AFRIMETS GUIDELINES FOR ACCEPTING A QUALITY SYSTEM

1. Pre-Amble

This document has been prepared to provide guidelines to AFRIMETS for accepting a Quality System from members as fit for purpose for the CIPM MRA (as explained below). The relevant International Committee for Weights and Measures (CIPM) and Joint Committee for Regional Metrology Organisations and the BIPM (the JCRB) documents can be found at http://www.bipm.org/en/cipm-mra/documents/, in particular CIPM MRA G-02, G-03, D-04 and the *Joint ILAC-CIPM Communication regarding the Accreditation of Calibration and Measurement Services of National Metrology Institutes*.

2. Background (see section 7, Confidence in Measurement, of the CIPM MRA)

The CIPM global mutual recognition arrangement (MRA) has as primary aim to increase confidence in measurements. This confidence already exists to a large extend and is based on the SI as the cornerstone of the international measurement system, realised by the national metrology institutes (NMIs). The function of this MRA is to extend and consolidate pre-existing worldwide confidence in measurements.

To this end, NMIs are expected to participate in the key and supplementary comparisons organised by the CIPM consultative committees (CCs) and the Regional Metrology Organisation (RMO) technical committees (TCs), to publish regular reports on the work of the laboratories and transmitting them to the BIPM, participate in relevant conferences and by taking part in the activities organised by the BIPM (and the RMOs). For the recognition of their calibration and measurement capabilities (CMCs), institutes require one of two procedures to establish the necessary mutual confidence (both requiring that an NMI operates a quality system that comply with JCRB guidelines and have been reviewed and accepted by the RMO):

A. a quality system (QS) that meets the requirements of ISO/IEC 17025, or equivalent, for an NMI, assessed by an accreditation body fulfilling the requirements of ISO/IEC 17011, or

B. a different way of assuring quality or a different QS, or a QS based on ISO/IEC 17025 without assessment by an accreditation body.

   The NMI then declares its CMCs and submits them to the local RMO for review and transmission to the JCRB.

RMOs are required to develop guidelines for accepting quality systems fit-for-purpose for the CIPM MRA. This document gives the AFRIMETS guidelines for accepting QS using both routes (A and B) and the evidence required to demonstrate compliance with the guidelines.

3. Basic Requirements

In order for AFRIMETS to accept a quality system of an NMI or Designated Institute (DI) as satisfying the requirements of the CIPM MRA, the AFRIMETS Technical Committee for Quality Systems (TC-QS) requires evidence demonstrating:

(i) the implementation of a quality system satisfying ISO/IEC 17025 (or for reference material producers, ISO 17034 or ILAC Guide 12, for proficiency test providers ISO/IEC 17043, or any other standard or guide as may be applicable), either officially assessed by an accreditation body as mentioned in A or approved by the AFRIMETS TC-QS, and

(ii) technical competence to provide a calibration and measurement service that can deliver the uncertainties claimed.

Note: Hereafter the term "NMI" is understood to also include "DI''.

4. Compliance for a QS in accordance with the CIPM MRA

Compliance with the requirements for a QS as stated in the CIPM MRA can be demonstrated through one of the following two pathways:

(a) Third party accreditation to ISO/IEC 17025 and/or ISO 17034, and or ISO/IEC 17043, or

(b) Attestation against the requirements of ISO/IEC 17025 and/or ISO 17034 or any other applicable standards or guides, by a team consisting of quality system experts and technical peers appointed by the TC-QS.

(c) Attestation by a team consisting of quality system experts and technical peers. This may be organized by the NMI or another recognized body, such as an accreditation body.

Notes:

- Pprocedure **A** and subsequently pathway **(a)** is the preferred route for compliance)
- Third party accreditation must be from an accreditation provider operating to ISO/IEC 17011 and that is a signatory to the ILAC MRA.
- Criteria for selecting technical peers and quality system experts are explained in document CIPM 2007-25, a summary of which is given in section 7 of this document.

5. Evidence

5.1 NMIs following pathway (a)

NMIs following pathway (a) - third party accreditation to ISO/IEC 17025 and/or ISO 17034 for reference material producers and/or ISO/IEC 17043 for proficiency test providers, must submit the following evidence to the AFRIMETS TC-QS:

- Copies of accreditation certificate(s),
- Scopes of accreditation covering the CMCs to be submitted,
- Names and affiliations of technical assessors,
- The Assessment report may be requested.
- Any other document may be requested by TCQS.

