SRI LANKA ATOMIC ENERGY REGULATORY COUNCIL

Procedure for Granting the Approval of Institutes Involved in Issuing Certification on Calibration of Radiation Measuring Equipment

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1. Purpose

The purpose of this procedure is to establish the criteria and outline the steps required for the approval of institutes responsible for certifying the calibration of radiation measuring equipment. This ensures that approved institutions are competent to perform calibration services in compliance with national and international standards, thereby maintaining the accuracy, reliability, and traceability of radiation measurements.

2. Scope

This procedure applies to any institutes seeking approval to certify the calibration of radiation measuring instruments including but not limited to dosimeters, survey meters, and spectrometers used for the detection and measuring of radiation, such as X-rays, gamma rays & neutrons.

3. Legal Background:

This document has been developed in accordance with section 12 (l) of chapter II of the Sri Lanka Atomic Energy Act, No. 40 of 2014, and establishes the requirements to be fulfilled by applicants seeking approval to issue certificates of calibration for radiation measuring equipment.

4. General Requirements for Issuing Certificates for Calibration of Radiation Measuring Equipment

4.1 Personnel

4.1.1 Qualifications of person/s to be authorized to issue the certificates (Technical Manager/Quality Manager)

Having a B.Sc. general degree with Physics as a subject from a university recognized by the UGC with minimum 3 years of experience in radiation measurements and radiation protection.

4.1.2 Qualification of Technical Staff:

Having a certificate of proficiency not below than the National Vocational Qualification (NVQ) level 4, and minimum 6 months on-the-job training under the supervision of a qualified person in the relevant field.

4.2 Laboratory Requirements for Calibration of Radiation Measuring Equipment

4.2.1 The laboratory shall be organized and operated in a manner that its facilities and activities meet the requirements of this section.

4.2.2 The laboratory shall:

a) be accredited by a recognized accreditation body in accordance with ISO/IEC 17025 (General Requirements for the Competence of Testing and Calibration Laboratories)

b) have managerial staff with the necessary authority and resources to effectively perform their assigned duties;

c) establish arrangements to ensure that personnel are free from any commercial, financial, or other conflicts of interest that could adversely affect the quality and impartiality of their work;

d) be structured and managed to maintain trust in its independence, impartiality, and integrity at all times;

e) clearly define document, and communicate the responsibilities and authorities of all personnel involved in managing, performing, or verifying calibration activities;

f) provide adequate supervision of calibration work by persons who are knowledgeable about the relevant methods and procedures, understand the objectives of the calibration, and are competent in evaluating the results;

g) appoint a technical manager (or equivalent) who has overall responsibility for the laboratory's technical operations;

h) appoint a quality manager (or equivalent) who is responsible for establishing, implementing, and maintaining the quality management system. The Quality Manager may also serve as the Technical Manager, provided there is no conflict of responsibilities;

4.3 Quality Management System

4.3.1 Interlaboratory Comparisons

The laboratory shall participate in interlaboratory comparisons for all calibration services it provides at least once per year and shall implement corrective actions if the results indicate any nonconformities or performance issues.

4.3.2 Recognized Standards

Interlaboratory Comparisons shall be conducted with nationally or internationally recognized standards laboratories.

4.3.3 Interval Between Comparisons

The interval between interlaboratory comparisons may be extended when justified; however, it shall not exceed 15 months.

4.3.4 Establishment of Quality System

The laboratory shall establish, implement, and maintain a documented quality management system appropriate to the scope and complexity of its calibration activities.

4.3.5 Responsibility of the Quality Manager

The Quality Manager shall be responsible for ensuring that the quality manual and associated documentation are kept current and effectively implemented.

4.3.6 Content of the Quality Manual

The quality manual and related documentation shall include, at a minimum:

