Accreditation Education Research & Scientific Service Center
Nepal

QUALITY

MANUAL

(Based on ISO/IEC 17011:2017 '*Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies*')

Reviewed by: CEO, AERSSC

Approved by: AERSSC Board

Revision Records

S. No.	Page No.	Section No.	Date of Revision	Revision No.	Revision Detail

2. Introduction

Accreditation is the independent evaluation of conformity assessment bodies against recognized standards to carry out specific activities to ensure their impartiality and competence.

The role of conformity assessment in world trade today has become very important. It has a great impact on the development and economy of a country. To achieve the above impact in the developing country like us, Accreditation Education Research & Scientific Service Center (AERSSC), Nepal operates an accreditation scheme for:

- Testing and Calibration Laboratories in accordance with ISO/IEC17025:2017
- Medical Laboratories in accordance with ISO 15189:2012
- Certification Bodies (management systems/personnel) in accordance with ISO/IEC 17021-1, ISO/IEC 17024 with the approval of International Accreditation Forum (IAF);
- Inspection Bodies in accordance with ISO/IEC 17020.

The accreditation certificate issued by Accreditation Education Research & Scientific Service Center (AERSSC), Nepal gives assurance of technical competence of Conformity Assessment Bodies (CABs) in the global market.

In operating the accreditation scheme, Accreditation Education Research & Scientific Service Center (AERSSC), Nepal uses the international standard ISO/IEC 17011:2017 ‘*‘Conformity Assessment – General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies’* and APLAC (Asia Pacific Laboratory Accreditation) /ILAC (International Laboratory Accreditation Cooperation) /APAC (Asia Pacific Accreditation Cooperation) publications for the purpose of Mutual Recognition Arrangements (MRA). Further, to demonstrate the compliance with the requirements of the international standard and applicable APLAC/ILAC/APAC publications, AERSSC has established, implemented and maintained its quality system in compliance with the requirements of ISO/IEC 17011:2017.

3. Quality Policy

Accreditation Education Research & Scientific Service Center (AERSSC), Nepal operates an Accreditation system with impartiality, fairness, efficiency and transparently in order to reach international recognition.

AERSSC accreditation is open to laboratories within and outside Nepal based on requests received.

AERSSC is committed to:

- Provide accreditation services in accordance to the prevailing latest international standards;
- Establish the national accreditation system in line with the international requirements, ISO/IEC 17011:2017;
- Develop and maintain the regional and international MRAs;
- Provide credible, cost effective accreditation services aimed at supporting trade, enhance the protection of consumers and the environment, and improve the competitiveness of Nepalese products and services in both the voluntary and regulatory areas;
- Provide external training services in accreditation associated activities.

The objective of the training programs is to create awareness on the benefits and importance of accreditation and to promote an understanding of the key accreditation standards requirements.

Furthermore, the training course delivered or facilitated by AERSSC are not a precondition of accreditation neither do they guarantee accreditation by AERSSC.

AERSSC ensures that Quality Policy, Objectives and target including the achievement of activities are communicated, implemented and are effectively acknowledged at all levels of staff.

(Chief Executive)
AERSSC, Nepal
28.01.2019

4. General Requirements

4.1 Legal entity

AERSSC is an independent Accreditation Body registered legal entity, a non-profit company incorporated under subsection (1) of the Companies Act 2006 of Government of Nepal, responsible for the accreditation of conformity assessment bodies (CABs) such as Testing, Calibration and Medical Laboratories, Certification Bodies (management systems/personnel), Inspection Bodies, to relevant international standards and the respective ILAC and IAF documents.

4.2 Accreditation Agreement

AERSSC will establish a legally enforceable arrangement with each conformity assessment body that requires the conformity assessment body to conform to at least the following:

- To provide access to those documents that provides insight into the level of independence and impartiality of the CAB from its related bodies, where applicable;
- To commit to fulfill continually the requirements for accreditation for the scope for which accreditation is sought or granted. This includes an agreement to adapt to changes in the requirements for accreditation;
- To provide access to CAB personnel, locations, equipment, information documents and records as necessary to verify fulfillment of requirements for accreditation;
- To cooperate as is necessary to enable the accreditation body to verify the fulfillment of the requirements for accreditation;
- To arrange the witnessing of CAB services when requested by AERSSC;.
- To claim accreditation only with respect to the scope for which it has been granted;
- To commit to follow the accreditation body's policy for the use of the accreditation symbol'
- Not to use accreditation in such a manner as to bring the AERSSC into disrepute;
- To inform the AERSSC of any significant changes relevant to its accreditation without delay in any aspects of its status or operation relating to:

  Its legal, commercial, ownership or organizational status;

Top management and key personnel of an organization;

Main policies.

Resources and premises.

Scope of accreditation and

Other such matters that affect the ability of the CAB to fulfill requirements for accreditation.

- To pay fees as determined by the accreditation body
- To assist in the investigation and resolution of any accreditation related complaints about the CAB referred to it by the accreditation body.

As a result of any change, the AERSSC will verify if the accredited laboratory has undertaken the necessary measure to implement or amend the procedures.

4.3 Use of accreditation symbols and other claims of accreditation

AERSSC posts in its website the current status of the accreditation that it has granted to its CABs and will be updated regularly. The information shall include the following:

- Name and address of the accredited CAB including contact person and telephone no.
- Dates of granting the accreditation and expiry dates, as applicable;
- Scope of accreditation in full.

4.3.1 AERSSC provides CABs with information about suitable ways to obtain traceability of measurement results in relation to the scope for which accreditation provided. AERSSC has policy 'Policy on Calibration and Traceability of Measurements' in-line with ILAC P9.

4.3.2 Accreditation information about international arrangements in which AERSSC is involved is provided through its website.

4.3.3 AERSSC gives due notice of any change in its requirements for accreditation through its website, newsletter or by informing individually. Once the target date of the implementation is over, AERSSC verifies the implementation of the changed requirements either by documentary evidence or on-site visit.

4.3.4 AERSSC will take measures to ensure that the accredited CAB:

a) Fully conform to the requirements of AERSSC for claiming accreditation status, when making reference to the accreditation in communication media;

b) Does not make any misleading or unauthorized statement regarding its accreditation;

c) does not refer to the accreditation in a way so as to imply that a product, process, service, management system or person is approved by AERSSC;

d) Inform its affected clients regarding any change in its status of accreditation including its scope, suspension, or withdrawal without undue delay.

4.3.5 When AERSSC has an accreditation symbol, AERSSC will have the legal right to use it and the accreditation symbol will be legally protected.

4.3.6 AERSSC has a documented policy (AERSSC-17) governing the use of the accreditation marks and claims of accreditation status which includes the following:

a) Requirement for the use and monitoring of the AERSSC logo in combination with any CAB mark;

b) Criteria for affixing AERSSC logo for a product, process or service if it has been certified or approved by AERSSC (if applicable later);

c) Requirements for any reference to accreditation;

d) Requirements for reproduction of the accreditation symbol/mark/logo

e) Requirements for the use of the AERSSC symbol/Mark/logo and claims of accreditation status in communication media;

f) Criteria for using AERSSC symbol/mark/logo and claims of accreditation status for the specific activities covered by the scope of accreditation.

