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MAURITAS
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Procedure for Assessment - Laboratories

Mauritius Accreditation Service

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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 categorized 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 organizations.

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Procedure for Assessment - Laboratories

1 Purpose

1.1 This procedure shall ensure a uniform, harmonized and correct execution of the processes associated with the accreditation of calibration and testing laboratories.

2 Scope and Responsibilities

2.1 This procedure sets out how MAURITAS assessments 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 level. This procedure also describes the preparation, conduct and reporting of MAURITAS laboratory assessments.

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 - 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/IAF JWG A-Series FAQ1**		
3.7	**ILAC P5**	**:**	ILAC Mutual Recognition Arrangement: Scope and Obligations
3.8	**ILAC P8**	**:**	ILAC Mutual Recognition Arrangement (Arrangement): Supplementary Requirements for the Use of Accreditation Symbols and for Claims of Accreditation Status by Accredited Conformity Assessment Bodies
3.9	**ILAC P9**	**:**	ILAC Policy for Proficiency Testing and/or Interlaboratory other than comparisons other than Proficiency Testing
3.10	**ILAC P10**	**:**	ILAC Policy on Metrological Traceability of Measurement Results
3.11	**ILAC P14**	**:**	ILAC Policy for Measurement Uncertainty in Calibration
3.12	**ILAC G17**	**:**	ILAC Guidelines for Measurement Uncertainty in Testing

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 Nonconformities
Major nonconformities are nonconformities where the credibility of the laboratory's accreditation is seriously threatened or where tests/calibration results are affected.

4.3 Minor Nonconformities
Minor nonconformities are nonconformities that are isolated and would not affect the results of the testing/calibration activities of the laboratory.

4.4 Technical Signatory
A Technical Signatory (not applicable to Medical Testing Laboratories) is 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.

4.5 Assessment programme
Set of assessments consistent with a specific accreditation scheme that MAURITAS performs on a specific laboratory during an accreditation cycle

4.6 Assessment plan
Description of the activities and arrangements for an assessment

4.7 MAURITAS Staff
Internal staff carrying out relevant accreditation activities during assessments.

4.8 Assessor
Person assigned by MAURITAS to perform, alone or as part of an Assessment Team, an assessment of a conformity assessment body

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

4.10 Technical Expert
Person assigned by MAURITAS, 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).

4.11 Case Officer
MAURITAS personnel who has been assigned specific laboratory files.

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 3.32**), duly completed Self-Assessment checklist (**F 3.23 or F 3.29**), CVs of potential Technical Signatories where relevant, method validation/measurement of uncertainty

reports and its quality documentation. It is however essential to verify 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, that is, **ISO/IEC 17025** or **ISO 15189** and **MAURITAS R** Series documents. In some circumstances specialised publications issued by MAURITAS or other national, regional (African Accreditation Cooperation (AFRAC) and Southern African Development Community Cooperation in Accreditation (SADCA)) or international organisations, (International Laboratory Accreditation Cooperation (ILAC)) and endorsed by MAURITAS, provide interpretations of these requirements.

5.2 The services of 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 an 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 the staff of MAURITAS, by external Assessors/Technical Experts/Observers 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 The MS will 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 to queries from the laboratory management on such matters during assessment visits. The MS will also assist the Technical Expert with the interpretation of MAURITAS requirements in appropriate circumstances.

5.6 This procedure is applicable to all sizes of laboratories including laboratories carrying out a wide range of calibrations/tests and those performing just a few calibrations/tests. Where reference is made in the assessment procedure to '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 assessment, re-assessment, extension of schedule, on-site clearance of nonconformities, 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 3.32**, providing details of its staff, equipment and facilities, and specifying the types of calibration/test for which accreditation is sought. It also submits to MAURITAS a copy of its Quality documentation, detailing the quality policies and procedures of the management system operating in the laboratory and pays the applicable Application Fee. The laboratory has to provide validation reports, uncertainty of measurement calculations, information on equipment, methods/techniques, CVs of potential Technical Signatories where relevant and its participation in Proficiency Testing (PT)/External Quality Assurance Schemes (EQAS) for calibrations/tests to be accredited. In addition,

all applicant laboratories shall carry out a Self-assessment exercise and submit the completed forms, **F 3.29** for medical testing laboratories and **F 3.23** for general calibration/testing laboratories.

6.2 On receipt of the Application Form and associated documentation, the Director of MAURITAS (hereinafter referred to as the Director) forwards same to the Accreditation Manager responsible for the Laboratory Accreditation Section, hereinafter referred to as the Accreditation Manager, to deal with the application. The Accreditation Manager will review the Application Form for its completeness and then assigns a Case Officer to further process the application. The Case Officer will discuss with the laboratory's representative of any shortcomings during the processing of the application. As far as possible, MAURITAS also ensures that the same Case Officer is responsible for processing that laboratory's application through to the accreditation stage and for liaising with the laboratory.

6.3 The Case Officer ensures that the Application Form and Self-assessment report have 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.

6.4 The Case Officer is responsible for proposing an Assessment Team considering the range and volume of calibration or testing involved. The Case Officer shall carry out a preliminary resource review exercise (**F 1.09**) to determine the ability of MAURITAS to accept the application, in terms of MAURITAS policy and procedures, competence and availability of suitable Team Leaders, Assessors and Technical Experts. The review shall also take into consideration the ability of MAURITAS to carry out the assessment in a timely manner as defined in Appendix B. MAURITAS shall inform the applicant laboratory if it is not able to carry out the initial assessment in a timely manner. The Resource Review (**F 1.09**) is then submitted to the Accreditation Manager for recommendation and to the Director for approval.

6.5 In the event that MAURITAS does not have the required resources, the laboratory will be informed that its application cannot be processed further.

6.6 If MAURITAS can process the application, the Case Officer will perform another resource review exercise (**F 1.09**) for document review and send to the Accreditation Manager for recommendation and to the Director for approval. Before confirming the composition of the Assessment Team with the laboratory management, MAURITAS shall request all the proposed members of the Assessment Team to declare any former, existing or envisaged link or competitive position between themselves/their parent organisation and the laboratory to be assessed by filling the form **F 1.23**. In the event that one or more of the proposed team members declare any interest or link, the Case Officer shall repeat the resource review process with new proposed team members.

