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NAB-MALTA REGULATIONS

RAB01 - Accreditation General Regulations

Revision 11

April 2022

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FOREWORD

Accreditation is the mechanism to assure customers of the competence of conformity assessment bodies (CABs).

The National Accreditation Board of the Malta (NAB-MALTA) is the single national accreditation body appointed as per Article 4 of Regulation (EC) No. 765/2008 with responsibility for accreditation in accordance with the relevant normative documents. It operates a management system which complies with the requirements established in EN ISO/IEC 17011.

International trade relies on certificates and reports issued by competent bodies. Confidence in certificates and reports is achieved by accreditation. Confidence in accreditation is based on a series of confidence building steps between the accreditation bodies and accredited conformity assessment bodies and the assurance given by the accreditation body that the accredited conformity assessment body constantly implements the relevant criteria and maintains and continuously develops its competence as defined in the relevant standard. This assurance is achieved through accreditation which includes regular assessments and other types of accreditation activities.

The services of the NAB-MALTA are accessible to all applicants whose requests fall within the current activities as offered by the NAB-MALTA and which are in compliance with the cross-border accreditation requirements as stipulated in Article 7 of Regulation (EC) 765/2008. Access is not conditional upon the size of the applicant CAB or membership of any association or group.

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


SCOPE OF PUBLICATION

This publication has been drawn up to define the general regulations applicable to applicant and accredited Conformity Assessment Bodies (CABs).

This is a mandatory document.


This document will come into effect as from 25-04-2022.

The requirements covering the use of the accreditation symbol and reference to accreditation are specified in document number **RAB02**.

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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.
- 1.2. **“accreditation activity”** means individual operational tasks of the accreditation process.
- 1.3. **“accreditation certificate”** means a formal document or a set of documents stating that accreditation has been granted for the defined scope.
- 1.4. **“accreditation criteria”** means the criteria specified by the NAB-MALTA to be complied with by the conformity assessment body in order to qualify for the accreditation sought or held including, without limitation, any relevant standards, policies, guidelines, or regulations.
- 1.5. **“accreditation decision”** means the decision on granting, maintaining, extending, reducing, suspending, and withdrawing of accreditation.
- 1.6. **“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 and Licensing Bodies (FALB) and, setting out the recommended practices and procedures to be followed in order to comply with accreditation criteria.
- 1.7. **“accreditation scheme”** means the rules and processes relating to the accreditation of conformity assessment bodies to which the same requirements apply. **Accreditation schemes are based on harmonized standards (or other normative documents) containing general requirements for conformity assessment bodies performing conformity assessment activities included in Level 2 (hereafter conformity assessment standards). These include, but are not limited to, EN ISO/IEC 17020, ISO/IEC 17021-1, EN ISO/IEC 17025, EN ISO/IEC 17024, EN ISO/IEC 17029, EN ISO 17034, EN ISO/IEC 17043, EN ISO/IEC 17065 and EN ISO 15189.**
- 1.8. **“accreditation process”** means the activities from application through to granting and maintenance of accreditation as defined by the accreditation scheme.
- 1.9. **“appeal”** means a request by a conformity assessment body for reconsideration of any adverse accreditation decision related to its desired accreditation status.

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- 1.10. **“application”** means any application in relation to accreditation made by the CAB including an application for accreditation, an application for extension to accreditation, and where relevant an application for renewal or reinstatement of accreditation.
- 1.11. **“assessment”** means the process undertaken by the NAB-MALTA to determine the competence of a conformity assessment body, based on standard(s) and/or other normative documents and for a defined scope of accreditation.
- 1.12. **“assessment programme”** means the set of assessments consistent with a specific accreditation scheme that the NAB-MALTA performs on a specific conformity assessment body during an accreditation cycle.
- 1.13. **“assessment technique”** means the method/s used by an accreditation body to performance an assessment.
- 1.14. **“assessor”** means a person assigned by the NAB-MALTA to perform, alone or as part of an assessment team, an assessment of a conformity assessment body.
- 1.15. **“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 conformity assessment body, where a response is expected.
- 1.16. **“conformity assessment”** means the process demonstrating whether specified requirements relating to a product, process, service, system, person, or body have been fulfilled.
- 1.17. **“conformity assessment activity”** means the activity conducted by a conformity assessment body when assessing conformity.
- 1.18. **“conformity assessment body - CAB”** means a body that performs conformity assessment activities including calibration, testing, inspection, certification, and verification and that can be the object of accreditation.
- *Whenever the word CAB is used in this document, it applies to both the “applicant and accredited CABs” unless otherwise specified.**
- 1.19. **“contract”** means the agreement in place between the NAB-MALTA and the CAB 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.

