



MAURITAS G1

MAURITAS assessments – A guide for
laboratories

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Foreword

The MAURITIUS ACCREDITATION SERVICE (MAURITAS) is a governmental body established in 1998 to provide a national, unified service for the accreditation of Conformity Assessment Bodies (CABs) such as calibration/testing laboratories, certification bodies and inspection bodies. Organizations that comply with the MAURITAS requirements are granted accreditation by MAURITAS.

About MAURITAS publications

MAURITAS publications are categorised as follows:

- R series Publications containing general policy and requirements related to MAURITAS accreditation.
- G series Publications providing guidance on MAURITAS requirements.
- A series Publications related to assessment procedures
- P series MAURITAS quality system procedures
- F series MAURITAS Forms
- Directories classified listing of accredited organisations.

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MAURITAS assessments - A guide for laboratories

1 Purpose

1.1 This guidance document should ensure a uniform and correct execution of the processes associated with the accreditation of calibration and testing laboratories.

2 Scope and Responsibilities

2.1 This guidance document sets out how MAURITAS assessments/visits are to be carried out in order to assess a laboratory's compliance with ISO/IEC 17025 or ISO 15189, MAURITAS requirements and any other requirements at sub-regional, regional and international levels. This document also describes the preparation, conduct and reporting of MAURITAS laboratory visits and is meant for use by all calibration/testing laboratories.

3 References

The following documents contain provisions which, through reference in this text, constitute provisions of the MAURITAS accreditation system. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated MAURITAS references, the latest edition of the document referred to, applies. MAURITAS maintains a register of the current valid MAURITAS accreditation documents.

- 3.1 **ISO/IEC 17025, General requirements for the competence of testing and calibration laboratories.**
- 3.2 **ISO 15189, Medical laboratories- Particular requirements for quality and competence**
- 3.3 **MAURITAS A Series documents**
- 3.4 **MAURITAS G Series documents**
- 3.5 **MAURITAS R Series documents**
- 3.6 **ILAC P8: ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Laboratories and Inspection Bodies**
- 3.7 **ILAC P9: ILAC Policy for Participation in Proficiency Testing Activities**
- 3.8 **ILAC P10: ILAC Policy on Metrological Traceability of Measurement Results**
- 3.9 **ILAC P14: ILAC Policy for Measurement Uncertainty in Calibration**
- 3.10 **ILAC G17: ILAC Guidelines for Measurement Uncertainty in Testing**
- 3.11 **ILAC/IAF JWG A-Series FAQ1**

4 Definitions

4.1 Accreditation

Accreditation is a third-party attestation related to a CAB conveying formal demonstration of its competence to carry out specific conformity assessment tasks

4.2 Major Non-Conformities

Major Non-Conformities are non-conformities where the credibility of the laboratory's accreditation is seriously threatened or where tests/calibration results are affected.

4.3 Minor Non-Conformities

Minor Non-Conformities are non-conformities that are isolated and would not affect the results of the testing/calibration activities of the laboratory **Technical Signatory**

(Not applicable to Medical Testing Laboratories) A technically competent person approved by MAURITAS, whose signature confers validity on the laboratory's certificates, reports and/or results issued under MAURITAS accreditation. The Technical Signatory accepts responsibility for the contents (results and/or measurements) of the certificate/report which he/she is signing or authorising.

4.4 Assessment programme

Set of assessments consistent with a specific accreditation scheme that the accreditation body performs on a specific laboratory during an accreditation cycle

4.5 Assessment plan

Description of the activities and arrangements for an assessment

4.6 Accreditation Body personnel

Internal or external individuals carrying out activities on behalf of the accreditation body

4.7 Assessor

Person assigned by an accreditation body to perform, alone or as part of an assessment team, an assessment of a conformity assessment body

4.8 Team Leader

Assessor who is given the overall responsibility for the management of an assessment

4.9 Technical Expert

Person assigned by an accreditation body, working under the responsibility of an assessor, who provides specific knowledge or expertise with respect to the scope of accreditation to be assessed and does not assess independently.

However, a technical expert can work in an area alone if an Assessor/Team Leader is available and periodically checking and communicating with the technical expert (this includes also keeping in touch via email or telephone or a mobile application).

Preparation for, conduct and reporting of MAURITAS visits

5 General

5.1 The main function of MAURITAS is to accredit calibration/testing laboratories for their technical competence to carry out specified calibrations/tests, and subsequently to ensure by monitoring that the required standards are maintained. Each applicant laboratory provides basic information on its activities, equipment and staff in the relevant Application Form (**F 3.15 or F 3.16/F 3.32**), duly completed Self-Assessment checklist (**F 3.23 or F 3.19/F 3.29**), CVs of potential Technical Signatories where relevant and its quality documentation, but it is essential to check the competence of the laboratory by assessment in the laboratory and other sites, where

appropriate. The purpose of this assessment is to determine whether a laboratory complies with the MAURITAS requirements for accreditation, **ISO/IEC 17025** or **ISO 15189** and **MAURITAS R** Series documents. In some circumstances specialised publications issued by MAURITAS or other national, regional or international organisations, for example the Southern African Development Community Cooperation in Accreditation (SADCA), the African Accreditation Cooperation (AFRAC) and the International Laboratory Accreditation Cooperation (ILAC) and endorsed by MAURITAS, provide interpretations of these criteria.

5.2 Assessors/Technical Experts are used to evaluate the competence of the laboratory to perform the calibrations/tests for which accreditation is sought. Their responsibility is therefore to assess a laboratory's compliance with **ISO/IEC 17025** or with **ISO 15189** and **MAURITAS R** Series documents. Their assessment should be confined to investigating and reporting the findings that result from witnessing and discussion with the laboratory personnel and through examination of laboratory documentation.

5.3 All information obtained before, during or after assessment, including the fact that a particular laboratory has applied for accreditation, or that an application for accreditation has been deferred or rejected, shall be treated as strictly confidential and as MAURITAS proprietary by staff of MAURITAS by the external Assessors/Technical Experts and by the Accreditation Committee.

5.4 MAURITAS makes use of Assessors/Technical Experts contracted from external sources to assess laboratories on its behalf. All MAURITAS Assessors/Technical Experts, including MAURITAS staff (hereafter referred to as the MS) acting as Assessors, must satisfy stringent requirements, as defined in **MAURITAS A2** document, in terms of their technical and professional qualifications, expertise and experience, and must have attended and satisfactorily completed such training as MAURITAS may specify. The MS may also act as an assessor if qualified as an assessor.

5.5 A MS will normally visit the laboratory as part of the Assessment Team where the assessment does not require the presence of a Team Leader. Technical Experts will also be accompanied by a MS as the latter, being familiar with MAURITAS policies, procedures and regulations, will be able to respond during visits to enquiries from the laboratory management on such matters. The MS will also assist the Technical Expert with the interpretation of MAURITAS requirements in appropriate circumstances.

