MAURITAS G1: 2017
Issue No. 4 -Revision 1
Date: March 2017

MAURITAS
G1

MAURITAS assessments – A guide for laboratories

Mauritius Accreditation Service

CONTENTS

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 and are entitled to use the MAURITAS Accreditation symbol.

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
- Directories classified listing of accredited organisations.

Mauritius Accreditation Service (MAURITAS)
4th Floor, Crescent House
Corner Deschartes and Foucault Streets
Port-Louis
Mauritius
Tel: +230 208 1690
Fax: +230 210 6101
Email : mauritas@govmu.org
Website :www.mauritas.org

MAURITAS assessments - A guide for laboratories

1 Purpose

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

2 Scope and Responsibilities

This guidance document sets out how MAURITAS assessments are to be carried out in order to assess a laboratory's compliance with MAURITAS requirements. It refers to MAURITAS, requirements and guidance for the preparation, conduct and reporting of MAURITAS laboratory visits.

This guidance document 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 G4 documents

3.4 MAURITAS G5 documents

3.5 MAURITAS R Series documents

4 Definitions

4.1 **Accreditation** is a third-party attestation related to a laboratory conveying formal demonstration of its competence to carry out specific tests/calibrations.

4.2 **Major Non-Conformities** are Non-Conformities where the credibility of the organisation's accreditation is seriously threatened or tests/calibration results are affected.

4.3 **Minor Non-Conformities** are Non-Conformities that are isolated and would not affect the results of the activities of the organisation.

4.4 **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.

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**), 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**, **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 International Laboratory Accreditation Cooperation (ILAC) and endorsed by MAURITAS, provide interpretations of these criteria.

5.2 Assessors/technical experts are used to judge 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**, **ISO 15189**, **MAURITAS R** Series documents. Their assessment should be confined to investigating and reporting the findings that result from witnessing and discussion in the laboratory and through examination of 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 by MAURITAS staff, the external assessors/technical experts and the Accreditation Committee.

5.4 MAURITAS normally uses assessors/technical experts contracted from external sources to assess laboratories on its behalf. All MAURITAS assessors/technical experts, including MAURITAS staff 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. MAURITAS staff may also act as an assessor if qualified as an assessor.

5.5 The MAURITAS Staff (hereafter referred to as the MS) will normally visit the laboratory as part of the Assessment Team in the case where the Lead Assessor is not a permanent staff of MAURITAS. 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 assist with the interpretation of MAURITAS requirements in appropriate circumstances, for the guidance of laboratory management or an assessor/technical expert.

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 Lead Assessor, 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 pre-assessment and initial assessment visit, but also to visits after accreditation has been granted, for the purposes of surveillance, 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 the relevant Application Form, **F3.15** or **F3.16** accompanied by the self-assessment form **F3.19**, 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 Manual, detailing the quality policies and procedures of the management system operating in the laboratory and pays the Application Fee. The laboratory has to provide information on its validation data and about its participation in Proficiency Testing.

6.2 MAURITAS reviews the Application Form to ensure that it has been correctly and fully completed and examines the Quality Manual to check that it addresses all the key elements of a quality system as specified in **ISO/IEC 17025, ISO 15189**, **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 relevant checklists (**F3.01** and **F 3.02** or **F 3.20** and **F 3.21**), 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 pre-assessment; or

b) the laboratory is ready for a pre-assessment; 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 pre-assessment or initial assessment, the latter has to submit to MAURITAS its validation data for the applied scope.

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

7 Pre-assessment

7.1 In the event that MAURITAS recommends or the laboratory requests that a pre-assessment 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 pre-assessment shall be carried out by MAURITAS per application made by laboratory.

7.4 The pre-assessment visit, which is carried out by the assessment team is completed in 1 day. The pre-assessment visit allows the assessment team to discuss with the laboratory management the extent to which the laboratory's management system, quality manual and operating procedures appear to comply, or not, with 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 3.01** and **F 3.02** or **F3.20** and **F 3.21**), 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 Pre-assessment findings form **F1.20**. The assessment team shall not, at any stage of the pre-assessment, 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 they 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 pre-assessment, the assessment team will indicate to the laboratory whether plans for initial assessment of the laboratory can proceed, or specific reasons why plans cannot proceed. The assessment team will hand over the Pre-assessment 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 pre-assessment.

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 MAURITAS policy 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 list, on their relevant Application Forms, the standard specifications or other methods or procedures relevant to the calibrations or tests concerned, the major items of laboratory equipment used to conduct those calibrations/tests and the potential technical signatories.

8.2 For schedules of calibration, the type of calibration, 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 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 Lead Assessor, 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 with a link to the ILAC, SADCA and AFRAC websites.

