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# NAB-MALTA REGULATIONS

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## RAB1 - Accreditation General Regulations

Revision 7      Jan 2009

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## **FOREWORD**

The National Accreditation Board of Malta (NAB-MALTA) is the Maltese National Authority with responsibility for accreditation of Conformity Assessment Bodies in accordance with the relevant normative documents. The NAB-MALTA is set up according to the requirements of ISO/IEC 17011 (Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies) and EC Regulation 765/2008 (Regulation setting out the requirements for accreditation and market surveillance relating to the marketing of products).

This document defines the regulations governing NAB-MALTA accreditation and applies to all the accreditation schemes and to all the applicant and accredited Bodies.


The regulations covering the use of the accreditation symbol and reference to accreditation are specified in document number **RAB2**.

All the documents related to the accreditation process are available for download from the NAB-MALTA website (<http://www.nabmalta.org.mt/downloads.htm>).

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## **1.0. DEFINITIONS**

- 1.1. **“Accreditation”** means a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks. (In the case of Certification Service Providers the term “accreditation” shall have the definition given to it in the Electronic Signatures Directive).
- 1.2. **“Accreditation Certificate”** means a formal document or a set of documents stating that accreditation has been granted for the defined scope.
- 1.3. **“Accreditation Criteria”** means the criteria specified by the NAB-MALTA to be complied with by the Body in order to qualify for the Accreditation sought or held including, without limitation, any relevant standards, policies, guidelines or regulations.
- 1.4. **“Accreditation Guidelines”** means guidelines issued by the NAB-MALTA or any other body, including but not limited to, the European co-operation for Accreditation (EA), the International Accreditation Forum (IAF), the International Laboratory Accreditation Co-operation (ILAC) and the Forum of Accreditation Bodies (FAB) and, setting out the recommended practices and procedures to be followed in order to comply with Accreditation Criteria.
- 1.5. **“Accredited CAB”** means any person or association of persons, whether corporate or unincorporate, private or public or person to which accreditation has been granted by the NAB-MALTA.
- 1.6. **“Appeal”** means a request by the Body for reconsideration of any adverse decision made by the NAB-MALTA related to the Body’s desired accreditation status.
- 1.7. **“Application”** means any application in relation to accreditation made by the Body including an application for Accreditation, an application for extension to accreditation, and where relevant an application for renewal or reinstatement of accreditation.
- 1.8. **“Assessment”** means the process undertaken by the NAB-MALTA to assess the competence of a CAB, based on particular standard(s) and/or other normative documents and for a defined scope of accreditation.
- 1.9. **“Assessor”** means a person assigned by the NAB-MALTA to perform, alone or as part of an assessment team, an assessment of a CAB.
- 1.10. **“Body”** means the applicant for, or holder of, Accreditation.

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- 1.11. **“Complaint”** means an expression of dissatisfaction, other than appeal, by any person or organisation, to the NAB-MALTA, relating to activities of the NAB-MALTA or of an accredited CAB, where a response is expected.
- 1.12. **“Conformity Assessment”** means a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. It includes activities such as testing, inspection, and certification as well as the accreditation of conformity assessment bodies.
- 1.13. **“Conformity Assessment Body - CAB”** means a body that performs conformity assessment services and that can be the object of accreditation. \*Whenever the word CAB is used, it applies to both the “applicant and accredited CABs” unless otherwise specified.
- 1.14. **“Contract”** means the agreement in place between the NAB-MALTA and the Body as to Accreditation comprised by the Application or Applications, these Regulations, the documents, standards, guidelines, Accreditation Criteria, Accreditation Guidelines, regulations or other materials imported into the agreement between the parties by the Application or Applications or by these Regulations.
- 1.15. **“Extending Accreditation”** means the process of enlarging the scope of accreditation.
- 1.16. **“Lead Assessor”** means the assessor who is given the overall responsibility for specified assessment activities.
- 1.17. **“NAB-MALTA”** means the National Accreditation Board – Malta.
- 1.18. **“NAB-MALTA Accreditation Symbol”** means a symbol comprising the NAB-MALTA Logo together with the registration number, accreditation standard and reference to the scope of accreditation in respect of the Body. This symbol can be used by the accredited CABs to indicate their accredited status.
- 1.19. **“NAB-MALTA Logo”** means the symbol used by NAB-MALTA to identify itself or a particular Accreditation scheme.
- 1.20. **“Reducing Accreditation”** means the process of cancelling accreditation for part of the scope of accreditation.
- 1.21. **“Related Body”** means a body which is linked to the Body by common ownership or directors, contractual arrangement, common elements in the name, informal understanding or other means such that the related body has a vested interest in the outcome of an assessment of an application or the fact or circumstances of an


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accreditation or has an input into the activities of the Body so as to be relevant to the assessment of an application or the circumstances of an accreditation.


- 1.22. **“Scope of Accreditation”** means the specific conformity assessment services for which accreditation is sought or has been granted.
- 1.23. **“Surveillance”** means the set of activities, except reassessment, to monitor the continued fulfilment by accredited CABs of requirements for accreditation. (*For EMAS Verifiers, the term “surveillance” should be replaced by “supervision” as defined in the EMAS Regulation*).
- 1.24. **“Suspending accreditation”** means the process of temporarily making accreditation invalid, in full or for part of the scope of accreditation.
- 1.25. **“Withdrawing accreditation”** means the process of cancelling accreditation in full.
- 1.26. **“Witnessing”** means the observation of a CAB carrying out conformity assessment services within its scope of accreditation.

