Accreditation Education Research & Scientific Service Center Nepal

Accreditation Procedure

Prepared by: CEO, AERSSC

Approved by: Conformity Assessment Accreditation Board of AERSSC

Issue No: 06

Issue date: 16th May 2022

Revision Records

S. No.	Page No.	Section No.	Issue Date	Issue. No.	Revision Detail
1	29	5	17/10/2020	02	5.1.1 Once a laboratory is assessed for competence in accordance with ISO/IEC 17025:2017 or ISO 15189:2012, it is granted accreditation for a period of three years. To ensure that it maintains its technical competence, it is subjected to yearly surveillance inspections to verify that it continues to comply with the requirements of ISO/ IEC 17025:2017 or ISO 15189:2012 and with the other terms and conditions of accreditation. The date of surveillance/reassessment visit is decided by CEO of AERSSC in consultation with the laboratory management.
2	30	5	17/10/2020	02	5.2.4 AERSSC shall inform the accredited laboratory at least three months before the due date of accreditation for conducting the surveillance visit and the laboratory shall conform its readiness within 15 days.
3	31	5	17/10/2020	02	5.3.1The laboratory may apply for assessment every 3 years by submitting an application 3 months before the expiry of accreditation in the prescribed application form (F 01a or b). A copy of the current Quality Manual of the laboratory which describes the Quality system

					in accordance with ISO 17025:2017 or ISO15189:2012 should be made available.
4	55-79	F 02 to F 13	9/4/2022	03	Forms Revised as per it's applicability for use
6	12	4.10	25/4/2022	04	Section 4.10 and Section 4.11 merged for clarity
7	55	F 02	25/4/2022	04	Form updated
8	26	Section 4.13 and Section 4.14	25/4/2022	04	Section updated for clarity
9	-	Section 10, 11 and 12	25/4/2022	04	Removed
10	-	Section 4.11.2.2	05/05/2022	05	Removal of clause for procedure for Constitution of Assessment Team
11	67	Form (F 09c)	05/05/2022	05	Amendment as per new version
12	15	Section 4.11.2.2	5/16/2022	06	Addition of the clause for arrangement for assessment duration

Table of contents

Preamble

This operational Procedure Manual is a supporting document to the Quality manual of AERSSC (AERSSC 01). It provides information on following aspects as supplement to the main Quality Manual AERSSC 01.

- Procedures of various functions of accreditation process
- Functions and responsibilities of various functionaries of Accreditation body
- Implementation process of laid down functions /procedures

  The adherence to the procedures is obligatory to ensure an effective quality management system and transparency at AERSSC for grant of accreditation.

Kathmandu

Date: 28/01/2019 Chief Executive Officer

1. Introduction and purpose

The procedure deals with initial stages of accreditation starting from enquiry stage to receipt of application.

1.1 Enquiries:

1.1.1 The Laboratory shall make enquiries about accreditation procedure, requirements of accreditation, scope, terms & conditions and fee structure etc.

1.1.2 The Chief executive or a designated officer at AERSSC shall update the laboratory with all necessary information and formalities involved estimation about the time frame. He shall also brief the laboratory about preparations needed and sources of study material. He shall send an application format and guidance for completing the application. The terms and conditions shall also be explained to the laboratory.

2. Definitions

The definitions in ISO/IEC17025:2017, ISO/IEC 17024 and ISO 15189:2012 are applicable.

2.1 Pre-assessment

The purpose of the assessment is to evaluate the organization's readiness for accreditation. The quality management system, the premises, the equipment and the competence of the personnel involved in the management system are evaluated during the pre-assessment.

2.2 Initial assessment

Initial assessment is an onsite assessment at the applicant's premises and consists of an assessment of the organization's competence to perform specific tasks for which accreditation is sought.

2.3 Surveillance visit

After granting accreditation AERSSC shall undertake periodical surveillance to the applicant's premises in order to have confidence that the organization always fulfills the accreditation requirements.

The first surveillance assessment shall be undertaken not more than twelve (12) months after the initial assessment. Intervals between surveillance assessments shall not exceed two years.

2.4 Extension of Accreditation Scope

An accredited laboratory can at any time apply for extension of its accreditation scope to AERSSC. AERSSC can assess the extension of accreditation scope at the same time as the surveillance assessment or separately.

2.5 Reassessment

The reassessment shall be a complete assessment covering the laboratory scope of accreditation and the results of proficiency Testing/Inter laboratory comparisons.

2.6 Assessment Report

After each assessment, the Team Leader shall submit the assessment report to AERSSC within two weeks after the assessment. The report shall include all inputs and recommendations from the assessment team.

2.7 Nonconformity

Nonconformity is defined as a non-fulfillment of the requirements.
Nonconformities are graded into two categories:
Major – A nonconformity which directly affects the quality management system and the results of tests/verification
Minor – A nonconformity which does not affect the results of tests and verification made by the laboratory.

3. The purpose of an assessment

The purpose of an assessment is to:

- Examine and evaluate the technical competence of a Conformity Assessment Body (CAB) to perform calibrations, tests, verifications;
- Certifications and /or other services covered by their scope of accreditation;
- Evaluate whether the CAB's documented management system complies with the requirements of the relevant accreditation standard;
- Confirm that the operational and technical activities being performed by the CAB are technically valid, appropriate and conform to the CAB's documented management system;
- Establish whether a CAB satisfies all relevant international requirements for Accreditation.

4. Application for Accreditation

4.1 Purpose

This procedure outlines the process for receiving and processing applications for Accreditation.

4.2 Scope

This procedure for applications for accreditation applies for all scopes of accreditation offered by AERSSC. Laboratories operating under Governmental system or under private managements are eligible to seek accreditation.

4.3 Responsibilities

All applications for accreditation shall be processed by the relevant Officer.

4.4 Procedure

The flowchart for processing applications for accreditation is annexed (Annexure 1). All applications to the AERSSC for accreditation must be:

- made using the Application Form (F 01 a or b)

- Include all necessary information
- Be accompanied with proof of payment of the prescribed fee
- Applications can be made electronically or in hardcopy.

4.5 Acknowledgement

The AERSSC shall designate an accreditation officer to deal with the applicant laboratory. He shall send an acknowledgement of receipt to the applicant.

4.5.1 It shall be responsibility of the accreditation officer to ensure that the customer's requirements are fully understood before admitting the application for accreditation. He shall be responsible for checking that AERSSC has adequate resources to meet the scope of accreditation of the applicant. He shall be responsible for ensuring that terms & conditions of accreditation are acceptable to the applicant. Besides, the assessment schedule and dates must be ensured in consultation with the applicant laboratory so that sufficient time is available for constituting competent assessment team and scheduling assessments.

The CAB is required to complete the application form with all necessary information, including signatures where required, make payment of the appropriate application fee and provide a proposed scope for which accreditation is sought in the format prescribed by AERSSC (F 01a or b)

4.5.2 The application form shall serve as the contract between the applicant and AERSSC in that it defines the terms and conditions under which the accreditation may be granted, including the payment of fees, and the rights and obligations of both AERSSC and the CAB following accreditation.

4.6 Procedure for Resource Review and Assigning Application

4.6.1 AERSSC shall accept all applications for accreditation that are within its scope of

Activity and is presented in the proper format. All applications are to be processed expeditiously.

4.6.2 Upon receipt of an application the CEO/Accreditation Officer shall examine the application along-with the document including its quality system, a list of methods and equipment including information about calibration status, the applied field(s), discipline(s) and scope of accreditation and review the resources in terms of availability of expertise, competent assessors/experts in the applied scope of Accreditation.

4.6.3 Once the application is complete a formal Application Acceptance shall be sent by the CEO/concerned Accreditation Officer to the Applicant. The date of this notification shall be the formal start date for the accreditation process.

The Application and any associated correspondence shall then be forwarded to the CEO/Accreditation Officer who shall then assign, with the approval of CEO/Quality Manager, a Team Leader to initiate accreditation process formally.

4.6.4 From the time of lodging an application, a laboratory shall be required to participate in all relevant proficiency testing programs. Evidence must be provided with application, if the laboratory had participated before in any Proficiency testing/inter-laboratory comparison.

4.7 Procedure for Registration of an Application and Acknowledgement

The application shall be registered in one of the following categories:

- Testing
- Medical

The file is sent to the CEO/ assigned dealing officer after completing the registration process and the records will be maintained separately for each category.