9 Preparation for the initial assessment visit

9.1 Based on the recommendations of the Lead Assessor after the document review or pre-assessment, the laboratory has to inform MAURITAS of its readiness to undergo initial assessment.

9.2 MAURITAS will 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 must have been 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.

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 perhaps actions will have to 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.

10 Summary of the initial assessment visit

10.1 Prior to the start of the initial assessment, an assessors' briefing meeting is carried out.

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 Lead Assessor 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 at which each member of the Assessment Team presents his findings. The Lead Assessor summarises the findings of the team. The team will wish to meet in private to prepare for this Closing Meeting. For assessments lasting longer than 1 day, the assessors/technical experts 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 on arrival 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 understands what is going to happen during the assessment. It is chaired by the Lead Assessor and should cover (**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 3.10** or **F 3.14** 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, luncheon breaks etc;

k) an opportunity for the Lead Assessor to invite the laboratory representatives to ask relevant questions.

12 Witnessing of the laboratory at work – the technical assessment

12.1 On-the-spot witnessing of the laboratory going about its normal business form the most important part of the assessment and follow the Opening Meeting. Assessors/technical experts need to establish the laboratory's overall competence, in particular the suitability of the methods and equipment for the work in hand including the state of maintenance and calibration of the equipment. In addition, for all measurements having a significant effect on the accuracy or validity of calibrations/tests, the traceability of the measurements to national or international standards shall be established. Assessors/technical experts need to assess the competence of the staff, particularly when performing calibrations/tests, and the effectiveness of the management system in ensuring that there are no errors or omissions in recording, analysing and reporting results.

12.2 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 Following the dispersal of the Assessment Team to various sections of the laboratory, the Lead Assessor starts the assessment of management requirements using the relevant checklist (**F 3.01** or **F 3.20**) with the designated Quality Manager and any other appropriate staff, and identify any Non-Conformities (**F 3.07**).

12.4 The technical assessor(s) or technical expert(s) accompanied by a MAURITAS Staff proceed/s with the assessment of the technical requirements using the relevant checklist (**F 3.02** or **F 3.21**), vertical assessment (**F 3.03** or **F 3.17**), witnessing (**F 3.04**) and approval of potential technical signatories (**F 3.05**) and identify any Non-Conformities (**F3.07**).

12.5 As detailed in the plan for the visit, the assessors/technical experts will examine 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 ask to see the equipment involved, the manufacturer's manuals, and establish the status of calibration of the equipment.

12.6 The technical assessors/technical experts will witness calibrations/tests (**F 3.04**) and examine documentation concerning calibrations/tests in progress. They will carry out vertical assessments (**F 3.03** or **F 3.17**) and trace back results from certificates or reports, to the original entries in the laboratory's notebooks or work sheets. 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 technical 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 technical assessors/technical experts to witness its performance on specific calibrations at locations chosen by MAURITAS.

12.8 The assessment team will record the results of latest participation in Proficiency Testing in **F 3.06**.

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**, **ISO 15189**, **MAURITAS R** Series documents, any other requirements specified by MAURITAS, and the laboratory's management system. Non-Conformities raised must be based on objective evidence and be recorded and verified before leaving the area under assessment. To secure agreement on the facts, and to avoid subsequent dispute, assessors/technical experts will detail Non-Conformities, as they occur, on Non-Conformity form (**F 3.07)**. Each Non-Conformity will be countersigned by the accompanying laboratory representative.

13 Recording failures to comply with MAURITAS requirements

13.1 The Non-Conformity form, **F 3.07**, recording failure of the laboratory's arrangements to comply with the MAURITAS requirements, and the information on the Individual Assessor's Report, **F 3.13** or **F 3.08**, provide the objective evidence on which the Assessment Team's recommendations on accreditation to MAURITAS will be based.

13.2 Non-Conformity form will contain only factual observations. These will be related to Non-Conformities with specific clauses in **ISO/IEC 17025**, **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 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) where appropriate, the name(s) of the person(s) with whom the matter was discussed;

f) the signatures of the accompanying representative(s) of the laboratory and of the assessor/technical expert.

13.4 Subsequently, each Non-Conformity will be classified into one of the two categories of Non-Conformity, identified 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 test/calibration;
- 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 test/calibration results.

Examples of Minor Non-Conformities would be*:*

- errors in recorded data in workbooks corrected but not initialled;
- a certificate not dated;
- an organisation chart in the quality manual not up-to-date;
- no calibration label on an item of equipment.

13.5 The exchange of information on matters such as the categorisation of Non-Conformities is an important reason for the Lead Assessor to hold a brief meeting of the Assessment Team at the end of each day of the assessment.