6.7 The Case Officer then advises the applicant of the proposed Assessment Team (and the organisation to which they belong) who have been selected to perform the document review prior to starting the exercise. New Assessment Team members shall have to be appointed if they are not accepted by the applicant, and actions shall have to be recommended based on the applicant's valid reasons. However, if the reasons are not considered to be valid and local Team Leaders/Assessors/Technical Experts are not available, the laboratory shall have to bear the cost of using foreign Team Leaders/Assessors/Technical Experts.

6.8 The Case Officer sends a copy of the Quality documentation, Self-assessment checklist, method validation report and uncertainty of measurement calculations submitted by the laboratory to the Assessment Team for document review, together with any comments that may be appropriate. The document review exercise shall be performed only once by the assigned Assessment Team for a particular application made by a laboratory.

6.9 Following the document review using the relevant Self-assessment checklists (**F 3.29** and **F 3.23**), the Team Leader shall provide same, together with a document review report to MAURITAS, giving detailed

comments on the laboratory's compliance with the relevant accreditation standard and MAURITAS requirements. The Assessment Team shall recommend which of the following actions should be taken:

a) the organisation is not in a position to proceed to preliminary visit; or

b) the organisation is ready for a preliminary visit; or

c) the organisation is ready for an initial assessment.

6.10 The document review report, together with the recommendation of the Assessment Team, is transmitted to the laboratory.

6.11 In the case that MAURITAS decides not to proceed with the on-site assessment based on the nonconformities identified during the document review exercise, the nonconformities shall be reported to the laboratory in writing and the application is rejected.

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

7 Preliminary Visit

7.1 In the event that the Assessment Team recommends or the laboratory requests that a preliminary visit be carried out, the Case Officer will make the arrangements for the visit, including an estimate for the assessment fee.

7.2 Where the recommendation of the Team Leader 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 an Assessment Team is completed in 1 day. The Case Officer will perform a resource review exercise (**F 1.09**) and send to the Accreditation Manager for recommendation and to the Director for approval. Before confirming the composition of the Assessment Team with the laboratory management, the Case Officer shall request all the proposed members of the Assessment Team to declare any former, existing or envisaged link or competitive position between themselves/their parent organisation and the laboratory to be assessed by filling the form **F 1.23**. In the event that one or more of the proposed team members declares any interest or link, MAURITAS shall assess whether the declared interest is considered as a threat to impartiality. The Case Officer shall repeat the resource review process with new proposed team members if there are any threats to impartiality.

The Case Officer then advises the applicant of the proposed Assessment Team (and the organisation to which they belong), the assessment dates and fees to be charged at least two weeks prior to the preliminary visit. New Team Leaders/Assessors/Technical Experts shall be appointed if they are not accepted by the applicant, and actions shall be recommended based on the applicant's valid reasons. However, if the reasons are not considered to be valid and local Team Leaders/Assessors/Technical Experts are not available, the laboratory shall have to bear the cost of using foreign Team Leaders/Assessors/Technical Experts.

7.5 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 MAURITAS requirements.

7.6 The visit shall 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 need 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 need 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.

7.7 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 3.30** and **F 3.31**), the Assessment Team should take the opportunity to discuss the proposed accreditation schedule as per **MAURITAS A13** and to carry out a brief examination of the laboratory's calibration/testing facilities. All nonconformities identified will be recorded on preliminary visit findings form **F 1.20**. The Assessment Team shall not, at any stage of the preliminary visit, provide guidance on how to implement the requirements of the relevant standard.

7.8 If the laboratory uses documented in-house methods for calibration/testing, the Assessment Team should discuss 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 PT programmes, and the laboratory's policy and procedures for estimating uncertainty of measurement.

7.9 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 a copy of the preliminary visit findings form, **F 1.20** to the laboratory.

7.10 Following the preliminary visit, the findings shall be reported by the Team Leader to the Case Officer, in writing. The report shall indicate:

a) whether plans for initial assessment of the laboratory can proceed; or

b) specific reasons why plans cannot proceed.

The recommendations should be supported by general and detailed comments.

MAURITAS shall inform the applicant laboratory, in writing, about appropriate course of action based on the recommendation of the Assessment Team. MAURITAS will not issue to the laboratory any detailed checklist or documents that have been used during the course of the preliminary visit.

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, **F 3.15** or **F 3.32** (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 The Assessment Team shall consider and discuss with the Case Officer the precise terms in which the accreditation is to be defined on the schedule. This shall be done as early as possible in the accreditation process.

8.3 For schedules of calibration, the type of calibration, the calibration method or procedure, the range of measurements and the technical signatories to be assessed shall be provisionally agreed prior to the initial assessment. During the initial assessment and after examination of the results of measurement audits, the content of the schedule shall 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.

8.4 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 Assessment Team to operate effectively, focusing their attention on those areas of activity detailed on the proposed accreditation schedule.

8.5 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 prepared accreditation schedule. In such cases, the Assessment Team, may be able to recommend accreditation for a suitably reduced or redefined accreditation schedule.

8.6 Accreditation schedules are in the public domain 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. The Case Officer shall carry out the resource review exercise (**F 1.09**). Before confirming the composition of the Assessment Team and any observers to the laboratory management, MAURITAS shall request all the proposed members of the Assessment Team and observers to declare any former, existing or envisaged link or competitive position between themselves/their parent organisation and the laboratory to be assessed by filling the form **F 1.23**.
In the event that one or more of the proposed team members or observers declare any interest or link, MAURITAS shall assess whether the declared interest is considered as a threat to impartiality. The Case Officer shall repeat the resource review process with new proposed team members or observer, if any, in case there are any threats to impartiality.

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

a) Calibration/Test method(s);

b) Updated method validation report;

c) Updated Measurement of Uncertainty calculations; and

d) Updated PT plan including results of PT participation prior to initial assessment.