4.3.7 Clear indication of the AERSSC symbol/logo/mark in the policy document (AERSSC-17) regarding the conformity assessment activity to which the accreditation is related.

4.3.8 Suitable action such as request for corrective action, suspension, withdrawal of accreditation will be taken for incorrect or unauthorized claims of accreditation status or misleading use of accreditation logo.

4.4 Impartiality requirements

4.4.1 AERSSC ensures the impartiality at all level of its operation.

4.4.2 AERSSC will be responsible for the impartiality of its accreditation activities and will not allow commercial, financial or other pressures to compromise impartiality.

4.4.3 AERSSC's top management has commitment to impartiality in carrying out its accreditation activities and managing conflict of interest.

4.4.4 Committees, groups or person that could influence the accreditation process shall act objectively. It is AERSCC policy to ensure that all personnel involved in accreditation process are free from any undue commercial, financial and other pressures that could compromise impartiality. AERSSC staff is governed by rules and regulations which ensure impartiality in their functions. The Assessors are governed by the 'Rules for Assessors' to act objectively and be impartial in conducting the assessments. Committees are constituted to avoid situations of undue commercial, financial or other pressures. All personnel involved in the accreditation are required to sign a Form of impartiality.

4.4.5. To safeguard impartiality, AERSSC has organized and structured in such a way that there is a balanced representation of significant interests in developing and reviewing the Accreditation policies. Various committees of AERSSC have members from Regulators, Industries and Laboratories with due take care of no single group domination.

4.4.6 AERSSC ensures that activities of related bodies do not compromise confidentiality, objectivity and impartiality of its accreditation. AERSSC has identified analyzed and documented the potential conflict of interest whether it arises within AERSSC or from the activities of related bodies.

4.4.7 AERSSC will document and demonstrate to eliminate or minimize any type of risk if they arise within the AERSSC or from the activities of other persons, bodies or organizations where such risks are identified.

4.4.8 AERSSC's Top management will be responsible for reviewing any residual risk to determine if it is within the level of acceptable risk.

4.4.9 AERSSC will not provide accreditation if an unacceptable risk to impartiality is identified which can not be mitigated to an acceptable level.

4.4.10 Accreditation policies and procedure under which AERSSC operates are non-discriminatory and administrated in a non-discriminatory manner. Procedures are not used to impede or inhibit access of CABs. The AERSSC has placed no geographic limitations of the CABs operation. The size, membership in any association or group, and the number of certified organizations are not conditions for accepting applications for accreditation.

4.4.11 AERSSC does not offer or provide directly or indirectly whether individually or group those services such as consultancy, designing and maintaining the quality system and services of CABs perform.

4.4.12 AERSSC has a procedure to ensure the evaluation of accreditation case by Accreditation Committee whose members are different from those who have carried out the assessment. The Assessors are selected out of the pool of qualified, experienced, trained and competent persons. The members of accreditation committees are also selected based on long proven track of their technical competence.

4.4.13 Nothing will be said or implied by AERSSC which suggest that accreditation would be easier, faster or less expensive if any specified person(s) or consultancy is used.

4.5 Financing and Liability

4.5.1 AERSSC will have the financial resources which can be demonstrated by records and/

or documents, required for the operation of its activities.

4.5.2 AERSSC will evaluate the risks arising from its activities and have arrangements to cover liabilities arising out of legal proceedings initiated by users of accredited laboratories. The liability of AERSSC is limited to the application fees charged by AERSSC.

4.6 Establishing Accreditation Schemes

4.6.1 AERSSC will adopt accreditation schemes published by various reputed International bodies like ILAC, APAC, EA or publicly available document of other accreditation bodies. AERSSC may develop specific guideline documents in future for each area with the help of technical Committees as and when necessary.

4.6.2 Only the guidance, application or normative documents developed by Committees or persons possessing the necessary competence including the participation of appropriate interested parties which does not contradict or exclude any of the requirements of the relevant International Standards will be used.

4.6.3 AERSSC has established a policy and documented procedure (AERSSC 18) to determine the suitability of the conformity assessment schemes and standards for accreditation purposes.

4.6.4 AERSSC is committed to extend its activities on request from interested parties. AERSSC has a documented procedure (AERSSC 18) to cover this aspect.

4.6.5 AERSSC will consider at least the following if it decide to discontinue an accreditation scheme in part or in full:

a) views of interested parties;

b) contractual duties;

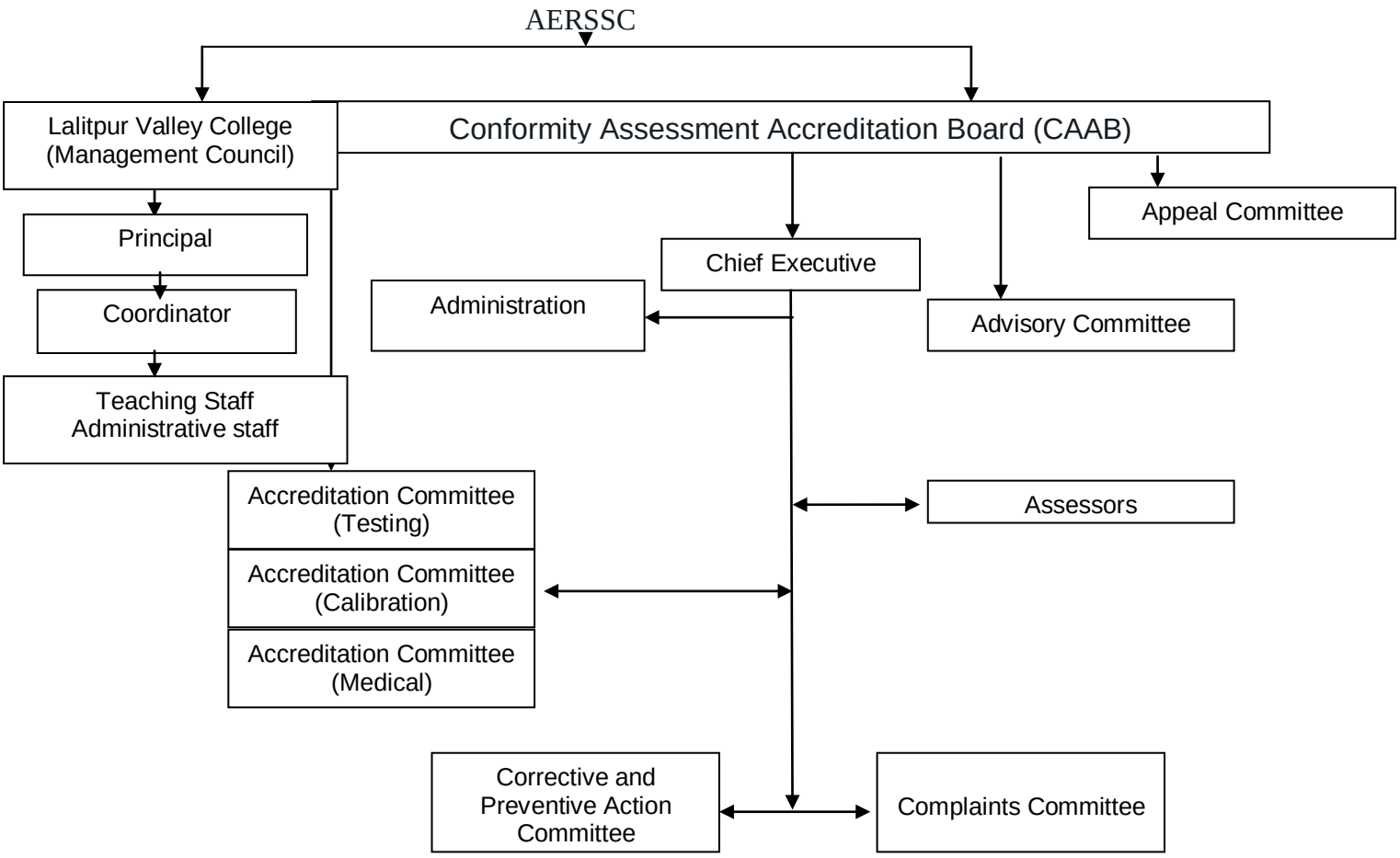
c) transition arrangements;