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- 1.20. **“extending of accreditation”** means adding conformity assessment activities to the scope of accreditation.
- 1.21. **“granting of accreditation”** means awarding accreditation for a defined scope of accreditation.
- 1.22. **“team leader”** means the assessor who is given the overall responsibility for the management of an assessment.
- 1.23. **“maintaining of accreditation”** means confirming the continuance of accreditation for a defined scope.
- 1.24. **“NAB-MALTA”** means the National Accreditation Board – Malta.
- 1.25. **“NAB-MALTA accreditation symbol”** means a symbol comprising the NAB-MALTA logo together with the registration number and accreditation standard in respect of the CAB. This symbol can be used by the accredited CABs to indicate they are accredited.
- 1.26. **“NAB-MALTA logo”** means the symbol used by NAB-MALTA to identify itself.
- 1.27. **“reassessment”** means the accreditation activity performed to renew the accreditation cycle.
- 1.28. **“reducing of accreditation”** means cancelling part of the scope of accreditation.
- 1.29. **“related body”** means a body which is linked to the CAB 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 accreditation or has an input into the activities of the CAB so as to be relevant to the assessment of an application or the circumstances of an accreditation.
- 1.30. **“remote assessment”** means the **off-site** assessment of the physical location or virtual site of a conformity assessment body using electronic means.
- 1.31. **“scope of accreditation”** means the specific conformity assessment activities for which accreditation is sought or has been granted.
- 1.32. **“accreditation activity”** means the individual operational tasks from application through to granting and maintenance of accreditation (*For EMAS Verifiers, the term “surveillance” should be replaced by “supervision” as defined in the EMAS Regulation*).

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- 1.33. “**suspending of accreditation**” means putting temporary restrictions in place for all or part of the scope of accreditation.
- 1.34. “**withdrawing of accreditation**” means cancelling accreditation for the full scope.
- 1.35. “**witnessing**” means the observation by the NAB-MALTA of a conformity assessment body carrying out conformity assessment activities 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 single national accreditation body appointed as required by Article 4(1) of Regulation (EC) No. 765/2008. It is responsible for granting, maintaining, extending, reducing, suspending, or withdrawing accreditation in accordance with the relevant normative documents using the applicable national, international, and European requirements and guidelines and other publicly available criteria covering testing, calibration, inspection, certification, verification and EMAS verifiers hereinafter referred to as "the accreditation schemes".
- 2.2 This document sets out the NAB-MALTA mandatory regulations. It shall be read and applied in conjunction with the requirements set out in the NAB-MALTA contract reference **NABC03**.
- 2.3 The mandatory regulations defining the use of the accreditation symbol and/or reference to accreditation are contained in publication **RAB02**.
- 2.4 The NAB-MALTA shall specify the procedure by which application for accreditation shall be made, the conditions for granting, maintaining and renewal of accreditation, and the conditions under which accreditation may be refused, suspended, reduced, or withdrawn.
- 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, maintaining and renewal of accreditation shall be afforded only to 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.

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2.7 **Monitoring** - The monitoring of compliance with these regulations and criteria is based on regular assessment activities.

2.7.1 The NAB-MALTA shall prescribe the frequency with which an accredited CAB shall be subject to an assessment. It shall depend, in any given case, on the types of activity for which it has been accredited but, as a general guide, assessments will normally take place at intervals of 12 months not exceeding 24 months, and reassessments will normally take place sufficiently on time to allow the accreditation cycle not to be longer than 5 years.

2.7.2 The first assessment following the initial award of accreditation shall take place not more than 12 to 18 months after the decision to grant accreditation by the Board unless there is a reason for such an assessment to take place earlier or later.


2.7.3 The NAB-MALTA reserves the right to carry out additional assessment activities including unannounced assessments and to carry out assessments, including reassessments at intervals other than those prescribed.

2.8 **Revisions** - The NAB-MALTA will, from time to time, revise these regulations or any of the relevant criteria prescribed by the NAB-MALTA. 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 be given such time, as in the opinion of the NAB-MALTA, is reasonable, to carry out the necessary adjustments. Accredited CABs shall inform NAB-MALTA when adjustments, where necessary, have been completed.

2.9 **Confidentiality** - All information received by the NAB-MALTA and by persons acting on its behalf during the accreditation process shall be treated as confidential between the CAB and the NAB-MALTA. Such information shall be handled within the NAB-MALTA on a confidential basis and shall not be disclosed to a third party without the express written consent of the management of the CAB, unless such disclosure is required by law. Personal data will be treated according to the Data Privacy regulations in force at the time.

2.9.1 The NAB-MALTA may need to consult with the appropriate regulator should an application be for a scope of accreditation making reference to European or national legislation for e.g., applications of CABs having the intention of becoming Notified Bodies. In such cases, the NAB-MALTA assessment team may be accompanied by representatives from specific regulators or competent authorities.

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2.9.2 As part of its obligation towards the peer evaluation process, the NAB-MALTA may share information with the European Co-operation for Accreditation (EA). CABs shall allow members from the EA peer evaluation team to have the same access rights as NAB-MALTA assessors when the EA teams are observing the assessment being carried out by the NAB-MALTA assessment team.