9.3 Prior to each assessment, applicant/accredited calibration laboratories shall also submit the calibration certificates for all relevant measurement standards and equipment for all parameters. These certificates shall demonstrate valid metrological traceability to the International System of Units (SI) or to appropriate national or international reference standards.

9.4 The Case Officer shall, in consultation with the approved Assessment Team, prepare an initial assessment plan. This plan shall indicate the section/activities in the laboratory to be assessed by each Assessor/Technical Expert. The plan shall also include the relevant clauses of the standard to be covered during the horizontal assessment, the witnessing, and the vertical assessment. The assessment of applicant Technical Signatories will be carried out. The plan shall meet the requirements of **MAURITAS A24** and 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 shall also take into consideration witnessing of a representative number of the laboratory's staff performing calibrations/tests so as to assess the competence of the laboratory across its schedule of accreditation. The Case Officer shall take into consideration any risks associated with the applicant laboratory's activities, location and personnel when developing the assessment plan (e.g. findings identified during the document review and/or preliminary visit stage).

9.5 The Case Officer shall 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 shall make use of a combination of witnessing and vertical assessments to cover the whole scope applied for accreditation as well as horizontal assessments to ensure that accreditation criteria are met.

9.6 The Case Officer then advises the applicant of the proposed Assessment Team and any observers (and the organisation to which they belong), the assessment dates and fees to be charged at least one week prior to the Initial Assessment. New Team Leaders/Assessors/Technical Experts and observers, if any, shall have to be appointed if they are not accepted by the applicant, and actions shall be recommended based on the applicant's valid reasons. However, if the reasons are not considered to be valid and local Team Leaders/Assessors/Technical Experts are not available, the laboratory shall have to bear the cost of using foreign Team Leaders/Assessors/Technical Experts.

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

9.8 The Case Officer makes use of the form **F 1.16** or **F 1.17** for preparation of the assessment packs which are then provided to the Assessment Team.

9.9 The Assessment Team shall perform the initial assessment as per the assessment plan. The Team Leader shall 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, a briefing meeting is carried out by the Team Leader/MS with the Assessment Team, using the form **F1.15** to ensure the following:

a) All Assessors/ Technical Experts/Observers have received the required documentation;

b) All Assessors/MS have carried out their respective review prior to the initial assessment;

c) Confirmation of parameters to be witnessed;

d) Confirmation of parameters for vertical assessment; and

e) Clarification of any queries.

10.2 The initial assessment visit begins with an Opening Meeting between the Assessment Team and representatives of the laboratory. 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 Assessor/Technical Expert proceeds with the assessment of the technical requirements/witnessing. Each Assessor/Technical Expert shall be accompanied by at least a laboratory staff nominated by the management. Only staff of the organisation will be assessed by MAURITAS. Consultants will not be assessed by MAURITAS and shall 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 present 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 more 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. The findings (if any) of each member of the Assessment Team may also be discussed during this meeting. An interim Closing Meeting may be held with the laboratory management if some members of the Assessment Team have completed their work or if the assessment lasts more 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 The purpose of the Opening Meeting is to ensure that the laboratory management and staff understand the processes involved during the assessment. It is chaired by the Team Leader and shall cover the agenda according to **F 1.01**. The laboratory shall be informed that no addition to the scope to be covered during the assessment would be allowed after the end of the Opening Meeting. During assessments, the Assessment Team may consider alterations to the scope to be covered only in exceptional cases, e.g. breakdown of specific equipment.

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 evaluate the laboratory's competence. The Assessors/Technical Experts shall emphasize on the following:

a) suitability of the methods;

b) equipment for calibrations/tests including its state of maintenance and calibration;

c) measurement traceability as per MAURITAS R3;

d) competence of laboratory staff;

e) technical records and reporting results; and

f) effectiveness of the management system.

12.2 Where relevant, the applicant 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 (calibration or testing) being assessed.

12.3 The Team Leader performs the horizontal assessment of management requirements using the relevant checklist (**F 3.24** or **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 (F 3.25 or F 3.31)**	**Vertical (F 3.26 or F 3.33)**	**Witnessing (F 3.04)**	**Interview of Technical Signatory (F 3.05)**
Initial Assessment	✓	✓	✓	✓

12.4 Any nonconformities identified shall be recorded in form **F 3.07** and shall be based on objective evidence. In order to avoid subsequent dispute, the Assessment Team shall record the nonconformities, as they occur and shall be agreed upon before leaving the area under assessment. Each nonconformity shall be acknowledged by the accompanying laboratory representative(s).

12.5 As detailed in the assessment plan, the Assessors/Technical Experts shall 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 in the techniques of the 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 shall verify the equipment involved, the manufacturer's manuals, and the status of calibration of the equipment.

12.6 Assessor(s)/Technical Expert(s) together with MS shall carry out vertical assessments (**F 3.26** or **F 3.33**). 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(s)/Technical Expert(s) shall 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 Assessor(s)/ Technical Expert(s) to witness its performance on specific calibrations at locations chosen by MAURITAS.

12.8 Assessors/Technical Experts together with the MS shall verify the results of participation in Measurement Audits or Proficiency Testing or External Quality Assurance Schemes (EQAS) as submitted by the laboratory in their latest updated PT plan submitted prior to the initial assessment.

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

12.10 Assessors/Technical Experts should restrict their assessment to the laboratory's compliance with MAURITAS requirements and to the calibrations/tests for which accreditation is sought. Assessors/Technical Experts shall have a positive attitude during assessment.

13 Recording failures to comply with MAURITAS requirements

13.1 The Nonconformity form, **F 3.07**, records failure of the laboratory to comply with the **ISO/IEC 17025** or **ISO 15189** and/or MAURITAS requirements and/or the laboratory's management system. It provides the objective evidence on which the Assessment Team's recommendations on accreditation to MAURITAS will be based.