## **2.0 GENERAL INTRODUCTION**

- 2.1 The National Accreditation Board of Malta, hereinafter referred to as NAB-MALTA, is the Maltese authoritative body appointed as required by Article 4(1) of EC/765/2008. It is responsible for granting, extending, suspending, reducing or withdrawing accreditation in accordance with the relevant normative documents and guides using the applicable national, international and European requirements and guidelines and other publicly available criteria covering testing, calibration, inspection, certification, verification, attestation, EMAS verifiers and E-signatures hereinafter referred to as “the schemes”.
- 2.2 This document sets out the NAB-MALTA mandatory regulations including payment of fees, clearance of nonconformities, withdrawal of accreditation, complaints and appeals. It should be read and applied in conjunction with the requirements set out in the NAB-MALTA Contract reference **NABC03**.
- 2.3. The regulations defining the use of the accreditation symbol and/or reference to accreditation are contained in publication **RAB2**.
- 2.4. The NAB-MALTA shall specify the procedures by which application for accreditation should be made, the conditions for granting, maintenance and renewal of accreditation, and the conditions under which accreditation may be refused, suspended, reduced or withdrawn.

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- 2.5 If for any reason an application form is not processed within three months due to some actions from the conformity assessment body, then the NAB-MALTA will take the necessary action which normally results in the application being withdrawn.
- 2.6. The granting and renewal of accreditation shall be afforded only to applicant and accredited CABs which comply with these regulations and with the relevant criteria and policies prescribed by the NAB-MALTA, which continue to comply with the terms of the contract entered into with NAB-MALTA, which pay such fees as are due to the NAB-MALTA, and which give such undertakings as the NAB-MALTA may require.
- 2.7. The monitoring of compliance with these regulations and criteria is based on regular surveillance and reassessment visits by trained assessors, acting on behalf of the NAB-MALTA, for the relevant scheme.
- 2.7.1 The NAB-MALTA shall prescribe the frequency with which an Accredited CAB shall normally be subject to surveillance and reassessment. It shall depend, in any given case, on the types of activity for which it has been accredited but, as a general guide, surveillance visits will normally take place at intervals of 12 months (except for the first surveillance visit which will take place six months after the date of award of accreditation) and reassessment at least every 5 years. The NAB-MALTA reserves the right to carry out additional and unannounced visits and to undertake surveillance or reassessment visits at intervals other than those prescribed.
- 2.8. The NAB-MALTA will, from time to time, revise these regulations or any of the relevant criteria prescribed by the NAB-MALTA. Accredited CABs shall comply with such changes.
- 2.8.1. The Accredited CAB shall be notified about changes relating to these regulations and the relevant criteria prescribed by the NAB-MALTA and shall also be given such time, as in the opinion of the NAB-MALTA, is reasonable, to carry out the necessary adjustments. The Accredited CAB shall inform NAB-MALTA when such adjustments have been made.
- 2.9. All information received by the NAB-MALTA and by persons acting on its behalf in the granting, surveillance and renewal of accreditation shall be treated as confidential between the Applicant/Accredited CAB and the NAB-MALTA. Such information shall be handled within the NAB-MALTA on a strictly confidential basis and shall not be disclosed to a third party without the express written consent of the management of the Accredited or an Applicant CAB, unless such disclosure is required by law.
- 2.10. *For EMAS Verifiers:* In the event that the NAB-MALTA is not satisfied that the activities of the Verifier were performed adequately enough to ensure that the requirements of the EMAS Regulation are met by an Organisation/site applying for EMAS registration,

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the NAB-MALTA report on the supervision shall be transmitted to the National Competent Body, to the Verifier and, where necessary, to the accreditation body who had originally accredited the EMAS Verifiers (in the case of EMAS Verifiers accredited in another Member State but working in Malta).

### **3.0. SIGNIFICANCE OF ACCREDITATION**

- 3.1. Accreditation does not diminish and should not be regarded as in any way diminishing the obligations and duties of the Accredited CAB towards its clients.
- 3.2. While accreditation is a sound indicator of the quality of service offered by the Accredited CAB for those activities for which it is accredited, it cannot be taken to constitute a representation by the NAB-MALTA that the Accredited CAB always maintains a particular level of performance.

### **4.0 OBLIGATIONS OF THE CONFORMITY ASSESSMENT BODY**

- 4.1. The CAB shall comply with all of its obligations and responsibilities related to the accreditation process, as defined in these regulations, the contract and all the relevant accreditation criteria.
- 4.2. The CAB shall pay the NAB-MALTA fees in accordance with its obligations as specified in these regulations.
- 4.3. The CAB shall:
  - (a) at all times comply with these regulations and with the relevant accreditation criteria, policies, regulations and other relevant requirements prescribed by the NAB-MALTA;
  - (b) only claim that it is accredited in respect of the activities which are defined by the NAB-MALTA in the 'scope of accreditation' and which are carried out in accordance with these regulations and other criteria prescribed by the NAB-MALTA;
  - (c) inform the NAB-MALTA immediately of any change bearing on the accredited body's compliance with these regulations and the relevant scheme criteria or otherwise affecting the accredited body's scope of activity.

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- (d) promptly pay such fees for application, management, assessment, surveillance and other services as shall be determined, from time to time, by the NAB-MALTA to be fair and appropriate;
- (e) not use its accreditation and Certificate of Accreditation in such a manner as to bring the scheme into disrepute, and shall not make any statement regarding the authority of the certificate-holder which the NAB-MALTA may reasonably consider to be misleading;
- (f) not use accreditation to imply that a product, process, system or person is approved by the NAB-MALTA; and
- (g) use its best endeavours to ensure that no part of its accreditation shall be used by a client, or be authorised by a client for use, for promotional or publicity purposes, in a way that the NAB-MALTA may reasonably consider misleading;
- (h) take due care that no report or certificate nor any part thereof is used in a misleading manner.