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

4.0 GENERAL OBLIGATIONS OF THE CONFORMITY ASSESSMENT BODY (CAB)

- 4.1 The CAB shall commit to fulfil continually the requirements for accreditation for the scope for which accreditation is sought or granted and to commit to provide evidence of fulfilment. This includes agreement to adapt to changes in the requirements for accreditation.
- 4.2 The CAB shall commit to fulfil its obligations and responsibilities related to the accreditation process, as defined in these regulations, the contract and all the relevant accreditation scheme requirements including policies, regulations and other normative requirements prescribed by the NAB-MALTA.
- 4.3 The CAB's responsibilities shall include, but not be limited to:
- (a) cooperate as is necessary to enable the NAB-MALTA to verify fulfilment of requirements for accreditation;

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- (b) claim accreditation only with respect to the scope for which it has been granted;
- (c) provide access to the NAB-MALTA to conformity assessment body personnel, locations, equipment, information, documents, and records as necessary to verify fulfilment of requirements of accreditation. Information, documents, and records include those used by the conformity assessment body for non-accredited activities or those held by related bodies. Such access shall be extended to evaluators (for e.g., EA and FALB peer evaluators) of the NAB-MALTA. The CAB shall allow the NAB-MALTA to take notes and records of the activities being witnessed in any form or manner (including for example photographic images);
- (d) arrange the witnessing of conformity assessment activities when requested by the NAB-MALTA;
- (e) have, where applicable, legally enforceable agreements with their clients that commit the clients to provide, on request, access to the NAB-MALTA assessment teams to assess the conformity assessment body's performance when carrying out conformity assessment activities at the client's site. Such access shall be extended to evaluators (for e.g., EA and FALB peer evaluators) of the NAB-MALTA;
- (f) commit to follow the NAB-MALTA's policy for the use of the accreditation symbol and shall not make any statement regarding the authority of the certificate-holder which the NAB-MALTA may reasonably consider to be misleading (refer to **RAB02**);
- (g) not use its accreditation in such a manner as to bring the NAB-MALTA into disrepute;
- (h) inform the NAB-MALTA without delay of significant changes relevant to its accreditation and shall submit an analysis explaining the impact, if any, of such change as detailed in [Clause 5 – Notification of Changes](#);
- (i) promptly pay such fees for administration, application, assessments, and other services as determined by the NAB-MALTA and as detailed in [Clause 10](#) - Payment of fees;
- (j) assist in the investigation and resolution of any accreditation-related complaints about the conformity assessment body referred to it by the NAB-MALTA;
- (k) fully conform to the regulations **RAB02** and any other NAB-MALTA requirements for claiming accreditation status and when referring to its accreditation in communication media;
- (l) prepare and submit documents and items as defined in NAB-MALTA application documents or the NAB-MALTA policy **ATG12**;

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- (m) participate in any proficiency or comparison testing scheme that the NAB-MALTA may reasonably deem to be necessary, as per NAB-MALTA Policy Document **ATG10**;
- (n) not use accreditation to imply that a product, process, system, or person is approved by the NAB-MALTA;
- (o) 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;
- (p) take due care that no report or certificate nor any part thereof is used in a misleading manner;
- (q) advise the arrangements and procedures used for carrying out conformity assessment activities in other countries.

4.4 The CAB shall offer to all clients a standard of service consistent with the accreditation scheme criteria to which it is accredited by the NAB-MALTA (as specified in **ATG18** – NAB-MALTA Mandatory and Guidance Documents) and with the regulations, policies and other relevant 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, subcontractors as well as peer evaluators 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 documents, 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.

4.7 **Communication** - All communication shall be channelled through NAB-MALTA.

4.7.1 Direct contact with Technical Assessors/Experts under contract with the NAB-MALTA shall not be permitted **unless there has been formal written approval by the Director of 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:

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- (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 legally 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 CAB performing conformity assessment activities at any site (e.g., certification/inspection body's audit team performing an audit/inspection at their client's site).

4.10 **Access to and Retention of Records** - 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**.

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 operating 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.

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- 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 clearly 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 a scheduled assessment activity, the CAB shall submit the documentation listed in **ATG12** and any other documentation as requested to the NAB-MALTA **within 30 days prior** to the scheduled assessment or following any request by the NAB-MALTA.
- 4.14 All reports/certificates issued by the CAB shall clearly show the name in full of the signatories.
- 4.15 Accredited CABs, especially certification bodies, should not provide any conformity assessment activities that denote conformity with any of the standards that are used as the basis for accreditation.
- 4.16 Applications for extension of scope shall be submitted to NAB-MALTA by using the proper forms. These forms shall reach the NAB-MALTA **4 months before** the next scheduled assessment activity. Where these are received later, the acceptance or otherwise shall be at the discretion of the NAB-MALTA.
- 4.16.1 The criteria for the assessment to extensions of scopes are identical to those for the initial assessment as outlined in this procedure.
- 4.16.2 For laboratories, applications shall be supported by validation data for any new methods and, where possible, proof of participation in proficiency testing schemes.