5.6 MAURITAS assessment procedures are applicable to all sizes of laboratory including laboratories carrying out a wide range of calibrations/tests and laboratories performing just a few calibrations/tests. Where reference is made in the assessment procedure to a 'Assessors' Meeting', this may be inappropriate for small laboratories, where a Team Leader, operating for 1 day or less, may well be all that is required. Assessors must take account of the size and complexity of the organisation when assessing the management system of a laboratory. The management system must provide assurance that the laboratory, whatever its size or complexity, meets the requirements of MAURITAS.

5.7 The procedures described in this publication apply not only to preliminary visit and initial assessment visit, but also to visits after accreditation has been granted, for the purposes of assessments, re-assessment, extension of schedule, on-site clearance of non-conformities, extra-ordinary visits or other purposes.

6 Processing of applications

6.1 A laboratory wishing to be accredited by MAURITAS, or to extend its accreditation, first completes and submits to MAURITAS the relevant Application Form, **F 3.15** or **F 3.16/F 3.32** accompanied by the self-assessment checklist **F 3.23** or **F 3.19/F 3.29**, providing details of its staff, equipment and facilities, and specifying the types of calibration/test for which accreditation is sought. It also supplies MAURITAS with a copy of its Quality documentation, including the quality policies and procedures of the management system operating in the laboratory, validation report and uncertainty of measurement calculations submitted by the laboratory and pays the relevant Application Fee. The laboratory has to provide information on equipment, methods/techniques, CVs of potential Technical Signatories where relevant and its participation in Proficiency Testing (PT) for calibrations/tests to be accredited.

6.2 MAURITAS reviews the Application Form and Self-assessment report to ensure that it has been correctly and fully completed and examines the Quality documentation to check that it addresses all the key elements of a quality system as specified in **ISO/IEC 17025** or **ISO 15189** and relevant **MAURITAS R** Series documents. If there are obvious major omissions, the documentation is returned to the applicant for revision.

6.3 If the documentation is complete, MAURITAS will proceed with the document review. Following this exercise, using the Self-Assessment checklists (**F 3.23** or **F 3.19/F 3.29**), MAURITAS will inform the laboratory about which of the following actions should be taken:

- a) the laboratory is not in a position to proceed to preliminary visit; or
- b) the laboratory is ready for a preliminary visit; or
- c) the laboratory is ready for an initial assessment.

6.4 The document review exercise should be performed only once by MAURITAS for a particular application made by a laboratory.

6.5 In the case that the laboratory is deemed to be ready for preliminary visit or initial assessment, the latter has to submit to MAURITAS its validation data and uncertainty of measurement data, as appropriate, for the applied scope. Measurement Audit/PT results shall be made available to MAURITAS/assessment team at latest during the initial assessment.

6.6 If there is evidence of fraudulent behaviour, if the applicant laboratory intentionally provides false information or if the applicant laboratory conceals information, MAURITAS will take necessary actions to reject the application or stop the accreditation process.

6.7 The laboratory will be required to follow the time line as defined in Annexes A and C.

7 Preliminary visit

7.1 In the event that MAURITAS recommends or the laboratory requests that a preliminary visit be carried out, the laboratory will be informed about arrangements for the visit, including a quotation for the fee.

7.2 Where the recommendation of MAURITAS differs from what the laboratory wants, MAURITAS will then discuss with the laboratory so as to reach a mutually agreed way forward.

7.3 Only 1 preliminary visit shall be carried out by MAURITAS per application made by laboratory.

7.4 The preliminary visit, which is carried out by the assessment team is completed in 1 day. The preliminary visit allows the assessment team to discuss with the laboratory management the extent to which the laboratory's management system, Quality documentation comply, or not, with relevant MAURITAS requirements.

7.5 The visit should be structured so that the assessment team can ascertain that the essential components of a management system have been put in place or have been addressed. In particular, the assessment team needs to establish whether the laboratory has a stated policy for defined responsibilities and a means to implement each of the requirements of **ISO/IEC 17025** or of **ISO 15189**. In carrying out this task, the assessment team needs to ensure that the laboratory management fully understands the purpose of a management system audit and the importance of a periodic review of the management system to check the effectiveness of the system.

7.6 In addition to examining the documented management system prepared by the laboratory against the relevant checklist (**F 3.24** and **F 3.25** or **F 3.20/F 3.30** and **F 3.21/F 3.31**), the assessment team should take the opportunity to discuss the proposed accreditation schedule and to carry out a brief examination of the laboratory's calibration/testing facilities. All non-conformities identified will be recorded on Preliminary Visit findings form **F1.20**. The assessment team shall not, at any stage of the preliminary visit, provide guidance on how to implement the requirements of the relevant standard.

7.7 If the laboratory uses documented in-house methods for calibration/testing, the assessment team should discuss them with the laboratory to ensure that these in-house methods have been validated and any necessary changes are made before the initial assessment. This discussion should cover the details of the laboratory's

experience with such methods, need for participation in relevant measurement audits or proficiency testing programmes, and the laboratory's policy and procedures for estimating uncertainty of measurement.

7.8 At the end of the preliminary visit, the Assessment Team shall indicate to the laboratory whether it can proceed to the initial assessment, or shall provide specific reasons why it cannot proceed. The Assessment Team shall hand over the preliminary visit findings form, **F 1.20** to the laboratory. MAURITAS will not issue to the laboratory any detailed checklist or documents that have been used during the course of the preliminary visit. MAURITAS shall inform the applicant laboratory, in writing, about appropriate course of action based on the recommendation of the Assessment Team.

7.9 MAURITAS will then prepare an estimate of the time required for the initial assessment, as the basis for determining the assessment fee for the applicant.

8 The schedule of accreditation

8.1 It is the policy of MAURITAS to define the Schedule of a laboratory's accreditation as precisely as possible. This ensures that clients are provided with an accurate and unambiguous description of the range of calibrations/tests covered by a laboratory's accreditation. Laboratories are therefore asked to specify, in detail, the types of calibration/test for which accreditation is sought. They are required to provide all the relevant information as required in their respective Application Forms (e.g. the standard specifications or other methods or procedures or equipment/method/technique, the major items of laboratory equipment used to conduct those calibrations/tests and the potential technical signatories, where applicable.

8.2 For schedules of calibration, the type of calibration, the calibration method or procedures, the range of measurements and the technical signatories to be assessed will be provisionally agreed prior to the initial assessment. During initial assessment and after examination of the results of measurement audits, the content of the schedule will be agreed with the laboratory. This will include confirmation of the measurements to be accredited, the range of measurement, the calibration and measurement capabilities (CMCs) and the names of approved technical signatories.