d) external communication regarding the discontinuation;

e) information published by the accreditation body

5 Structural requirements

5.1 The organization chart of AERSSC, Nepal is given below. The organization chart and reporting linkages takes care of impartiality, fairness, efficiency and transparently operation of AERSSC, Nepal.



5.2 Conformity Assessment Accreditation Board (CAAB) acts as the apex body of AERSSC regarding accreditation activity and having the following terms of reference:

- Formulating policies pertaining the operation of AERSSC.
- Oversees the implementation of the policies relating to accreditation by the Chief Executive.
- Oversees the finances for the operation of AERSSC.
- Establishes policies on appeals and complaints regarding AERSSC.
- Formulate other measures to ensure that the AERSSC will operate transparently and effectively at all level of its operation.
- The establishment of other committees such as Accreditation Committee, Appeal Committee,
- Advisory Committee, Complaints Committee and Corrective, Preventive Action and Improvement Committee as required.

5.3 AERSSC is the registered legal entity in the context of ISO/IEC 17011:2017. It is a private non-governmental body and makes no claim to be connected with any government.

5.4 AERSSC is a trading name for Conformity Assessment Accreditation Board (CAAB) of Accreditation Education Research and Scientific Service Center Pvt. Ltd., a non-profit company incorporated under subsection (1) of Section 5 of the Companies Act 2006.

5.5 On recommendations of Accreditation Committee, Conformity Assessment Accreditation Board is empowered to take decisions relating to accreditation, including the granting, maintaining, extending, reducing, suspending and withdrawing of accreditation. Chief Executive after approval from two third members of Conformity Assessment Accreditation Board may confirm the decision on behalf of Conformity Assessment Accreditation Board.

5.6 The role of various committees is described as follows:

Accreditation Committee: Accreditation Committees evaluate the assessment report including on-site, surveillance and re-assessment report and make necessary recommendation for decision on grant of accreditation. Members are drawn from different organization so that no single group or organization predominate the committee.

Advisory Committee: Advisory committees are responsible for developing and reviewing the technical documents for AERSSC.

Appeal Committee: Appeal committee operates whenever there is an appeal against any decision related to accreditation taken by AERSSC.

Complaints Committee: Committee constituted for dealing with complaints received from various sources.

Corrective, Preventive Action and Improvement Committee: responsible to review and propose changes/amendments to the management system documents.

The duties, responsibilities of personnel working with AERSSC as follows:

Chief Executive has the overall authority to properly manage the administration, finance and operation of AERSSC. He is responsible for the overall management of the accreditation and assessment activities as well as to ensure the impartiality, fairness, efficiency and transparency in the system.

The CEO being the management Representative responsible Quality Manager for ensuring amongst other duties that AERSSC complies with the requirements of ISO/IEC 17011:2017.

Quality Manager ensures that the establishment, implementation and maintenance of AERSSC management system in accordance with ISO/IEC 17011:2017. He is also responsible for Internal Audit, Management Review, Complaint, Assessor management and other related management system activities.

Assessors are experts from the public and private sectors as well as from technical institutions/associations who have been trained, qualified and registered as assessors by AERSSC or other accreditation bodies. Assessment teams consist of a Lead Assessor and an appropriate number of Technical Assessors as required depending upon the scope of accreditation. The lead Assessor is responsible for organizing, directing and conducting assessments, report findings and to evaluate corrective action. During the assessment, the Lead Assessor is also responsible for assessing the quality management system of the applicant as well as undertaking technical assessment within his/her field of expertise. The Technical Assessors are responsible for advising the Lead Assessor on specialist technical matters relating to the applicant's scope of accreditation.

5.7 AERSSC has defined the overall authority and responsibility of major functionaries as follows:

a. Development of policies relating to the operation of the accreditation body: Conformity Assessment Accreditation Board.
b. Supervision of the implementation of the policies and procedures: Chief Executive
c. Supervision of the finances of the accreditation body: Chief Executive (with help of Administration)
d. Decisions on accreditation : Conformity Assessment Accreditation Board on recommendation of Accreditation Committees
e. Contractual arrangements: Chief Executive
f. Delegation of authority to committees or individuals, as required, to undertake defined activities on behalf of top management: Conformity Assessment Accreditation
g. Provision of adequate resources;
h. Performance of assessments and accreditation processes;
i. Development or adoption of activities of the schemes for which it provides accreditation;
j. Accreditation decisions shall not be subject to approval by any other organization or person.

5.8 AERSSC has access to necessary expertise for advising on matter directly relating to accreditation. Such expertise available with AERSSC is in the form of Accreditation Committee (AERSSC-15), Advisory Committee (AERSSC-08), Appeal Committee (AERSS-07), Lead Assessors (AERSSC-04), Technical Assessors and Staff. AERSSC (AERSSC-16) may take help of any expert as and when it feels necessary.

5.8.1 The responsibility to formulate the various committees for AERSSC lies with Conformity Assessment Accreditation Board (CAAB), AERSSC has a procedure for selection of members for various committees and their terms of reference.

5.8.2 The organization structure referred in 5.2. of this document shows the entire structure of AERSSC.

6 Resource requirements

6.1 Competence of personnel

6.1.1 General

AERSSC has developed policy (AERSSC-05) for ensuring qualification, training and skills of its personnel regarding appropriate knowledge relevant to the accreditation schemes and geographic areas in which it operates.

6.1.2 Determination of Competence criteria

6.1.2.1 AERSSC have established a documented process for determining and documenting the competence criteria for personnel involved in the management and performance of assessments and other accreditation activities. Competence criteria for new field will be developed with regard to the requirements of each accreditation scheme including the required knowledge and skills for performing accreditation activities.