4.4. The CAB shall offer to all clients a standard of service consistent with the criteria to which it is accredited by the NAB-MALTA (as specified in **ATGO3** – List of Applicable Accreditation Criteria) and with the regulations, policies and other relevant technical publications issued by the NAB-MALTA.

4.5. The CAB shall perform to the best of its ability the activity which it contracts to undertake.

4.6. The CAB shall afford to the NAB-MALTA and/or its representatives, agents or subcontractors all such information, assistance and cooperation as is necessary to enable the NAB-MALTA to carry out its functions and shall at its own expense, provide or arrange to have provided any tests, studies, evaluations or reports required by the NAB-MALTA and shall conduct or arrange to have conducted any additional tests, studies, evaluations or reports required by the NAB-MALTA and provide the results of same to the NAB-MALTA.

4.6.1. In particular, but without limitation the CAB shall:


- (a) do everything necessary to enable the NAB-MALTA to assess the competence of the CAB;
- (b) afford the NAB-MALTA access to relevant areas of the CAB for the witnessing of activities and for any other purpose as the NAB-MALTA considers necessary for the purposes of carrying out its functions;

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- (c) undertake any reasonable checks to enable the NAB-MALTA to verify the competence of the CAB;
- (d) prepare, pack and dispatch items needed by the NAB-MALTA for its assessment or for verification purposes;
- (e) permit scrutiny by the NAB-MALTA of the records held including proficiency tests and, where necessary, the records of associated bodies;
- (f) participate in any appropriate programme of proficiency or comparison testing that the NAB-MALTA may reasonably deem to be necessary (as per NAB-MALTA technical guide **ATG10**);
- (g) provide access to the CAB's computer system, facilities, information, documents and records as necessary (and where necessary shall use its best endeavours to facilitate access to those of a related body) for the assessment and maintenance of the accreditation;
- (h) provide access to information to those documents that provide insight into the level of independence and impartiality of the CAB from its related bodies, where applicable;
- (i) afford the NAB-MALTA access for the witnessing of any conformity assessment activity carried out by the CAB as requested and selected by the NAB-MALTA;
- (j) issue a register of the bodies certified by the CAB at intervals as stipulated by the NAB-MALTA;
- (k) advise the arrangements and procedures used for carrying out certifications in other countries.

4.7. The CAB shall notify the NAB-MALTA of changes in any aspect of its status or operation relating to its

- (a) legal, commercial, ownership or organisational status;
- (b) organisation, top management and key personnel;
- (c) policies or procedures, where appropriate;
- (d) premises;

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- (e) personnel, equipment, facilities, working environment or other resources, where significant;
- (f) authorised signatories;
- (g) scope of accreditation;
- (h) other such matters that may affect the accredited body's ability to fulfil requirements for accreditation.


4.7.1. EMAS Verifiers shall inform the NAB-MALTA immediately if they have not performed EMAS verification/validation within the previous 2 years in any scope area for which accreditation has been awarded by the NAB-MALTA.

4.8. The CAB shall afford its clients reasonable assistance and co-operation to enable them to monitor the performance of the CAB in relation to the contract binding them. This co-operation shall include but not be limited to the CAB:


- (a) undertaking or facilitating any reasonable checks to enable the client to verify the capability of the CAB;
- (b) affording the client or its representative reasonable access to relevant areas of the CAB and for the witnessing of activities performed for the client, subject to the confidentiality of work for other customers; and
- (c) preparing, packing and dispatching of test pieces, samples or other items needed by the client for verification purposes.

4.9. CABs shall have enforceable arrangements with organisations holding an accredited certificate that commit the holder of the accredited certificate to provide, on request, access to NAB-MALTA assessment teams to witness the certification/inspection body's audit team performing an audit at the originator's site.

4.10. Without prejudice to the CAB's general legal obligations in relation to the maintenance and making available of its records the CAB shall keep, for a minimum period of five (5) years, and upon request, make readily available to the NAB-MALTA, records of all information, original observations, calculations and derived data and records related to its management system. Test/calibration/inspection certificates and reports and other certificates issued under the scope of accreditation shall be kept for a minimum period of ten (10) years.

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- 4.10.1 Such records as are required to be held by the CAB shall be in a form which allows fast and accurate checks to be made.
- 4.10.2 The NAB-MALTA or its duly authorised representative shall have the right at any reasonable time during business hours to enter onto the CAB's premises or the premises of a Related Body of the CAB and to assess any matter affecting accreditation generally and to inspect and audit the said records of the CAB and any other book, record or invoice relating to the CAB's accredited activities or those activities for which the CAB has applied for accreditation or relating to the CAB's non-accredited activities, if the NAB-MALTA believes, in its sole discretion, that the CAB's non-accredited activities or the manner in which such activities are being carried out impacts or may impact in any way on the CAB's accreditation or accredited activities as a result of diversion of the CAB's resources, use of the NAB-MALTA accreditation symbol, or otherwise howsoever and the NAB-MALTA or its duly authorised representative shall be entitled to take copies or extracts from any such records and shall have the right to interview any officer, employee or agent of the CAB and shall be entitled to the full assistance and co-operation of the CAB and its officers, employees or agents.
- 4.11. The CAB shall retain updated records on the qualifications, training, competence and experience of each member of its staff and shall provide each member with clear documented instructions pertaining to his duties and responsibilities.
- 4.12. The CAB shall not refer to its accreditation as certification and shall place a similar restriction on all clients.
- 4.12.1 Accredited certification bodies shall ensure that their clients do not refer to their certification as accreditation.
- 4.13. In the case of surveillance visits, the Accredited CAB will make the requested documentation available to the NAB-MALTA **within 30 days** of the request by the NAB-MALTA.
- 4.14. In the case of surveillance visits, the accredited CAB shall submit the quality manual and the master list of documents **within 30 days prior** to the scheduled on-site visit.
- 4.15. All reports/certificates issued by the CAB shall clearly show the name in full of the signatories.
- 4.16. Accredited CABs, especially certification bodies, should not provide any conformity assessment services that denote conformity with any of the standards that are used as the basis for accreditation.