8.3 For schedules of testing, every effort will have been made to reach agreement with the laboratory on the content of the accreditation schedule and the potential technical signatories, if applicable, prior to the initial assessment. This is important, not only to avoid possible misunderstandings, but also to help the Assessors/Technical Experts to operate effectively, concentrating their attention on those areas of activity detailed on the proposed accreditation schedule.

8.4 In some cases, as the assessment proceeds, it may become clear that the laboratory is not really in a position to achieve accreditation in certain areas within the originally conceived accreditation schedule. In such cases, the Team Leader, in consultation with the Assessment Team, may be able to recommend accreditation for a suitably reduced or redefined accreditation schedule.

8.5 Accreditation schedules are in the public domain, unless otherwise requested by the laboratory, and form the basis of MAURITAS List of Accredited Entities published on its website and can also be accessed through the SADCA, AFRAC and ILAC websites.

9 Preparation for the initial assessment visit

9.1 Based on the recommendations of the Assessment Team after the document review or preliminary visit, the laboratory has to inform MAURITAS of its readiness to undergo initial assessment.

9.2 In addition to the latest reports of internal audits, management review and complaints, the laboratory should submit the following for calibrations/tests for which the laboratory is seeking accreditation:

- Calibration/Test method(s)-Validation data
- Measurement uncertainty calculations and
- ‘-Updated PT plan including results of PT participation prior to initial assessment and
- PT plan for the first accreditation cycle

MAURITAS will, in consultation with the approved Assessment Team, prepare an initial assessment plan including the composition of the assessment team and the various activities which will be carried out during the exercise. All standard operating procedures for the calibrations/tests for which the laboratory is seeking accreditation, latest reports of internal audits and management review should be submitted at this stage. This plan will indicate the section/activities in the laboratory to be assessed by each Assessor/Technical Expert. The plan will also indicate when the relevant clauses of the standard, the witnessing, the vertical assessment, the approval of potential technical signatories will be carried out. The plan will also take into consideration the assessment of all other locations of the laboratory where key activities (collection points, sampling points, etc...) are carried out and which is covered by the schedule of accreditation. The plan will also take into consideration witnessing of a representative number of the laboratory's staff performing tests/calibrations so as to assess the competence of the laboratory across the schedule of accreditation. MAURITAS will take into consideration any risks associated with the applicant laboratory's activities when developing the assessment plan (e.g. findings/non-conformities identified during the document review and/or preliminary visit stage)

9.3 MAURITAS will perform a sampling of similar testing/calibration techniques (including similar steps) for different parameters so that the whole scope applied for accreditation is assessed during the initial assessment. In the event that it is not possible to witness all the similar techniques, the Assessment Team will make use of a combination of witnessing and vertical assessments to cover the whole scope applied for accreditation.

9.4 MAURITAS then advises the applicant of the proposed Assessment Team and fees to be charged. New Assessors/Technical Experts will have to be appointed if they are not accepted by the applicant, and actions will be recommended based on the applicant's valid reasons. However, if the reasons are not considered to be valid and local Assessors/Technical Experts are not available, the laboratory will have to bear the cost of using foreign Assessors/Technical Experts.

9.5 The laboratory should confirm acceptance in writing to the fees and plan before the assessment visit takes place.

9.6 The Assessment Team performs the initial assessment as per the assessment plan. The Team Leader will inform MAURITAS in the event that the assessment team is not able to perform the initial assessment as per the assessment plan and the reasons thereof.

10 Summary of the initial assessment visit

10.1 Prior to the start of the initial assessment, an assessors' briefing meeting is carried out by the Team Leader/MS with the Assessment Team (**F1.15**) to ensure the following:

- All Assessors/ Technical Experts have received the required documentation
- All Assessors/MS have carried out their respective review prior to the initial assessment
- Confirmation of parameters to be witnessed
- Confirmation of parameters for vertical assessment and
- Clarification of any queries.

10.2 The initial assessment visit begins with an Opening Meeting between the Assessment Team and representatives of the laboratory. On some occasions the team may then find it necessary to make a brief tour of the facilities before starting the assessment. After the tour, the Team Leader accompanied by the designated staff of the laboratory starts the assessment of management requirements and the technical Assessor/Technical Expert proceeds with the assessment of the technical requirements/witnessing. Each Assessor/Technical Expert should be accompanied by a member of the laboratory staff nominated by the management. An Assessor/Technical Expert may be accompanied by several different members of staff in the course of the assessment. Only staff of the organisation will be assessed by MAURITAS. Consultants will not be assessed by MAURITAS and will not be allowed to participate or interfere in one way or the other during the assessment. They may attend the Opening and Closing meetings as observers.

10.3 The initial assessment ends with a Closing Meeting, involving the Assessment Team, laboratory representatives and laboratory/organisation top management whereby each member of the Assessment Team presents his findings. The Team Leader then summarises the findings of the team. The Assessment Team can also meet privately to prepare for this Closing Meeting. For assessments lasting longer than 1 day, the Assessment Team may also hold an assessors' meeting at the end of each day to compare notes and discuss any changes to the assessment schedule which may have become necessary. An interim Closing Meeting may also be held with the laboratory management if some members of the Assessment Team have completed their work or if the assessment lasts longer than 1 day.

11 The Opening Meeting

11.1 This is held prior to starting the assessment to enable the Assessment Team and the laboratory's representatives to become acquainted, to clear up any difficulties and to confirm the purpose of the assessment and what is expected of the laboratory during the assessment.

11.2 This Opening Meeting sets the scene, and its purpose is to ensure that the laboratory management and staff understand the process involved during the assessment. It is chaired by the Team Leader and should cover the agenda according to the Agenda for Opening Meeting (**F 1.01**), but not necessarily in this order:

- a) introductions;
- b) an explanation of the purpose of the assessment, the functions of the Assessors/Technical Experts and confirmation that the laboratory staff understand the procedure;
- c) discussion of the significance of the quality manual;
- d) discussion of the range of calibration/testing covered by the laboratory's application and how this should be defined in the laboratory's Schedule of Accreditation. No addition/reduction/alteration in the Schedule of Accreditation would be allowed after the end of the opening meeting;
- e) a review of the assessment plan, and confirmation of any changes, and of the programme for witnessing calibrations/tests;
- f) confirmation that a representative of the laboratory has been assigned to accompany each Assessor/Technical Expert, and an explanation of the role of this representative in the assessment, particularly in agreeing observations recorded on the **F 3.07** Forms concerning any possible failures to comply with MAURITAS requirements (it may be helpful to mention types of Non-Conformity);
- g) an explanation of what will happen at the Closing Meeting (presentation of findings using **F 3.07**, **F 3.14/F 3.34** and **F 3.09**) and confirmation of the attendees, time and venue;
- h) an assurance that all findings will be treated in strict confidence;
- i) arrangements for providing an office and any services needed by the Assessors/Technical Experts, e.g. photocopying;
- j) confirmation of work hours, lunch breaks etc;
- k) an opportunity for the Team Leader to invite the laboratory representatives to ask relevant questions.