4.8 Procedure for Preliminary Review for Adequacy of Application

4.8.1 The CEO/assigned Accreditation Officer scrutinize the completeness of application(s) including the scope of accreditation by examining the applicant(s) Quality Manual to verify all the requirements of ISO/IEC 17025:2017 or ISO15189:2012 and records the detail in the prescribed format (F 02).

4.8.2 The applicant shall be allowed 30 days within which it must respond to with deficiencies with corrective actions, failing which the application shall be considered to have lapsed. The CAB will be advised accordingly.

Having satisfied with the contents of the application and documents sent along, the Chief Executive Officer/Accreditation Officer shall inform the applicant about the status of application and the proposed Team Leader. The CEO/accreditation officer shall ensure that the Team Leader has been selected on merit and who is well trained, experienced and has clean track record.

4.9 Procedure for Appointment of Team Leader

4.9.1 The main responsibility of Team Leader shall be detailed review for the adequacy of Quality Manual and application, to lead the team assessors/technical assessor or expert and manage the assessment in judicious manner. Hence, the selection of the Team Leader shall be made carefully.

The Team Leader appointed shall have following traits:

- Should have technical knowledge of the specific/type of accreditation/test for which the application has been made;
- Should be available for full assessment including submission of report;
- that his/her organization has not offered consultancy to the same laboratory;
- Is acceptable to the applicant laboratory including his team and requests if the CAB has any conflict of interest or justified objection on a member of the team.

Note: Rejection of assessors will only be considered if there is a conflict of interest.

4.9.2 Once the Team Leader alongwith application form filled as per Form 32 is appointed, AERSSC shall enter into formal contracts with him/her as per Form (F 03) and declaration of Impartiality and Confidentiality as per Form (F 04a).

4.9.3 The role of a Technical assessor/Expert shall be to:

- assess the adequacy of qualifications, experience and competence of technical staff through interviews and review of CVs;
- evaluate the suitability of equipment, range of use, the status of calibration of each equipment used and maintenance and labeling equipment,
- assess the appropriateness of the methods of procedures;
- evaluate the suitability of the premises of the laboratory for the scope applied for, check that the environmental parameters have been recorded and if the laboratory has a system for following up on results of such measurements;
- evaluate the results of internal quality control

4.10 Pre-assessment and procedure for organizing the Pre-assessment

AERSSC will appoint a Team Leader if a request from the laboratory is received for pre-assessment. Before pre-assessment Adequacy Check of the Quality Manual will be examined.

4.10.1 Adequacy Check of the Quality Manual

The Team Leader appointed by AERSSC shall examine the quality manual for compliance with ISO/IEC 17025:2017 or ISO 15189:2012 (as the case may be) and shall provide his observations/recommendations on prescribed format (F 05). The concerned laboratory shall be asked for further information and for completion of deficiencies in the quality manual where required. The revised quality manual and other information submitted by the laboratory shall be examined by the Team Leader.

If satisfied, he shall:

- Confirm to the CEO/ concerned accreditation Officer about the adequacy of the quality manual;
- Recommend to constitute an assessment team;
- Recommend to arrange pre-assessment of the laboratory

The laboratory shall be instructed to carry out the necessary corrective actions if any and submit the same to AERSSC marking a copy to the Team Leader within 30 days of such communication before pre-assessment.

4.10.2 A one day pre-assessment visit shall be arranged on request. The designated Team Leader shall be required to visit the Laboratory. The pre-assessment can be carried out at a specified location (generally the central office) of the testing/calibration/medical laboratories to:

- discuss any findings related to the documentation;
- seek further information on the quality system;
- briefly examine the systems which have been established and implemented;
- agree the proposed scope(s) of accreditation

4.10.3 Findings of Pre- Assessment: The Team Leader shall prepare in the report of his findings using prescribed checklist as a guide in the prescribed format (F 06) and submit the same within ten days after he concludes his visit.

4.10.4 The report will contain comments on any nonconformity, areas which are not addressed, areas where actions are needed, areas where there are concerns or weaknesses and a recommendation on the way forward.

4.10.5 Once all the findings raised during the pre-assessment have been effectively cleared, AERSSC will arrange the initial on-site assessment of the laboratory within six months.

Note: No technical assessment of the laboratory's technical capabilities of competencies will be conducted during the assessment.

4.11 Confirmation of Readiness Visit

4.11.1 Objective of assessment: AERSSC shall organize assessment of a laboratory to find out to what extent the applicant laboratory : i) has a quality management system in place, ii) has necessary technical competency in terms of man power, equipment, resources, space environment controls and maintenance of the laboratory and iii) has capability and capacity to generate technically valid results.

- During the visit, the lead assessor shall meet the manager of the laboratory and other concerned functionaries. He shall explain the purpose of his visit and he shall discuss following;
- Explains the assessment methodology and the tasks of assessors. He shall specifically make clear to the laboratory about the methodology the assessment team would adopt;
- Explains the laboratory's obligations to confirm that it understands the procedures. The laboratory shall be required to demonstrate some experiments/tests/calibrations;
- A tour to the laboratory and facilities shall be taken up by the Team Leader.

4.11.2 Initial Assessment

4.11.2.1 Initiation of Assessment: In view of the pre-assessment visit report from the lead Assessor, the CEO/accreditation officer, shall determine to what extent the laboratory is prepared for undergoing assessment. If satisfied that Initial Assessment can be undertaken, s/he shall determine how many and what kind of assessors/experts shall be needed, s/he shall take the duration of the assessment into consideration while constituting the assessment team. The Process of on-site assessment shall then, start with formal information to the laboratory regarding Team Leader and other members of the assessment team.

4.11.2.2 Arrangement for Assessment duration

For each section or area of activity of the laboratory competent assessor whose specialties are in conformity with the conformities assessment activities of the applicant/accredited laboratory will be appointed:

a) When a testing laboratory cover multiple technical disciplines, specialties of the lead assessor shall cover at least one technical discipline, and give consideration in priority to technical discipline with more items of the application items if it is feasible.

b) Number of assessors both Team leader and Technical assessors as per below requirement which has been discussed and approved by already accredited/applicant laboratories for which the laboratories have given their consent.

- Clinical Biochemistry of small sized lab number of assessors will be one Team leader and one Technical Assessor for one day from the field in which they have expertise;
- Clinical biochemistry of medium sized lab number of assessors will be one Team leader and one Technical Assessor for two days or one Team leader and two technical assessors for one day from the field in which they have expertise;
- For microbiology, serology and Molecular biology of small sized lab number of assessors will be one Team leader and one Technical Assessor for one day from the field in which they have expertise;
- For microbiology, serology and Molecular biology of medium sized lab number of assessors will be one Team leader and one Technical Assessor for two days or one Team leader and two technical assessors for one day from the field in which they have expertise;
- For Haematology, Histo and Cyto pathology of small sized lab number of assessors will be one Team leader and one Technical Assessor for one day from the field in which they have expertise;
- For Haematology, Histo and Cyto pathology of medium sized lab number of assessorswill be one Team leader and one Technical Assessor for two days or one

Team leader and two technical assessors for one day from the field in which they have expertise;

- For small and medium sized lab Team Leader will also be a Technical Assessor from the field in his or her area of expertise assisted by Technical expert;

In general there will be one Team leader for all levels of lab for all assessment. Under rare circumstances there could be more than two assessors assisting Team Leader in addition to Technical assessor for large and very large sized laboratories. The duration mentioned above will be applicable for surveillance assessment.

The assessment team headed by Team leader will be assisted by subject experts too during initial and reassessment of accredited labs for same duration.

4.11.2.3 The Assessment Team: The team shall be constituted of following:

S.no #	Team Member –Title	No.	Function
1	Team Leader (Preferably drawn from AERSSC).	01	S/he shall be an expert and trained and experienced in QMS related to ISO/IEC 17025:2017 and ISO 15189:2012 standard. He shall assess the QMS documents and implementation.
2	Technical Assessor (Hired from outside)	As per need	They shall be technical experts and specialists in areas for which accreditation is sought by the Laboratory. They shall assess technical aspects such as methods, procedures and testing skills.
3	Observers (internal/external)	01 / 02	They are potential assessors and shall be observers only. They shall be inducted with the purpose of learning assessment techniques.

In case the Team Leader is appointed from out-side, AERSSC shall ensure that CEO/one officer from its office accompanies the assessment team as management representative to over view the assessment and shall ensure that the assessment is conducted in a conducive manner, smoothly amicably without violating any rule and in strict compliance to the requirements.

