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1. Procedure Manual for Management System

1.1 Purpose

To ensure documents of Management System are controlled prior to issue.

1.2 Scope

The procedure is applicable to all documents related to quality system in accordance with clause no 5.3 of ISO/IEC 1711:2004.

1.3 Responsibility

1.3.1 The quality officer is responsible for establishing and maintaining procedures to control all documents.

1.3.2 The quality officer is responsible for distribution of the controlled copy of documents to all users and maintains a master list thereof, to ensure distribution of currently revised documents.

1.3.3 The quality officer is responsible for periodically review/revise of the document, if necessary.

1.4 Related documents and REFERENCES

1.4.1 Quality Manual Clause no.5.3

1.5. Procedure

1.5.1 Document Preparation, Review and approval

1.5.1.1. Document Preparation and Review: All documents related to Management System/Technical documents shall be prepared by Quality Officer followed by comments/suggestions from the concerned technical experts/users of the laboratories/assessors/members of the Accreditation Committee.

1.5.2 Document Amendment & Approval

1.5.2.1. Documents may be changed on account of changes in standard/feedbacks received from internal or external sources/in

response to nonconformities or comments raised during internal audits and APLAC evaluation etc.

1.5.2.2 The master copy of approved amendment and amended sheet, reflecting the amendment made is maintained as record.

1.5.3 Document issue and control

1.5.3.1 Quality Officer shall be responsible for issue and control of all documents which shall bear the signature of the approving authority.

1.5.3.2 Document name, Document Number, Issue number, Issue date, Latest amendment number and Date of latest amendment shall be mentioned in the document.

1.6 Records

Master list of documents
Distribution Checklist

2. Procedure for control of Records

2.1 Purpose

2.1.1 To maintain records for verifying compliance with the Standard and effective operation of Quality System.

2.2 Scope

2.2.1 This procedure covers the entire Quality system and technical operations of AERSSC in accordance with clause no. 5.4 of ISO/IEC 17011:2004.

2.3 Responsibility

2.3.1 The Quality officer is responsible for maintaining various records related to management system.

2.3.2 Concerned Technical Officers are responsible for maintain Technical records related to the accreditation of laboratories.

2.4 References

2.4.1 Quality Manual Clause No. 5.3

2.5 Procedure

2.5.1 All the records are kept legible, readily identifiable, stored with adequate protection against deterioration, damage or loss, protected and easily retrievable.

Retention period are defined as per the stipulated minimum amount of retention period as specified by National Regulation.

All the records are held secured to ensure confidentially.

2.6 Records

2.6.1 Records Register

3. Procedure for Control of Nonconformities and Corrective Action

3.1.1 To identify any nonconformance and to limit and control such nonconformance

3.1.2 To undertake corrective action whenever any departure from policies and procedures in the quality system or nonconformities are identified.

3.2 Scope

3.2.1 Applicable to the Management System of AERSSC in accordance with clause no 5.5 of ISO/IEC 17011:2004

3.3 Definitions

3.3.1 Non Conformity: The non-fulfillment of a requirement.

3.3.2 Corrective action: Action taken to eliminate nonconformity.

3.4 Responsibility

3.4.1 Quality Officer is responsible for implementation of appropriate corrective action, if nonconformities identified through Accreditation Officers, staff and members of various committees.

3.5 References

3.5.1 Quality Manual Clause no 5.5
3.5.2 Procedure for Internal Audit
3.5.3 Procedure for Preventive Action
3.5.4 Procedure for Management Review

3.6 Procedure

3.6.1 Sources of Non Conformities

3.6.1.1 The Non Conformities may be identified through any of the following sources:

- Internal Audits
- Complaints from laboratories, AERSSC staff/Assessors/Committee member, etc
- APLAC-MRA Evaluation

3.6.1.2 These non conformities may be related to:

- Established policies and procedures;
- Accreditation Activities

3.6.2 Identification and Management of Non-Conformities

All interested parties are encouraged to look for identification of nonconformities since it is considered as the first step towards improvement.

3.6.3 Correction of Identified Non Conformities

3.6.3.1 Quality Officer uses cause analysis to identify potential causes and corrective actions. Potential corrective actions are evaluated and these most likely to eliminate the problem and prevent its recurrence are implemented which may include revision of document.

3.6.3.2 The Quality Officer shall maintain records of corrective actions taken.

3.6.4 Verifying Implementation and Effectiveness of Corrective Action.

3.6.4.1 Results shall be monitored to ensure the effectiveness of such actions by Quality Officer.

3.7 Records

3.7.1 Constitution of Corrective, Preventive Action and Improvement Committee.
3.7.2 Record register

4. Procedure for Taking Preventive Action

4.1 Purpose

To identify potential sources of non-conformities as a proactive measure to prevent their occurrence.

4.2 Scope

This procedure covers the management system of AERSSC in accordance with cause no. 5.6 of ISO/IEC 17011:2004.

4.3 Responsibility

4.2.1 Quality Officer, together with the Accreditation Officers, is responsible for implementing the procedure.

4.4 Definitions

4.4.1 Action taken to eliminate the cause of a potential nonconformity or other potentially undesirable situation.

4.2.2 Preventive Actions are identified through the following:

- Problems identified by staff, laboratories, assessors, Accreditation Committee members etc
- Observations made during internal audits;
- APLAC and ILAC meetings.

4.4 References

4.5.1 Quality Manual Clause No. 5.6
4.5.2 Procedure for Control of Non-Conformities and Corrective action

5. Procedure for Carrying out Internal Audit

5.1 Purpose

5.1.1 To establish management system of AERSSC (as per relevant clauses of ISO/IEC 17011:2004) and to evaluate the effectiveness of the system.