13.2 The Nonconformity form, **F 3.07**, must contain only factual observations. These shall be related to requirements with specific clauses in **ISO/IEC 17025** or in **ISO 15189** and any other requirements specified by MAURITAS or against laboratory's own policies and procedures. The Assessors/Technical Experts must avoid making provocative or emotive statements in the Report, or using it as an opportunity to lecture the laboratory on how to manage its affairs. The Assessment Team may find it useful to use wordings identical or similar to the relevant reference in **ISO/IEC 17025** or in **ISO 15189** and/or **MAURITAS R** Series documents, while describing the nonconformity in **F 3.07**.

It is the responsibility of the Team Leader to check the wordings of all nonconformities in consultation with the Assessment Team, including the MS where appropriate, to allocate formally nonconformities against particular clauses of **ISO/IEC 17025** or **ISO 15189** and/or MAURITAS requirements or against laboratory's own policies and procedures and to categorise them before completing the Summary of Nonconformities form, **F 3.28** or **F 3.34** and the Recommendation Report, **F 3.09**.

13.3 Each Nonconformity form, **F 3.07**, shall be completed with the following information, but not limited to, at the time of assessment:

a) where each nonconformity was made (location/activity);

b) the system, calibration or test under discussion;

c) any documents involved;

d) a record of the nonconformity (where a particular nonconformity is repeated, this fact should be noted alongside the first nonconformity);

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; and

g) reference to the specific clause of the standard or MAURITAS Requirements.

13.4 Subsequently, the classification of nonconformities is done in consultation with the other team members during Assessors' Meeting.

13.4.1 A major nonconformity shall be allocated for the failure of a system, within the overall management system, to comply with MAURITAS requirements.

Examples of major nonconformities would be*:*

a) the absence of a document-control system;

b) the absence of a procedure for internal audit or management review and evidence of implementation;

c) a deviation that affects the result of the calibration/test;

d) a calibration system that is not supported by laboratory-held MAURITAS calibration certificates or certificates issued by other laboratories recognised by MAURITAS;

e) failure to take necessary corrective actions on previously raised nonconformities by MAURITAS;

f) staff not technically competent to perform particular calibrations or tests; and

g) failure to control the quality of calibration/test data.

13.4.2 A minor nonconformity shall 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 nonconformities would be*:*

a) errors in quality records corrected but not initialled;

b) a certificate not dated;

c) an organisation chart in the quality manual not up-to-date and

d) evaluation of external service providers not carried out as scheduled.

14 Summary of findings

14.1 At the end of the assessment, after the Assessors/Technical Experts have completed their individual assignments, it is essential to hold an Assessors' Meeting at which each team member can summarise his or her conclusions and contribute to a co-ordinated view of the performance of the laboratory's management system.

14.2 At this stage, the Team Leader, in conjunction with the Assessment Team, shall review the nonconformities on each **F 3.07** raised during the assessment. The Team Leader shall then complete the Summary of Nonconformities form **F 3.28** or **F 3.34**, considering his/her own findings and those of any other Assessors/Technical Experts/MS involved. In the event that the members of the assessment team cannot reach a conclusion with respect to a particular finding, the Team Leader shall refer the matter to MAURITAS (Assistant Accreditation Manager/Accreditation Manager/Director) for clarifications before a decision is made.

14.3 The Recommendation Report **F 3.09** must summarise the Assessment Team's findings, 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 nonconformities 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 must make it clear which of these recommendations is being made. MAURITAS accreditation will be recommended for grant only after MAURITAS has received any evidence requested and has confirmed, after consultation with the Assessment Team, that all nonconformities have been cleared.

14.4 The completion of the Recommendation Report is one of the most important duties of the Team Leader. The completed form is a formal record of the team's observations and conclusions and, as such, it must be based on facts and be complete. It must always contain a concise recommendation on the extent to which the laboratory complies with the MAURITAS requirements and is competent to carry out the calibrations/tests for which accreditation has been sought. Being an essentially critical record, it must be carefully prepared to avoid any financial or legal commitments or implications.

14.5 The Recommendation Report shall be based on the contents of the **F 3.07** forms and Summary of Nonconformities, **F 3.28** or **F 3.34** form, and shall indicate:

a) the recommendation of the Assessment Team on the accreditation of the laboratory;

b) any areas for improvement;

c) the strengths of the laboratory;

d) the comment of Assessment Team on competence as determined through conformity;

e) where relevant, recommended Technical Signatory(ies); and

f) the deadline for submission of proposed and implemented corrective actions.

The Recommendation Report should avoid any provocative or emotive statements.

15 Factors affecting recommendations on accreditation

15.1 Where no nonconformities are found, the Assessment Team shall recommend that accreditation be granted for the scope applied.

15.2 Where nonconformities are found, the recommendation shall be that accreditation be granted subject to the:

a) submission of proposed corrective actions and root cause analysis within a period of 1 month from the initial assessment and satisfactory clearance by the Assessment Team;

b) submission of implemented corrective actions within a period of 3 months from the initial assessment and satisfactory clearance by the Assessment Team.

Depending upon the nature of the nonconformities, evidence that the corrective action has been taken shall be provided either by posting or emailing copies of the necessary documents to MAURITAS or through a further on-site visit by an Assessment Team.

15.3 Where there are one or more areas of calibration or testing where major nonconformities 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 nonconformities found is such that the laboratory's management system and organisation is demonstrably inadequate, the Assessment Team shall 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 matter shall be included in the formal presentation of findings that do not appear in the Recommendation Report, **F 3.09** or in the related Summary of Nonconformities, **F 3.28** or **F 3.34** forms.

16.2 The Closing Meeting shall be chaired by the Team Leader and shall be as per the agenda **F 1.04**.

The Team Leader shall specify the deadlines for submission of:

a) the proposed corrective actions and root cause analysis, to be not more than 1 month for an initial assessment and not more than 1 week for an assessment/re-assessment;

b) the implemented corrective action to be not more than 3 months for an initial assessment and not more than 1.5 months for an assessment/re-assessment.