The assessors shall always behave objectively and in a friendly and unbiased manner with the laboratory staff with whom they are assessing. The assessors have to be open minded to accept new solutions of old problems as long as the criteria of accreditation are met in an acceptable way.

Note: *The Potential assessor who has successfully completed the 5 days training course shall be encouraged accompany the team as an observer. The Team Leader shall be requested to provide him/her guidance and a performance report at the end of the assessment.*

The assessment team is then set up and the dates of Initial Assessment finalized by the management of the laboratory and the Team Leader.

4.11.2.4 Criteria of Selection of Assessment Team

The criteria of selection of the team shall be based on;

I. Availability of the assessors and is willing to take up assignment
II. Training in QMS and in technical areas.
III. Competency, expertise and experience in assessment of laboratory in areas for which accreditation has been sought.
IV. The clean track record. No adverse comments from any source reported about the assessor.
V. Are free from any conflicts of interest
VI. Have not rendered consultancy to the applicant Laboratory.
VII. His/her employer can spare him/her for period of assessment.

4.11.2.5 Contract with Team Leader and Assessors

The AERSSC shall enter into a contract with members of the assessment team so that their commitment is ensured. The contract shall be inked in a prescribed form (F 03).

4.12 Conducting the Initial Assessment (On-site Assessment)

4.12.1 After having received consent of the laboratory and from the assessment team member, the CEO or designated Accreditation officer shall formally inform the schedule. S/he shall then execute contract with the assessment team members.

4.12.2 Briefing session**:** Before commencement of the actual assessment of the laboratory, the assessment team shall meet and plans the assessment program. The Team Leader shall allocate the work to different members of the assessment team. Each assessor shall be supplied with a check list. However, preferably he/she shall prepare a checklist based on various clauses of the documents and the particular requirements of the standard that are to be assessed. This checklist, which will serve as an aide memoir during assessment is finalized by each assessor in consultation with the Team Leader.

4.12.3 Opening Meeting**:** The actual on- site assessment process shall begin with opening meeting between the assessment team and the laboratory CEO/ quality manager and key officials. The Team Leader shall explain the objectives, scope and strategy of assessment s/he shall explain what is expected from the laboratory and shall discuss the assessment plan. The laboratory shall be asked to demonstrate a test/calibration for which accreditation has been sought. The laboratory shall assign a guide or coordinator to accompany each assessor. A tour of the laboratory shall be undertaken along with the guides.

NOTE -1 the records of the meeting shall be prepared on prescribed format (F 08) and shall be a part of the assessment report;

NOTE-2: The consultants, if present during assessment from Laboratory side, shall not take any active part in assessment in any manner what so ever

including guidance to the laboratory personnel. They shall be prevented to effect/influence the assessment.

4.12.4 Actual Assessment phase

The assessment team shall determine "compliance with the accreditation criteria" in depth during on-site assessment process.

During this phase of assessment, members of the assessment team shall proceed to various sections according to the tasks allotted to them. The assessment shall be carried out using check sheets based on various clauses and sub clauses of ISO/IEC 17025:2017 or ISO 15189:2012 as the case may be. The assessors shall give special attention on following major activities such as competency aspects, controlled environment of laboratory, management of equipment, calibration of and measurement traceability, reference materials and metrological traceability, in-house calibrations, method documentation and validation, sampling and handling of test items (or samples) and monitoring the validity and reliability of test results through:

- Verify availability of documented procedures, scopes and work instructions for carrying out the various tests and associated tasks;
- Interview personnel from different sections to verify that they understand the relevant procedures and instructions and actually follow them during their operations.
- Check that test equipment has the necessary capability to test/measure according to the specifications;
- Check the calibration status of equipment and reference materials used by the laboratory. Also verify from records that calibrations are being carried out regularly and is valid on assessment date;
- Check Calibration policy and procedure;
- Check records of monitoring environmental conditions, where these are required;

- Where possible, get certain samples retested in the presence of laboratory personnel and compare these with the results recorded earlier;
- Check the records of important activities to verify that these are being carried out in accordance with the defined procedures;
- Check personnel records, particularly the qualifications and experience of those who supervise testing and who sign the test certificates;
- Verify the existence of a procedure for determining uncertainty of measurements;
- Check records of internal quality control, inter-laboratory comparisons and participation in proficiency testing schemes;
- Check records of nonconformity in testing and the corrective/preventive actions taken;
- Check records of feedback and complaints received from customers and how these are processed;
- Check records of internal audits and corrective actions. Verify the effectiveness of a few corrective actions;
- Check records of management review and verify whether actions decided on in the last management review have been carried out;
- Check certificates already issued;
- Check the quality assurance systems

4.12.5 Suspension/Interruption of assessment process: During assessment, if it is noticed by the assessors that the quality system is not implemented in critical areas or if there are other major short comings that will make the assessment purposeless, the Team Leader may interrupt the assessment. The Team Leader after meeting with assessment team and after contacting the CEO/chairman of AERSSC, shall inform the CAB (laboratory being assessed), about the reason for this decision.

4.12.6 Major/Minor NCRs: In general any observations about partial compliance or non-compliance with the requirements of the standards are authenticated by the

coordinator or guide from the laboratory to avoid any controversy later. There may be minor nonconformities in the quality system which can be corrected, and the assessors may advise the laboratory about these so that they can correct them during the audit itself, if possible.

In case the assessment team members observe major nonconformities in the documents and their implementation, AERSSC Secretariat shall be consulted before concluding the assessment process.

4.12.7 Witnessing of activities

Witnessing of activities is an essential part of the AERSSC assessment of laboratory applicable to their fields of operation. This is particularly important to determine the competency of the analyst/technician where the personnel professional judgment is crucial to the outcome of tests or /calibration results. It will be necessary to examine equipment and documentation, such as procedures and instructions, records, reports and planning arrangements. If an analyst/technician/metrologist operates in different locations, this examination will be arranged at a mutually acceptable location.

AERSSC assessors will ensure that their role during witnessing of activities is one of observer and they will not influence the activity being performed. The team will be looking at to see that as a minimum:

- The analyst/technician/metrologist's has the competence for the test/calibration performed;
- The analyst/technician/metrologist's competencies are consistent with the records;
- The analyst/technician/metrologist's has been supplied with all necessary documented testing/calibration methods and procedures;

Note: the laboratories shall preferably use standard methods. New versions of Standard methods shall be implemented within six months after their publication unless otherwise specified by the regulatory authorities.

- The procedures are up to date;
- Records of all observations are made while on-site as required by the procedure;
- Records clearly identify what has been inspected using what method/procedure and when

4.12.8 Closing meeting

Each assessor shall prepare a report based on his findings. The assessors shall discuss their reports with the Team Leader and shall prepare a consolidated report. The Team Leader shall evaluate this report and his findings and shall decide whether to recommend the scope of accreditation applied for. All members of the assessment team sign the report with its recommendation. The report is then discussed with the management of the laboratory in the closing meeting. The Team Leader shall present a summary of the team's findings along with NCRs and the recommendations. The information which could not be provided during assessment may be deferred to correspondence channel, shall be considered by the team. Finally, the Team Leader shall document all findings and matters settled during closing meeting as interim report.

An interim written report as per AERSSC Forms (F 08-12) shall be prepared and hand over to the laboratory before leaving. Occasionally, a specific issue raised in the report may also be referred for review to other technical experts where further advice is sought. In such cases, the identity of the applicant laboratory concerned is kept confidential.

Where necessary, the final report will detail any non-conformity needing to be addressed by the applicant laboratory to allow accreditation to be recommended. In these cases, an applicant laboratory will be asked to provide AERSSC with the necessary evidence that corrective actions have been taken and NCRs have been discharged. The nature and magnitude of the nonconformities determines the type of verification needed to clear the nonconformities which means:

- in the simplest case, submission of documented evidence of corrective action taken;
- In a serious situation, an on-site 'clearance of findings" visit may be required within three months of the assessment for the assessors to verify implementation of the corrective actions.

This visit will be specifically to examine the areas of concern as disclosed in the previous assessment. However, in some rare situations (e.g. where the CAB has been suspended) the range of condition(s) is so great that a complete re-assessment is required.

The evidence must be provided within 30 working days of the issue of the confirmed report. A grace period shall be considered if sufficient evidence is submitted by the laboratory to warrant extension.

The applicant laboratory is required to communicate the corrective action take along with the documentary evidences to the AERSSC Secretariat within the time agreed upon at the end of the assessment and evidences will be sent to Team Leader once received.

The Team Leader is required to submit the assessment report within two weeks of completion of Initial Assessment. Once the nonconformity can be signed off as

cleared and dated the Team Leader sends the final report with his recommendation to the Accreditation Board.