5.2 Scope

5.2.1 Applicable to the established quality system of AERSSC as per clause no. 5.7 of ISO/IEC

5.3 Responsibility

5.3.1 The Quality Officer is responsible for the planning and execution of internal audits.

5.4 Related Documents and References

5.4.1 ISO/IEC 17011:2004
5.4.2 APLAC MR001
5.4.3 AERSS documents (Quality Manual and other Procedure Manual)
5.4.4 Previous audit findings and actions taken

5.5 Procedure

5.5.1 Internal Audit Frequency

5.5.1.1 The internal audit shall be scheduled at a minimum of once per year for each area/activity, as defined in the quality system.
5.5.1.2 Findings of the audit shall be classified as either:

- Non-conformity
- Concern
- Comment

5.5.2 Personnel for Auditing

5.5.2.1 The auditor appointed by Quality Officer shall normally be a trained and qualified of auditing techniques, accreditation activities and requirements of ISO/IEC 17011:2004.

5.5.2.2 While constituting the auditors for the conduct of audits, it shall be ensured by the Quality officer that auditors are in no way involved in the activities being audited.

5.5.3 Internal Audit Planning

5.5.3.1 The Quality Officer shall establish an audit plan which includes the audit scope, the audit criteria, the audit schedule reference documents (such as quality manual and audit procedure) audit team members and dates of audit.

5.5.3.2 The audit plan may include both horizontal audits and vertical audits so that every aspect/clause of the quality system, including the work of concerned officer, is audited.

5.5.3.3 Each auditor may be assigned specific quality elements or activity. Such assignments are made by the Quality Officer in consultations with the auditors concerned.

5.5.4 Audit Preparation

5.5.4.1 An audit time table is required to be developed by each auditor in conjunction with their auditee to ensure the smooth and systematic progress of the audit.

5.5.4.2 Prior to the actual audit a review of documents, manuals, preparation of checklist is required to be made by the audit team member(s) to finalize an overall action plan for the conduct of the Audit.

5.5.5 Procedure for Conduct of Internal Audit

5.5.5.1 Internal audit shall be conducted with an opening meeting to confirm the audit scope and procedure and to clarify any relevant details including the time, date and attendees for the closing meeting.

5.5.5.2 An internal audit includes investigation and analysis. The investigation process for gathering objective evidence, involves asking questions, observing activities and examining records for verifying the conformity of the activities with the quality system.

5.5.5.3 After all activities audited, the audit team shall carefully review and analyze all their findings as non-conformances or as comments or as recommendations for improvement.

5.5.5.4 Prior to preparing the audit report the closing meeting with those responsible for the sections audited shall be organized by the audit team to discuss the findings and the period required for the implementation of any corrective actions.

5.5.5.5 The audit team shall prepare a clear and concise report supported by objective evidence of non-conformances and with recommendations for improvement including corrective actions agree upon the time period allowed for their completion and the person responsible for carrying them out.

5.5.6 Follow up Actions

5.5.6.1 Concerned staff responsible for the activity audited shall take any necessary corrective action within a specified time frame and inform the quality officer.

5.5.6.2 The Quality Officer may arrange for additional internal quality audits to verify the implementation of corrective action at appropriate time.

5.5.6.3 Quality Officer shall maintain complete record of the audit (even if no non-conformance exists) and corrective actions taken.

5.5.6.4 The audit report shall be circulated to all concerned to assess their impact on all related activities.

5.6 Records

5.6.1 Internal Audit Reports

6. Procedure for Conduct of Management Review

6.1 Purpose

6.1.1 To conduct Regular Management Reviews in order to ensure the continuing suitability, effectiveness and improvement of the quality system.

6.2 Scope

6.2.1 Applicable to the entire management system of AERSSC in accordance to clause no. 5.8 of ISO/IEC 17011:2004.

6.3 Responsibility

6.3.1 The Chairman/CEO, AERSSC is responsible for review of management system as described in ISO/IEC 17011:2004. CEO is responsible for organizing these review meetings and keeping the record.

6.4 References

6.4.1 Quality Manual clause no. 5.8
6.4.2 Quality Manual clause no. 5.2.1
6.4.3 Procedure for Internal Audit
6.4.4 Procedure for Control of Non-Conformities and Corrective Action
6.4.5 Procedure for Preventive Action

6.5 Procedure

6.5.1 Management Review Meetings shall be conducted once a year after the internal audits.

6.5.2 The agenda for management review meetings shall include:

- Minutes of the previous management review;
- The suitability of policies and procedure;
- The outcome of internal audits;
- Corrective and Preventive actions;
- Feedback from interested Parties;
- Complaints;
- Opportunities for improvement;
- New areas of accreditation;
- Resources and Staff training;
- Participation in International activities, where relevant;

- Results of peer evaluation where relevant

6.5.3 The management review is chaired by the Chairman/CEO and attended by the Quality Officer, Technical Officer and any other invitees as described in ISO/IEC 17011:2004.

6.5.4 The CEO shall be responsible for preparation of agenda. The Quality Officer is responsible for the reporting n the findings of the Internal Audit as we as preparation of minutes of the management review.

6.5.5 Approved minutes mentioning the summary of the Quality system review covering the decisions taken, responsibility for actions and target dates of implementation shall be circulated.

The Quality Officer is responsible for monitoring actions on the decisions of management to ensure the effectiveness of the decision.

6.6 Records

6.6.1 Agenda and Minutes of Main Review Meetings and any other summary/analysis report for presentation at the Management Review Meetings.

6.6.2 Form