5.0 NOTIFICATION OF CHANGES

- 5.1 A “notification of change” is an assessment activity.
- 5.2 The CABs shall immediately and without any undue delay inform the NAB-MALTA of any changes to their operations which would impact on their ability to meet the applicable accreditation scheme requirements. Such changes include:
- (a) legal, commercial, ownership or organisational status;

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- (b) organisation, top management, and key personnel;
- (c) policies or procedures, where appropriate;
- (d) premises;
- (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 CAB's accreditation and its ability to fulfil the applicable normative requirements.
- (i) **Change of use of the accreditation symbol and reference to accreditation**

5.3 **“Change information form” NABG11** shall be completed to communicate changes to the NAB-MALTA. All information shall be provided in full, as soon as it becomes available and in any event before the effective operations date of the change, unless such changes are immediately necessary to ensure business continuity or in emergency situations. Nevertheless, CABs shall not wait until the next assessment to notify such changes and shall still notify the NAB-MALTA immediately and perform an impact analysis of such a change.


5.4 The CAB shall submit an analysis of the **risks and** impact of such changes. The CAB shall **maintain** clear records of this **risk and** impact analysis and of any resulting action plans, showing how it has controlled this change so as not to affect the accreditation status.

5.5 **During the review of a Notification of Change, the NAB-MALTA may identify that the nature of the notified changes warrants the completion of an Extension to Scope application.**

5.6 Where a CAB makes a significant change or requests an amendment to an accredited method, the CAB must make a formal written request to the NAB-MALTA in line with the above. Documentation and validation and/or verification data may need to be submitted. The CAB shall not make any claim for accreditation for the amended method until a new scope of accreditation has been published by the NAB-MALTA or as long as this is covered by a flexible scope. **It may be that such a change will have to be processed as an Extension to Scope.**

5.7 Depending on the outcome of the review by the NAB-MALTA, an additional assessment of the CAB may be needed **to close off a Notification of Change. Findings may also be raised by the NAB-MALTA should the information provided be neither adequate nor sufficient.**

5.8 Any changes to the structure of an inspection body shall be documented through an impact analysis on impartiality and independence with confirmation of Inspection Body “type” (refer to Clause 4 and Annex A of ISO17020).


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- 5.9 If the staff changes include changes to key top management positions a C.V. of the member of staff filling that role shall be submitted together with the impact analysis.
- 5.10 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.
- 5.11 Review of notifications of change will be carried out against a payment according to the time effort needed for processing. An invoice will be issued, and payment of this invoice is to be affected within 30 days of the date of this invoice. Payments are to be made to the NAB-MALTA. As per Contract of Accreditation and Regulations **RAB01**, accreditation may be suspended and/or withdrawn if the payment is not received within the time stipulated in this invoice. A surcharge on the amount quoted on this invoice may be made by the NAB-MALTA to cover additional costs for e.g., due to changes in assessor travelling costs, where applicable.

(**Note:** It is strongly recommended to immediately contact the NAB-MALTA in cases where there is a doubt as regards the notification of any change.)

6.0. SUBCONTRACTING

- 6.1 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.
- 6.2 Accreditation is granted to a CAB only for activities it performs itself and for which the NAB-MALTA has verified its competence. The CAB shall not subcontract on a permanent basis any of the activities listed in the scope of accreditation. Should the CAB need to carry out permanent subcontracting, such activities will be excluded from the scope of accreditation.
- 6.3 If a CAB, due to extraordinary and unforeseen reasons, subcontracts any of the accredited activities, it shall
- keep the client informed in advance and obtain its written approval;
 - verify and record details of its investigation of the competence of the subcontractor for the specific activity (for e.g., the accreditation of a subcontractor for the subcontracted activity by an AB that has signed the EA MLA is acceptable);
 - clearly indicate in the reports/certificates which activity (for e.g., test, sampling) has been subcontracted;
 - shall maintain a register of the details of all subcontracted work.

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6.4 Serial subcontracting (i.e., subcontracting by the subcontractor of the accredited CAB) of the activities listed in the scope of accreditation shall not be permitted.

7.0. FINDINGS

7.1 Findings are categorised as follows:

7.1.1 **Nonconformity:** failure to meet the requirements specified in the applicable normative documents as applicable to an accreditation scheme or documents issued by the CAB being assessed.

7.1.2 **Observation:** An observation normally indicates a potential nonconformity or an opportunity for improvement in the operations of the CAB. The CAB shall inform the NAB-MALTA with its review of the observation and whether an action resulting from such an observation has been or will be taken.

7.2 Findings may be raised as a result of any accreditation activity.

7.3 CABs shall implement corrective actions in response to the findings raised by the Assessment Team in a timely and efficient manner and within the timeframes stipulated in this Clause and in [Appendix A](#).