The Board examines it and communicates the outcome to the laboratory. The Board may advise the laboratory about non-conformances detected by the assessment team which were not resolved during the assessment. The laboratory is given an opportunity to take necessary corrective action with these and any other remaining concerns and is asked to submit a report to the Board within a specified period. When significant non-conformances are identified during the onsite assessment, the Board may arrange for a further verification visit to resolve these.

4.12.9 Feedback from the Laboratory**:** The Team Leader shall request the laboratory manager to fill in the feedback form and send the same to AERSSC directly. The feedback shall be required about following traits in a prescribed format (F- 11)

The general behavior of the assessment team:

It is important for the Team Leader/technical assessor/assessor to act, look and work in a professional manner that represents AERSSC in a positive and professionally.

Dress: Dressing for an assessment must be neat and professional;

Politeness: Be polite and act in a professional manner at all times; Never get into debate on any issue and refer any disputes to the Team Leader/or AERSSC;

Consulting: Under no circumstances can a Team Leader/assessor/Technical Expert advice, teach, give opinions or consult on any issues with the CAB and/or the staff before, during or after the assessment;

Gifts and Meals: No gifts shall be accepted from AERSSC clients. Any dining invitation or gifts while participating in an assessment should be viewed as hospitality token. Small gifts may be given at the conclusion of an assessment as a token of

appreciation for your time and effort. However, common sense and awareness of usual business practice within culture is the best guide.

4.12.10 Knowledge of the team members about the subject under assessment:

Through the assessment, it is important to maintain a professional approach by paying attention to the following aspects:

- Cooperation with laboratory staff;
    1, Always be fair, flexible and prepared to listen and to reason;
    2. be sensitive;
    3. be factual;
    4. be decisive;
    5. Bear in mind staff sensitiveness and
    6. be aware of time
- Assessment skills

    The following points should be considered carefully:

    1. How to establish the procedures are being correctly and fully implemented?
    2. How to establish the technical competence of personnel in the scope of work covered by the schedule of accreditation?
    3. How to conduct a witnessing assessment?
    4. How to conduct a vertical assessment?
- Team work

    A spirit of teamwork is essential. During an assessment, team work involves a common purpose amongst all team members. It involves a mutual understanding of team roles and willingness:

1. To support one another;
2. Do not interrupt one another;
3. Do not undermine anyone in the team;

4. Respect each team members approach;
5. Avoid conflict or arguing with the facility personnel.

- Time management ability

  During the time allocated for the assessment, the Lead assessor/Assessors/Technical expert must:

  1. Gather all the information about the CAB as efficiently and effectively as possible;
  2. Constantly evaluate findings against the CAB's documented management system (i.e. against its policies, operational procedures, methods, etc.) and AERSSC requirements;
  3. Identify through objective evidence any breakdown in the technical system or departures from operating procedures;
  4. Be thorough and objective at all times.
  5. Expectation for any undue favor in cash or in kind.
  6. Any monetary gifts may not be accepted.

4.13 Procedure for Analysis of Assessment & Preparation of Assessment Summary

On receipt of the assessment report for chemical testing (F 9a, F 9b, F 9c and F 10b) and for the medical lab(F 12), the following procedure is followed by the assigned officer:

- Examine the assessment report and seek clarification from the laboratory/assessment team, if required.
- In case of significant non-conformities, closely monitor the corrective actions taken by the laboratory.
- Prepare a brief summary of the information gathered during the process of application, assessment including the additional information received from the laboratory, recommendation of the AERSSC

secretariat for presentation to the members of the Accreditation Committee.

4.14 Accreditation Committee

4.14.1 The recommendation to grant, extend, reduce, maintain or deny the accreditation as formulated by the Accreditation Committee based on the assessment report for chemical testing (F 09a, F 09b, F 09c and F 10b) and for the medical lab(F 12) based on the information provided by the AERSSC Secretariat. The detailed procedure is based on the Procedure and Terms of Reference for Accreditation Committees (AERSSC 15).

4.14.2 Procedure for placing Reports before the Accreditation Committee

The assigned officer is satisfied that the information available with him is adequate to formulate a recommendation he/she shall precede with the following:

- The summary
- Recommended scope
- Non-conformities
- Test witnessed
- PT/ILC records

Occasionally, the Accreditation Committee may recommend that a further visit by AERSSC Team Leader or that another assessment be conducted due to the inability to assess certain aspects of an applicant laboratory during the scheduled visit because of lack of availability of key staff or to review the effective implementation of the corrective action taken as a result of the assessment.

Record minutes of the proceedings of the Accreditation Committee meeting with respect to decision for granting, extending, reducing or maintaining accreditation, any

actions to be communicated to the laboratory and any further clarification to be sought from the laboratory/assessment team members.

4.15 Procedure for preparation and Issue of Accreditation Certificate

After satisfactory corrective action has been taken by the laboratory, the accreditation committee of the Board examines the assessment report and any other additional information received from the laboratory and the consequent verifications. If the committee finds deficiencies in the assessment report, the secretariat obtains clarification from the Team Leader or laboratory. If however everything is in order the accreditation committee recommends the accreditation of the laboratory to the Chairman of the Accreditation Board through CEO (F 10b or F 12) for approval. Laboratories are free to appeal against the findings of assessment or decision on accreditation.

When accreditation is granted, the accreditation Board issues an Accreditation certificate with a unique number, the date of validity, and the scope of accreditation.

The accreditation certificate defines the field of testing, the materials or products that can be tested, the specific tests to be performed or the parameters which can be tested, the range of testing or limit of detection, and the accuracy. The applicant laboratory must pay the fees to the Accreditation Board before any certificates are issued to the laboratory.

4.16 Validity of Accreditation

The AERSSC accreditation certificate shall be valid for a period of three years. On grant of accreditation, the applicant laboratory is permitted to use Symbol/claim of accreditation as per guidelines/instruction for using AERSSC symbol and claim of accreditation.

5. Procedures for Surveillance and Reassessment

5.1 Surveillance

5.1.1 Once a laboratory is assessed for competence in accordance with IEC/ISO 17025:2017 or ISO 15189:2012, it is granted accreditation for a period of three years. To ensure that it maintains its technical competence, it is subjected to yearly surveillance inspections to verify that it continues to comply with the requirements of IEC/ISO 17025:2017 or ISO 15189:2012 and with the other terms and conditions of accreditation. The date of surveillance/reassessment visit is decided by CEO of AERSSC in consultation with the laboratory management.

5.1.2 A flow diagram shown at the annexure 1 indicates the sequence of activities for conducting the on-site surveillance visit.

5.1.3 The surveillance team is headed by a Team Leader and is provided with a copy of the previous assessment report by the AERSSC secretariat. Surveillance focuses on selected aspects of the laboratory in such a way that all aspects are covered during various visits over a three year period. The surveillance team:

- Carefully studies the previous assessor's report and any complaints received by the laboratory and prepares an assessment plan;
- Concentrates in particular on those areas of testing where non-compliances were observed during previous visits, or where there is reason to believe that standards may not have been maintained.
- Seeks information on any change in staff or test equipment since the last assessment and examines, in particular, those areas where changes may have affected the capability of the laboratory as described in the scope of accreditation.
- Confirms that the laboratory has participated in the proficiency testing/inter-laboratory comparison program organized by the Accreditation Board, and

checks its conformance. If performance was not satisfactory, it checks whether necessary corrective action have been taken and verifies their effectiveness.

- As mentioned above, the accreditation of a laboratory is valid for only three years. Six months before the expiry of accreditation, laboratories are required to apply for renewal. A re-assessment visit normally takes place three months prior to the expiry date. It involves a comprehensive re-examination of the laboratory's management system and testing activities along the same lines as at the initial assessment. After successful renewal of accreditation, yearly surveillance continues.
- Any revisions to the quality system will be reviewed during these visits. Extensive changes may require additional assessment time.

5.2 Procedure for organizing On-site Surveillance Visit

5.2.1 Shorter intervals may also be specified at the relevant Accreditation committee or follow up on site visits may be necessary. Such intervals and any requirement for follow up visits will be determined on the significance of issues identified during a prior scheduled visit to a lab or any doubt over a laboratory's continuing compliance with the accreditation criteria.

5.2.2 Laboratory must respond to Surveillance visit findings within deadline otherwise the status of their accreditation will be reviewed.