a) A Quality policy statement outlining objectives and management's commitments to Quality.
b) The Organizational and management structure including relevant organizational charts.
c) A description of the relationship between management, technical operations, support services, and the quality management system.
d) Procedures for the control, approval, revision, and maintenance of documents.
e) Job descriptions of key personnel and references to other relevant staff responsibilities
f) Identification of personnel authorized to sign calibration certificates and reports.
g) Procedures ensuring measurement traceability to national or international standards.
h) A clearly defined scope of calibration services including applicable radiation types, energy ranges, and dose rates.
i) Procedures for reviewing new requests or contracts to confirm the availability of adequate facilities, equipment, and competent personnel.
j) References to established calibration and verification procedures.
k) Procedures for receipt, handling, storage, and disposal of calibration or test items.
l) References to major equipment and reference standards used in calibration activities.
m) Procedures for equipment calibration, verification, maintenance, and performance checks.
n) Methods for verifying the quality of calibration results, including participation in interlaboratory comparisons, use of. reference materials, and internal quality control measures.
o) Procedures for identifying nonconformities and implementing corrective actions.
p) Management arrangements for handling permitted deviations from established policies or standards.
q) Procedures for receiving, evaluating, and resolving complaints.
r) Procedures to ensure confidentiality of information and protection of proprietary rights.
s) Procedures for reviewing calibration programs and measurements processes to ensure continued suitability and effectiveness.
t) Statements of measurement uncertainties for all calibration services, including identification and quantification of individual uncertainty components.

4.4 Facilities and Environment

4.4.1 The Laboratory shall be provided with adequate facilities including appropriate calibration areas, electrical power sources, lighting, heating, and ventilation to ensure the proper performance of calibration activities.

4.4.2 The environment conditions under which calibrations and related activities are undertaken shall be controlled to ensure that the validity of results and the specified measurement uncertainty are not adversely affected.

4.4.3 The laboratory shall establish and maintain suitable arrangements to monitor, control, and record environmental conditions where such conditions may influence calibration results.

4.4.4 Attention must be given to environmental factors such as dust, electromagnetic interference, humidity, power stability, temperature, noise, and vibration, as appropriate to the nature of the calibrations performed.

4.4.5 The laboratory design shall ensure adequate separation and protection between areas where the activities are incompatible.

4.4.6 Access to areas that may affect the quality of calibration and related activities shall be clearly defined and effectively controlled.

4.4.7 The laboratory shall comply with all relevant health and safety requirements.

4.4.8 Appropriate storage facilities shall be provided for reference standards, equipment, documented instructions, manuals, and calibration certificates and reports to prevent damage, deterioration, or loss.

4.5 Equipment

4.5.1 The laboratory shall be equipped with all necessary equipment required for accurate and reliable performance of calibrations activities.

4.5.2 All equipment relevant to calibration processes shall be properly maintained and corresponding maintenance procedures shall be documented.

4.5.3 Where applicable, each item of equipment shall, be labeled, marked, or otherwise identified to indicate its calibration status.

4.5.4 The laboratory shall maintain comprehensive records for each item of equipment that significantly influences calibration results. These records shall include:

a) the name and the identification of the equipment;
b) the manufacturer's name, model or type identification, and serial number or other unique identification;
c) the date of receipt and the date place in to service;
d) the current location of the equipment, where appropriate;
e) the condition of the equipment upon receipt (new, used or reconditioned);
f) the dates and results of calibrations and/or verifications, including due date for the next calibration or verification;
g) the name and signature of the person who performed the calibrations and/or verifications;
h) details of maintenance carried out as well as planned maintenance activities; and
i) the history of any damage, malfunction, modification, or repair.

4.6 Measurement Traceability and Calibration

4.6.1 All measuring equipment that affects calibration accuracy shall be calibrated or verified prior to use and the laboratory shall establish, implement, and maintain a documented calibration and verification programme.

4.6.2 The Calibration and verification programs shall ensure that all measurements are traceable to national or international standards where such standards are available Calibration Certificates shall clearly demonstrate traceability, and shall include measurement results with associated uncertainty and/or a statement of compliance with specified requirements.

4.6.3 Where traceability to national or international standards is not possible, the laboratory shall demonstrate the correlation and reliability of results through interlaboratory comparisons or other methods recognized by the relevant competent authority.

4.6.4 Reference standards shall be used exclusively for calibration purposes unless it can be demonstrated that other uses do not compromise their validity or accuracy.

4.6.5 All reference standards shall be traceable to national or international standards and shall be included in the laboratory's calibration or verification program.

4.6.6 Reference standards and measuring equipment shall undergo appropriate in-service checks between scheduled calibrations or verifications to ensure continued reliability.

4.7 Calibration Methods

4.7.1 The laboratory shall maintain documented, and up-to-date instructions covering equipment use, dosimeter handling and preparation and calibration procedures. These instructions shall be readily available to relevant staff.

4.7.2 Appropriate and validated methods and procedures shall be applied for all calibrations and related activities. This includes handling, transport, storage, preparation of dosimeters, estimation of measurement uncertainty, and data analysis. All activities shall be performed consistently with the required level of accuracy and applicable standards.