In the case of long assessments, where one or more assessors have completed their work before the Closing Meeting, the Team Leader shall present the findings of the assessor(s) 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);

16.3 The efficient conduct of the Closing Meeting will leave a lasting impression of the professionalism of the Assessment Team and of the value of the assessment process. It must therefore be conducted with impartiality and with an objective professional approach. The Team Leader should make it clear in his opening remarks that the object of the assessment is to assess the management system of the laboratory against the requirements of the relevant standard, MAURITAS criteria and the laboratory's own policies and procedures. Where non-conformities exist, the laboratory shall correct them so as to meet the requirements. The aim is not to amass enough evidence to justify rejecting the application. It is essential that the Nonconformity Form **F 3.07**, the Recommendation Report Form **F 3.09** and the Summary of Nonconformities Form **F 3.28** or **F 3.34** are carefully completed during the assessment to avoid any misunderstandings or difficulties during or after the visit.

16.4 In presenting the Recommendation Report, the Assessment Team should not be drawn into debating the validity of their conclusions or the recommendations. If these are questioned, the Assessment Team may, however, enumerate the individual nonconformities which justify the recommendations in question and point out the combined effect of the observations on the assessment. If the laboratory is still unwilling to accept the recommendations, or contests the overall assessment, the Team Leader shall advise them to take up the matter with MAURITAS. It is important to note that the signing by management of the forms **F 3.28** or **F 3.34** and **F 3.09** is solely an acknowledgement that the report has been presented.

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

17 Post assessment

17.1 Within 1 week of the assessment, the Team Leader shall report his recommendations to MAURITAS on Recommendation Report **F 3.09**.

17.2 On receipt of proposed corrective actions along with the respective root cause analysis for non-conformities raised during the Initial Assessment, the Case Officer shall 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, the Case Officer will act on the Assessment Team's recommendation and request the laboratory to submit new proposed corrective actions for the respective nonconformities within 1 week. The Case Officer 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.

17.3 On receipt of evidence of corrective action for nonconformities raised during the Initial Assessment, the Case Officer shall consult with the Assessment Team who will confirm within 1 week, whether the non-conformities have been cleared. If the nonconformities have not been fully cleared, the Case Officer will act on the Assessment Team's recommendation and request the laboratory to submit new implemented corrective actions for the respective nonconformities within 1 week. When evidence has been obtained that all nonconformities have been cleared, the Team Leader will finalise and submit an accreditation report to the Secretary of the Accreditation Committee. If the contents of the accreditation report differ from the Recommendation Report submitted at the Closing Meeting, MAURTAS shall provide an explanation to the assessed laboratory, in writing.

The accreditation report together with the Director's recommendation for an agreed Schedule of Accreditation for calibrations or tests shall then be submitted to the Accreditation Committee for the decision on accreditation. If the recommendation is approved by the Accreditation Committee, the Case Officer will notify the applicant accordingly without undue delay. If the recommendation is not approved by the Accreditation Committee, the Case Officer shall 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.

17.4 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 shall not grant accreditation for the relevant scope.

17.5 When a further visit is required, the Assessor(s)/Technical Expert(s) shall assess specifically the clearance of the nonconformities on site. If other potential nonconformities are observed during the visit, the Assessor(s)/Technical Expert(s) shall bring this to the attention of management of the laboratory and report this, in writing, to MAURITAS.

17.6 Upon grant of accreditation, the Accreditation Manager shall assign a unique accreditation number to the laboratory. The Case Officer shall prepare the formal grant of accreditation, the certificate, schedule as per **MAURITAS A13** and contract agreement, **F 1.13**. The Case Officer shall arrange for the relevant signatures and submit them to the laboratory within one week of the decision by the Accreditation Committee. On receipt of the signed contract agreement, the Case Officer shall forward a soft copy of the Accreditation symbol/combined mark to the laboratory and shall communicate the tentative assessment dates in the four-year accreditation cycle. The laboratory shall also be requested to pay the annual fees.

17.7 Laboratories which have been accredited for the scope for which MAURITAS is signatory to the ILAC MRA, that is, for Testing and Calibration (ISO/IEC 17025), can make use of the Combined Mark, if they wish. The Case Officer shall prepare the Contract Agreement, **F 1.26**, stating the conditions for use of the Combined Mark. On receipt of the signed contract agreement, the Case Officer shall forward a soft copy of the Combined Mark to the laboratory. Prior to using the Combined Mark, the laboratory shall submit to MAURITAS a proof of print of the material for approval.

17.8 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 **F 1.02** before the assessment and the signing the accreditation report after completion of the assessment.

18 Assessment and Re-assessment

18.1 Following accreditation, laboratories shall be subject to periodic assessment and re-assessment visits. The first assessment visit is carried out six months after the date of accreditation. Subsequent visits are carried out at yearly intervals. The three assessment visits covering all the requirements of **ISO/IEC 17025 or ISO 15189** are carried out during the accreditation cycle.

For testing laboratories performing in-house calibrations, the Case Officer 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) using the Witnessing Form, **F 3.04** and/or vertical assessments **F 3.26** or **F 3.33**.

The Case Officer is responsible for establishing and maintaining an assessment programme, **F 3.39** for the laboratory. The Case Officer shall ensure that the assessment and re-assessment visits are carried out within 1 month of the scheduled date. (Refer to Appendix C for timeline)

The Accreditation Manager shall advise the Director at the beginning of the calendar year of the assessment and re-assessment schedule of accredited laboratories. Same is continually monitored during regular meetings. Any change or proposed change to the laboratory's activities shall be reported and the Director shall advise the Assessment Team of any issues of concern.

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/MS shall establish whether all significant changes in the laboratory status or operation have been notified to MAURITAS (see **MAURITAS R1**).

18.3 Before each assessment or re-assessment visit, the Case Officer shall carry out the resource review as per **F 1.09.** Before confirming the composition of the Assessment Team and any observers with the laboratory, MAURITAS shall request all the proposed members of the Assessment Team and observers to declare any former, existing or envisaged link or competitive position between themselves/their parent organisation and the laboratory to be assessed by filling the Declaration of Impartiality form, **F 1.23**. In the event that one or more of the proposed team members or observer declares any interest or link, the Case Officer shall repeat the resource review process with new proposed team members or new observer.