5.2.3 The desktop surveillance consists of calling records from the accredited laboratory to ensure that the laboratory continues to maintain the requirements of ISO/IEC 17025:2017 and ISO 15189:2012 as applicable.

5.2.4 AERSSC shall inform the accredited laboratory at least three months before the due date of accreditation for conducting the surveillance visit and the laboratory shall conform its readiness within 15 days.

5.2.5 The accredited laboratory during the validity of accreditation may request to enhance the scope of accreditation which they should apply two months before the conduct of

assessment/surveillance. If a laboratory requests scope extension independent of surveillance visit, AERSSC will arrange separate assessment visit.

5.2.6 Surveillance visits are conducted by an AERSSC Team Leader and involve review of the management system in full and selected technical elements against the accreditation criteria.

5.2.7 Surveillance assessment visit follow the same general process as the initial assessment. The summary of the surveillance report along with other relevant information shall be submitted to CEO for continuation of accreditation.

5.3 Reassessment

Reassessment visits will involve a comprehensive re-examination of the laboratory's activity quality system and testing/calibration activities and will be similar in format and content to the initial assessment. A review of the full documentation shall be undertaken prior to the on-site assessment as follows:

5.3.1 The laboratory may apply for assessment every 3years by submitting an application 3 months before the expiry of accreditation in the prescribed application form (F 01a or b). A copy of the current Quality Manual of the laboratory which describes the Quality system in accordance with ISO 17025:2017 or ISO15189:2012 should be made available.

5.3.2 The laboratory may request for extension of scope of accreditation, which should explicitly be mentioned in the application form.

5.3.3 The procedure for processing of renewal application or on-site reassessment visit is similar to that of initial assessment visit except that there is no adequacy audit and pre-assessment.

5.3.4 On submission of a written request, AERSSC shall assess the laboratory for extension of scope during surveillance/reassessment visit or be organizing a supplementary/special visit.

5.3.5 Unscheduled visits may be conducted to investigate a complaint that casts doubt over the laboratory's continuing compliance with the accreditation criteria.

5.4 Extension of Validity

5.4.1 The AERSSC accreditation certificate shall be valid for a period of three years. On grant of accreditation the lab shall use AERSSC mark on all of test reports covered within the scope of accreditation granted.

5.4.2 During the validity of accreditation, the laboratory must continuously comply with the requirement of ISO/IEC 17025:2017 to ISO 15189:2012.

6. Supplementary Visits

6.1 AERSSC may also conduct supplementary/special visit at any time during the validity of accreditation, if:

- There is a change in the general accreditation criteria ISO/IEC 17025:2017 and ISO 15189:2012 or specific criteria of AERSSC.
- Changes have been reported to AERSSC affecting the laboratory's operation such as changes in legal or ownership or organizational status/structure, main policies, premises, accommodation, scope of accreditation etc.
- Accreditation certificate/logo has been misused.
- A complaint has been received and the facts have to be verified.

7. Voluntary with-drawl

The laboratory at any time during the validity of accreditation may discontinue their accreditation voluntarily by making a written request to AERSSC. Until such time as the withdrawal request has been processed, the accredited lab continues to be bound by AERSSC rules.

8. Suspension/Withdrawal/Termination of Accreditation

8.1 AERSSC shall have right to suspend, withdraw/terminate Accreditation granted under following Circumstances;

i. the laboratory fails to comply with the terms and conditions of accreditation
ii. The laboratory is found to involve in practices forbidden by law.
iii. The laboratory operated from several locations on the strength of single accreditation
iv. The laboratory misrepresents accreditation scope in any form
v. Complaints from any source found to be genuine
vi. Any activity of the laboratory which may harm reputation of AERSSC;
vii. If found to conceal facts or provide false information during assessment or thereafter;
viii. Refuses to undergo surveillance /surprise visit;
ix. The court of law recommends suspension/withdrawal/withholding accreditation status.
x. Any other reason which in view of AERSSC the withdrawal/suspension becomes necessary.

8.2 Procedure**:** Upon receiving any complaint/information or suspicion about any or more of above, AERSSC shall initiate investigations. Following steps shall be followed:

i. The CEO shall appoint an Investigation Officer (IO)
ii. S/he shall specify terms and conditions and scope of investigation
iii. The investigating officer shall gather facts and evidence.
iv. The IO shall take the assistance of experts for fact finding
v. If needed, the IO shall visit the laboratory alone or along with experts.
vi. The material collected shall be presented to CEO in the form of report and recommendation.

vii. The CEO shall review facts/evidence and recommendations carefully. The CEO shall forward his opinion to the chairman AERSSC for decision;

- The CEO shall take appropriate action to enforce the decision;
- The decision of Chairman and actions taken shall be conveyed to the Laboratory;
- The laboratory shall be provided a fair opportunity to make appeal against decision.

9 Appeals

The laboratory shall have right to make appeal against any decision of AERSSC related to accreditation:

9.1 AERSSC shall entertain appeals against its own decisions where the accreditation is refused, suspended, withdrawn, withheld**,** terminated or granted on questionable grounds.

i. The appeals shall be addressed to the Chairman of AERSCC;

ii. The CEO of AERSCC shall receive the appeal; He shall acknowledge the receipt and forward it to the chairman. He shall assign an officer to monitor appeal proceedings;

iii. The Chairman shall assign responsibility to an officer either from AERSSC or any other source;

iv. The designated officer shall investigate the complaint and collect facts based on documentary evidence, interview or by visits to AERSSC and/or laboratory;

v. The committee shall have a right to call laboratory to present its case before the committee members;

vi. The facts and information gathered by the investigating officer shall be compiled in the form of a report;

vii. The report shall be submitted to the chairman;

viii. The chairman shall appoint a committee of experts who will examine the report and submit their recommendations;

ix. The chairman shall decide upon the recommendations and direct the CEO of AERSSC to take necessary actions;

x. The decision of the Chairman shall be final.

xi. The secretariat of AERSSC shall maintain records of the appeal and all related proceedings.

xii. From initial stages till final decision /resolution.

Application form for Accreditation Of Medical/Clinical Laboratories

Issue No.: 01; Issue Date: July 01, 2012

Amendment No. :00; Amendment Date:.....

APPLICATION FORM FOR ACCREDITATION OF MEDICAL/CLINICAL LABORATORIES

We apply for AERSSC accreditation of our **Medical testing laboratory** on .....as per details given below:

☐ First Accreditation ☐ Scope Extension ☐ Renewal of Accreditation

1. Laboratory Details

1.1 ***Name of the Medical testing Laboratory*** _____

Address _____

_____

Telephone _____ Facsimile _____

Fax No _____ e-mail _____

NOTE If the Laboratory operates in different locations with same legal identity, separate applications are to be submitted.

1.2 ***Name of Parent Organization*** _____
(If part of an organization)

Address _____

_____

Telephone No. _____ Fax No._____ e-mail _____

1.3 ***Legal status and date of establishment*** _____
(Please give Registration No. and name of the authority who granted the registration)

_____

1.4 ***Clients of Testing Services***
(please tick in as appropriate)

Individual Clients ☐ On contract for Corporate Clients ☐ an in-house activity ☐

percentage ☐ Percentage ☐ percentage ☐

1.5 **Details of primary sample collection facilities**
(Please tick in ad appropriate and provide list of all facilities with complete contact details)

At Permanent facility ☐ (Laboratory Premises) at Site ☐ (Visit Patient) Other Locations ☐ (Collection Centers)

1.6 ***Do you conduct Testing in the following Category?***
(if yes, please clearly indicate in the scope of accreditation, para 2.3, the test conducted)

a. At Site (Undertaking testing at site of the client) Yes ☐ ☐ No

b. Temporary Facility (when a facility is created temporarily for testing) ☐ Yes ☐ No

c. Mobile Laboratory Yes ☐ ☐ No

1.7 ***Is testing Subcontracted*** ☐ Yes ☐ No
(if yes, please specify the subcontracted work)

1.8 **Size of Laboratory**

Small laboratory (< 50 Test Requests per day) ☐ Medium laboratory (51- 400 Test Requests per day) ☐ Large laboratory (> 400 Test Requests per day) ☐

1.9 Other accreditations _____

2. Accreditation Details

2.1 ***Field of Testing for which accreditation is sought***
(Please tick as appropriate)

- Clinical Pathology ☐
- Chemical Pathology / Clinical Biochemistry ☐
- Molecular Biology ☐
- Microbiology and Serology ☐
- Histopathology / Cytopathology ☐
- Immunology ☐
- Hematology and Immunohematology ☐
- Pharmacology ☐
- Nuclear medicine (in-vitro tests only) ☐

2.2 ***If the Laboratory is already accredited, indicate the Scope & Tests for which accreditation granted***

2.3 ***Scope of Accreditation***

S. no	Materials examined/tested	Specific tests/ examination performed	Specification, standard (method) or technique used	Range of testing/ Limit of detection	MU (±)

Note 1. When referring to publications of ICSH, ISH, IFCC, IUMS, WHO etc. please mention reference details (chapter/page) and year of publication as appropriate.