12 Witnessing of the laboratory at work – the technical assessment

12.1 Witnessing of the laboratory performing its activities forms the most important part of the assessment through which Assessors/Technical Experts need to establish the laboratory's competence. The Assessors/Technical Experts should emphasize on the following:

- suitability of the methods
- equipment for calibrations/tests including its state of maintenance and calibration
- measurement traceability as per MAURITAS R3
- competence of laboratory staff
- technical records and reporting results
- effectiveness of the management system.

12.2 Where relevant, the potential Technical Signatories will be assessed by the Assessors/Technical Experts on their knowledge about the relevant accreditation standards as well as their knowledge on the techniques being assessed.

12.3 The Team Leader performs the horizontal assessment of management requirements using the relevant checklist (F 3.24 or F 3.20/F 3.30). The Assessor(s) or Technical Expert(s) together with the MS proceed(s) with the technical assessment as indicated in the table below:

Type of assessment	Horizontal (F3.25 or F3.21)	Vertical (F3.26 or F3.17)	Witnessing (F3.04)	Interview of TS (F3.05)
Initial Assessment	✓	✓	✓	✓
Assessment		✓	✓	
Re-assessment	✓	✓	✓	
Extension of scope		✓ (where relevant)	✓	
Approval of TS			✓	✓

12.4 Any non-conformities identified will be recorded in form F 3.07 and will be based on objective evidence. In order to avoid subsequent dispute, the assessment team will record the non-conformities, as they occur and must be agreed upon before leaving the area under assessment. Each non-conformity must be acknowledged by the accompanying laboratory representative(s).

12.5 As detailed in the assessment plan, the Assessors/Technical Experts will assess the calibration/test procedures and their implementation in the laboratory. It may not always be necessary to examine every procedure in operation because of the similarities between some calibrations/tests, but it is essential that the Assessors/Technical Experts check the implementation of the procedures for the calibrations/tests listed on the assessment plan. The Assessors/Technical Experts will verify the equipment involved, the manufacturer's manuals, and establish the status of calibration of the equipment.

12.6 The Assessor together with the MS will carry out vertical assessments (F3.17/F 3.33 or F3.26) Results from certificates or reports are traced back to the original entries in the laboratory's records. Aspects which require evidence from some other area of the laboratory before they can be settled may be noted down for further investigation, or may be referred to the member of the Assessment Team dealing with the area concerned.

12.7 During assessments of calibration laboratories, the Assessor/Technical Expert will establish the capability of the laboratories to make measurements that are traceable to national standards and according to the CMCs claimed for each parameter for which accreditation is being sought. This will include the examination of calibration certificates to ensure that imported CMCs and drift contributions can be substantiated. They will also examine the results obtained by the laboratories in measurement audits. In order to confirm the technical competence of the laboratory for calibrations carried out at customers' premises, it is necessary for Assessors/Technical Experts to witness its performance on specific calibrations at locations chosen by MAURITAS.

12.8 Assessors/Technical Experts together with the MS will verify the results of participation in Measurement Audits or Proficiency Testing as submitted by the laboratory in their latest updated PT plan submitted prior to the initial assessment.

12.9 The object of assessment is to establish by observation whether the work of the laboratory is being carried out in accordance with **ISO/IEC 17025** or of **ISO 15189**, relevant **MAURITAS R** Series documents, any other requirements specified by MAURITAS, and the laboratory's management system.

13 Recording failures to comply with MAURITAS requirements

13.1 The Non-Conformity form, **F 3.07**, records failure of the laboratory's arrangements to comply with the MAURITAS requirements and provide the objective evidence on which the Assessment Team's recommendations on accreditation to MAURITAS will be based.

13.2 The Non-Conformity form, **F3.07**, will contain only factual observations. These will be related to non-conformities with specific clauses in **ISO/IEC 17025** or in **ISO 15189** and any other requirements specified by MAURITAS.

13.3 Each Non-Conformity form, **F 3.07**, will be completed with the following information, but not limited to, at the time of assessment:

- a) where each non-conformity was made (location/activity);
- b) the system, calibration or test under discussion;
- c) any documents involved;
- d) a record of the non-conformity (where a particular non-conformity is repeated, this fact should be noted alongside the first non-conformity);
- e) the name(s) of the accompanying representative(s) of the laboratory with whom the matter was discussed;
- f) the signatures of the accompanying representative(s) of the laboratory and of the respective Assessment Team member.
- g) reference to the specific clause of the standard or MAURITAS Requirements.

13.4 Subsequently, each non-conformity identified will be classified. as major or minor.

13.4.1 A major non-conformity will be allocated for the failure of a system, within the overall management system, to comply with MAURITAS requirements.

Examples of major non-conformities would be:

- the absence of a document-control system;
- the absence of a procedure for internal audit or management review and evidence of implementation;
- a deviation that affects the result of the calibration/test;
- a calibration system that is not supported by laboratory-held MAURITAS calibration certificates or certificates issued by other laboratories recognised by MAURITAS;
- failure to take necessary corrective actions on previously raised non-conformities by MAURITAS;

- staff not technically competent to perform particular calibrations or tests;
- failure to control the quality of calibration/test data.

13.4.2 A minor non-Conformity will be allocated for a less significant failure to comply with MAURITAS requirements that will neither affect the integrity of the management system nor the calibration/test results.

Examples of minor non-conformities would be:

- errors in quality records corrected but not initialled;
- a certificate not dated;
- an organisation chart in the quality manual not up-to-date;
- evaluation of external service providers not carried out as scheduled.

13.5 Classification of non-conformities is done in consultation with the other team members during Assessors' Meeting.

14 Summary of findings

14.1 At the end of the assessment, after the Assessors/Technical Experts have completed their individual assignments, an Assessors' Meeting will be held at which each team member can summarise his or her own conclusions and contribute to a co-ordinated view of the laboratory's work.

14.2 At this stage, the Assessment Team will complete the Recommendation Report **F 3.09** which will summarise the Assessment Team's findings, key areas needing corrective action, strengths and weaknesses of the laboratory and the recommendation of the Assessment Team to MAURITAS. The recommendation may be for an unconditional offer of accreditation, for an offer to be deferred until the Non-Conformities have been cleared, or for refusal. In some cases, it may be appropriate for an offer of accreditation to be made for a reduced schedule. The Recommendation Report will make it clear which of these recommendations is being made. MAURITAS accreditation will be granted only after MAURITAS has received any evidence requested and has confirmed, after consultation with the Assessment Team, that all non-conformities have been cleared.

14.3 The Recommendation Report will be based on the content of the **F 3.07** forms and Summary of Non-Conformities, **F3.28** or **F 3.14/F 3.34** forms, and will indicate:

- the recommendation of the Assessment Team on the accreditation of the laboratory
- any areas for improvement
- the strengths of the laboratory
- the comment of Assessment Team on competence as determined through conformity
- where relevant, recommended Technical Signatory(ies)
- the deadline for submission of proposed and implemented corrective actions.

