment will be considered when determining the number and type of certifications to be witnessed.
- 14.7 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 Certification Body's quality system. The same criteria as those used during the initial assessment will be used to determine the number and type of certifications to be assessed.
- 14.8 The reassessment team shall have the competence to assess both the quality system components of the criteria and the full range of operational activities of the accredited Certification Body.

## **15. Extensions to Scope**

- 15.1 Following receipt of an application for extension to scope, NAB-MSA 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:

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- (a) existing scope of accreditation;
- (b) Certification Body's competences within scopes;
- (c) the range of scopes;
- (d) the location at which the extension to scope is sought.

15.2 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.

**END**