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4.17 Applications for extension of scope shall be submitted to NAB-MALTA by using the proper forms. These forms shall reach the NAB-MALTA *at least 3 months before* the next scheduled assessment visit.

4.17.1 The criteria for the assessment to extensions of scopes are identical to those for the initial assessment as outlined in this procedure.

4.17.2 In particular for laboratories, applications shall be supported by validation data for any new methods and proof of participation in proficiency testing schemes.

## **5.0. SUBCONTRACTING**

5.1 The CAB acknowledges that subcontracting of any activity or elements of an activity will usually impact on the CAB's right to claim accreditation in respect of its activities and undertakes to pay particular attention to the requirements of the accreditation criteria in this respect.

5.2 The CAB shall record details of its investigation of the competence and compliance of sub-contractors and shall maintain a register of the details of all sub-contracted work. These details shall be available on request to the NAB-MALTA.

## **6.0. OBSERVATIONS AND NONCONFORMITIES**

6.1. Findings are categorised and advised to the client as follows:


### 6.1.1. Minor Nonconformity:

An isolated failure by the CAB to meet the accreditation scheme requirements or to follow its own rules or procedures which does not compromise the confidence that can be placed in the overall system and/or the certificates awarded.

### 6.1.2. Major Nonconformity:

The absence of or failure to implement or maintain, one of the accreditation scheme requirements, or to follow the procedures of the CAB, such as to compromise the confidence that can be placed in the accredited activity and the certificates awarded.


6.1.2.1. A number of minor nonconformities can be judged by the NAB-MALTA Lead Assessor to be collectively so significant as to compromise the confidence that can be placed in the accredited activity, and therefore collectively merit a major nonconformity.

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### 6.1.3 Observation

An observation normally indicates an opportunity for improvement in the operations of the CAB. Whilst no evidence of corrective action is required to be sent to NAB-MALTA, NAB-MALTA expects the CAB to take the appropriate measures to cover such findings.

- 6.2. It is without prejudice to the NAB-MALTA's right in appropriate cases to withdraw an Accredited CAB's accreditation forthwith for failure to clear nonconformities.
- 6.3. The NAB-MALTA will require CABs to implement corrective actions in response to nonconformities with the accreditation criteria in a timely and efficient manner.
- 6.4. All communications shall be channelled through the NAB-MALTA, except where the NAB-MALTA expressly approves otherwise in which case copies shall be sent to the NAB-MALTA.
- 6.5. Proposals for corrective actions shall normally be agreed and accepted during the final meeting of the assessment visit. In cases where some more time is needed to decide on the proposed corrective action the CAB shall submit the information to the NAB-MALTA within one week of the date of assessment or as otherwise agreed with the Lead Assessor and the NAB-MALTA.
- 6.5.1 Depending on the type of nonconformity, the timeframe for the clearance of nonconformities by the CAB shall not exceed **3 months** from the date of the NAB-MALTA accepting the proposed corrective actions for initial assessments and/or extensions to scope and **1 month** from that date in all other cases. Stricter time limits or immediate corrective action may need to be taken, especially by Accredited CABs.
- 6.5.2. The NAB-MALTA may permit an extension to these timeframes where the CAB can establish that more time is justified. In such circumstances the extension to the timeframe will apply only to the clearance of the particular nonconformity(ies) requiring the extension to the timeframe. All other nonconformities must be cleared within the agreed timeframes.
- 6.6. The CAB is required to provide one complete set of responses to all nonconformities raised, together with an additional set for each assessor relevant to the nonconformities raised by him. The evidence submitted by the CAB shall clearly identify the corrective action taken for each nonconformity.
- 6.7. The NAB-MALTA shall review the Accredited CAB's accreditation status in the event that:

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- (a) the proposed corrective actions are not submitted to the NAB-MALTA; or
- (b) the responses to nonconformities raised are not submitted to the NAB-MALTA within the agreed timeframe; and/or
- (c) incomplete or inadequate responses are submitted to the NAB-MALTA within the requested timeframe.

6.7.1. This review may result in the Accredited CAB's scope of accreditation being reduced or withdrawn or, where appropriate, suspended until the outstanding nonconformity(ies) has been satisfactorily cleared.

6.7.2. Following the review of the corrective actions, the NAB-MALTA will require the CAB to submit satisfactory evidence of the outstanding nonconformity(ies) **within 3 working days** and, in such cases, shall inform the CAB in writing. The timeframe for the satisfactory clearance of the outstanding non-conformity(ies) shall not exceed one month except where the Accredited CAB is suspended in which case a timeframe of up to 6 months will apply. Where the Accredited CAB under suspension fails to clear all nonconformities within the agreed timeframe that Accredited CAB's accreditation may be reduced or withdrawn.


6.8. The NAB-MALTA shall suspend, reduce or terminate, as appropriate, all or part of the accredited body's scope of accreditation if the CAB:

- (a) consistently fails to clear nonconformities within agreed timeframes;
- (b) fails to clear a major nonconformity within the agreed timeframe.