15 Factors affecting recommendations on accreditation

15.1 Where no Non-Conformities are found, the Assessment Team will recommend that accreditation be granted for the scope applied.

15.2 Where non-conformities are found, the recommendation will be that accreditation be granted subject to the satisfactory clearance of all the non-conformities within a period of 3 months for initial assessment. The laboratory must also submit the root cause analysis for all non-conformities raised. Depending upon the nature of the non-conformities, evidence that the corrective action has been taken will be provided either by posting or emailing copies of the necessary documents to MAURITAS or through a further on-site visit by a MAURITAS Assessment Team.

15.3 Where there are one or more areas of calibration or testing where major non-conformities have been identified/recorded, but there are no overall significant system failures, the Assessment Team may recommend accreditation for an appropriately reduced schedule.

15.4 Where the seriousness of the non-conformities found is such that the laboratory's management system and organisation is demonstrably inadequate, the Assessment Team will not recommend accreditation.

16 The Closing Meeting

16.1 The purpose of the Closing Meeting is to enable the Team Leader to present the laboratory management with a summary of the results of the assessment and to inform the management of the recommendations that the Assessment Team will make to MAURITAS. No matters will be included in the formal presentation of findings that do not appear in the Recommendation Report, **F3.09** or in the related Summary of Non-Conformities, **F 3.28** or **F3.14/F 3.34**.

16.2 The Closing Meeting will be chaired by the Team Leader who should, after referring to the purpose of the visit as explained at the Opening Meeting and will be as per the agenda **F1.04**, address the following items, normally in the order listed (**F 1.04**):

- a) thank the laboratory for its assistance and co-operation and refer to individuals as appropriate;
- b) emphasise that, because of the nature of the assessment, it does not follow that no non-conformities exist in areas where none have been reported;
- c) ask for questions to be deferred until after the findings have been presented, although points of clarification should not be refused;
- d) invite each Assessor/Technical Expert to summarise his or her findings, based on their Non-Conformity Forms **F 3.07**;
- e) in the case of long assessments, where assessors have completed their work before the Closing Meeting, the Team Leader should present the findings of any assessor not present. (In such instances, those reports would normally have been the subject of interim Closing Meetings with the laboratory management prior to the assessor's departure);
- f) present the summary, conclusions and recommendations which will take into account the factors described in section 'Factors affecting recommendations on accreditation' above;
- g) hand over the Non-Conformity forms, **F 3.07**, for management to sign and date each form;
- h) specify a date by which the proposed corrective actions recorded on **F3.07** along with the root cause analysis have to be submitted to MAURITAS (the period allowed should not be more than 1 month for an initial assessment and not more than 1 week for an assessment/re-assessment);
- i) specify a date by which any required corrective actions will be implemented (the period allowed should not be more than 3 months for an initial assessment and not more than 1.5 months for an assessment/re-assessment);
- j) obtain the signature of a management representative, or authorised deputy, on the Summary of Non-Conformities forms, **F 3.14/F 3.34** or **F3.28** and Recommendation Report **F 3.09**;

- k) provide the laboratory with an opportunity to discuss the assessment and to ask any questions;
- l) leave copies (not originals) of each Non-Conformity form, **F 3.07**, the Recommendation Report **F 3.09** and the Summary Report, **F 3.14/F 3.34 or F3.28**, with the laboratory. If copying facilities are not available, the originals should be returned immediately to MAURITAS for copying and despatch to the laboratory;
- m) close the meeting.

16.3 The Team Leader will fill in a Feedback on Assessment Form **F 1.21** at the end of each assessment and submit same to MAURITAS to indicate general aspects of the assessment process.

17 Post assessment

17.1 On receipt of proposed corrective action for any outstanding non-conformities, MAURITAS will consult with the Assessment Team who will confirm within 1 week, whether the proposed corrective actions are acceptable. If the proposed corrective actions are not acceptable, MAURITAS will act on the Assessment Team's recommendation and request the laboratory to submit new proposed corrective actions for the respective non-conformities within 1 week. MAURITAS will inform the laboratory when all proposed corrective actions are accepted and request the laboratory to submit evidence of implementation of same as per the agreed deadline.

17.2 On receipt of evidence of corrective action for any outstanding non-conformities, MAURITAS will consult with the Assessment Team who will confirm within 1 week, whether the non-conformities have been cleared. If the non-conformities have not been fully discharged, MAURITAS will act on the Assessment Team's recommendation and request the laboratory to submit new implemented corrective actions for the respective Non-Conformities within 1 week. When evidence has been obtained that all non-conformities have been satisfactorily discharged, the Team Leader/MS will submit this evidence in an accreditation report to the Director. The accreditation report together with the Director's recommendation for an agreed Schedule of Accreditation for calibrations or tests will then be submitted to the MAURITAS Accreditation Committee for the decision on accreditation. If the recommendation is approved by the Accreditation Committee, MAURITAS will notify the applicant accordingly. If the recommendation is not approved by the Accreditation Committee, MAURITAS will notify the applicant of the reasons and of any further action required. A decision not to grant accreditation, by the Accreditation Committee, can only be based on failure to meet MAURITAS requirements as evidenced through the above documentation.

17.3 In the event that the laboratory does not submit the proposed/implemented Corrective Actions as per agreed deadlines without any justified reason(s) or the laboratory continuously submits unsatisfactory proposed and implemented corrective actions, MAURITAS will not grant accreditation for the relevant scope.

17.4 When a further visit is required, the Assessor(s)/Technical Expert(s) will return to look specifically at the clearance of the non-conformities. Should some other potential Non-Conformity be observed during the visit, the Assessor(s)/Technical Expert(s) should bring this to the attention of management of the laboratory and report this, in writing, to MAURITAS.

17.5 MAURITAS accreditation also requires satisfactory completion of a MAURITAS measurement audit or proficiency testing.

17.6 MAURITAS will prepare the formal grant of accreditation, the certificate, schedule as per **MAURITAS A13** and contract agreement, **F1.13**. MAURITAS will arrange for the relevant signatures and submit them to the laboratory. On receipt of the signed contract agreement, MAURITAS will forward a soft copy of the Accreditation symbol/combined mark to the laboratory and indicate the tentative assessment dates in the 4-year accreditation cycle. The laboratory will also be requested to pay the annual fees.

17.7 After completion of the assessment, the assessment team destroys/deletes all Quality documentation as well as complaints, management review, internal audit reports, PT plan, Test Methods, Standard Operating Procedures and any other documents provided by the laboratory prior to the assessment. This is done by all assessment team members signing the form **F1.02** before the assessment and the signing the accreditation report after completion of the assessment.