Note 2. Laboratories performing site testing shall clearly identify the specific tests/examination performed at site.

Note 3. Uncertainty of Measurement (MU) at a confidence probability of 95%.

3. Organization

3.1 ***Senior Management*** (Name, Designation, telephone, Fax, e-mail)

3.1.1 Chief Executive of the laboratory_____

3.1.2 Laboratory Director, if different from 3.1.1 _____

3.1.3 Person responsible for the laboratory management system _____

3.1.4 Person responsible for technical operations_____

3.1.5 Authorized Representative for AERSSC_____

3.1.6 Authorized signatories for issue of test certificates and reports (please refer relevant specific criteria)

S. no	Name & Designation of Signatory	Qualification with Specialization	Relevant Training	Authorized for which specific area of testing

Note. If opinions or Interpretations are given on test reports, please indicate such information as well with relevant qualification

3.1.6 Information regarding any individual or organization that has provided consultancy for being prepared towards AERSSC accreditation;

a. Development of Quality Management System: _____

b. Development of Technical Operations: _____

c. Specific Training: _____

d. Conducting Internal Audits: _____

e. Other: _____

3.2 *Organization Chart*

3.2.1. Indicate in an organization chart the operating departments of the testing laboratory for which accreditation is being sought (please append)

3.2.2 Indicate how the testing laboratory is related to external organizations or to its own parent organization (where applicable)

3.3. *Employees*

3.3.1 Total number in testing laboratory for the specific field(s) applied_____

3.3.2 Total number in testing laboratory for which accreditation is being sought_____

3.3.3 Details of staff (please clearly indicate staff responsible for site testing, if applicable)

S.no	Name	Designation	Academic and Professional Qualifications*	Experience related to present work (in years)

* Please clearly indicate the field of specialization

3.3.4 If services of consultants are obtained. Please provide details.

3.3.5 If Trainees or Contracted persons are employed, please indicate details.

4. Equipment and Reference Materials

4.1 Equipment List

please list down all significant items of equipment, providing details of make, model, serial number, range , if applicable and calibration status (date of last calibration, name of calibrating authority), if available.
The preferred order is: Reference equipment - Weights, balances, thermometers etc;

b) Testing equipment - auto analyzers, spectrophotometers, etc;

c) Ancillary equipment – autoclaves, centrifuge etc;

S. no	Name of equipment	Model/ type/ year of make	Receipt date & date placed in service	Range and accuracy	Date of last calibration	Calibration due on *	Traceability**

4.2 List of reference materials

Please list down all reference materials used for verification or validation of test method or technique applied for Accreditation

5. EQA and PT Programs

Please list down the details of EQA or PT programs currently participated by the Laboratory

Sl. no.	Name of reference material/ strain/ culture	Source	Date of expiry/ validity	Traceability**

Sl.no.	Materials examined/ Tested	Specific tests/ examination performed	Test method or group of methods applied for Accreditation	EQA/PT program	Service provider	Frequency

6. Willingness to undergo Assessment

We declare that

6.1 We are familiar with and will abide by the terms and conditions of maintaining AERSSC accreditation included in the agreement to be signed by both parties, which is enclosed.

6.2 We agree to comply fully with ISO 15189: 2012 for the accreditation of medical testing laboratory.

6.3 We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result.

6.4 We agree to co-operate with the assessment team appointed by AERSSC for examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of accreditation.

Signature of Chief Executive or his authorized representative_____

Name & Designation_____

Date & Place _____

Application for Testing Laboratories

F-01b

Accreditation Education Research and Scientific Services Center, Nepal

Application for Testing Laboratory

Issue No.: 01; Issue Date: July 01, 2012

Amendment No. :00; Amendment Date:.....

1. Laboratory Details

Name of the laboratory

:_____

Address:_____

__

_____

_____

____

Parent Organization (If any)

:_____

_____

__

Website:

_____

Legal Identity

:_____

Contact Person:

_____

Telephone No.:

_____

Mobile No. :

_____

Fax No.

:_____

E-mail :

---

1. Application for

☐ First Accreditation ☐ Renewal of Accreditation

☐ Extension of Accreditation

2. Type of Facility:

☐ Permanent Facility ☐ Site Facility

☐ Mobile Facility

3. Accreditation Details (Disciplines) :

☐ Chemical ☐ Biological

☐ Mechanical ☐ Non-destructive

☐ Electrical ☐ Electronics

4. Scope of Accreditation *(Please provide Annexure)***:**

S. No.	Product / Material / Item tested	Specific Tests / Types of Tests	Specification / Standard Method / Technique	Range of Testing/ Limit of Detection	Measurement Uncertainty (±)

5. About the Organization

Chief Executive of the Laboratory

_____

Quality Manager of the Laboratory

_____

Contact Person of the Laboratory

Staff Details :

S. No.	Name & Designation	Qualification	Total Experience	Relevant Training

Authorized Signatories:

S. No.	Name & Designation	Qualification	Total Experience	Relevant Training	Authorization for which specific area of testing

Organization Chart

(a) Provide the Organization Chart of the Laboratory indicating the position of all the staff.

(b) Provide the organization chart of the parent organization indicating the position of testing laboratory (if applicable)

6. Detail of Facilities:

Equipment Details:

S. No.	Name of Equipment	Model / Type / Make	Range and Accuracy	Date of Last Calibration	Calibration Due on	Calibrated by

Reference Standards Details:

S. No.	Name of reference material/ strain/ culture/ standard	Source	Date of expiry/ Calibration validity	Traceability

7. Internal Audit and Management Review

Date of last Internal Audit _____

Date of last Management review Details of Proficiency Testing / Inter Laboratory Comparisons:

S. No.	Product/ Material	Details of Test(s)	Date of Testing	Nodal Laboratory/ PT Provider (Accreditation Body/ Country)	Performance in terms of Z score	Corrective Action Taken (if any)

8. Application Fees

DD/ChequeNo. _____

Date of issue of _____

Amount_____

Name of the Bank----------

9. Declaration by the laboratory

We declare that

- ✓ ***We are familiar with the terms and conditions of maintaining accreditation and will abide by them.***
- ✓ We agree to comply fully with ISO/IEC 17025: 2017 for the accreditation of testing laboratory.
- ✓ We agree to comply with accreditation procedures, pay all costs for pre-assessment, assessment, verification visit (if any), surveillance and reassessment irrespective of the result.

- ✓ We agree to co-operate with the assessment team in examination of all relevant documents by them and their visits to those parts of the laboratory that are part of the scope of accreditation.
- ✓ We satisfy all national, regional and local regulatory requirements for operating a laboratory.
- ✓ _____ has provided consultancy for preparing towards accreditation.
- ✓ All information provided in this application is true.

Signature of Laboratory Head: _____

Name & Designation _____

Date & Place: _____

------ END ----

Accreditation Education Research and Scientific Service Center
Checklist for Completeness of Application

1. Name of the Applicant :
2. Field (Testing/Medical) :
3. Date of receipt of Application :
4. Checklist for Completeness of Application : Yes/No
   - 4.1 Requisite copies of QM and Application Form
   - 4.2 Quality Manual
   - 4.3 Organization Chart and legal Identity
   - 4.4 List of Staff
   - 4.5 List of Major Equipment (Range/Accuracy/Calibration Status)
   - 4.6 List of Certified Reference Materials
   - 4.7 Scope of Accreditation (product, tests, test method/standards)
   - 4.8 Internal audit & Management review conducted
   - 4.9 Satisfactory Participation in a PT/ILC
   - 4.10 Additional Information
5. Lab ID

Name of Officer Signature

Agreement between AERSSC and Team Leader/Assessor

This Agreement made on the _____ of _____ in the year 20…. .

By and between

Accreditation Education Research& Scientific Services Centre (AERSSC), Nepal
Herein after called the "1st party"

And Mr ……S/o …… .R/o
…….
Herein after called the "2nd Party"

WITNESSETH: that the 1st party and 2nd party undertake and agree as follows:

ARTICLE A-1 THE WORK

(A) The 1st Party shall:

(a) designate "Accreditation Officer" on its behalf to deal with 2nd party

(b) Satisfy itself about the suitability of the assessor to be hired.