7.4 It is without prejudice to the NAB-MALTA's right in appropriate cases, to withdraw a CAB's accreditation forthwith for failure to clear any findings.

7.5 All communications about the clearance of the findings shall be channelled through the NAB-MALTA.

7.6 The CAB is required to provide one complete set of responses to all findings in separate electronic folders clearly identified by the NAB-MALTA finding numbers. The folders are to be sent in a single compressed file. The information submitted by the CAB shall clearly identify:

- the root cause analysis,
- the corrective action taken
- the evidence for each finding.

The CAB shall also submit the updated and completed findings sheet **NABG10** in electronic format, clearly explaining the root cause analysis carried out, the corrective actions taken and clear references to the evidence submitted.

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7.7. The timeframe for the submission of evidence for the clearance of findings by the CAB shall not exceed **3 months** from the date of the initial assessment and/or extensions to scope and **30 days** from the date of issue of such findings to the CAB in all other cases.

7.7.1 Depending on the severity of the finding stricter time limits may be set for corrective action(s) and submission of evidence of such action(s), especially by accredited CABs and especially where the lack of such action(s) may affect the scope of accreditation.

7.7.2 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 finding(s) requiring the extension to the timeframe. All other findings must be cleared within the agreed timeframes.


7.8. Should the submitted replies (corrective actions and evidence) not be satisfactory and require additional evidence to be submitted by the CAB, replies shall be submitted to the NAB-MALTA within **5 working days**, or as otherwise agreed with the NAB-MALTA. This may result in an additional fee being charged to the CAB.

7.9. The NAB-MALTA shall review the additional evidence submitted. Should this result to be unsatisfactory, the CAB will be given another opportunity to provided additional evidence **within 5 working days**, or as otherwise agreed with the NAB-MALTA. Should the additional evidence still be unsatisfactory it will be at the discretion of the NAB-MALTA as to whether it will give the opportunity to the CAB to submit any further evidence for clarification. Unsatisfactory closure of findings shall result in suspension, reduction or termination of accreditation as further explained in Clause 8. This may result in an additional fee being charged to the CAB.

7.9.1 This process can be repeated for a maximum of three times, after which the assessment team will consider that the CAB is not in a position to close the finding/s. For each round of submission, the assessment team may opt for an additional assessment to be carried out, if it deems that this is necessary for the appropriate closure of the findings.

7.10 CABs shall make their best effort to close off the findings on the first attempt. CABs shall pay due attention to ensure that they provide the extent of the findings, the root cause, details of the corrective action and the corresponding objective evidence showing that action has been completed. It is expected that the additional 2nd and 3rd rounds are reserved for clarification of a minimal number of findings and not for a resubmission of corrective action for the majority of the findings.

7.10.1 The CABs are reminded to ensure that they understand the nature of the findings during the assessment, in the presence of the assessment team.

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7.10.2 There will be additional charges should the NAB-MALTA need additional time to that planned to close off findings.

7.11. The NAB-MALTA shall review the accredited CAB's accreditation status if:

- (a) the responses to the findings raised are not submitted to the NAB-MALTA within the agreed timeframe; and/or
- (b) incomplete or inadequate responses are submitted to the NAB-MALTA within the requested timeframes.


7.11.1. This review may result in the accredited CAB's scope of accreditation being reduced or withdrawn or, where appropriate, suspended until the outstanding finding(s) has (have) been satisfactorily cleared.

7.12. The NAB-MALTA shall suspend, reduce, or terminate, as appropriate, all or part of the accredited body's scope of accreditation if the CAB fails to clear findings within agreed timeframes, especially if this happens frequently or if the finding(s) is severe in nature.

7.13. In the case of an initial application where the CAB fails to clear the findings within the requested timeframes a re-assessment shall be required unless otherwise agreed.

7.14. In the event of a critical finding being raised, the Team Leader in consultation with the NAB-MALTA shall:


- (a) consider recommending suspending, reducing, or withdrawing the scope of accreditation of a CAB;
- (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 assessment is required to witness the clearance of the finding or to address any issues relating to its clearance;
- (d) review the reports from previous assessments of the CAB to ascertain if the history of the CAB, when taken together with the critical finding raised, indicates an underlying problem with the maintenance of accreditation;

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- (e) ensure that the integrity of the NAB-MALTA accreditation is not compromised by any action or timeframe requested to address the finding.