6.1.2.2 The procedure for selection of assessment teams and conduct of assessments is documented (AERSSC-14). Adequate care is taken while selecting the assessment teams that the assessors are having appropriate expertise to each area of laboratory

including assessment principles, practice and techniques as well as general management system principles and tools.

6.1.2.3 The procedure for selection of assessment teams and conduct of assessments is documented on AERSSC-14. Adequate care is taken while selecting the assessment teams that the assessors are having appropriate expertise to each area of laboratory including accreditation body's rules and processes, accreditation and accreditation scheme requirements and relevant guidance and application documents as well as conformity assessment scheme requirements, other procedures and methods used by the conformity assessment body.

6.1.2.4 The procedure for selection of assessment teams and conduct of assessments is documented on AERSSC-14. Adequate care is taken while selecting the assessment teams that the assessors are having appropriate expertise to each area of laboratory including knowledge of risk based assessment principle as well as its demonstration.

6.1.2.5 The procedure for selection of assessment teams and conduct of assessments is documented on AERSSC-14. Adequate care is taken while selecting the assessment teams that the assessors are having appropriate expertise to each area of laboratory including knowledge of general regulatory requirements related to the conformity assessment activities.

6.1.2.6 The procedure for selection of assessment teams and conduct of assessments is documented on AERSSC-14. Adequate care is taken while selecting the assessment teams that the assessors are having appropriate expertise and demonstration skills for practices and processes of the conformity assessment body business environment, communication skills appropriate to interact with all levels within the conformity assessment body, note taking and report writing skills, interviewing skills and assessment management skills.

6.1.2.7 The procedure for selection of personnel is documented on AERSSC-05. Adequate care is taken while selecting the personnel having note taking and report writing skills.

6.1.2.8 The Board Member will be trained to understand the applicable accreditation scheme requirements to evaluate the outcomes of the assessment including related recommendations of the assessment team as and when necessary by concerned experts.

6.1.2.9 Additional specific competence criteria may be developed for a specific accreditation scheme wherever applicable.

6.1.3 Competence Management

6.1.3.1 AERSSC Employees, Assessors and Accreditation Committee members are selected based on their qualification, experience and competence. The minimum qualification, experience and skill requirements for each category of personnel are defined by AERSSC. AERSSC contracts on a needs basis, a number of qualified and registered assessors and technical experts.

6.1.3.2 AERSSC endeavors to expand its pool of assessors from all appropriate sources. In order to be empanelled, Assessors are required to qualify the AERSSC / Equivalent Assessor Training Course conducted by any other international Accreditation Body having APLAC / ILAC MRA.

6.1.3.3 For ensuring satisfactory performance of the accreditation process, AERSSC has a system of monitoring the performance of all personnel involved in accreditation process.

6.1.3.4 AERSSC has a system of monitoring the performance of its assessors by way of taking feedbacks from peer assessors, laboratories and the committee members and complaint against person from any source. The feedbacks are evaluated and appropriate actions are taken to improve the performance. AERSSC also performs the assessor's conclave to bring the uniformity in the assessment process.

6.2 Personnel involved in the Accreditation Process

6.2.1 AERSSC only employs personnel who have the prerequisite qualifications and experience to enable them to undertake the work for which they are employed for. All AERSSC staff shall sign an employment contract and a copy of a job description which outlines his/her responsibilities/duties. As part of its staff development, training is given to all staff in both technical and administrative areas as appropriate. All personnel are given the opportunity to undertake further training to advance their career. Training plans are discussed with all personnel.

6.2.2 AERSSC permanent staff, contracted assessors/technical experts are required to sign a contract with AERSSC that specifies their agreement to confidentiality, impartiality and non-conflict of interest. Copies of signed contracts shall be kept at the AERSSC office. In addition, each assessor/technical expert shall sign a non-disclosure/confidentiality statement indicating any relationship they may have or had with the organization/facility being assessed. AERSSC Board and committee members shall sign a non-disclosure/confidentiality statement upon appointment. Copies of confidentiality and conflict of interest are kept at AERSSC office.

6.2.3 AERSSC hall plan training/workshop/communication of assessors and ongoing continuous professional development (CPD) attended by each assessor shall be recorded. All relevant and up to date documented assessment procedures and information shall be provided to assessors.

6.2.4 The training program for AERSSC assessors is in line with APLAC TR 001 and ISO 19011 'Guidelines for Quality and/or Environmental Management System Auditing'.

6.3 Personnel Records

AERSSC maintains records of qualifications, training, experience and the area of expertise of all personnel (including their position held and in the case of assessors/experts position held in their own organizations) involved in accreditation process including Accreditation Committee Members.

6.4 Outsourcing

As a matter of policy, AERSSC does not subcontract any part of the assessment activity. AERSSC outsources various functions including IT and website maintenance, legal and litigation, human resources and marketing and communication. Subcontractors who may have access to confidential information and where deemed necessary shall sign confidentiality statements from AERSSC and the confidentiality statements shall be maintained in a file by the Accreditation Administrator.

7. Process Requirements

7.1 Accreditation Requirements

7.1.1 General Requirements for Accreditation

AERSSC aims to achieve and maintain international recognition of all the accreditation schemes it operates. AERSSC policy is therefore to accredit conformity assessment bodies that fully meet the requirements of the relevant international standard and/or normative documents and the appropriate ILAC/IAF guidance or interpretations thereof.

7.1.2 Accreditation Criteria

a. Testing laboratories

The criteria which laboratories must comply with to obtain accreditation are contained in ISO/IEC 17025 and the appropriate AERSSC requirement documents which include the appropriate ILAC criteria. Laboratories have to fully comply with all the requirements of the relevant standard for which accreditation is sought.

b. Medical laboratories

The criteria which laboratories must comply with to obtain accreditation are contained in ISO 15189. Medical laboratories that perform only medical testing shall be accredited to this standard. Medical laboratories can also be accredited to ISO/IEC 17025. Medical laboratories may decide on which standard to be accredited to, based on guidance from AERSSC.

c. Certification Bodies

AERSSC accredits management systems/product/personnel certification bodies.

i) Management System Certification Bodies

AERSSC accredits quality/environmental/occupational health and safety/food safety management systems. The criteria which quality/environmental/occupational health and safety management systems certification body must comply with to obtain accreditation are contained in ISO/IEC 17021-1 and the IAF guidance or interpretations thereof.

The criteria which food safety management systems certification bodies must comply with to obtain accreditation are contained in ISO/TS 22003 and the relevant IAF guidance or interpretations thereof.

ii) Personnel Certification Bodies

The criteria which personnel certification bodies must comply with to obtain accreditation are contained in ISO/IEC 17024 and the relevant IAF guidance or interpretations thereof.

iii) Inspection Bodies

The criteria which inspection bodies must comply with to obtain accreditation are contained in ISO/IEC 17020 and the relevant ILAC guidance or interpretations thereof.