(c) hire 2nd party as assessor through a formal letter of invitation in confirmation to His/her appointment for a short duration and for specific task/responsibility

(d) send the letter of offer to 2nd party well in advance which shall mention the Duration of assignment and the amount of remuneration /facilities along with the Plan of payments

(e) specify the terms and conditions of reference to the 2nd party

(B) The 2nd party shall:

(a) Perform all the work as an assessor in the assessment of…… (Name, address of the Laboratory) as required by the Terms of the Contract

(b) Do and fulfil terms and conditions indicated by this Agreement, and

(c) Undertake the work as on the _____ day of _____, 20…. and substantially perform the work of this Contract as certified by the Accreditation Officer of AERSSC by the _____ day of _____ 20….

ARTICLE A-2 Contract Documents (Terms & Conditions: Ref Article A-1)

The 2nd party shall;

a) Formally confirm acceptance of offer to work as assessor for the Laboratory.
b) accept terms and conditions of payments/facilities offered by 1st party
c) accept all terms &conditions pertaining to the work assignment
d) Declare that it has no partnership/consultancy or any other conflict of interest with the laboratory for which the assignment is offered/undertaken.
e) available for the period of assessment
f) Undertake travel to the assesse laboratory by air/land as per eligibility under administrative rules.
g) participate in briefing meetings, opening meetings and during on sight assessment
h) assess judiciously the documents, traceability status ,technical ability of the laboratory by witnessing tests/interviews/discussions ,collecting objective evidence of performance with the assesse
i) Avoid any arguments/conflicts with the assesse or other team members.
j) Not overdo and try to impose his/her views on the assesse.
k) Prepare a comprehensive report of findings of assessment of his/her area in a stipulated time.
l) Submit the report in stipulated time.
m) examine the corrective actions submitted by the assesse and submit report

ARTICLE A-3 : Payments

The 1st party shall pay for;

a) Travel
b) Stay
c) Compensation/remuneration *flexible as per location.
d) The payments shall be made after the report of assessment is submitted.
e) The accreditation officer shall be responsible for making payments He shall satisfy himself about the completion of the wok before releasing payments.

ARTICLE A-4 Disputes

All disputes shall be settled amicably by discussion. The chairman of the Board of AERSSC shall have a final word. His decision shall be binding on all parties.

IN WITNESS WHEREOF both the parties hereto have executed this Agreement/contract.

SIGNED, SEALED AND DELIVERED
In the presence of:

1st party (AERSSC representative:	**2nd party (assessor)**
_____	_____
Signed	**Signed**
_____	_____
Name and title	**Name and title**
_____	_____
Date	**Date**

ACCREDITATION EDUCATION RESEARCH AND SCIENTIFIC SERVICE CENTER

Declaration of impartiality & confidentiality

(To be filled in by each Team Leader/Assessor along with the Assessment report)

Name		**Assessor ID:**
Designation		
Organization		
Address		
Present Position	**Team Leader/Technical Assessor/Observer**	
Laboratory Assessed		
Date of visit(s)		
Type of visit	**Assessment/1st Surveillance/2nd Surveillance/Re-Assessment Follow-up**	

I _____hereby declare that

- I have not offered any consultancy/supervision or other services to the laboratory, in any way.
- I am/am not an ex-employee of the laboratory.
- I undertake to maintain strict confidentiality of the information acquired in course of discharge of my responsibility and shall not disclose to any person other than that required by AERSSC

Date: **Place:**	**Signature**

F 05

Adequacy Check Form

1. Name of the Applicant :
2. Field (Testing/Medical) :
3. Discipline :
4. Date of receipt of Application :
5. Checklist for Completeness of Application : Yes/No
   - 5.1 Requisite copies of QM and Application Form
   - 5.2 Quality Manual
   - 5.3 Organization Chart and legal Identity
   - 5.4 List of Staff
   - 5.5 List of Major Equipment (Range/Accuracy/Calibration Status)
   - 5.6 List of Certified Reference Materials
   - 5.7 Scope of Accreditation (product, tests, test method/standards)
   - 5.8 Internal audit & Management review conducted
   - 5.9 Satisfactory Participation in a PT/ILC
   - 5.10 Additional Information
6. Lab ID

Signature/Date/Name of Officer

*will be applicable if request for pre assessment is received.

F 06

Pre-assessment report for laboratories

Date of Visit:		Duration (day):
Organization:		
Physical address:		Postal address:
Tel:	Fax:	Mobile:
Field of operation		Scope of Application
Number of personnel involved in each field (if applicable):		
Number of personnel applying for Technical signatory:		
Facility Management Structure		
Name and Position:		Responsibility

*****applicable if visit for pre-assessment was performed.

Person responsible for the implementation and maintenance of the management system: (Nominated Representative)	
Conformity with the accreditation standard:	
Estimated time required for the initial assessment:	
Number of Technical Assessors required and field of expertise required:	
Other information e.g. Directions, flight arrangements, car arrangements, accommodation requirements, safety requirements, security requirements	
Team Leader: _____	Signature: _____ Date: _____

Approval Letter for Assessment Team

F 07

Accreditation Education Research and Scientific Services Center
(MRA Signatory of ILAC)
Phone no: 015445852 Email:sitaramjoshi9@gmail.com
Jawalakhel Lalitpur

Date:

AERSSC/ASS-1/2015

Dr.

Dear,
I would like to inform you that the on-site assessment of your laboratory in the field of Medical will be conducted as per the schedule given below:

Name and Contact Details	Capacity	From Date-To date	Field(s) of Expertise
Dr.	Team Leader		
Dr.	Technical Assessor		
Dr.	Technical assessor		

You are required to send the latest copy of the Quality manual to all above assessors in advance to enable them to prepare for the assessment.
I will appreciate if you contact with the team members, arrange travel tickets and make local arrangements (transport and accommodation) and keep me informed.
Other payments like honorarium, local allowance etc shall be paid by AERSSC to the above team members. Kindly note that laboratory is not required to make any payments directly to the team members. The expenditure incurred for this assessment will be charged to the laboratory as per AERSSC rules.
I am enclosing form for sending feedback information for each assessor, in confidence to the undersigned.
Kindly confirm the acceptance of the assessment team and dates.
Remarks:
Assessment is as per ISO15189:2012

Yours Sincerely

Chief Executive Officer

ATTENDANCE SHEET (OPENING / CLOSING MEETING)

(To be filled separately for Opening and Closing meeting)

Laboratory:		**Laboratory ID No:**	
Date & Time :			
Type of Visit: *Assessment / 1st Surveillance / Re-Assessment / Supplementary Visit*			
Sl.	**Assessors / Lab Personnel Present**	**Capacity/ Designation**	**Signature**

Name of Assessor: **Signature**

ASSESSOR'S OBSERVATIONS

Laboratory:		Laboratory ID No.:
Date:	Department/Section:	Audit Criteria:
Audited:		

SL	OBSERVATION	REMARKS

Name of Assessor:

Signature

*Applicable to Chemical Testing Laboratories only

F 09b

ASSESSOR'S SUMMARY ON NON-CONFORMITY

(Please use separate sheet for raising each Non-Conformity)

Laboratory:		
Date:	Department/Section:	Activity Assessed:
NC No:	Reference to Observation No. in Assessor Observation Sheet:	
NON-CONFORMITY RAISED:		
Ref to ISO/ IEC 17025:2017 Clause No.		Type of NC: **MAJOR / MINOR**
Signature & Name of Laboratory Representative		Signature & Name of Assessor
Assessor's comments on corrective action proposed by the laboratory Signature of Assessor		
REMARKS BY TEAM LEADER, IF ANY: Signature & Name of Team Leader		

*Applicable to Chemical Testing Laboratories only

F 09c

CONSOLIDATED NON-CONFORMITIES

Laboratory:		Date(s) of Visit:	
ISO 17025 Clause No.	**ISO / IEC 17025: 2017 Requirement**	**No. of Non-Conformity raised during Assessment**	
		Major	**Minor**
4	General requirements		
4.1	Impartiality		
4.2	Confidentiality		
5	Structural requirements		
6	Resource requirements		
6.2	Personnel Management System		
6.3	Facilities and Environmental Conditions		
6.4	Equipment		
6.5	Metrological Traceability Subcontracting of Tests and Calibration		
6.6	Externally provided product and services i) Purchasing Services and Supplies ii) Service to the Customer		
7	Process requirements		
7.1	Review of Requests, Tenders and Contracts		
7.2	Selection, verification and validation of methods		
7.3	Sampling		
7.4	Handling of Test and Calibration Items		
7.7	Ensuring the validity of Results		
7.8	Reporting of Results Preventive Action		
7.9	Complaints		
7.10	Nonconforming work		
8	Management System requirements		
8.3	Control of management system documents		
8.4	Controls of Records		

8.5	Actions to address risks and opportunities		
8.6	Improvement		
8.7	Corrective Action		
8.8	Internal Audits		
8.9	Management reviews		

The non-conformities raised during the assessment are as a result of limited sampling and therefore it shall not be assumed that other non-conformities do not exist.