18 Assessment and re-assessment

18.1 Following accreditation, laboratories will be subject to periodic assessment and re-assessment visits. The first assessment is normally carried out six months after the date of accreditation. Subsequent visits are carried out at yearly intervals. MAURITAS will establish and maintain a regular assessment and re-assessment visit programme. MAURITAS will ensure that the assessment and re-assessment visits are carried out within 1 month of the scheduled date (Refer to Annex B for Timeline).

The three assessment visits covering all the requirements of **ISO/IEC 17025 or ISO 15189** will be carried out during the accreditation cycle.

For testing laboratories performing in-house calibrations, MAURITAS will ensure that the laboratories' calibration systems are assessed at least once in every accreditation cycle.

This exercise will be carried out through witnessing of in-house calibration(s) **F 3.04**, vertical assessments **F 3.17/F 3.33** and assessment against relevant clauses under Technical Requirements **F 3.21/F 3.31 or F 3.25**.

18.2 The purpose of these visits, is to determine whether or not a laboratory is continuing to comply with **ISO/IEC 17025 or ISO 15189**, **MAURITAS R** Series documents, and any other requirements specified by MAURITAS. The general approach described in this publication shall be followed for the conduct of assessment or re-assessment visits. In addition, at the Opening Meeting, the Team Leader will establish whether all significant changes in the laboratory status or operation have been notified to MAURITAS (see **MAURITAS R1**).

18.3 If, during a assessment or re-assessment visit, it is found that there have been significant changes, e.g. of staff, equipment or the range of services available, these matters will be recorded by the Assessment Team who will check whether the changes are not such as to diminish the laboratory's capabilities as described in the Schedule of Accreditation, and that they have already been fully notified to MAURITAS as required by **ISO/IEC 17025 or ISO 15189** and **MAURITAS R1**.

18.4 During a single assessment visit, Assessors/Technical Experts will not be expected to check the whole of the calibration/testing work for which a laboratory is accredited. However, MAURITAS will ensure that the Assessment Teams assess the complete range of calibrations or tests for which the laboratory is accredited during the accreditation cycle as detailed in the assessment programme. MAURITAS will assess key elements of the management system, including but not limited to management review and internal audit, during each assessment visit.

18.5 A re-assessment visit will involve a comprehensive re-examination of the laboratory's management system and calibration/testing activities and will be similar in format and detail to the initial assessment. The first re-assessment visit will take place three and a half years after the date of accreditation, and thereafter at four-yearly intervals.

18.6 MAURITAS will perform a sampling of all other locations of the laboratory where key activities (collection points, sampling points, etc...) are carried out, to be assessed by the Assessment Team so as to have a representative sample of the laboratory's activities are assessed. MAURITAS will also perform a sampling similar to testing/calibration activities (including similar steps) so that the whole schedule of accreditation is assessed during the three assessments and re-assessment visits. MAURITAS will also ensure that a representative number of the laboratory's staff is witnessed at the different assessment and re-assessment visits. The Assessment Team will make use of a combination of witnessing and vertical assessments to cover a sample of the accredited scope as well as horizontal assessments to clauses of the accreditation standard in case of re-assessments. MAURITAS will request, at least one month prior to the assessment or re-assessment, the updated

Quality documentation, complaints, updated PT plan received since last assessment visit as well as latest management review and internal audit reports.

In the case of re-assessment, the laboratory will be required to submit the PT plan for the next cycle so that MAURITAS can analyse same and determine whether it is appropriate.

The Assessment Team may be asked to concentrate particularly on any areas of calibration/testing where there is reason to believe standards have not been maintained, where non-conformities were observed during previous visits, or where there have been changes in staff.

18.7 The Team Leader or the MS forming part the Assessment Team, at the conclusion of an assessment or re-assessment visit, as with an initial assessment, will be required to submit an assessment report along with the recommendation to MAURITAS on the continuing accreditation of the laboratory, using the same forms as used at the initial assessment. Depending on the seriousness of non-conformities identified, the Assessment Team will recommend whether accreditation should be:

- a) maintained unconditionally (this recommendation will be made only when no non-conformities have been identified),
- b) maintained on the understanding that proposed corrective actions are submitted to MAURITAS within a specified time period (usually no more than 1 week),
- c) maintained on the understanding that implemented corrective actions are submitted to MAURITAS within a specified time period (usually not more than 1.5 months),
- d) maintained, but for a reduced Schedule of Accreditation,
- e) suspended until the laboratory has corrected the Non-Conformities found within a specified time period (normally no more than 6 months), or

NOTE: A recommendation that the accreditation of a laboratory is suspended will almost certainly require a further visit to confirm that the non-conformities have been cleared.

- f) withdrawn/terminated.

18.8 Suspension or withdrawal/termination of accreditation will only be recommended where the seriousness of the non-conformities found is such that the laboratory's management system has broken down, and MAURITAS requirements can no longer be met.

18.9 In the event that the laboratory does not submit the proposed/implemented corrective actions as per agreed deadlines without any justified reason(s) or the laboratory continuously submits unsatisfactory proposed and implemented corrective actions, MAURITAS will proceed with the suspension or reduction of scope of the laboratory or withdrawal/termination.

18.10 On receipt of the confirmation by the Assessment Team that all non-conformities have been cleared, the Team Leader will finalise and submit an accreditation report to the Secretary of the Accreditation Committee. The accreditation report together with the Director's recommendation will then be submitted to the MAURITAS Accreditation Committee for the decision on accreditation. When the maintenance of accreditation is not related to re-assessment and there is no modification to the scope, the decision will be taken by the Director. MAURITAS will inform the laboratory of the decision of the Accreditation Committee within one week.

18.11 When the maintenance of accreditation is not related to a re-assessment and there is no modification to the scope, the decision may be taken by the Director, except in the following cases:

- the scope of accreditation contains more than three testing and calibration fields;
- the number of non-conformities, in particular, major ones is consequent; and
- the risks associated with the laboratory's activities, location and personnel is considerable.

18.12 Applications for major changes to a Laboratory's Schedule of Accreditation involving extension to new fields of testing or calibration or to new parameters within the same accredited testing or calibration field or addition of new Technical Signatories should be submitted to MAURITAS at least 3 months before the next visit in order for the assessment to be arranged, including the appointment of new Assessors/Technical Experts as necessary. Such applications should be made on the relevant application form and accompanied by the associated documentation and fees.

18.13 When a decision is taken for renewal of a laboratory's accreditation, MAURITAS will ensure that there are no laps/discontinuation in the accreditation cycle and therefore, the following shall be applicable:

- In the event that the process is completed before the expiry date, the renewal of accreditation will be effective on a date right after the expiry.
- In case the process is not yet completed before the expiry date:
 - MAURITAS will suspend the laboratory for a maximum period of 4 months in case the delay for renewal is attributable to the laboratory. The re-instatement/renewal will be effective on the date right after the expiry;
 - The Accreditation Committee will extend the validity of the accreditation for a maximum period of three months in case the delay for renewing is attributable to MAURITAS. The re-instatement/renewal of accreditation will be effective on the date right after the expiry.