18.4 The Case Officer then advises the laboratory of the proposed Assessment Team (and the organisation to which they belong), the assessment date(s) and fees to be charged at least one week prior to the assessment or re-assessment. New Team Leaders/Assessors/Technical Experts and observers, if any, shall have to be appointed if they are not accepted by the applicant, and actions shall be initiated based on the applicant's valid reasons. However, if the reasons are not considered to be valid and Team Leaders/Assessors/Technical Experts are not available locally, the laboratory shall bear the cost of using foreign Team Leaders/Assessors/ Technical Experts.

18.5 The Assessment Team shall perform the assessments/re-assessments as per the assessment plan. The Team Leader shall inform MAURITAS in the event that the Assessment Team is not able to perform the assessments/re-assessments as per the assessment plan and the reasons thereof.

18.6 The Team Leader performs the horizontal assessment of management requirements using the relevant checklist (**F 3.24** or **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 (F 3.25 or F 3.31)**	**Vertical (F 3.26 or F 3.33)**	**Witnessing (F 3.04)**	**Interview of Technical Signatory (F 3.05)**
Assessment		✓	✓	
Re-assessment	✓	✓	✓	
Extension of scope		✓ (where relevant)	✓	
Approval of Technical Signatory			✓	✓

18.7 If, during an assessment or a 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 shall be recorded by the Team Leader.

The Assessment Team shall check that the changes are not such as to diminish the laboratory's capabilities as described in the Schedule of Accreditation, and that they have already been fully notified to MAURITAS as required by **ISO/IEC 17025 or ISO 15189** and **MAURITAS R1**.

18.8 During a single assessment visit, the Assessment Team will not be expected to check the whole of the calibration/testing work for which a laboratory is accredited. However, MAURITAS shall 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, **F 3.39**. MAURITAS performs a sampling exercise so that the whole accreditation schedule is assessed during an accreditation cycle and the Case Officer refers to **MAURITAS A24** when performing the sampling. MAURITAS will assess key elements of the management system, including but not limited to complaint, management review and internal audit, during each assessment visit.

18.9 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.

18.10 Prior to each assessment and re-assessment visit, the Case Officer, in consultation with the Accreditation Manager, will discuss any required change in the Assessment Team composition with the Director. The Case Officer shall ensure that all accredited calibration/testing fields are assessed during each assessment and re-assessment visit. The Case Officer shall refer to **MAURITAS A24** and 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. The Case Officer shall also perform a sampling similar to calibration/testing activities (including similar steps) so that the whole schedule of accreditation is assessed during the three assessment and re-assessment visits.

18.11 Prior to each assessment and re-assessment visit, MAURITAS shall review the participation in PT in the current and/or coming accreditation cycle. MAURITAS shall evaluate, analyse and manage the risks associated to non-participation in PT and same shall be documented in the respective assessment programmes, **F 3.39**. MAURITAS shall initiate actions accordingly as per MAURITAS A12.

18.12 The Case Officer shall also ensure that a representative number of the laboratory's staff is witnessed at the different assessment and re-assessment visits. The Case Officer shall request, two weeks prior to the assessment or re-assessment, the updated Quality documentation, as well as latest management review, internal audit reports, complaints, list of analysts and the updated PT plan which are provided to relevant members of the Assessment Team. In the case of re-assessment, the laboratory shall additionally 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 shall 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. The Assessment Team shall assess whether the PT plan meets the requirements of **MAURITAS R2**. The Case Officer shall also forward the latest Accreditation Report relative to the accredited laboratory to all the members of the Assessment Team.

18.13 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 nonconformities were observed during previous visits, or where there have been changes in staff as discussed during the review of the assessment programme, **F 3.39**.

18.14 The Case Officer makes use of the Checklist for Assessor's pack **F 1.16** or **F 1.17** for preparation of the assessment packs for the members of the Assessment Team.

18.15 The Team Leader or the MS forming part the Assessment Team, at the conclusion of an assessment or a 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 nonconformities identified, the Assessment Team shall recommend whether accreditation should be:

a) maintained unconditionally (this recommendation shall be made only when no nonconformities have been identified);

b) maintained subject to submission of proposed corrective actions and root cause analysis to MAURITAS within 1 week from the assessment or re-assessment visit;

c) maintained subject to submission of implemented corrective actions to MAURITAS within 1.5 months from the assessment or re-assessment visit;

d) maintained but for a reduced Schedule of Accreditation;

e) suspended until the laboratory has corrected the nonconformities identified within 4 months); and

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

f) withdrawn/terminated.

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

18.17 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 shall proceed with the suspension or reduction of scope of the laboratory or withdrawal/termination.

18.18 On receipt of proposed corrective actions along with the respective root cause analysis for nonconformities raised during the assessments/re-assessments, the Case Officer shall 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, the Case Officer 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. The Case Officer 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.

18.19 On receipt of evidence of corrective action for nonconformities raised during the assessments/re-assessments, the Case Officer shall consult with the Assessment Team who will confirm within 1 week, whether the nonconformities have been cleared. If the nonconformities have not been cleared, the Case Officer will act on the Assessment Team's recommendation and request the laboratory to submit new implemented corrective actions for the respective nonconformities within 1 week.

18.20 On receipt of the confirmation by the Assessment Team that all nonconformities 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 shall then be submitted to the MAURITAS Accreditation Committee for the decision on accreditation. The Case Officer shall inform the laboratory of the decision of the Accreditation Committee within one week.

18.21 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:

a) the scope of accreditation contains more than three testing and calibration fields;

b) the number of nonconformities, in particular, major ones is consequent; and

c) the risks associated with the laboratory's activities, location and personnel is considerable.

18.22 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 shall 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 Team Leaders/Assessors/ Technical Experts as necessary. Such applications shall be made on the relevant application form and accompanied by the associated documentation and fees.