6.9. In the case of an initial application where the CAB fails to clear the nonconformities within the requested timeframes a re-assessment shall be required unless as otherwise agreed as per Clause 6.7.2.

6.10. In the event of a major nonconformity being raised, the Lead Assessor in consultation with the NAB-MALTA shall:

- (a) consider recommending suspending, reducing or withdrawing the scope of an accredited body;
- (b) in the case of an initial application, recommend refusal of accreditation for part or all of the scope of accreditation;
- (c) decide if an additional visit is required to witness the clearance of the nonconformity or to address any issues relating to its clearance;

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- (d) review the reports from previous visits to the Accredited CAB to ascertain if the history of the Accredited CAB, when taken together with the major nonconformity raised, indicates an underlying problem with the maintenance of accreditation;
- (e) ensure that the integrity of the NAB-MALTA accreditation is not compromised by any action or timeframe requested to address the major nonconformity.

## **7.0. SUSPENDING, REDUCING OR WITHDRAWING ACCREDITATION**

7.1. The policy of the NAB-MALTA in relation to the suspending, reducing or withdrawing of accreditation shall involve a range of measures which are designed to protect the integrity of the accreditation system and to ensure that the CAB respects the requirements of accreditation.

7.1.1. These measures shall include,


- (a) voluntary suspension,
- (b) suspension,
- (c) resignation, and
- (d) withdrawal

of all or of part of the accredited body's scope of accreditation.

7.2. The NAB-MALTA may suspend, reduce or withdraw accreditation, or require reassessment if the Accredited CAB fails to notify the NAB-MALTA of changes in any aspect of its status or operation as defined in Clause 4.7 of these regulations.

7.2.1. The Director of the NAB-MALTA may authorise immediate suspension in severe cases which may jeopardise the accreditation status of the accredited CAB, the reliability and confidence in the accreditation services it provides and the reputation of accreditation in Malta. In the case of EMAS Verifiers, a final decision will be taken after the EMAS Verifier has had the possibility of a hearing in line with the EMAS Regulation, unless the EMAS Verifier chooses to go for voluntary suspension.

7.2.2. The Board is responsible for confirming suspensions, or otherwise and for authorising reductions in scope and termination of accreditation.


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7.3. The NAB-MALTA may impose involuntary suspension of the CAB's accreditation in the event:

- (a) the CAB, being an individual, is declared bankrupt or enters into a composition with its creditors;
- (b) the CAB, being a company, has a receiver, examiner or administrator appointed over the whole or any part of its assets or the CAB is struck off the register of companies in the jurisdiction where it was incorporated or an order is made or a resolution passed for winding up the CAB (unless such order or resolution is part of a voluntary scheme for the reconstruction or amalgamation of the CAB as a solvent corporation and the resulting corporation, if a different legal entity, undertakes to be bound by the Accreditation Criteria, regulations and contract);
- (c) of any change in structure, personnel, staff responsibility, equipment, premises or scope of activity of the CAB that the NAB-MALTA considers, in its sole discretion, affects the CAB's ability to comply fully or at all with the Accreditation Criteria;
- (d) the CAB fails to pay the any outstanding fees due to the NAB-MALTA;
- (e) of any change in the Accreditation Criteria applicable to the CAB which the CAB is not in a position to comply with fully, or at all, by the date designated by the NAB-MALTA;
- (f) that the CAB breaches any accreditation criteria or the Accreditation Contract;
- (g) that the NAB-MALTA considers that accreditation has been or is likely to be brought into disrepute by the CAB, its Related Bodies or its clients either as a result of accredited or non-accredited activities;
- (h) where in the reasonable view of the NAB-MALTA, the CAB has made unreasonable or irresponsible use of sub-contracting;
- (i) the CAB has engaged in any fraudulent or dishonest conduct or fails in any respect to comply with the laws of Malta.


7.4. Subject to Clauses 7.5., 7.6. and 7.7., the CAB may choose to suspend or resign its accreditation at any time.

7.5. In the event that during the currency of its accreditation, the CAB is unable for any reason to comply with the Accreditation Criteria and/or the Contract, the CAB shall

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immediately apply to the NAB-MALTA for voluntary suspension or resignation of its accreditation PROVIDED THAT in the event of there being no objectively justifiable cause to consider the inability to comply as being temporary the CAB shall apply for resignation of its accreditation.


- 7.6. For the avoidance of doubt, the duty to apply for voluntary suspension or resignations, as outlined in clause 7.7. above, applies even where the cause for the inability to comply is not due to any fault of the CAB itself, for instance where the voluntary suspension is necessitated by the relocation of the CAB, etc.
- 7.7. The NAB-MALTA may in its sole discretion refuse voluntary suspension or resignation and impose involuntary suspension or withdrawal of the CAB's accreditation.
- 7.8. Upon suspension, resignation or withdrawal, the Accredited CAB shall notify its clients in writing of its new accreditation status prior to undertaking work in an area for which the Accredited CAB's accreditation is under suspension or withdrawn and shall forward a sample copy of the said notification to the NAB-MALTA.
- 7.9. The NAB-MALTA may decide to withdraw the CAB's accreditation immediately on written notice (such withdrawal to be effective as and from the date of that notice) if any of the event set out at sub-clauses (a) to (h) of Clause 7.3 or where it otherwise considers in its sole discretion that withdrawal is warranted. On the withdrawal of accreditation the CAB shall:
- (a) promptly return its certificate of accreditation to the NAB-MALTA following withdrawal or resignation of its accreditation;
  - (b) for a minimum of six months notify its clients in writing of its new accreditation status prior to undertaking activities for which the CAB's accreditation is resigned or withdrawn and require its clients to amend any representations made by the said clients in relation to the CAB's accreditation status accordingly;
  - (c) immediately discontinue all use of the NAB-MALTA accreditation symbol and/or reference to accreditation by the NAB-MALTA on or in relation to the activities falling within its withdrawn accreditation including on all specific reports, certificates, label or other documentary outputs relating to specific activities for clients activities falling within its withdrawn accreditation and also on all documentation, brochures, advertising and publicity material relation to activities fall within its withdrawn accreditation generally and shall ensure that all of the CAB's clients immediately discontinue reference to accreditation by the NAB-MALTA in respect of those activities in all documentation, brochures, advertising and publicity material that such clients may generate.