The first time the NMI applies for the approval of the QS as fit-for-purpose for the CIPM MRA, where possible the NMI will be visited by the AFRIMETS TC-QS or its appointed representatives to assess the above documentation on site.

5.2 NMIs following pathway (b)

NMIs following pathway (b) - attestation by a team consisting of quality system experts and technical peers, preferably organised through a recognised accreditation body, must submit the following evidence to the AFRIMETS TC-QS (in compliance with CIPM MRA-G-02);

- Report by the review team. This report must be prepared after the review visits were made for assessment against the relevant* requirements of the selected standard/guide and must have the following minimum contents:
  - Names, affiliations, qualifications, and experience of the quality experts;
  - Scope of the review (including the QMS)
  - Schedule of the review;
  - Organogram of the NMI;
  - Quality system management mechanism;
  - Detailed table of contents of the quality manual;
  - List of administrative and technical procedures;
  - Table of cross references between ISO/IEC 17025 and ISO 17034 (relevant applicable standard) and the Quality documentation of the NMI;
  - List of calibration capabilities covered by the quality system;
  - Customer complaints –process employed and statistics;
  - Non-confirming work –process employed & corrective actions;
  - Report on internal audits;
  - Status of management reviews.
  - Any other document may be requested by TCQS.

- Final attestation by the reviewers, or at least the leader of the review team, stating that all the non-conformances raised during the review process have been satisfactorily addressed.

** A requirement would be considered 'not relevant' only if the function/activity was not carried out by the NMI, e.g. sampling.*

6. Annual Report Guidelines

As part of the regular reports to the JCRB, the RMO must provide annual summary reports on the status of the QS of the NMIs in their regions. For this purpose, NMIs must report annually on the status of the QS to the AFRIMETS TC-QS and in particular;

- Whether and when each member NMIs' QS was approved by the RMO and when the last review occurred;
- Summary of the RMO's QS review process;

- Of changes in key personnel, new installations and of changes in facilities that would restrict the NMIs capability to provide measurement services covering the CMCs;
- Other relevant information, which will help build inter-regional confidence (e.g. training, and courses/workshops on QS, exchange of information between NMIs on QS, interaction with other RMOs on QS with other RMOs on QS);
- An update on greyed out CMCs, e.g. progress towards the re-instatement.

Note: The QS implemented to support the CMCs of the NMIs must undergo a review in accordance with 5.1 or 5.2 with a period not longer than five years. AFRIMETS is responsible for this review, under the auspices of the TC-QS.

7. On-site Peer Review Visits (Summary of Requirements in CIPM 2007-25)

Ideally on-site peer reviews are made within peer review groups to compensate the associated costs by a high level of mutual exchange of peer reviewers. Alternatively, the institute interested in an on-site review, or that is requested to conduct a review by the AFRIMETS TC-QS, shall mutually agree with the AFRIMETS TC-QS on the peer reviewers considering their professional experience and their recognition by the international metrological community. This is with the purpose of having a team with adequate technical depth to review both the quality system and laboratory's activities and the way it realizes and maintains its technical competence and one which will enjoy international credibility. Each peer review group should ideally present a 5-year plan of peer reviews.

The aim is to cover all the declared CMCs of the concerned institute which will have to be reviewed by each peer reviewer in accordance with their area of expertise. The requirements are basically given by ISO/IEC 17025 and ISO 17034, if applicable.

If the laboratory decides to use a reference document for the review it shall indicate it in advance to the peer reviewer(s). The specialists shall consider their technical competence and knowledge of the reference documents proposed for the review to accept or reject the request.

In general;

- Technical peers and quality system experts must be independent of the NMI being assessed/reviewed.
- Technical peers (assessors/ reviewers) must be acceptable to the TC-QS and the relevant regional technical WG. It is recommended that this acceptance be obtained in advance.

  Assessors/reviewers may be considered acceptable if;

  1. they have relevant technical competence,
  2. have had some formal training in laboratory assessments, and
  3. have laboratory assessment experience.

  If, during the review, the technical assessors/peer reviewers work with or under the guidance of quality system experts, it may not be necessary to insist on 2 and 3 above.
- It is required that technical assessors/peer reviewers be selected from NMIs with capabilities similar to or higher than the NMI being assessed/reviewed, with relevant

CMCs accepted in the BIPM Key Comparison Database (KCDB), or that have demonstrated competence (internationally) in the relevant field.

However, in exceptional circumstances, technical assessors/peer reviewers from outside organisations may be selected, with the approval of the relevant regional technical WG and the AFRIMETS TC-QS.