18.23 At each re-assessment, the Director and the Head of Laboratory Accreditation Section shall consider the accredited laboratory's current Schedule of Accreditation and review the composition of the Assessment Team in advance of the visit. The Laboratory Accreditation Section shall review the current assessment programme, **F 3.39**, to identify any trends. Following the re-assessment visit, which will follow the same general procedure as the initial assessment, and the receipt of evidence of clearance of nonconformities, the accreditation report and recommendation will be submitted by the Director for consideration and a decision by the Accreditation Committee, for renewal of accreditation for a further four-year period.

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

a) In the event that the process is completed before the expiry date, the renewal of accreditation shall be effective on a date right after the expiry.

b) In case the process is not yet completed before the expiry date:
- MAURITAS shall 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 shall be effective on the date right after the expiry;

- The Accreditation Committee shall extend the validity of the accreditation for a maximum period of 3 months in case the delay for renewing is attributable to MAURITAS. The re-instatement/renewal of accreditation shall be effective on the date right after the expiry.

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

19 Extension of scope of accreditation

19.1 When a laboratory applies for an extension of scope of Accreditation, including the addition of new Technical Signatories, MAURITAS shall 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 shall be performed by a combination of witnessing and/or vertical assessment.

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

19.3 If the extension is performed independently from a scheduled visit, the visit is planned and performed as per relevant clauses of sections 'Preparation for the initial assessment' and 'Assessment and Re-assessment' with the exception that the Assessment Team may comprise an MS instead of a Team Leader.

19.4 Decisions with respect to extension of scope are done as described in section 'Post Assessment'

19.5 The laboratories shall be required to follow the timelines as defined in Appendix D.

20 Change in scope following updates in calibration/test methods

20.1 When a laboratory informs MAURITAS about changes in the version of the accredited calibration/test methods, the following actions shall be taken:

a) For minor or no change within the calibration/test methods, the schedule will be amended accordingly after approval of the Director.

b) For major changes within the calibration/test methods, the laboratory will be requested to submit a validation/verification report which will be reviewed by an Assessor/Technical Expert/TAC. The schedule will be amended accordingly after approval of the Director.

20.2 Where a certificate/schedule has been amended, the updated certificate/schedule shall be uploaded on the MAURITAS website.

21 Duration of assessments

21.1 The durations of laboratory assessments are normally as per the table below:

Type of Assessment	Number of Assessors	Number of days	Remarks
Preliminary visit	1 Team Leader + at least 1 Assessor / (Technical Expert + MS)	1	
Initial Assessment	1 Team Leader + at least 1 Assessor / (Technical Expert + MS)	Minimum of 2 days	The duration of the Initial Assessment will depend on the scope for which accreditation has been applied for and will be determined after consultation with the Accreditation Manager/Director and the members of the Assessment Team
Assessments	1 Team Leader + at least 1 Assessor / (Technical Expert + MS)	Minimum of 1 day	The duration of the Assessment will depend on the sample of the accredited scope to be covered as per A24 and will be determined after consultation with the Accreditation Manager /Director and the members of the Assessment Team.
Re-assessment	1 Team Leader + at least 1 Assessor / (Technical Expert + MS)	Minimum of 2 days	The duration of the Re-Assessment will depend on the sample of the accredited scope to be covered as per A24 and will be determined after consultation with the Accreditation Manager /Director and the members of the Assessment Team.
Extension of scope	1 Team Leader or MS + at least 1 Assessor/ (Technical Expert + MS)	Minimum of 0.5 day	The duration of the Extension of scope will depend on the scope for which extension of scope has been applied for and will be determined after consultation with the Accreditation Manager /Director and the members of the Assessment Team

21.2 The factors influencing the duration of assessments and the composition of MAURITAS Assessment Teams are:

a) the number of fields and the number of Technical Signatories for which the laboratory has applied; or

b) the number of fields for which the laboratory is accredited;

c) the sample of the accredited scope to be assessed as determined by MAURITAS A24;

d) the number of analysts and the number of Technical Signatories; and

e) the risks associated with the accredited laboratory's activities, location and personnel.

22 Related Forms

FORMS USED DURING ASSESSMENT, ASSESSMENT AND RE-ASSESSMENT VISITS	GENERAL LABORATORIES	MEDICAL LABORATORIES
Application for Accreditation: General Laboratories: ISO/IEC 17025	F 3.15	-
Application for Accreditation: Medical Laboratories: ISO 15189	-	F 3.32
Self-Assessment Checklist: ISO/IEC 17025:2017	F 3.23	
Self-Assessment on ISO 15189:2022 Requirements	-	F 3.29
Resource Review Form	F 1.09	F 1.09
Declaration of Impartiality	F 1.23	F 1.23
Declaration of Confidentiality for Assessors/Technical Experts	F 1.02	F 1.02
Checklist for Assessor's Pack ISO/IEC 17025	F 1.16	-
Checklist for Assessor's Pack ISO 15189	-	F 1.17
Agenda Opening Meeting	F 1.01	F 1.01
Agenda Closing Meeting	F 1.04	F 1.04
Attendance Sheet	F 1.03	F 1.03
Briefing Meeting with Assessors/ Technical Experts	F 1.15	F 1.15
Assessment Management Requirements: ISO/IEC 17025:2017	F 3.24	-
Assessment Technical Requirements: ISO/IEC 17025:2017	F 3.25	-
Vertical Assessment: ISO/IEC 17025:2017	F 3.26	-
Recommendation for Technical Signatory	F 3.05	-
Assessment of Management Requirements: ISO 15189:2022	-	F 3.30
Assessment of Technical Requirements: ISO 15189:2022	-	F 3.31
Vertical Assessment: ISO 15189:2022	-	F 3.33
Witnessing Sheet: ISO/IEC 17025 / ISO 15189	F 3.04	F 3.04
Nonconformity Form: ISO/IEC 17025 / ISO 15189	F 3.07	F3.07
Summary of Nonconformities: ISO/IEC 17025:2017	F 3.28	-
Summary of Nonconformities: ISO 15189:2022	-	F 3.34
Recommendation Report: ISO/IEC 17025 / ISO 15189	F 3.09	F 3.09
Feedback on Assessment Form	F 1.21	F 1.21
Assessment Programme	F 3.39	F 3.39