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 for the assessors/technical experts to summarise their respective findings.

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 discharged.

14.3 The Recommendation Report will not simply be a reiteration of the contents of the Non-Conformity form **F 3.07**. It will be based on the content of the **F 3.07** forms and **F 3.10** or **F 3.14** forms, and will indicate any weaknesses in the quality system, or in the competence of the laboratory to perform calibrations/tests.

15 Factors affecting recommendations on accreditation

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

15.2 Where Non-Conformities are found, the recommendation will be that accreditation to be granted subject to the satisfactory discharge of all the Non-Conformities within a period of 3 months for initial assessment and a period of 1.5 months for surveillance and re-assessment. Depending upon the nature of the Non-Conformities, evidence that the corrective action has been taken may be provided either by posting 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 Lead Assessor 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 or in the related **F 3.10** or **F 3.14** and **F 3.09** forms.

16.2 The Closing Meeting will be chaired by the Lead Assessor who should, after referring to the purpose of the visit as explained at the Opening Meeting, 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) explain the significance of the categories of Non-Conformity;

e) invite each assessor/technical expert to summarise his or her findings, based on their Non-Conformity forms **F 3.07**. Reference should be made to Individual Assessor's Report Forms, **F 3.08** or **F 3.13**, but these should not normally be discussed in detail;

f) similarly, present his or her own findings as an individual assessor;

g) in the case of long assessments, where assessors have completed their work before the Closing Meeting, the Lead Assessor 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);

h) present the summary, conclusions and recommendations which will take into account the factors described in section 'Factors affecting recommendations on accreditation' above;

i) hand over the Non-Conformity forms, **F 3.07**, for management to sign and date each form;

j) specify a date by which the proposed corrective actions recorded on **F3.07** 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 a surveillance/re-assessment);

k) 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 a surveillance/re-assessment);

l) obtain the signature of a management representative, or authorised deputy, on the Summary of Non-Conformities forms, **F 3.10** or **F 3.14** and Recommendation Report **F 3.09**;

m) provide the laboratory with an opportunity to discuss the assessment and to ask any questions;

n) leave copies (not originals) of each Non-Conformity form, **F 3.07**, the Recommendation Report **F 3.09** and the Summary Report, **F 3.10** or **F 3.14**, with the laboratory. If copying facilities are not available, the originals should be returned immediately to MAURITAS for copying and despatch to the laboratory;

o) close the meeting.

16.3 The Assessment Team 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 satisfactorily discharged. 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 Lead Assessor/MAURITAS Staff 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 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 recommendation 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), 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 and contract agreement, 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 to the laboratory and indicate the tentative surveillance dates in the accreditation cycle. The laboratory will also be requested to pay the annual fees.

18 Surveillance and re-assessment

18.1 Following accreditation, laboratories will be subject to periodic surveillance and re-assessment visits. The first surveillance visit 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 surveillance and re-assessment visit programme. MAURITAS will ensure that the surveillance and re-assessment visits are carried out within 1 month of the scheduled date (Refer to Annex B for Timeline).

The three surveillance 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) **F3.04**, vertical assessments **F3.03** or **F3.17** and assessment against relevant clauses under Technical Requirements **F3.02** or **F3.21**.

18.2 The purpose of these visits, is to determine whether or not a laboratory is continuing to comply with **ISO/IEC 17025, 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 surveillance or re-assessment visits. In addition, at the Opening Meeting, the Lead Assessor will establish whether all significant changes in the laboratory status or operation have been notified to MAURITAS (see **MAURITAS R1** document).

18.3 If, during a surveillance 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, ISO 15189** and **MAURITAS R1**.

18.4 During a single surveillance visit, assessors/technical experts will not be expected to check the whole of the calibration/testing work for which a laboratory is accredited. However, assessors/technical experts should examine the complete range of calibrations or tests for which the laboratory is accredited during the

accreditation cycle. MAURITAS will assess key elements of the management system, including but not limited to management review and internal audit, during each surveillance 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 surveillance and re-assessment visits. MAURITAS will also ensure that a representative number of the laboratory's staff is witnessed at the different surveillance and re-assessment visits. MAURITAS will request, at least one month prior to the surveillance or re-assessment, the updated Quality Manual and relevant associated quality procedures, complaints received since last assessment visit as well as latest management review and internal audit reports.

Assessors/technical experts 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 Lead Assessor, at the conclusion of a surveillance 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 found, the Assessment Team will recommend whether accreditation should be:

a) maintained unconditionally (this recommendation will be made only when no Non-Conformities have been found),

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 no more than 1.5 month),

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 corrected.

f) terminated.