Signature & Name of Authorised representative of Laboratory	**Signature & Name of Team Leader**

*Applicable to Chemical Testing Laboratories only

F 10a

TESTING/RE-TESTING WITNESSED DURING ASSESSMENT

Laboratory assessed			
Discipline of Testing		Date(s) of Assessment	

	Test 1	***Test 2***	***Test 3***
Product / Material of Test			
Test Witnessed			
Test Method Specification used			

Range of Testing / Limits of Detection			
Accuracy/Measurement Uncertainty			

1. Re-testing of Retained Sample

Sample ID			
Date of Earlier Testing			
Earlier Tested by			
Earlier Reported Results			
Results of Test Witnessed			
Test conducted by			

(same person)			
Test conducted by (different person)			

2. Testing of RM/CRM / SRM

Reference Material			
Specified Value			
Results of Test Witnessed			

Remarks*:*

Deviations observed, if any			
Conclusion on the technical competence of the lab for the test witnessed			

(Enclose all supporting data sheets for tests witnessed)

(Signature & Name of Assessor)

SUMMARY OF THE ASSESSMENT

Laboratory:		**Laboratory ID No:**
Quality Manager:		**Date(s) of Visit:**
Type of Visit: *Assessment / 1st Surveillance / Re-Assessment / Supplementary Visit*		
Field :*Testing/Calibration:*	**Discipline(s):**	
Facility (s):*Permanent / Site/Mobile*		
Team Leader:	**Assessor 1:**	**Assessor 2:**
Assessor 3:	**Assessor 4:**	**Observer:**
Date of earlier visit:	*Non-Conformities during earlier visit have/ have not been discharged.*	
ASSESSMENT SUMMARY:		

Assessment Team Comment on compliance of laboratory to:

(a) Use of AERSSC Accreditation Logo:

(b) Traceability of Measurement:

(c) Participation in PT:

(d) Calibration and Measurement Capability (applicable for calibration laboratories only):

Non-Conformities raised during the assessment	**MAJOR**	**MINOR**

RECOMMENDATIONS OF ASSESSMENT TEAM:

Only If accreditation is recommended, date by which the Corrective Action to be taken by the Laboratory for the above Non-Conformities are cleared: ----------

Enclosure	Form 9a	Form 9b	Form 9c	Supporting documents if any
No. of pages				

Acknowledgement by Authorised Representative of Laboratory & Date	Signature of Team Leader & Date

F 11

FEED BACK FORM

The Team Leader shall hand over the form to the laboratory and request for a fare opinion about the assessment and about the assessors including Team Leader. The laboratory is requested to furnish information about the assessment and assessors including Team Leader. The feedback shall become a key parameter to improve the assessment and compatible to International practices. The laboratory should ink its opinion on following aspects by allocating marks on 10 point scale and send the form directly to AERSSC office.

NAME of the assessor/Team Leader

……

Date of pre-assessment/assessment/surveillance/check visit

……..

QUESTIONAIR:

1) The general behavior of the assessment team member ……. ☐
2) Knowledge of the team member about the subject
   Under assessment…… ☐
3) Cooperation with laboratory staff…… ☐ …..
4) Assessment skills …… ☐ ……..
5) Communication skills …… ☐ ……
6) Time management ability…… ☐ …….
7) Expectation for any undue favor in cash or in kind…… ☐
8) Is s/he over doing? …… ☐ ……..
9) Can his findings improve upon your competence? ☐
10) His/her ability to become a consultant/Team Leader …… ☐

Pl add your general opinion if not covered as above in few lines

……

……

Name of the Laboratory ……

Name of the Laboratory Chief/Manager ----------

Signatures of the Laboratory Chief/ Manager……

Date ……..

Assessment Report

Accreditation criteria ISO 15189:2012

Part 1: General Information

☐ Pre-Assessment	☐ Accreditation Assessment	☐ Surveillance
☐ Unannounced Visit	☐ Extension of Scope	☐ Re-Assessment

Part 2: Assessment Team Details

Team Leader:

Name: **Signature:**

Date

TECHNICAL ASSESSOR:

Observer:

Part3: Assessment Details

STAFF INTERVIEWED:

S. No.: Name: Position:

Scope Covered and Comments:

Clause No.	Comments
4.1	•
4.2	•
4.3	•
4.4	•
4.5	•
4.6	•
4.7	•
4.8	•
4.9-4.13	•
4.14	•
4.15	•
5.1	•
5.2	•
5.3	•
5.4	•
5.5	•
5.6	•
5.7	•
5.8	•
5.9	•

5.10	•
PT Participation	•

Assessment Findings:

#	Type of Findings	Statement	Clause No.	Follow up required	Corrective action status
1	☐ MAJOR ☐ MINOR				
2	☐ MAJOR ☐ MINOR				
3	☐ MAJOR ☐ MINOR				
4	☐ MAJOR ☐ MINOR				
5	☐ MAJOR ☐ MINOR				
6	☐ MAJOR ☐ MINOR				
7	☐ MAJOR ☐ MINOR				
8	☐ MAJOR ☐ MINOR				
9	☐ MAJOR ☐ MINOR				
10	☐ MAJOR ☐ MINOR				
11	☐ MAJOR ☐ MINOR				
12	☐ MAJOR ☐ MINOR				
13	☐ MAJOR ☐ MINOR				
14	☐ MAJOR ☐ MINOR				
15	☐ MAJOR				

	☐ MINOR				

Part 4: Detailed Recommendations for Scope of Accreditation

Note:

A Accredit the Test Method/ Continued Accreditation (surveillance/re-assessment),

B Accreditation shall be granted/Continue only corrective action is submitted and verified

C Not Accredit/suspended Test Method. Finding/s observed detrimental to the final results

D Pending Scope that was not assessed during visit

CAB is conformity assessment body

Part 5: Proposed CA from Lab

Part 6: Conclusion and recommendation of Team Leader

☐ Accreditation shall be granted/ continue	☐ Accreditation shall be granted/ continue subject to acceptance of corrective actions evidence
☐ Accreditation shall be suspended	☐ Accreditation shall be withdrawn
☐ Scope shall be extended	☐ Scope shall be extended subject to acceptance of corrective actions evidence
☐ Re-witness	☐Follow up visit is required
☐ CAB is ready for initial assessment	☐ CAB can be ready for initial assessment subject to closing the Pre- assessment findings

Part 7: Submission of the Final Report

FOR OFFICE USE ONLY

1. Submission of final report for decision

Name:_______________________________ **Signature:**____________

Date: [Publish Date]

2. Decision Regarding Accreditation of CAB:

_ _
_ _
_ _
_ _
_ _

Head of Section:

Name:__________________________ **Signature:**____________

Date: **[Publish Date]**

3. Approval of accreditation Board Director

_ _
_ _
_ _

Name:______________________________ **Signature:**____________

Date: **[Publish Date]**

Desk Top Surveillance Form

S. No	Item			Details
1	Laboratory (Lab ID)			
2	Field			
3	Facility			Permanent
4	Accreditation Cycle			
5	Date of last On-site assessment visit			
6	Documents to be provided by the laboratory for Desktop Surveillance			Status of Document submitted by lab
	6.1	Information on the following (since the last on-site assessment visit)		
		i	Internal audit and corrective actions	
		ii	Management review	
		iii	Types of internal quality checks and their frequency	
		iv	Participation in ILC/PT programs and corrective actions, if any	
		v	List of CRMs/reference standards available and used	
		vi	Change in legal status, ownership, top management, key personnel, main policies, resources, premises, scope of accreditation, if any	
		vii	List of authorized signatories and changes, if any	
	6.2		Self-declaration on calibration status of equipment, reference materials etc	

Name of Representative of AERSSC Sitaram Joshi **Signature**

Accreditation Process at a Glance