7.2 Application for Accreditation

7.2.1 The applicant laboratory interested in seeking accreditation is required to apply in the prescribed format, duly signed by the head of the laboratory or an authorized representative. The applicant is also required to submit signed terms and conditions for maintaining AERSSC accreditation.

7.2.2 Apart from the basic information about the operation of the laboratory, the applicant laboratory is also required to provide a list of standards, test/ calibration methods, range of testing / calibration along with limit of detection / Calibration measurement capability (CMC), corresponding to scope applied for. The laboratory is also required to submit list of authorized signatories for signing the reports, list of equipment / reference material with calibration and traceability details and participation in proficiency testing and its results, along with Quality Manual and other supporting documents / records.

7.2.3 The preliminary review for the adequacy of the application and quality manual submitted by the laboratory is carried out by AERSSC whereas the detailed review is carried out by Lead Assessor.

7.2.4 At any point in the application, or initial assessment process, if there is evidence of fraudulent behavior, if the conformity assessment body intentionally provides false information, the accreditation body will reject the application or terminate the assessment process.

7.2.5 AERSSC conducts a pre-assessment visit (if request is made from the applicant) of the laboratory before the final assessment. This is carried out by the appointed lead assessor after the completion of adequacy audit of quality manual. The primary purpose of pre-assessment is to assess the preparedness of the laboratory for the final assessment and to estimate the time frame, and number of assessors required for assessment.

7.3 Resource Review

7.3.1 AERSSC, on receiving of application, reviews for the resources available throughout the accreditation process including decision making to process the application in timely manner.

7.3.2 If the initial assessment cannot be undertaken in a timely manner, AERSSC will communicate to the conformity assessment body.

7.4 Preparation for Assessment

7.4.1 A competent assessment team is identified to evaluate the applicants documented system, and to conduct the assessment on behalf of AERSSC. Technical Experts, where required also form part of the assessment team. AERSSC ensures that the team members act in an impartial and non-discriminatory manner through a declaration of impartiality and confidentiality for avoiding conflict of interest.

7.4.2 The laboratory is informed about the members of the assessment team in advance to allow the laboratory to object to the appointment of any particular assessor or expert. The procedure for dealing with such objections is covered in AERSSC. Once the assessment team has been finalized, AERSSC confirms to the laboratory in writing.

7.4.3 While the laboratory is informed about the assessment team a copy of this communication along with required documents is send to all the members of the assessment team. The task to be undertaken by each member of the assessment team is detailed in the communication.

7.4.4 AERSSC has documented procedures to assess the competence of a conformity assessment body to perform all activities in the scope of accreditation irrespective of where these activities are performed. These procedures will include assessment techniques used in the accreditation of conformity assessment bodies sufficient to provide confidence in the conformity with the relevant accreditation criteria.

7.4.5 All locations must be working to the same requirements and will be subject to an on-site assessment on a sampling basis as part of the accreditation process to provide evidence of the operation and effectiveness of the system.

7.4.6 Selection of activities to be assessed is on a sampling basis which takes into account the risk associated with the activities, locations and personnel covered by the scope of accreditation.

7.4.7 The assessment plan and date of the assessment will be forwarded to the laboratory for which a written acceptance will be required before an on-site assessment can be undertaken. The time required for assessment will be dependent on the complexity of the conformity assessment body, the geographical spread of its activities, the structure of the quality system, the proposed scope(s) of accreditation and where relevant, the combination of multi-standards for accreditation.

7.4.8 For initial assessment, all premises of the laboratory where key activities are performed are assessed.

7.4.9 Each member of the assessment team is provided the assessment plan along-with the relevant documents as applicable, to carry out the assessments in an effective manner. These documents include - ISO/IEC 17025:2017 or ISO 15189:2012; relevant Specific criteria document; Quality Manual of the laboratory; copy of the application with details of scope of accreditation; relevant portion of previous assessment report and complaint against the laboratory, if any; performance in proficiency testing copy of the pre-assessment report and corrective action (if any) taken by the laboratory and any relevant information pertaining to the laboratory.

7.5 Review of Documentation Information

7.5.1 The adequacy of documentation is reviewed by the lead assessor before on-site assessment/assessment visit. Further, even during the on-site assessment assessors are required to review the document to evaluate its conformity with ISO/IEC17025:2017

or ISO15189:2012 as applicable and the relevant specific criteria documents and of AERSSC policy documents. The assessment team shall use the appropriate checklist as a guide in reviewing the quality documentation and reports the status suitably vide the assessment report.

7.5.2 If there are gross non-conformities by the team member(s), it may be decided not to proceed with the on-site assessment and the non-conformities are reported in writing to laboratory.

7.6 Assessment

7.6.1 AERSSC has documented procedures which describe the assessment techniques used, the time scale for the accreditation process and reporting to the conformity assessment body on the findings raised from the assessment.

7.6.2 Procedure for conducting on-site assessment is detailed by AERSSC, which includes procedure for conducting an opening meeting. During the meeting, where the assessment team and the key personnel of the laboratory are present, the team explains to the laboratory, the purpose of assessment, the accreditation criteria, the assessment schedule and the scope of assessment is confirmed.

7.6.3 The assessment team conducts the assessment based on the assessment plan.

7.6.4 The assessment team is required to verify all relevant information and evidence gathered during the document and record review and the on-site assessment. Based on this the team is required to determine the extent of competence and ascertain whether the work of the laboratory is being performed in accordance with the assessment criteria. The detailed procedure for analysis of information gathered and consolidation of audit findings is given by AERSSC. The procedure for conducting an on-site assessment is addressed by AERSSC. The initial assessment covers all aspects of the organization's scope of application.

7.6.5 As per AERSSC procedures, when the assessment team need clarification/interpretation on any aspect or if there arises a conflict between assessment team and the laboratory, there exists provision for referring the matter to AERSSC.

7.6.6 AERSSC procedure for conduct of assessment requires that a closing meeting between the assessment team and the laboratory management takes place. During the closing meeting the assessment team briefs the laboratory about the findings of the assessment and provides clarifications on the queries raised by the laboratory. A written report is prepared, consistent with the proceedings of the assessment. The procedure is addressed by AERSSC.

7.6.7 AERSSC remains responsible for the contents of the assessment report including non-conformities.

7.6.8 AERSSC procedure ensures that the responses of the laboratory to resolve the nonconformities raised by the assessment team are reviewed to verify their adequacy and effectiveness. If required additional information is called for, the closure of non-conformities is either done based on review of evidence of effective implementation of corrective actions or through a follow-up visit, as appropriate. The detailed procedure is addressed by AERSSC.