18.14 If there is evidence of fraudulent behaviour, if the accredited laboratory intentionally provides false information or if the accredited laboratory conceals information, MAURITAS will take necessary actions for withdrawal/termination of accreditation.

19 Extension of scope of accreditation

19.1 When a laboratory applies for an extension to its Schedule of Accreditation, including the addition of new Technical Signatories, MAURITAS will carry out an on-site assessment to ascertain whether the laboratory is technically competent to carry out the extension applied for or whether the Technical Signatories are competent. The extension of scope will be performed by a combination of witnessing and vertical assessment.

19.2 If the extension is assessed during a scheduled visit it should not be allowed to reduce the effectiveness and coverage of the normal assessment/re-assessment visits.

19.3 The laboratories will be required to follow the timelines as defined in **Annex C**.

20 Related Forms

FORMS USED DURING INITIAL ASSESSMENT, ASSESSMENT AND RE-ASSESSMENT VISITS	GENERAL LABORATORIES	MEDICAL LABORATORIES
Application Form: General Laboratories: ISO/IEC 17025	F 3.15	-
Self-Assessment Checklist	F 3.23	-
Application Form: Medical Laboratories: ISO 15189	-	F3.16
Self-Assessment for ISO 15189:2012 Requirements	-	F3.19
Agenda Opening Meeting	F 1.01	F1.01
Agenda Closing Meeting	F1.04	F1.04
Attendance Sheet	F1.03	F1.03
Summary of Participation in Proficiency Testing: ISO/IEC 17025 / ISO 15189	F 3.06	F3.06
Assessment Management Requirements: ISO/IEC 17025	F 3.24	-
Assessment Technical Requirements: ISO/IEC 17025	F3.25	-
Non-Conformity Form: ISO/IEC 17025 / ISO 15189	F3.07	F3.07
Vertical Assessment : ISO/IEC 17025	F 3.26	-
Vertical Assessment : ISO 15189	-	F 3. 17
Witnessing Sheet: ISO/IEC 17025 / ISO 15189	F 3.04	F3.04
Recommendation for Technical Signatory	F 3.05	-
Summary of Non-Conformity: ISO/IEC 17025	F 3.28	-
Assessment of Management Requirements- ISO 15189:2012	-	F 3.20
Assessment of Technical Requirements- ISO 15189 :2012	-	F 3.21
Recommendation Report: ISO/IEC 17025 / ISO 15189	F 3.09	F 3.09
Summary of Non-Conformity: ISO 15189	-	F 3.14
Declaration of Confidentiality for Assessors/Technical Experts	F 1.02	F1.02
Checklist for Assessor's Pack ISO/IEC 17025	F 1.16	-
Checklist for Assessor's Pack ISO 15189	-	F1.17
Feedback on Assessment Form	F1.21	F1.21
Self-Assessment on ISO 15189:2022 Requirements	-	F 3.29
Assessment of Management Requirements: ISO 15189:2022	-	F 3.30
Assessment of Technical Requirements: ISO 15189:2022	-	F 3.31
Application Form: Medical Laboratories: ISO 15189:2022	-	F 3.32
Vertical Assessment: ISO 15189:2022	-	F 3. 33
Summary of Non-Conformity: ISO 15189:2022	-	F 3.34

Appendix A: Amendment Table

SN	Section	Amendment
1.	9.2	'-Updated PT plan including results of PT participation prior to initial assessment and -PT plan for the first accreditation cycle' has been amended
2.	18.6	1. 'In the case of re-assessment, whether it is appropriate' has been added after the first paragraph
3.	Throughout the document, where relevant	1. The codes of the new forms that will be used for ISO 15189:2022 have been included.
4.	6.1	1. 'validation report, uncertainty of measurement calculations' has been added to the sentence to include which documents the laboratory has to submit at the time of application
5.	12.3	1. A table has been included which provides information when horizontal assessment has to be carried out on the technical requirements
6.	17.3 and 18.9	1. 'or the laboratory continuously submits unsatisfactory proposed and implemented corrective actions' has been added to the paragraph
7.	17.7	1. A new paragraph has been added regarding destroying documents submitted by laboratories after completion of assessment

Annex A: Timeline for Applicant Laboratories

Process	Time Frame (Days)
<p>Application</p> <p>MAURITAS receives a Complete Application form from Laboratory with associated documents (Quality documentation and Self-Assessment Checklists) and the application fee.</p>	Day 01
↓	
<p>Review of Quality documentation, Self-Assessment Checklist, Application Form and selection of assessors</p> <p>MAURITAS reviews the application form and verifies that the Quality documentation addresses all the key elements as specified in ISO/IEC 17025 or ISO 15189 and MAURITAS R Documents. This process lasts for a maximum of <u>3 MONTHS</u>.</p>	Day 90
↓	
<p>Preliminary Visit (Optional)</p> <p>After reviewing the Quality documentation, MAURITAS will inform the laboratory whether it is in a position to proceed with a preliminary visit, an initial assessment or it is not ready at all. The optional preliminary visit exercise is usually carried out by the Team Leader and Assessor in <u>1 DAY</u>.</p>	Day 120
↓ (assuming that the lab is ready within 3 months)	
<p>Initial Assessment</p> <p>Based on the recommendations of the Team Leader on the Document review or the preliminary visit, the laboratory will inform MAURITAS when it is ready for an initial assessment. MAURITAS will then inform the lab of the initial assessment plan, the proposed Assessment Team and the assessment Fee. The initial assessment will normally last for <u>3 DAYS or more, depending on the scope of accreditation</u>.</p>	Day 210
↓	
<p>Proposed Corrective actions submitted by CAB</p> <p>Within 1 month, the CAB shall provide any proposed corrective action with root cause analysis that they intend to implement in order to address the non-conformities raised during the initial assessment.</p>	Day 240
↓	
<p>Acceptance by Assessors</p> <p>MAURITAS will then consult with the Assessment Team involved and within 1 week, the latter will confirm whether the non-conformities have been satisfactorily addressed. If not, the laboratory is given an additional 1 week to send to MAURITAS a new proposed corrective action with root cause analysis to which the Assessment Team will take another 1 week for approval.</p>	Day 254(Max) Day 247 (Min)



Implemented Corrective Action

Following the approval of Assessment Team on the proposed corrective actions, the laboratory has 3 months' time from the date of the assessment to submit to MAURITAS evidence for implementation of corrective actions for the non-conformities.