8.0. SUSPENDING, REDUCING OR WITHDRAWING ACCREDITATION

- 8.1. 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.
- 8.1.1. These measures shall include;
- (a) suspension, **voluntary or otherwise**
 - (b) withdrawal, **voluntary or otherwise**
- of all or of part of the CAB's scope of accreditation.
- 8.2. The NAB-MALTA may suspend, reduce, or withdraw accreditation, or require reassessment if the CAB fails to notify the NAB-MALTA of changes in any aspect of its status or operation as defined in [Section 5](#) of these regulations.
- 8.3. The Director may authorise immediate suspension in severe cases which may jeopardise the accreditation status of the accredited CAB, the reliability and confidence in the conformity assessment activities 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.*
- 8.4. Where there is evidence of fraudulent behaviour, or the CAB intentionally provides false information or conceals information, the NAB-MALTA shall initiate its process for withdrawal of accreditation.**
- 8.5. The Board is responsible for confirming suspensions, or otherwise and for deciding on reductions in scope and termination of accreditation.
- 8.6. The NAB-MALTA may impose 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

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(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 able 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) the CAB fails to clear findings within the agreed timeframes, as per [Clause 7](#) above;
- (h) 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;
- (i) where in the reasonable view of the NAB-MALTA, the CAB has made unreasonable or irresponsible use of sub-contracting;

8.6 In the event that during its accreditation, the CAB is unable for any reason to comply with the accreditation scheme criteria and/or the contract, the CAB shall immediately apply to the NAB-MALTA for **voluntary suspension or withdrawal** of its accreditation.


8.6.1 For the avoidance of doubt, the duty to apply for voluntary suspension or **withdrawal**, as outlined in clause 8.6. 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.

8.6.2 The NAB-MALTA may in its sole discretion refuse voluntary suspension or resignation and impose involuntary suspension or withdrawal of the CAB's accreditation.

8.7 The CAB may choose to suspend or **withdraw** its accreditation at any time.

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- 8.8 The NAB-MALTA may decide to withdraw the CAB’s accreditation immediately on written notice (such withdrawal **will** be effective as and from the date of that notice) for any of the events set out at sub-clauses (a) to (j) of **Clause 8.5** or where it otherwise considers in its sole discretion that withdrawal is warranted.
- 8.9 On the suspension, reduction, or withdrawal of accreditation the CAB shall:
- (a) inform, where applicable, its affected clients of the suspension, reduction or withdrawal of its accreditation and the associated consequences without undue delay;
 - (b) 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 **suspended or withdrawn** accreditation including on all specific reports, certificates, label or other documentary outputs relating to specific activities for clients activities falling within its suspended/withdrawn accreditation and also on all documentation, brochures, advertising and publicity material relation to activities fall within its **suspended/withdrawn** accreditation generally;
 - (c) ensure that all 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.
- 8.10 The provisions of record keeping, use of the NAB-MALTA symbol, confidentiality, limitation of liability and indemnity shall survive **withdrawal** of the CAB’s accreditation and termination of the accreditation contract.
- 8.11 Withdrawal of accreditation by the CAB shall automatically terminate those accreditations that require or are dependent on the continued existence of the withdrawn accreditation.
- 8.12 The period of suspension, whether voluntary or involuntary, **shall normally be brief and not exceed six months (in exceptional circumstances, this period of suspension may be extended by 3 months)**. The CAB shall take all the necessary actions to ensure that the suspension is lifted within the shortest time possible and not exceeding the timeframes as agreed with the NAB-MALTA.
- 8.12.1 The period of suspension, in total, includes the following activities which shall be completed by within the agreed suspension period:**
- **corrective actions taken by the CAB**
 - **review of actions and evidence by the NAB-MALTA which may result in the need for additional assessment, whether on-site or remote**
 - **decision by the Board**

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8.12.2 The corrective actions taken by the CAB and related impact analysis and evidence, shall be submitted to the NAB-MALTA not later than **3 weeks before the date of the end of the suspension period**. Non receipt of such information will result in immediate withdrawal of accreditation.

8.12.3 The CAB shall submit clear evidence to justify lifting suspension of accreditation. Such evidence will be reviewed by the NAB-MALTA. This will then be reported to the Board who will then decide to lift suspension of accreditation or otherwise.

8.12.4 If, after the review by the NAB-MALTA, further clarification and/or assessment is needed to close off findings related to a suspension, the NAB-MALTA may consider extending the suspension period.

8.12.5 Irrespective of agreed timeframes, when the suspension period **exceeds three months**, an additional assessment shall be carried out.

8.12.5 Failure to clear findings related to the suspension within the agreed timeframes shall result in **withdrawal** of accreditation.


8.13 When suspension is lifted, the NAB-MALTA will inform the CAB and it will update its records and its website with the new accreditation status of the CAB.

8.14 If the period of suspension exceeds the accreditation cycle (i.e., a reassessment cannot be carried out within the period that will allow the accreditation cycle not to exceed 5 years), then this may lead to the withdrawal of accreditation.

8.14.1 CABs suspended (voluntarily or otherwise) very close to the date due for a reassessment, risk having their accreditation withdrawn.

8.15 Accreditation may be withdrawn by the CAB upon giving one month's notice in writing to that effect to the NAB-MALTA.