7.6.9 The findings from the assessment are recorded as nonconformities where the conformity assessment body needs to submit corrective action. Where corrective action by the conformity assessment body is required the applicant organization shall be invited to identify and propose corrective actions to address the raised nonconformities within one month after the assessment and have corrective action cleared within three months after the assessment. For surveillance assessments conformity assessment bodies shall be invited to identify and propose corrective action within one month after the surveillance assessment.

a) AERSSC reviews the responses of the conformity assessment body to determine if the actions are considered sufficient and appropriate. Where the conformity assessment body's response is found to be insufficient, further information shall be requested. Evidence of effective implementation may be requested or a follow up assessment may be carried out to verify effective implementation. The AERSSC name and logo;

b) Name of the accredited conformity assessment body and name of the legal entity if different;

c) Scope of accreditation;

d) Locations of the accredited conformity assessment body, the conformity assessment activities performed at each location and covered by the scope of accreditation;

e) Unique identification number;

f) Contact details of the accredited facility

7.7 Accreditation Decision Making

7.7.1 The CEO or designated officer analyses the assessment report received from the assessment team; if required, seeks further information and when fully satisfied prepares a summary.

7.7.2 AERSSC Secretariat organizes Accreditation Committee meetings at regular intervals. The Accreditation Committee is provided with adequate information, to take a decision regarding recommendation for grant, reduction, extension, maintenance or withdrawal of accreditation.

7.7.3 AERSSC will provide information to the decision maker on unique identification of the laboratory, dates of the on-site assessment, names of assessors/experts involved in assessment, unique identification of all premises assessed, proposed scope, assessment report, a statement on the adequacy of internal organization, information

on the resolution of all non-conformities, summary of results of proficiency testing or Inter-laboratory comparisons and any other relevant information.

7.7.4 Accreditation Committee will decide only if the information provided to them is adequate.

7.7.5 Based on the recommendation of the accreditation committee, CAAB of AERSSC takes the decision on accreditation. An accreditation certificate with unique identification number is then issued to the laboratory.

7.7.6 AERSSC have policy of making use of assessments already performed by another accreditation body for use by its decision taking system.

7.8 Accreditation Information

7.8.1 The accreditation certificate for the type and range of activities is also accompanied by an annexure containing details of the scope of accreditation. The certificate shall include the following information:

- The AERSSC name and logo;
- Name of the accredited conformity assessment body and name of the legal entity if different;
- Scope of accreditation;
- Locations of the accredited conformity assessment body,t the conformity assessment activities performed at each location and covered by the scope of accreditation;
- Unique identification number;
- Contact details of the accredited facility.

7.8.2 Effective date of granting accreditation i.e. the date of issue of certificate and date of expiry of certificate.

7.8.3 The scope of accreditation shall, at least, identify the following,

a) For certification bodies;

- The type of certification;
- Certification scheme;
- the standards, normative documents and/ or regulatory requirements to which management systems, products, processes and services, or persons are certified, as applicable;
- industry sectors, where relevant;
- product, processes, service and persons categories where relevant.

b) For inspection bodies:

- the type of inspection body (as defined in ISO/IEC 17020);
- inspection schemes, where relevant;
- the field and range of inspection for which accreditation has been granted;
- the regulations, inspection methods, standards and/or specifications containing the requirements against which the inspection is to be performed, as applicable

c) For calibration laboratories:

- the calibration and measurement capability (CMC) expressed in terms of :
- measurand or reference material;
- calibration or measurement method or procedure and type of instrument or material to be calibrated or measured;
- measurement range and additional parameters where applicable, e.g. frequency of applied voltage;
- measurement uncertainty.

d) For testing laboratories (including medical laboratories:

- materials or products tested;
- component, parameter or characteristic tested;
- tests or types of tests performed and , where appropriate, the techniques, methods and/or equipment used.

e) For other conformity assessment bodies:

- the specific conformity assessment activities the conformity assessment body is accredited for;
- the standards, normative documents and/or regulatory requirements containing the requirements against which the conformity assessment activity is to be performed, as applicable;
- conformity assessment scheme, where relevant;
- industry sector, where relevant.

7.8.4 AERSSC does not use flexible scope of accreditation.

7.9 Accreditation Cycle

7.9.1 AERSSC grants accreditation to laboratories for a period of 3 years. The periodic on-site assessment shall be undertaken not more than 12 months after the date of accreditation. AERSSC conducts an annual surveillance and re-assessment every three years. The surveillance is conducted on site after every one year of assessment/re-assessment. Re-assessment is to be conducted by a new assessment team at least in one of the accredited labs.

7.9.2 After the grant of accreditation, a plan is prepared for conducting the surveillance and re-assessments of laboratories. AERSSC shall take into account knowledge of the accredited organization's activities, management system and performance obtained from previous assessments and the possible risk thereof. The design of the plan is such that it ensures that for each accredited laboratory, the representative samples of the scope of accreditation are assessed during surveillance/re-assessment.

7.9.3 Reassessments will be conducted at least six months (flexible for three months at the time of evaluation of AB itself) before the end of an assessment cycle. The reassessment shall be a complete assessment covering the organization's scope of

accreditation and including all elements of the relevant standard. During surveillance or re-assessment, when non-conformities are identified, the laboratory is given a maximum time of two months to take corrective actions and implement them.

7.9.4 After the re-assessment, the laboratory is informed by AERSSC about the decision of continuation of accreditation, in writing. After the re-assessment visit, if the accreditation is renewed, a new certificate bearing the old accreditation number and having new validity period is issued.

7.9.5 AERSSC may also conduct special surveillance visit as a result of complaints or changes effecting the laboratory operations.

7.10 Extending Accreditation

The laboratories at any time during the accreditation cycle can request for extension of scope. AERSSC has a policy of either conducting special assessment visit or to club it with the forthcoming assessment visit. The procedure to be followed is same as that for the initial assessment except that adequacy audit and pre-assessment are not carried out.

7.11 Suspending, withdrawing or reducing Accreditation

7.11.1 AERSSC has established procedures for suspension, withdrawal or reduction of the scope of accreditation, which are documented by AERSSC.

7.11.2 AERSSC includes the procedure for dealing with cases where the laboratory fails to meet the requirements of accreditation or the terms and conditions of maintaining accreditation. This procedure also includes cases where the laboratory itself may request for withdrawal of accreditation.

7.11.3 AERSSC also includes procedure for dealing with cases where the appropriate action by AERSSC results in reduction in scope of accreditation including cases where laboratory itself asks for reduction in its accredited scope.

7.11.4 A suspended accreditation will be withdrawn if the organization is not able to submit the necessary corrective actions within the timelines acceptable to AERSSC. The appeals procedure includes appointment of an independent Individual/Appeals Committee, to decide validity of the appeals received. The CEO or designated officer of AERSSC will inform the laboratory of the final decision and to take follow up actions, if required.

7.11.5 Reducing accreditation is the process of cancelling accreditation for part of the scope of accreditation.

7.11.6 Decisions to suspend/withdraw/reduce scope of accreditation shall be made by the Board.

7.12 Complaints

AERSSC acts on complaints raised by the CABs or other interested parties following the Appeals and Complaints procedure. AERSSC takes appropriate corrective and preventive actions after evaluation and investigation of the complaints. The actions are evaluated to determine its effectiveness. In case the complaints relate to an accredited CAB, AERSSC informs the concerned CAB to take appropriate action. AERSSC maintains records of all complaints filed as well as remedial actions taken. The outcome of the process will be communicated to the complainant.