- A quality system expert should be a person who normally conducts or in the past has normally conducted assessments for accreditation on behalf of an accreditation provider operating to ISO/IEC 17011 and that is a signatory to the ILAC MRA.

The planning and execution of the on-site peer review must be conducted according to the following sections:

7.1. On-site visit preparation

This section contains guidance on planning and conducting peer-review activities. The extent to which provisions of this section are applicable depends on the scope and complexity of the peer-review and the intended use of the peer-review conclusions. In all cases of the on-site visits by peers, the peer-reviewed shall meet at least the criteria outlined in CIPM/2007-25, Section 3 . It is recommended that the on-site peer review includes at least the following activities:

7.1.1 Visit preparation

Prior to the visit, it is recommended that the following points are agreed upon between the peer reviewers and the peer-reviewed institute:

- Objective and scope of the review;
- Place and date of the visit;
- Language for oral and written communication;
- The financial arrangements (see Section 8).

7.1.2 Document review

It is recommended that before the visit, the peer reviewers have the following information:

- The list of services included in Appendix C of the KCDB - CMCs to be reviewed by reference to the KCDB (see http://kcdb.bipm.org/);
- The list of participation in key, supplementary or any other comparisons since the last review visit;
- Measurement and/or calibration procedures used;
- Reference to written document standards (if applicable);
- Quality manual (its relevant part or parts).

The peer reviewer reviews the documentation and verifies if it is sufficient and adequate to support the activities needed for the CMCs and/or the quality management system.

7.2 On-site visit activities

7.2.1 Opening meeting

The first activity is an opening meeting among the peer reviewer(s) and the staff of the reviewed laboratory, with the purpose of verifying the objectives and scope of the visit by the peers. At least the Quality Manager of the reviewed institute should be present at the opening meeting. The work program during the visit as well as the laboratory staff to participate in the activities is also to be agreed upon here.

In this meeting, the laboratory will assign the responsible person to attend each peer reviewer during the exercise.

7.2.3 Collecting and verifying information

The most important aspects of the review are (as applicable):

a) The technical competence of the staff to perform the measurement and/or calibration activities to be reviewed, including their education, experience, and abilities.

b) If the equipment, staff, methods, and ambient conditions are adequate to obtain results technically valid in accordance with the measurement and calibration capabilities declared in Appendix C.

c) The compliance of the quality management system with the requirements of the CIPM MRA and its full implementation.

It is expected that each CMC of the Appendix C of the MRA declared in the scope of the on-site visit by peers will ideally be covered – as this is unrealistic in some cases, preferences should be established in planning the audit based on the following:

1. newly submitted CMCs.
2. a risk assessment of CMCs to be covered:
    - complaints
    - identified non-conformities
    - unsatisfactory performance in KCs or SCs
    - sampling of CMCs to review their validity
    - peer reviewer´s own experience with technically demanding areas.

7.2.3 Documentation of findings

The findings identified should be documented stating the subject and the level of concern for each finding. The level of concern may range from Critical, a finding that seriously compromises the laboratory's ability to support a CMC, to a Recommendation, which is simply a suggestion that may help the laboratory in a given task (an opportunity for improvement).

7.2.4 Peer review conclusions

All the findings (including observations, improvement opportunities and additional information requests) and agreed actions with deadlines shall be given in a Peer Review Record. An example – see Annex 1.

7.2.5 Visit closure meeting

A visit closure meeting takes place among the peer reviewer(s) and the involved institute staff. The draft Peer Review Record (or at least, orally the findings) is presented, and any problems or misunderstandings are clarified in the meeting.

7. 3 Review visit by peers - final record

After the peer reviewer(s) receive any additional requested information from the laboratory and analyses it, the final Peer Review Record is written. These records are to be issued separately for each reviewed field inclusive of the management system. The peer review records are to be

written and forwarded to the Quality Manager of the laboratory within a short and agreed upon time after the closure meeting – ideally on-the spot. The records should be addressed to the contact person of the given country in TC-QS or the TC-QS representative who will send any records immediately to the TC-QS Chair and the AFRIMETs Secretariat to be placed in the TC-QS database.

8. Mechanisimis for On-site Peer Review under Unexpected Circumstances

8.1 Remote Review

During the pandemic period or any unexpected circumstances, Members following pathway a and b are allowed to change the on-site review to a Remote Review, in which reviewers stay in his/her economy and take the review through online video communication with the Member under review.