8.16 The NAB-MALTA shall send an acknowledgment to the CAB confirming the withdrawal of its accreditation. It shall detail the actions required by the CAB and, in the case of voluntary or involuntary suspension, it shall include the procedure for re-instatement of accreditation.

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8.17 In the case of EMAS Verifiers, any decision taken by the NAB-MALTA to terminate or suspend accreditation or reduce the scope of accreditation shall be taken only after the environmental verifier has had the possibility of a hearing.

9.0. INFORMATION ABOUT ACCREDITED CABs

9.1 The NAB-MALTA publishes information on the accredited CABs, including the name and address, scopes, and effective dates of accreditation, on its website. Such information will include, where applicable, information on suspension or withdrawal of accreditation.

9.1.1 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 CAB or other problems or losses.

9.2 The CAB shall ensure that the information which it gives to the NAB-MALTA, generally and in response to specific requests for information, is accurate and not misleading. The CAB further undertakes to immediately inform the NAB-MALTA of any inaccuracy which appears in the published information related to its entry and of any change which occurs which necessitates an amendment to such information within **3 working days** of the said inaccuracy coming to the CAB's attention or of the said change occurring, whichever is the earlier.

9.3 In the event of the accreditation of the CAB being suspended, reduced, or withdrawn, either voluntarily or involuntarily, the listing in respect of that CAB shall be immediately amended.


9.4 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 CAB.

9.5 The NAB-MALTA shall not be liable to the CAB for any loss or damage including injury to reputation suffered by the CAB as a result of the use by the public of the online information or the NAB-MALTA website.

9.6 The NAB-MALTA shall not be liable in respect of any omission of an entry for the CAB.

9.7 The 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 publicly available; 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.

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

9.8 The 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 9.7.

10.0. PAYMENT OF FEES

10.1 The NAB-MALTA shall charge fees for the operation of its accreditation schemes.

10.2 All fees are determined on a case-by-case basis and cover **the effort needed to carry out an assessment/review activity. Costs include** administration costs, the assessor/s daily rates, accommodation, travel arrangements and other ancillary costs related to the accreditation process.


10.3 The non-payment of any fees due to the NAB-MALTA shall lead to the suspension or withdrawal of accreditation.

10.4 The NAB-MALTA reserves the right to cancel confirmed assessment activities at any time if any outstanding fee payable by the CAB remains unpaid. Cancellation of assessments due to outstanding payments shall result in the suspension or withdrawal of accreditation. In addition, cancellation fees may be charged to the CAB.

10.5 No contracting of assessors/experts shall be made by the NAB-MALTA unless the payments requested by the NAB-MALTA have been made.

10.6. Application and Preliminary Visit Fees


10.6.1 On receipt of the application form, the NAB-MALTA will issue an invoice. The applicant CAB shall be given a maximum period of **30 days** from the date of issue to pay this invoice. Unless payment is received, the accreditation process shall not continue.

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- 10.6.2 The application and preliminary visit fee shall be levied to offset costs involved in the appointment of the assessment team, the review of documentation and the carrying out of the preliminary visit.
- 10.6.3 In cases where the NAB-MALTA considers that a preliminary visit is not required and that the CAB can proceed directly to an initial assessment, two separate invoices will be issued – one as an application fee and one covering the initial assessment costs.
- 10.6.4. 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.
- 10.6.5. Subsequent applications for the accreditation of related bodies not included in the original application form may be subject to a further application fee.
- 10.6.6 Should the documentation made available by the CAB be sufficient to cover the requirements of accreditation and depending on the advice provided by the Team Leader, the NAB-MALTA will proceed to plan a date for the preliminary visit.

10.7. Initial Assessment Fee

- 10.7.1 The invoice for the initial assessment fee will be issued after the invoice covering the application fee. The applicant CAB shall be given a maximum period of **30 days** to pay this invoice. The initial assessment shall not be carried out if there are any outstanding payments which are due to the NAB-MALTA. No further processing can be made before the receipt of the payment, which shall be received in time as stipulated on the invoice.
- 10.7.2 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), witnessed assessments and assessment of the implementation of the requirements as set by the specific accreditation schemes.
- 10.7.3 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.
- 10.7.4 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 granting accreditation. In many cases it will be possible to provide the evidence electronically to the NAB-MALTA (e.g., revised documentation, updated calibration certificates, photos). Sometimes, however, an

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additional assessment may be necessary (e.g., to confirm that laboratory environment control equipment is functioning correctly), and the cost of such activity shall be charged to the CAB. A separate invoice shall be issued by the NAB-MALTA to the CAB.

10.7.5 No certificates of accreditation shall be issued unless any outstanding balance with the NAB-MALTA is cleared by the applicant CAB.

10.8. Fees related to accreditation activities

10.8.1 The accredited CAB shall be subject to fees to offset the cost of activities related to administering its accreditation and to permit its proper monitoring.

10.8.2 The NAB-MALTA may conduct additional on-site assessments as 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. The costs of such activities shall be borne by the CABs.