Complaints which have not been resolved through the AERSSC complaints handling system are classified as disputes and shall be brought to the attention of the Chief Executive Officer for resolution.

7.13 Appeals

7.13.1 AERSSC has established policy and procedure for dealing with appeals from laboratories against its own decisions. The cases may involve refusal of accreditation or scope reduction for applicant/renewal laboratories and abeyance, suspension, forced withdrawal or scope reduction for accredited laboratories. The procedure is addressed by AERSSC.

7.13.2 The appeals procedure includes appointment of an independent Individual/Appeals Committee, to decide validity of the appeals received. The CEO or designated officer of AERSSC will inform the laboratory of the final decision and to take follow up actions, if required.

7.14 Records on CABs

7.14.1 AERSSC has a system of maintaining all the records on laboratories, to demonstrate that the requirements for accreditation and competence have been effectively fulfilled. These records are regularly updated by concerned officers.

7.14.2 AERSSC has a policy and system for maintaining all the records pertaining to laboratories secured to ensure confidentiality. The hard copies of all records related to each laboratory are available in respective laboratory files . Each record is identified by a unique identification number and the number is displayed on the file. The files are stored at appropriate place and properly indexed. These records are kept in safe custody under lock and accessible to authorized staff of AERSSC. Certain information and databases are also available on AERSSC computer system for use by authorized staff of AERSSC. The access to the computers is password protected. The procedure of maintaining is addressed by AERSSC.

7.14.3 The records shall contain at least the following information:

- Applicant forms;
- A copy of the accreditation certificate and schedule of accreditation;
- Correspondence including correspondence with assessors;

- Information on proficiency testing/inter-laboratory comparisons (where relevant)
- Assessment records and report; and
- Records of committee deliberations, if applicable, and accreditation decisions.

AERSSC ensures that all accredited /applicant organization's records are held in a confidential manner and access is controlled.

The accreditation scopes for all accredited organizations are kept in AERSSC database and are published in the Directory of accredited facilities on the AERSSC website.

8. Information Requirements

8.1 Confidential Information

The agreement with CAB includes commitment of AERSSC to maintain as confidential and not to use or disclose to any third party, any information derived from the Body in connection with the services without consent of the CAB. AERSSC shall inform the CAB, in advance, of the information it intends to place in the public domain.

Information about the CAB obtained from sources other than the conformity assessment body (e.g. complainant, regulators) shall be confidential between the conformity assessment bodies and AERSSC.

All AERSSC employees/Assessor/Technical Expert shall sign an agreement with AERSSC that specifies their agreement to confidentiality, impartiality and non-conflict of interest as well as not to use or disclose to any third party except if such information is required as evidence in any court of law.

In addition AERSSC maintains confidentiality in its operations by also requiring Board members, Committee Members to sign a declaration of confidentiality where

they commit that no information gained while working for AERSSC shall be revealed to others than the relevant staff in AERSSC.

8.2 Publicly Available Information

8.2.1 AERSSC Policy manual and relevant procedures are freely available to all assessors including all other interested parties to download from the AERSSC website:http://www.lvc.edu.np/aerssc or www.aerssc.com.np. It is the responsibility of users to ensure that they are using up to date documents by comparing with the contents list on the AERSSC website. The AERSSC policy manual contains amongst others information about the authority under which AERSSC operates; description of AERSSC rights and duties; AERSSC activities.

8.2.2 AERSSC makes publicly available on the website the current status of the accreditation it has granted to conformity assessment bodies. Some information such as Board Members and Accreditation Committee/Advisory committees are available upon request form AERSSC office.

8.2.3 Should there be changes to any of the accreditation requirements AERSSC shall, taking into account the views expressed by interested parties decide on the precise form and effective date of change and within a reasonable period of time, notify all accredited conformity assessment bodies affected by any such changes. AERSSC shall give sufficient time for the accredited CABs to accommodate the changes as per IAF/ILAC stipulations.

8.2.4 AERSSC shall verify actions implemented to address the change(s). Following the publication of changed requirements for accreditation, AERSSC shall verify that each accredited body conforms to the changed requirements.

9. Management system requirements

9.1 General

9.1.1 In order to have confidence in the operation of the accreditation scheme, AERSSC has established and documented its management system in accordance with the requirements of ISO/IEC 17011:2017. AERSSC implements and maintains its management system for supporting staff, assessors in their work. The CEO has the overall responsibility for AERSSC management system.

9.1.2 AERSSC procedures and operating guidelines are documented, implemented and maintained based on formulated policies. The documented system comprises of in accordance with option A which shall address the following:

Management system;
Document control;
Records control;
Non-conformities and corrective actions;
Improvement;
Internal audits;
Management review

9.2 Management System

9.2.1 The management System is documented and consists of a Policy Manual, procedures, forms and other documents.

9.2.2 The overall quality objectives of AERSSC are as follows:

- To promote, implement and maintain an Accreditation system for laboratories/Certification system/Inspection bodies in accordance with the relevant national and International Standards;
- To provide timely accreditation service to applicant laboratories;
- To establish linkages with International and regional bodies such as ILAC, IAF and APAC through active participation in various meetings.

9.2.3 The CEO/Quality manager shall report to the Management Review Meeting regarding the performance of the AERSSC management system and shall seek suggestion for improvement. The CEO/ Quality manager shall arrange for internal audits. The results of internal audit shall be reviewed as part of the management review process. The CEO/Quality Manager arranges for the AERSSC Management Review Meetings. The CEO is responsible QM until the appointment of QM by the Board.

Hierarchy of AERSSC Documents

Document Type	Prefix
Quality Manual	QM
Accreditation Procedural Documents	AP
AERSSC Forms	F
Specific Guidelines Documents	SG
Technical Requirements Documents	TR
Advisory Documents	AD

9.3 Document Control

The AERSSC operates a system to control all documents by assigning specific identification number that affect the operation of the accreditation scheme. These documents are approved prior to issuance. Any changes in the documents shall be reviewed, updated and reapproved to ensure that changes and the current revision status are identified.

The system for document control is described in the Document Control Procedures. The list of QMS documents indicates the current issue, status and date of affectivity of all AERSSC documents. The list is maintained by CEO/Quality Manager to ensure that relevant versions of applicable documents are available at point of use by thee accreditation personnel, applicants and accredited CABs, as appropriate to their needs. Internally within AERSSC, all documents are maintained in soft copy in PDF format. The documents related to accreditation are available in its website. The

document control procedure also provides mechanism to ensure that AERSSC documents are secured properly identified and remain legible.

9.3.1 Structure of the quality management system manual

9.3.1.1 Quality Manual

The AERSSC Quality Manual describes the AERSSC Management System which is designed to ensure AERSSC compliance with the requirements of ISO/IEC 17011 and of ILAC and IAF, and to support AERSSC staff in their work as well as serve as information to other stakeholders.

9.3.1.2 Procedures Manual

AERSSC has a number of procedures that detail the rules to be followed in AERSSC work.