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- 7.9.1 The provisions of record keeping, use of the NAB-MALTA symbol, confidentiality, limitation of liability and indemnity shall survive termination or resignation of the CAB's accreditation and termination of the accreditation contract.
- 7.9.2 Withdrawal or resignation of its accreditation by the CAB shall automatically terminate those accreditations that require or are dependent on the continue existence of the withdrawn accreditation.
- 7.10. The period of suspensions or voluntary suspension shall not exceed three months. In exceptional circumstances the NAB-MALTA may permit an extension of this period to a maximum of six months.
- 7.10.1 Failure to clear nonconformities, following suspension or voluntary suspension, within the agreed time frame shall result in termination of accreditation.
- 7.11. Accreditation may be resigned by the accredited body upon giving one month's notice in writing to that effect to the NAB-MALTA.
- 7.12. The NAB-MALTA shall send a letter to the body confirming the withdrawal of its accreditation. It shall detail the actions required by the Accredited Body and, in the case of voluntary or involuntary suspension, it shall include the procedure for re-instatement of accreditation.
- 7.13 In the case of EMAS Verifiers, any decision taken by the NAB-MALTA to terminate or suspend accreditation or curtail the scope of accreditation shall be taken only after the environmental verifier has had the possibility of a hearing.

## **8.0. INFORMATION ABOUT ACCREDITED BODIES**

- 8.1. All details of the status of the CAB's accreditation will be kept by the NAB-MALTA in whatever form the NAB-MALTA in its sole discretion deems appropriate and may be made available by the NAB-MALTA to any person on request.
- 8.2 The NAB-MALTA will, but for the avoidance of doubt shall not be any under obligation to, maintain a register of accredited CABs.
- 8.3. The NAB-MALTA shall, in its absolute discretion, determine what information in relation to the Accredited CAB and its Accreditation Status should be included in the register. The basic information to be given in the register published or maintained by the NAB-MALTA will include the name and address of each Accredited CAB, the dates of granting accreditation and expiry dates and the scope of accreditation.

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- 8.3.1. The NAB-MALTA may include in the register published or maintained by it other information relevant to the Accredited CAB or its accreditation, which it may deem appropriate to include from time to time.
- 8.4. The Accredited CAB shall ensure that the information which it gives to the NAB-MALTA, generally and in response to specific requests for information for the purposes of publishing an entry in the register, is accurate and not misleading. The Accredited CAB further undertakes to immediately inform the NAB-MALTA of any inaccuracy which appears in the register and of any change which occurs which necessitates an amendment to the register entry for that Accredited CAB within **3 working days** of the said inaccuracy coming to the Accredited CAB's attention or of the said change occurring, whichever is the earlier.
- 8.5. In the event of the accreditation of the Accredited CAB being suspended, reduced or withdrawn, either voluntarily or involuntarily, the listing in respect of that Accredited Body shall be immediately amended or removed from the register.
- 8.5.1. In the event of accreditation being reinstated, the Accredited CAB shall be listed once more in the register.
- 8.6. The NAB-MALTA shall have sole control over the format, composition and distribution of the contents and the pages of the NAB-MALTA website and the positioning of any entry relating to any Accredited CAB within the register.
- 8.7. The NAB-MALTA may publish its register on-line. The NAB-MALTA shall not be liable for any Internet or telecommunications failure, computer virus, loss of data, third party interference or other third party software or hardware that may interrupt or delay access to the website or cause problems in relation to the computer system of the Accredited CAB or other problems or losses.
- 8.8. The NAB-MALTA shall not be liable to the Accredited CAB for any loss or damage including injury to reputation suffered by the Accredited CAB as a result of the use by the public of the online directory or the NAB-MALTA website.
- 8.9. The NAB-MALTA shall not be liable in respect of any omission from the register of an entry for the Accredited CAB.
- 8.10. The Accredited CAB warrants that:
- (a) it has the right to make the basic information available to the NAB-MALTA and to authorise the NAB-MALTA to make the basic information available in the register; and

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(b) the basic information and the act of making the basic information available on the NAB-MALTA website does not infringe any intellectual property, publicity or privacy right of any third party or of any other law or regulation including data protection legislation.

8.10.1. The NAB-MALTA may, at any time, review any register maintained or published by it and it may, without any liability to the Accredited CAB in question, remove any entry or part of any entry for an Accredited CAB where it deems that the Accredited CAB has failed to comply with the requirements of these regulations.

8.11. The Accredited CAB shall indemnify the NAB-MALTA, its officers, employees and agents from any third party claims, liability, damages, and/or costs arising from a breach of the warranty regulation specified in clause 8.10.

8.12. The withdrawal of the Accredited CAB's entire scope of accreditation, revised scope, resignation or termination shall be published in the annual register of accredited CABs and shall be entered in the online directory.