4.7.3 All calculations and data transfers shall be appropriately verified to ensure accuracy and integrity.

4.8 Handling of Client's Dosimeters

4.8.1 The laboratory shall maintain. a documented system to uniquely identify each dosimeter at all stages of receipt, storage, preparation, calibration, and reporting.

4.8.2 The condition of dosimeter shall be recorded upon receipt. If a dosimeter is found to be unsuitable, unclear, damaged or improperly prepared, the laboratory shall consult the client before proceeding with the calibration.

4.8.3 Documented procedures and facilities shall be established to prevent damage during storage, handling, preparation, and calibration.

4.8.4 Procedures shall be documented for receipt, retention, and safe disposal of dosimeters ensuring protection of laboratory integrity and compliance with applicable requirements.

4.9 Record-Keeping by the Laboratory

4.9.1 The laboratory shall maintain a record system complies with regulatory requirements and meets its operational needs. Records shall include;

a) original observations and measurement data,
b) calculations and, derived data,
c) calibration records,
d) copies of certificates/reports,
e) records shall be retained for a sufficient period to allow repetition or verification of calibrations, where necessary. All records shall clearly identify the personnel involved in the calibration activities.

4.9.2 All records, certificates, and reports shall be securely stored, adequately protected against damage or loss, and consider confidential information to the client.

4.10 Certificates and Reports

4.10.1 Calibration results shall be reported accurately, clearly and objectively, in accordance with the method used. Results shall normally be issued in the form of a calibration certificate or a calibration report, containing all necessary information for proper interpretation.

4.10.2 Each certificate or report shall include as a minimum:

a) Title ("Calibration Certificate" or "Calibration Report")
b) Name and address of the laboratory and the location where calibration was performed (if different)
c) Unique identification number for the certificate or report and page numbering
d) Client's name and address (where applicable)
e) Clear description or identification of dosimeters (supplier, type, batch)
f) Condition and characterization of dosemeters
g) Dates of receipt and calibration
h) Reference to the calibration method used (or description of non-standard method)
i) Details of any deviations, additions, or exclusions, and relevant environmental conditions
j) Calibration results including measurements, tables, graphs, sketches, or photographs where applicable, and identification of any non-conformities
k) Statement of overall uncertainty (where relevant)
l) Name, title, signature of responsible person(s) and date of issue
m) Statement that results apply only to the calibrated dosimeters
n) Statement that the certificate or report shall not be reproduced except in full, without written approval of the laboratory

4.10.3 Certificates and reports shall be clearly arranged, easy to read, and formatted with standardized headings.

4.10.4 Amendments to issued certificates or reports shall be made only through a supplementary document or data transfer marked "Supplement to Calibration Certificate/Report" referencing the original serial number.

4.10.5 The clients shall be notified immediately, both verbally and in writing if defective equipment or other issues cast doubt on reported results.

4.10.6 When results are transmitted electronically (e.g. by phone, fax, or email) documented procedures shall be followed to ensure accuracy, confidentiality, and compliance with applicable requirements.

4.11 Complaints

4.11.1 A complaint is defined as any expression of dissatisfaction with a calibration service.

4.11.2 The laboratory recognizes that all complaints are important. Every complaint received from customers or other parties on calibration services shall be handled promptly, impartially, and professionally. A record shall be maintained of all complaints and of all actions taken by the laboratory to resolve them.

4.11.3 Valid complaints may include:

a) broken, damaged, or missing dosimeters or equipment
b) excessive delay beyond the estimated completion date without reasonable explanation
c) missing or incomplete data in the calibration report

4.11.4 The following situations shall not be considered complaints:

a) the estimated completion date does not match the customer's preferred schedule
b) calibration fees are considered as excessive
c) the type of calibration service offered does not meet the customer's specific needs
d) reported uncertainties are considered too large

4.11.5 The laboratory shall provide reasonable assistance to customers where possible; however, service schedules and operational priorities shall not be determined solely by customer demands.

4.12 Complaint Process Procedures

4.12.1 Every complaint received by phone, fax, e-mail, or in person shall be recorded in a Complaint Log. The log shall include;

a) customer name and address,
b) contact person and telephone number,
c) date received,
d) date closed,
e) assigned group Leader,
f) complaints shall be numbered sequentially in chronological order.