9.3.1.3 AERSSC documents and forms

AERSSC documents and forms are published to provide information to applicants and other interested parties and to facilitate daily work. List of forms and documents are available.

9.3.2 Authorization

All documents shall be authorized by the AERSSC Board prior to issue.

9.3.3 Implementation and maintenance

The Chief Executive Officer shall be responsible for ensuring the implementation of the AERSSC quality management system. The CEO/Quality Manager shall, amongst other duties, be responsible for managing the AERSSC Quality Management System and ensuring that it

complies with the requirements of ISO/IEC 17011 and other relevant criteria in order to achieve and maintain international recognition.

9.3.4 Distribution

All staff in AERSSC and assessors/experts shall, be informed by email whenever amendments or new documents are issued and in turn they shall acknowledge receipt and confirm that they have understand the document and further commit to implement the document .

9.3.5 Amendments

All amendments to the Quality Manual, Procedures Manual, documents and forms shall be authorized by the Board. Information about amendments is issued by the CEO/Quality Manager and distributed electronically. When a documents or section of the Quality manual is amended the " issue number" effective date and approval date shall change accordingly.

9.4 Record Control

9.4.1 To demonstrate that the accreditation process is effectively implemented, AERSSC operates a record management system to ensure that all AERSSC record are identified, managed as required by ISO/IEC17011and disposed in such a way that integrity of the accreditation process and confidentiality of the records are maintained and safeguarded.

9.4.2 Records maintained include amongst others, personnel and accredited organizations/applicant organizations, checklist and assessment reports, applications for accreditations and extensions, accreditation decisions, accreditation fees, AERSSC staff/assessor/experts records etc. AERSSC ensures that all accredited/applicant organization's records are held in a confidential manner and access is controlled.

9.4.3 Retention period of these records is defined and consistent with what is required by the law. Procedure for controls of Records is established for records management.

9.5 Nonconformities and Corrective Actions

The AERSSC establishes procedure to identify and manage non-conformities, deviation or lapses in its documented system and operations. Where necessary, AERSSC takes actions to eliminate the causes of non-conformities to prevent recurrence. Corrective actions will be evaluated to determine its appropriateness to the problems encountered.

The established procedure for Non-conformities and Corrective Actions uses the Incident Report Form to ensure that the requirements of ISO/IEC 17011:2017 on this clause are fully covered. Records of results of action taken will be documented and made available.

9.6 Improvement

AERSSC has established mechanisms for the identification of opportunities for improvement and to take action. AERSSC has developed a risk profile which is reviewed annually by the Board with measures being put in place to militate against the identified risks. Progress on implementing the improvement measures shall be an input to the management review meetings and shall be reported upon by the CEO/Quality Manager.

9.7 Internal Audits

The internal audits are conducted annually covering all the requirements of ISO/IEC 17011:2017. The CEO/Quality Manager is responsible for the internal audit process with the following objectives:

- To verify conformance to the requirements of the ISO/IEC 17011:2017 and other relevant documents as specified in the Quality Manual, Procedures manual, job descriptions and other documents;

- To confirm that established quality system is effectively implemented and maintained;
- To identify opportunities for improvement.

Internal audit are conducted by qualified and trained personnel different from those who perform the activity to be audited. The results of audits are documented, maintained and reported to concerned personnel for their information, and/or prompt, appropriate effective corrective action(s). The effective implementation of corrective action is verified by CEO/Quality Manager. The results of the internal audit shall be reviewed as part of the management review process.

9.8 Management Reviews

Management Review is conducted annually to improve the effectiveness of the established management system and ensure that the requirements of ISO/IEC 17011:2017 are satisfied.

Members of management Review Committee comprise at least 2/3rd members of Conformity Assessment Accreditation Board, Chief Executive/Quality Manager as well as AERSSC staff/assessor.

Inputs or agenda items for the management review meetings shall include:

a) Results of audits;
b) Results of peer evaluation;
c) Participation in international activities;
d) Safeguarding impartiality;
e) Feedback from interested parties;
f) New areas of accreditation;
g) Trends in nonconformities;
h) Status of corrective actions;
i) Status of actions to address risks and opportunities;
j) Follow up actions from earlier management reviews;
k) Fulfillment of objectives;

l) Changes that could affect the management system;

m) Analysis of appeals; and

n) Analysis of complaints.

The output of Management Reviews shall include actions to:

- Improve the management system and its processes;
- Improve service delivery;
- Define and redefining policies, goals and objectives;
- Address resource issues.

The minutes of the management review meetings shall be filed for records.

10. Cross Frontier Accreditation

Applications received for accreditation by AERSSC from foreign countries shall be handled in accordance with the national cross frontier procedure or by the ILAC/IAF cross frontier accreditation principles of cooperation.

11. Proficiency Testing/Inter-laboratory Comparisons for laboratories

Testing laboratories

Applicant and accredited laboratories are required to participate in appropriate proficiency testing schemes/inter laboratory comparisons and where such schemes are available in their technical field of work in order to demonstrate their capabilities and to assist in maintaining quality of laboratory performance. Laboratories are required to maintain complete records of participation in such schemes and to have procedures for evaluation of performance and implementation of corrective action. AERSSC assesses performance during assessments, surveillance and reassessments as per ILAC P9 or AERSSC policy for participation in proficiency testing activities.

12. TRACEABILITY

Equipment and instrument used by testing/medical laboratories and having a significant impact on the measurements results shall be calibrated. AERSSC accepts evidence of traceability through

- Record of calibration method validation;
- Documentation for assuring the quality of calibration results;
- Documentation for the competence of staff;
- Documentation for accommodation and environmental conditions

Where this is not possible, traceability shall be to specified reference materials provided by a competent supplier and/or other specified methods or consensus standards.

REFERENCES

ISO/IEC 17011:2017 – Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies

ISO/IEC 17025:2017 – General requirements for the competence of testing and calibration laboratories

ISO 15189:2012 – Medical laboratories – Particular requirement for quality and Competence

ISO/IEC 17043:2010 – Conformity assessment – General requirements for proficiency testing

ISO 19011:2018 – Guidelines for auditing management systems

ISO/IEC 17000:2004 Conformity assessment – Vocabulary and General principles

APLAC MR001 – Procedure for Establishing and Maintaining Mutual Recognition Arrangements among accreditation bodies

APLAC MR002 – Asia pacific Laboratory Accreditation Cooperation Mutual Recognition Arrangement (MRA) text

APLAC TR001:08/2014 – Guidelines on training Course for Assessors

IAF/ILAC-A2:01/2018 - IAF/ILAC Multi-Lateral Mutual Recognition Arrangements: Requirements and procedures for Evaluation of a Single accreditation body

ILAC G3:08/2012 – Guidelines for training courses for Assessors used by Laboratory Accreditation Schemes

ILAC G21:09/2012 – Cross frontier Accreditation – Principles for Avoiding Duplication

ILAC P9:06/2014 – ILAC Policy for participation in Proficiency Testing Activities