Day 344 (Max)

Day 337 (Min)



Acceptance of Implemented Corrective Actions

After receiving evidence of implemented corrective action, MAURITAS will again consult with the Assessment Team to confirm whether the non-conformities have been satisfactorily cleared within 1 week. If not, the laboratory is given an additional 1 week to send to MAURITAS a further evidence for the implemented corrective action to which the assessors will take another 1 week for approval.

Day 365 (Max)

Day 344 (Min)



Accreditation Report

Upon satisfactory clearance of all non-conformities, within 1.5 months, the Team Leader will prepare the Accreditation report where he/she will present evidence of clearance of non-conformities. This Accreditation report will be submitted to the Accreditation Committee.

Recommendation for accreditation is also made to the Accreditation Committee.

Day 410 (Max)

Day 389 (Min)



Accreditation Committee

Based on the Accreditation report and on satisfactory evidence that the requirements of standards and regulations are being met, the Accreditation Committee will grant accreditation to the Laboratory.

Day 440 (Max)

Day 419 (Min)

Total

Max: 440 days (15 months)

Min: 419 days (14 Months)

Annex B: Timeline for Accredited Laboratories

Process	Time Frame (Days)
<p>Assessment / Re-assessment</p> <p>Once the laboratory has been granted accreditation, it will be subject to periodic visits by MAURITAS. The First assessment visit is usually scheduled 6 months after the date of grant of accreditation. The second and third assessments are then carried out on a yearly basis. 1 year after the 3rd assessment, a re-assessment is done marking the start of the 2nd accreditation cycle. The laboratory is informed of the assessment date (usually within 1 month of the scheduled date), the plan, Assessment Team and fees.</p>	Day 01
↓	
<p>Proposed Corrective Action</p> <p>The laboratory has 1 weeks' time to send to MAURITAS the proposed corrective actions with root cause analysis for the non-conformities raised during the assessment visit.</p>	Day 08
↓	
<p>Acceptance by Assessors</p> <p>MAURITAS will then consult with the Assessment Team involved and within 1 week; the latter will confirm whether the non-conformities have been satisfactorily addressed. If not, the laboratory is given an additional 1 week to send to MAURITAS a new proposed corrective action with root cause analysis to which the Assessment Team will take another 1 week for approval.</p>	Day 29 (Max) Day 15 (Min)
↓	
<p>Implemented Corrective Action</p> <p>Following the approval of Assessment Team on the proposed corrective actions, the laboratory has 1.5 months' time from the date of the assessment to submit to MAURITAS evidence for implementation of corrective actions for the non-conformities.</p>	Day 74 (Max) Day 60 (Min)
↓	
<p>Acceptance of Implemented Corrective Actions</p> <p>After receiving evidence of implemented corrective action, MAURITAS will again consult with the Assessment Team to confirm whether the non-conformities have been satisfactorily discharged within 1 week. . If not, the laboratory is given an additional 1 week to send to MAURITAS further evidence of implemented corrective actions to which the Assessment Team will take another 1 week for approval.</p>	Day 95 (Max) Day 67 (Min)
↓	
<p>Accreditation Report</p> <p>Upon satisfactory clearance of all non-conformities, within 1.5 months, the Team Leader will prepare the Accreditation report where he/she will present evidence of clearance of non-conformities. This Accreditation report will be submitted to the Accreditation Committee. Recommendation for accreditation is also made to the Accreditation Committee.</p>	Day 140 (Max) Day 112 (Min)



Accreditation Committee

Based on the Accreditation report and on satisfactory evidence that the requirements of standards and regulations are being met, the Accreditation Committee will grant accreditation to the Laboratory. When the maintenance of accreditation is not related to re-assessment and there is no modification to the scope, the decision will be taken by the Director.

Day 170 (Max)

Day 142 (Min)

Total

Max of 170 days (6
mnths)

Min of 142 days (5
mnths)

Annex C: Timeline for Extension of Scope of Accreditation

Process	Time Frame (Days)
<p>Application for Extension to Schedule of Accreditation</p> <p>When the laboratory applies for an Extension of its Schedule of Accreditation, it has to send a completed application form to MAURITAS along with the respective application fee, the method procedures, method validation reports and evidence of participation in Proficiency Testing for the scope applied.</p>	Day 01
↓	
<p>Review of Application Form and Selection of Assessors</p> <p>MAURITAS reviews the application form and performs a Resource Review for the availability of technical Assessors/Technical Experts in the fields for which extension has been applied.</p>	Day 31
↓ (assuming that the lab is ready within 1 month)	
<p>On-site Assessment</p> <p>Following the Application review and Resource Review, MAURITAS will then inform the laboratory whether and when it will proceed with an on-site assessment. The on-site assessment is done to ascertain whether the laboratory is technical competent to carry out the extension it has applied for. The duration of the on-site assessment may vary from 1 DAY to 3 DAYS depending on the size of the extension applied.</p>	Day 61
↓	
<p>Proposed Corrective Action</p> <p>The laboratory has 1 weeks' time to send to MAURITAS the proposed corrective actions with root cause analysis for the non-conformities raised during the on-site visit.</p>	Day 68
↓	
<p>Acceptance by Assessors</p> <p>MAURITAS will then consult with the Assessment Team involved and within 1 week; the latter will confirm whether the non-conformities have been satisfactorily addressed. If not, the laboratory is given an additional 1 week to send to MAURITAS a new proposed corrective action to which the assessors will take another 1 week for approval.</p>	Day 89(Max) Day 75 (Min)
↓	
<p>Implemented Corrective Action</p> <p>Following the approval of assessors on the proposed corrective actions, the laboratory has 1.5 months' time from the date of the assessment to submit to MAURITAS evidence for implementation of corrective actions for the non-conformities.</p>	Day 134 (Max) Day 120 (Min)
↓	
<p>Acceptance of Implemented Corrective Actions</p>	Day 149

<p>After receiving evidence of implemented corrective action, MAURITAS will again consult with the Assessment Team to confirm whether the non-conformities have been satisfactorily discharged within 1 week. If not, the laboratory is given an additional 1 week to send to MAURITAS further evidence for implemented corrective actions to which the Assessment Team will take another 1 week for approval.</p>	<p>(Max) Day 127 (Min)</p>
↓	
Accreditation Report	
<p>Upon satisfactory clearance of all non-conformities, within 1.5 months, the Team Leader will prepare the Accreditation report where he/she will present evidence of discharge of non-conformities. This Accreditation report will be submitted to the Accreditation Committee. Recommendation for accreditation is also made to the Accreditation Committee.</p>	<p>Day 194 (Max) Day 172 (Min)</p>
↓	
Accreditation Committee	
<p>Based on the Accreditation report and on satisfactory evidence that the requirements of standards and regulations are being met, the Accreditation Committee will grant/maintain accreditation to the Laboratory.</p>	<p>Day 224 (Max) Day 202 (Min)</p>
Total	
	<p>Max of 224 days (7.5 mnths) Min of 202 days (7 mnths)</p>