Appendix A: Amendment Table

SN	Section	Amendment
Issue 1, Revision 5		
1.	17.3	(i) At the end of the paragraph, the following line has been added: "If the contents of the accreditation report differ…provide an explanation to the assessed laboratory, in writing"
2.	Throughout the document	(i) "non-conformity" has been rewritten as "nonconformity" to align with the correct wording used in the standard ISO/IEC 17021:2017
Issue 2, Revision 5		
1.	5.3, 9.1, 9.4, 10.1, 18.3, 18.4	(i) Reference has been made to observers in the Assessment Team
Issue 3, Revision 5		
1.	9.3	(i) A new sub-section 9.3 "Prior to each assessment, … or to appropriate national or international reference standards." has been added (ii) Previous sub-section 9.3 is now 9.4 and so on.
Issue 4, Revision 5		
1.	18.11	(i) A new sub-section 18.11 has been added "Prior to each assessment and re-assessment visit, MAURITAS shall review the …MAURITAS shall initiate actions accordingly as per MAURITAS A12." (ii) Previous sub-section 18.11 is now 18.12 and so on.
2.	Throughout the document	(i) "F 3.39" has been referenced next to "assessment programme".

Appendix B: Timeline for Applicant Laboratories

Process	Time Frame (Days)
Application MAURITAS receives a Complete Application Form from Laboratory with associated documents (Quality documentation and Self-Assessment Checklists) and the application fee.	Day 01
↓	
Review of Quality documentation, Self-Assessment Checklist, Application Form and selection of assessors 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 3 MONTHS.	Day 90
↓	
Preliminary Visit (Optional) 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(s) in 1 DAY.	Day 120
↓ (assuming that the lab is ready within 3 months)	
Initial Assessment 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 3 DAYS or more, depending on the scope of accreditation.	Day 210
↓	
Proposed Corrective actions submitted by CAB Within 1 month, the CAB shall provide proposed corrective actions along with the root cause analysis that they intend to implement in order to address the nonconformities raised during the initial assessment.	Day 240
↓	
Acceptance by Assessors MAURITAS will then consult with the Assessment Team involved and within 1 week, the latter will confirm whether the nonconformities have been satisfactorily addressed. If not, the laboratory is given an additional 1 week to send to MAURITAS new proposed corrective actions to which the Assessment Team will take another 1 week for approval.	Day 254(Max) Day 247 (Min)

↓	
Implemented Corrective Actions 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 nonconformities.	Day 344 (Max) Day 337 (Min)
↓	
Acceptance of Implemented Corrective Actions After receiving evidence of implemented corrective actions, MAURITAS will again consult with the Assessment Team to confirm whether the nonconformities have been cleared within 1 week. If not, the laboratory is given an additional 1 week to send to MAURITAS further evidence for the implemented corrective actions to which the Assessment Team will take another 1 week for approval.	Day 365 (Max) Day 344 (Min)
↓	
Accreditation Report Upon satisfactory clearance of all nonconformities, within 1.5 months, the Team Leader will prepare the Accreditation report where he/she will present evidence of clearance of nonconformities. 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)

Appendix C: Timeline for Accredited Laboratories

Process	Time Frame (Days)
Assessment/ Re-assessment 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.	Day 01
↓	
Proposed Corrective Action The laboratory has 1 weeks' time to send to MAURITAS the proposed corrective actions along with the root cause analysis for the nonconformities raised during the assessment visit.	Day 08
↓	
Acceptance by Assessors MAURITAS will then consult with the Assessment Team involved and within 1 week; the latter will confirm whether the nonconformities 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 Assessment Team will take another 1 week for approval.	Day 29 (Max) Day 15 (Min)
↓	
Implemented Corrective Action 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 nonconformities.	Day 74 (Max) Day 60 (Min)
↓	
Acceptance of Implemented Corrective Actions After receiving evidence of implemented corrective actions, MAURITAS will again consult with the Assessment Team to confirm whether the nonconformities have been cleared 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.	Day 95 (Max) Day 67 (Min)
↓	
Accreditation Report Upon satisfactory clearance of all nonconformities, within 1.5 months, the Team Leader will prepare the Accreditation report where he/she will present evidence of clearance of nonconformities. This Accreditation report will be submitted to the Accreditation Committee. Recommendation for accreditation is also made to the Accreditation Committee.	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 a re-assessment and there is no modification to the scope, the decision may be taken by the Director.	Day 170 (Max) Day 142 (Min)
Total	Max of 170 days (6 months) Min of 142 days (5 months)

Appendix D: Timeline for Extension of Scope of Accreditation

Process	Time Frame (Days)
Application for Extension to Schedule of Accreditation 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.	Day 01
↓	
Review of Application Form and Selection of Assessors MAURITAS reviews the application form and performs a Resource Review for the availability of Assessors/Technical Experts in the fields for which extension has been applied.	Day 31
↓ (assuming that the lab is ready within 1 month)	
On-site Assessment 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.	Day 61
↓	
Proposed Corrective Action The laboratory has 1 weeks' time to send to MAURITAS the proposed corrective actions along with the root cause analysis for the nonconformities raised during the on-site visit.	Day 68
↓	
Acceptance by Assessors MAURITAS will then consult with the Assessment Team involved and within 1 week; the latter will confirm whether the nonconformities 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 Assessment Team will take another 1 week for approval.	Day 89(Max) Day 75 (Min)
↓	
Implemented Corrective Action 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 nonconformities.	Day 134 (Max) Day 120 (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 nonconformities have been cleared 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.	Day 149 (Max) Day 127 (Min)
↓	
Accreditation Report Upon satisfactory clearance of all nonconformities, within 1.5 months, the Team Leader will prepare the Accreditation report where he/she will present evidence of clearance of nonconformities. This Accreditation report will be submitted to the Accreditation Committee. Recommendation for accreditation is also made to the Accreditation Committee.	Day 194 (Max) Day 172 (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/maintain accreditation to the Laboratory.	Day 224(Max) Day 202 (Min)
Total	Max of 224 days (7.5 months) Min of 202 days (7 months)