## **9.0. PAYMENT OF FEES**

9.1. This section sets out the NAB-MALTA regulations concerning the payment of fees.


9.2. The NAB-MALTA shall charge fees for the operation of its accreditation schemes. The costs of accreditation shall be set out in invoices issued at different stages of the accreditation process.

9.3. All fees are determined on a case-by-case basis and cover administration costs, the assessor/s daily rates, accommodation, travel arrangements and other ancillary costs related to the accreditation process. The fees cover both on-site and office-based activities.

9.4. The NAB-MALTA reserves the right to cancel confirmed visits at any time prior to such visit in the event that any outstanding fee payable by the CAB remains unpaid.

9.5. No contracting of assessors will be made by the NAB-MALTA unless the payments requested by the NAB-MALTA have been made.


### **9.6. Application and Preliminary Visit Fee**

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- 9.6.1. On receipt of the application form, the NAB-MALTA will issue an invoice within a minimum period of 10 days. The applicant body shall be given a maximum period of **30 days** from the date of issue to pay this invoice. Unless payment is received no contracting of assessors will be made.
- 9.6.2 The application fee shall be levied to offset costs involved in appointing the Lead Assessor, the review of documentation and the carrying out of the preliminary on-site visit, when such visit has been requested by the applicant body.
- 9.6.3 In cases where the NAB-MALTA considers that a preliminary visit is not required and that the CAB can undergo directly an initial assessment, two separate invoices will be issued – one as an application fee and one covering the initial assessment costs.
- 9.6.4. The application fee shall be per body or group of bodies at a single location and listed at the time of application on the application form.
- 9.6.5. Subsequent applications for the accreditation of related bodies not included in the original application form may be subject to a further application fee.
- 9.6.6 Should the documentation made available by the applicant CAB be sufficient to cover the requirements of accreditation and depending on the advice provided by the Lead Assessor, the NAB-MALTA will proceed to plan a date for the preliminary visit.

#### 9.7. Initial Assessment Fee

- 9.7.1. The invoice for the initial assessment fee will be issued after the invoice covering the application fee. The applicant body shall be given a maximum period of **30 days** to pay this invoice. Unless payment is received no contracting of assessors will be made.
- 9.7.2. The initial assessment fee shall be levied to offset the costs involved at the first assessment in carrying out documentation review, Head Office assessment (in case of Inspection and Certification Bodies), on-site witnessed assessments and assessment of the implementation of the quality management system.
- 9.7.3. The initial assessment fee depends on the work to be undertaken by the NAB-MALTA and the number of assessors and assessor days required for the assessment of the CAB in any particular case as required by the scope of accreditation.
- 9.7.4. The initial assessment shall not be carried out if there are any outstanding payments related to accreditation activities which are due to the NAB-MALTA. No further processing can be made before the receipt of the payment, which has to be received in time as stipulated on the invoice.

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9.7.5 In cases where accreditation is conditional on specific corrective actions being implemented by the CAB, the NAB-MALTA 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-MALTA (e.g. revised procedure documents, up-to-date calibration certificates). Sometimes, however, an additional visit to the CAB may be necessary (e.g. to confirm that laboratory environment control equipment is functioning correctly), and the cost of such visits will be charged to the CAB. A separate invoice shall be issued by the NAB-MALTA to the CAB.

9.7.6 No certificates of accreditation shall be issued unless any outstanding balance with the NAB-MALTA in relation to accreditation activities is cleared by the Applicant CAB.

#### 9.8. Annual Management Fee

9.8.1. The Accredited CAB shall be subject to an annual management fee to offset the cost of administering its accreditation including the annual assessment visit.

9.8.2. The annual management fee shall depend on the work to be undertaken by the NAB-MALTA and the number of assessors and assessor days required for the assessment of the CAB as required by the scope of accreditation.

9.8.3. Full annual management fees shall be due for the year in which the Accredited CAB's accreditation is terminated or suspended, including voluntary suspension.


9.8.4. The full annual membership fees shall become due in January each year.

#### 9.9. Cancellation Fee

9.9.1. Where the Accredited CAB postpones a confirmed visit, a cancellation fee of 50% of the assessment or of the annual management fee shall be levied in addition to the assessment or annual management fee.

9.9.2 Where the Accredited CAB fails to pay any fees due to the NAB-MALTA under these regulations, the cancellation referred to in regulation 9.8.1 shall be charged.

9.9.3. Where the Accredited CAB resigns its accreditation on or before 30 June of the current year it shall be liable for 50% of the full annual membership fee. Where resignation occurs thereafter the full annual membership fee shall be due.

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#### 9.10. Fees for Additional Visits

9.10.1. The NAB-MALTA shall have the right to levy additional fees if additional visits are found to be necessary or if, at any stage, a failure to comply with the NAB-MALTA requirements imposes additional work on the NAB-MALTA or its assessors.

9.10.2. The NAB-MALTA may conduct additional assessment visits as a result of complaints, key changes within the CAB or for any other good and sufficient reason.

#### 9.11 Fees for Extensions to Scope of Accreditation

9.11.1. Where an extension to scope application can be managed within the normal visit programme, no fee shall apply.

9.11.2. A fee shall be levied for an extension to scope of accreditation where such an extension requires a visit.

9.11.3. A fee may be charged where an extension to scope requires additional assessor time or need for additional assessors at the routine annual assessment.


9.11.4. A fee shall be charged when an Accredited CAB applies for an extension to scope of accreditation that the NAB-MALTA could consider granting by correspondence. This fee shall depend on the amount of additional effort involved in reviewing the supporting documentation and application and any follow up documentation required to consider such applications for extension to scope of accreditation.