1) It should be noted that for Remote Reviews, only approved experts from NMIs/DIs may be reviewers.
2) After searching for reviewer candidate(s), the Member wishing to run a Remote Review shall check and confirm that video communication between the Member and the reviewer is smooth enough to run a Remote Review, and confidentiality is maintained.
3) Any planned Remote Review should be put forward by the Member by asking permission to run a Remote Review to TCQS Chair.
4) TCQS Chair shall contact the reviewer(s) from the TCQS Reviewers list and confirm the availability of smooth and secured video communication.
5) When the application is approved, all information necessary for the review shall be sent to the reviewer at least one month ahead of the date of review so that the reviewer(s) can have enough time to revise the documents.
6) The Member under review shall ensure that the reviewer(s) will be able to see all places he/she would see in a normal on-site peer review.
7) In this mechanism witness for calibration activities can be done remotely (recorded videos and/or streaming) according to predefined witness-plan approved by TCQS and disseminated to the concerned Institute.

8.2 Hybrid Review system

In this mechanism of review, the reviewing process can be conducted remotely for the QMS documentation as described above, with on-site technical peer reviews for selected activities by technical expert(s) as approved by TCQS. The rest of the activities can be witnessed remotely as described above.

9. Financial arrangements

To cover the costs incurred during on-site peer reviews the following principles are recommendable and most convenient for peer review:

- NMI/DI should cover accommodation and all travel expenses required.
- It is the responsibility of the concerned NMI/DI to contact donors for assistance with flights and accommodation costs.
- Full accommodation is arranged and paid for by the hosting institute.

Peer review groups can agree on different financial rules at their discretion. All direct costs associated with the visit + working hours will have to be covered by the hosting institute if not agreed otherwise.

Annex 1

Summary Report by Review Team - Minimum contents for non-accredited laboratories

An AFRIMETS NMI that chooses to pathway (b) and undergoes a peer review process, is required to obtain a summary report by the review team for submission to the AFRIMETS TC-QS WG. The minimum contents expected in this summary report are described below.

This summary report should preferably be prepared at the same time as when the full report is being prepared.

(a) Scope of the review

- what is being reviewed (specific areas of the laboratory);
- to which standard/guide or part of the standard/guide, is the review being conducted (e.g. ISO/IEC 17025, ISO 17034, ILAC Guide 12, Clause 5 of ISO/IEC 17025).

(b) Schedule of the review

dates, times, locations.

(c) Names and affiliations of the reviewers

Names and affiliations of the reviewers with the leader of the team clearly identified. If different reviewers were responsible for different areas, this should be noted.

(d) Details of the following

- Organogram of the NMI;
- Quality system management mechanism;
- Detailed table of contents of the quality manual;
- List of administrative and technical procedures;
- Table of cross references between ISO/IEC 17025 and ISO 17034 (any relevant standard) and the Quality documentation of the NMI/DI;
- List of calibration capabilities covered by the quality system (*equivalent to the scope of accreditation of NMIs following 7.3(a))*;
- Customer complaints –process employed and statistics;
- Non-confirming work –process employed & corrective actions;
- Report on internal audits, and
- Status of management reviews.

(e) Findings of the Review Team (*see next page for recommended format)*

Findings of the review team given with reference to the relevant sub-clauses of the standard/guide (non-conformances must be described).

(f) Any other comments.

(g) Attestation by the reviewers

Attestation by the reviewers that subject to the satisfactory resolution of the non-conformances, the laboratory has demonstrated

(i) the implementation of a quality system satisfying the relevant standard/guide, and

(ii) technical competence to provide a calibration and measurement service that can deliver the uncertainties claimed.

i) Signatures and dates.

Note 1: AFRIMETS could, if deemed necessary, request additional information; e.g. details of the corrective actions taken to address a given non-conformance.

Note 2: Once the non-conformances have been addressed, a separate attestation must be made by the reviewers, or at least by the leader of the review team, stating that all the non-conformances have been satisfactorily addressed.

RECOMMENDED FORMATS

(d) Findings of the Review Team

Use **OK** for "Complying with requirement", **NC** for "Non-conformance found" and **NR** for "Not reviewed" in column 2 (Code) of the table below.

Clause Number(s)	**Code** (OK/NC/NR)	**Description of the non-conformance and/or any other comments**
e.g. 4.1		
4.2		
4.3		
e.g. 5.1		
5.2		
5.3		

(d) Listing of NMI's Measurement Capabilities

Measurand (Quantity, Instrument/Artefact)	**Range**	**Expanded Uncertainty (95%)**	**Special Conditions/Comments**