10.8.3 Fees depend on the work to be undertaken by the NAB-MALTA and the number of assessors and assessor days required for the monitoring of the CAB, as required by the scope of accreditation.

10.8.4 Payment of fees shall be within the time stipulated in the invoice. Non-payment of fees shall result in the suspension, or withdrawal (especially in cases of repeated late payments), of accreditation.

10.9. Cancellation Fee


10.9.1 Where the CAB postpones or cancels a confirmed assessment, the CAB shall be liable to pay all the fees already incurred by the NAB-MALTA.

10.10 Fees for Extensions to Scope of Accreditation

10.10.1 A fee shall be levied to cover the related costs including desk review carried out, additional time during a scheduled assessment, costs related to additional assessors/experts, etc...

10.11. Payment of Fees

10.11.1 Fees shall be settled through direct bank transfer.


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11. APPEALS


- 11.1 Decisions on the award, extensions, suspensions, reduction, withdrawals, and maintenance of accreditation of CABs 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 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,
Mizzi House, 1st Floor,
National Road,
Blata l-Bajda, HMR9010
Malta
- 11.5 The costs of the appeal which may include travelling, accommodation, and professional fees of technical assessors/experts, shall be borne by the Appellant unless the appeal is successful.

12. COMPLAINTS

- 12.1 Complaints may be distinguished into two main categories:
- Complaints concerning the activities of the NAB-MALTA (excluding accreditation decisions)
 - Complaints concerning the accredited activities of a CAB accredited by the NAB-MALTA.
- 12.2 Conformity assessment bodies may address a complaint, other than an accreditation decision by the NAB-MALTA for which the appeals process in [Clause 11](#) of these regulations, to the NAB-MALTA.
- 12.3 Complaints shall be dealt with in accordance with the current complaints' procedure, details of which will be furnished by the NAB-MALTA upon request.


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- 12.4 Complaints shall be submitted in writing to the Director of the NAB-MALTA clearly stating the nature and justification.
- 12.5 Authentication of a complaint normally involves the receipt of a letter and/or other documentary evidence. Such documentary evidence must include the name and address of the Complainant.
- 12.6 Complaints may be received from many varied sources including private individuals.
- 12.7 No investigation of complaints shall be pursued on the basis of hearsay.
- 12.8 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.
- 12.9 The Director of the NAB-MALTA shall designate an Officer to deal with the complaint, who is in no way connected to the complaint.
- 12.10 The designated officer shall acknowledge the complaint in writing to the Complainant.
- 12.11 The NAB-MALTA shall take all necessary measures to preserve the confidentiality of information obtained during the investigation of a complaint.
- 12.12 The NAB-MALTA reserves the right to carry out additional visits if considered necessary as part of the investigation.
- 12.13 When the investigation has been completed the Officer shall submit a written report on the complaint to the Director of the NAB-MALTA.
- 12.14 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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Appendix A – Summary of timeframes

Issue	Timeframe	NAB-MALTA Reference
Prior to application - Minimum period of operation of the CAB's management system according to the accreditation requirements Note: A full cycle of internal audits plus a management review must be carried out prior to the initial assessment.	3 months	ATG01, ATG05
Post preliminary visit - Submission of revised documents	30 days prior to the initial assessment.	ATG12
Initial assessment and/or Extensions to Scope: Maximum allowed timeframe for clearance of findings	3 months (may be extended with justification)	RAB01
First scheduled assessment following initial assessment	Shall take place not more than 12 -18 months after the decision to grant accreditation, unless there is a reason for such an assessment to take place later	RAB01
Scheduled assessments - Maximum allowable timeframe for completion date for the submission of evidence re findings	30 working days Stricter time limits or immediate corrective action may need to be taken depending on the nature, risk, and extent of the finding.	RAB01
Submission of additional information and/or evidence for the closure of the findings	5 working days from the request of the Lead Assessor for further evidence	RAB01
Submission of information requested by ATG12	At least 30 days prior to the scheduled assessment	ATG12 RAB01
Extensions to scope - Submission of "Application form For Extension to Scope of Accreditation" (NABAF01/E)	At least 120 working days in advance of the next scheduled assessment.	RAB01 ATG12
Scheduled assessments	Normally every year	RAB01
Reassessment	The period (accreditation cycle) between an initial accreditation or	RAB01

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Issue	Timeframe	NAB-MALTA Reference
	decision after reassessment shall not be longer than 5 years.	
Additional assessments	As required	RAB01
Suspension of accreditation	Normally a maximum of 6 months for completion of all activities related to a suspension.	RAB01
Suspension of accreditation – submission of impact analysis, corrective actions, and evidence by suspended CAB	1 month prior to the last agreed date of end of suspension period. Period may vary if suspension will mean that decision will go beyond the maximum 5-year accreditation cycle.	RAB01
Withdrawal of accreditation	6 months after the suspension period	RAB01

END