#### 9.12. Payment of Fees

9.12.1. Payment of fees shall be sent to

The Director,  
NAB-MALTA,  
Second Floor, Evans Building,  
Merchants Street,  
Valletta, VLT 1179.

## **10.0. PROFICIENCY TESTING/INTERLABORATORY COMPARISONS AND TRACEABILITY**

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- 10.1. Applicant and Accredited laboratories (and applicant and accredited inspection bodies as appropriate) shall meet the policy of the NAB-MALTA on traceability of measurement (**ATG11**), proficiency testing and interlaboratory comparisons (**ATG10**) and other policies published by the NAB-MALTA.
- 10.2. Where a programme of proficiency testing or interlaboratory is required, the applicant and accredited body concerned shall be responsible for the necessary arrangements and costs.

## **11.0. APPEALS**

- 11.1. Decisions on the award, extensions, suspensions, reduction, withdrawals and maintenance of accreditation of accreditation are made by the Board. Decisions on the immediate suspension of accreditation (except for EMAS Verifiers) may be made by the Director of the NAB-MALTA.
- 11.2. Where the CAB disagrees with an accreditation decision made by the NAB-MALTA it may appeal against the decision.
- 11.3. The Appellant shall be the Applicant or Accredited CAB lodging the appeal.
- 11.4. The appeal shall be submitted in writing within two weeks of the date of the decision to:
- The Director,  
NAB-MALTA,  
Second Floor, Evans Building,  
Merchants Street  
Valletta, VLT 1179
- 11.5. The costs of the appeal shall be borne by the Appellant unless the appeal is successful.
- 11.6. The NAB-MALTA shall appoint, as and when necessary, a suitably competent, impartial and independent external assessor, or assessors depending on the nature of the appeal. It shall investigate the appeal and make appropriate recommendations. All the costs of the external assessors (including travelling and accommodation costs) shall be borne by the Appellant unless the appeal is successful.


## **12.0. COMPLAINTS**

- 12.1. If the CAB has a complaint in respect of any matter relating to the NAB-MALTA's performance of its functions in relation to the accreditation covered by the Contract of

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Accreditation, other than a decision by the NAB-MALTA not to grant accreditation to the CAB or an extension to the scope of the CAB's accreditation or to grant a more limited scope of accreditation that that applied for by the CAB or to suspend or withdraw the CAB's accreditation or not to renew or re-instate the CAB's accreditation, for which the Appeals process in Clause 11 of these regulations is designed, the CAB may address a complaint to the NAB-MALTA which will be dealt with in accordance with its current procedures in relation to complaints, details of which will be furnished by the NAB-MALTA upon request.

- 12.2 Complaints shall be submitted in writing to the Director of the NAB-MALTA clearly stating the nature and justification.
- 12.3. Authentication of a complaint would normally involve the receipt of a letter and/or other documentary evidence. Such documentary evidence must include the name and address of the Complainant.
- 12.4. Complaints may be received from many varied sources including private individuals.
- 12.5. No investigation of complaints shall be pursued on the basis of hearsay.
- 12.6. From time to time, the NAB-MALTA may receive well authenticated information which raises questions requiring actions similar to those required for a formal complaint e.g. arising from publicity material. In such cases the regulations set out in this Section 12 will be followed as far as is reasonable and practicable.
- 12.7. The Director of the NAB-MALTA shall designate an Officer to deal with the complaint, who is in no way connected to the complaint.
- 12.8. The designated officer shall acknowledge the complaint in writing to the Complainant.
- 12.9. The NAB-MALTA shall take all necessary measures to preserve the confidentiality of information obtained during the investigation of a complaint.
- 12.10. The NAB-MALTA reserves the right to carry out additional visits if considered necessary as part of the investigation.
- 12.11. When the investigation has been completed the Officer shall submit a written report on the complaint to the Director of the NAB-MALTA.
- 12.12. The Director of the NAB-MALTA will then formally reply to the Complainant detailing the results of the investigation and actions to be taken by the NAB-MALTA where applicable.

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### **13. SUMMARY OF TIMEFRAMES**

<b><u>NAB-MALTA Reference</u></b>	<b><u>Issue</u></b>	<b><u>Timeframe</u></b>
ATG01 Cl. 1.2	Minimum period of operation of the CAB's management system according to the accreditation requirements	3 months
ATG01 Cl. 5.1.1	Sending of revised documents following Preliminary Visit	6 weeks prior to the scheduled assessment visit.
RAB1 Cl.2.7.1	First Surveillance Visit	6 months after date of decision by the Board.
RAB1 Cl.2.7.1	Surveillance Visits (except first surveillance visit, as above)	Every Year
RAB1 Cl.4.14	Submission of quality manual prior to surveillance and reassessment visits	30 days.
RAB1 Cl.2.7.1	Reassessment	Every 5 years
RAB1 Cl.2.7.1	Additional Visits	As required
RAB1 Cl.4.16 ATG01 Cl.15.2	Application for extension to scope	3 months in advance of the next scheduled visit.
RAB1 Cl.6.5.1	Clearance of nonconformities by the CAB for initial assessments and/or extensions to scope and	Shall not exceed <b>3 months</b> from the date of the NAB-MALTA accepting the proposed corrective actions.
RAB1 Cl.6.5.1	Clearance of nonconformities by the CAB for surveillance and other visits	<b>1 month</b> from the date of the NAB-MALTA accepting the proposed corrective actions. Note: <b><u>Stricter time limits or immediate corrective action</u></b> may need to be taken depending on the type of NC.

**END**