18.8 Suspension or 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), MAURITAS will proceed with the suspension or reduction of scope of the laboratory or termination.

18.10 On receipt of the confirmation by the Assessment Team that all Non-Conformities have been cleared satisfactorily, the Lead Assessor or the MAURITAS Staff will prepare the accreditation report and submit to the Director who will then submit a recommendation together with the accreditation report to the Accreditation Committee.

18.11 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 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.

19 Extension of schedule 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.

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 surveillance/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 ASSESSMENT, SURVEILLANCE AND RE-ASSESSMENT VISITS	GENERAL LABORATORIES	MEDICAL LABORATORIES
Application Form: General Laboratories: ISO/IEC 17025	F 3.15	-
Application Form: Medical Laboratories: ISO 15189	-	F3.16
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 3.01	-
Assessment Technical Requirements: ISO/IEC 17025	F3.02	-
Non-Conformity Form: ISO/IEC 17025 / ISO 15189	F3.07	F3.07
Vertical Assessment : ISO/IEC 17025	F 3.03	-
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	-
Individual Assessor's Report: ISO/IEC 17025	F 3.08	-
Summary of Non-Conformity: ISO/IEC 17025	F 3.10	-
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
Individual Assessor's Report: ISO 15189	-	F 3.13
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	F1.16	-
Checklist for Assessor's Pack ISO 15189	F1.17	
Feedback on Assessment Form	F1.21	F1.21

Annex A: Timeline for Applicant Laboratories

Process	Time Frame (Days)
Application MAURITAS receives a Complete Application form from Laboratory with associated documents (Quality Manual and Procedure Manual) and the application fee.	Day 01
↓	
Review of Quality Manual, Application Form and selection of assessors MAURITAS reviews the application form and verifies that the Quality Manual addresses all the key elements as specified in ISO/IEC 17025, ISO 15189 and MAURITAS R Documents. This process lasts for a maximum of 3 MONTHS.	Day 90
↓	
Pre-assessment (Optional) After reviewing the Quality Manual, MAURITAS will inform the laboratory whether it is in a position to proceed with a pre-assessment, an initial assessment or it is not ready at all. The optional pre-assessment exercise is usually carried out by the Lead assessor in 1 DAY.	Day 120
↓ (assuming that the lab is ready within 3 months)	
Initial Assessment Based on the recommendations of the Lead Assessor on the Document review or the pre-assessment, 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.	Day 210
↓	
Proposed Corrective actions submitted by CAB Within 1 month, the CAB shall provide any proposed corrective action that they intend to implement in order to address the non-conformities raised during the initial assessment.	Day 240
↓	
Acceptance by Assessors MAURITAS will then consult with the assessors 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.	Day 254(Max) Day 247 (Min)

↓	
Implemented Corrective Action Following the approval of assessors 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 assessors 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 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 lead assessor 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.	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)
Surveillance/ Re-assessment Once the laboratory has been granted accreditation, it will be subject to periodic visits by MAURITAS. The First Surveillance visit is usually scheduled 6 months after the date of grant of accreditation. The second and third surveillances are then carried out on a yearly basis. 1 year after the 3rd surveillance, a re-assessment is done marking the start of the 2nd accreditation cycle. The laboratory is informed of the surveillance 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 for the non-conformities raised during the surveillance visit.	Day 08
↓	
Acceptance by Assessors MAURITAS will then consult with the assessors 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.	Day 29 (Max) Day 15 (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 non-conformities.	Day 74 (Max) Day 60 (Min)
↓	
Acceptance of Implemented Corrective Actions After receiving evidence of implemented corrective action, MAURITAS will again consult with the assessors 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 assessors will take another 1 week for approval.	Day 95 (Max) Day 67 (Min)
↓	
Accreditation Report Upon satisfactory clearance of all non-conformities, within 1.5 months, the lead assessor will prepare the Accreditation report where he/she will present	Day 140 (Max) Day 112 (Min)

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.	
↓	
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 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)
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 technical assessors/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 for the non-conformities raised during the on-site visit.	Day 68
↓	
Acceptance by Assessors MAURITAS will then consult with the assessors 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.	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 non-conformities.	Day 134 (Max) Day 120 (Min)
↓	
Acceptance of Implemented Corrective Actions After receiving evidence of implemented corrective action, MAURITAS will again consult with the assessors to confirm whether the non-conformities have been	Day 149 (Max) Day 127 (Min)

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 assessors will take another 1 week for approval.	
↓	
Accreditation Report Upon satisfactory clearance of all non-conformities, within 1.5 months, the lead assessor 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.	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 mnths) Min of 202 days (7 mnths)