4.12.2 A complaint response form shall be completed for each complaint. The form shall include;

a) name of the person receiving complaint,
b) date of received,
c) complaint number,
d) assigned group leader,
e) customer information,
f) description or copy of complaint,
g) action taken,
h) date of closure,
i) Upon closure, the form shall be reviewed and endorsed by the Technical Manager.

4.12.3 resolve each complaint. All actions taken shall be documented, dated, and recorded on the Complaint Response Form. immediate and reasonable action shall be taken to resolve each complaint and all actions shall be recorded on the Response Form.

5. Application Process for Granting Approval

5.1 Submission of Application

The institution shall submit a detailed application form along with the following documents.

a) Proofs of the educational qualifications and experience of the person/s authorized to issue the certificate
b) Accreditation certificate
c) Proofs of the educational qualifications, training, and experience of technical staff.
d) Business Registration (if applicable only for private entities).

5.2 Review of Application

5.2.1 Council on receipt of the application form along with the relevant documents including the application processing fee, the Council shall review the application for completeness, ensuring the applicant meets the basic eligibility criteria.

5.2.2 Council may request additional information or clarification(s), if necessary, from the applicant.

5.3 Assessment of Capabilities

5.3.1 A technical review shall be conducted to assess:

a) the capability of calibration of measuring equipment and their traceability to primary standards.
b) the competence of the technical staff.
c) the quality management system in place (e.g., adherence to ISO/IEC 17025, internal audits).
d) having adequate radiation protection protocols and safety measures.

5.3.2 If deficiencies or inadequacies are identified during the evaluation process, the applicant shall be notified accordingly. The applicant shall be granted a maximum of one month from the date of notification to address and rectify these issues. If the applicant requires additional time, a request for an extension of up to two weeks shall be submitted in writing. This request shall be evaluated by the Council to determine its appropriateness.

5.3.3 The application shall be re-evaluated upon receipt by the Council of the information and documents addressing the completion or resolution of deficiencies and inadequacies within the specified timeframe.

5.3.4 If the deficiencies and inadequacies are not completed or corrected at the end of the given period, the application is canceled and the decision shall be informed to the relevant parties. However, the application processing fee paid for authorization is non-refundable.

5.4 On-Site Inspection

5.4.1 If the requirements mentioned above are deemed satisfactory, the Council shall schedule an on- site inspection to;

a) verify the quality management system.
b) inspect facilities, equipment, and work environment.
c) evaluate the use of safety protocols and regulations.
d) review calibration records and ensure traceability to national/international standards as appropriate.

5.4.2 Demonstrating in inter-comparison testing to verify calibration accuracy.

5.4.3 The fee for the initial on-site inspection shall be determined by the Council.

5.4.4 During the on-site inspection, if deficiencies and inadequacies are detected, the applicant is informed, and a maximum of one month from the date of notification is given to complete or correct the deficiencies and inadequacies. Should the applicant be unable to rectify the identified defects and deficiencies within the one-month time frame, they may submit a written explanation outlining the reasons for the delay. If the council deems the provided reasons satisfactory, an extension of up to another two weeks may be granted. In cases where the deficiencies and inadequacies are not completed or corrected at the end of the given period, the application is canceled and the situation is reported to the institute responsible for calibration of radiation measuring equipment. The fee for the on-site inspection is non-refundable.

5.4.5 An on-site inspection may be carried out again to determine that the deficiencies and inadequacies have been completed or eliminated. In this case, the applicant applies to the Council by paying the follow-up on-site inspection fee determined by the Council for re-on-site inspections.

6. Approval Decision

6.1 Approval Criteria

- The institute shall demonstrate competence in all required areas, including:

a) coverage of the scope of calibration services
b) adequate calibration standards and facilities.
c) compliance with safety and regulatory requirements.
d) experience and qualifications of staff members.
e) demonstrated proficiency in performing the calibration of radiation measurement equipment.

6.2 Issuance of Approval

6.2.1 **Approval Fee:** Approval fee determined by the Council should be paid by the institute.

6.2.2 **Approval:** Upon fulfillment of all applicable criteria by the applicant, formal approval shall be issued by the Council. This approval shall clearly define the scope of authorized calibration services, indicate the date of issuance, specify the period of validity, and outline the requirement for renewal upon expiry. Furthermore, the approval shall be publicly announced on the official website of the Council.

6.2.3 **Validation:** Approval is valid for five years from the date of issue.

6.2.4 **Modification**: The calibration service provider shall formally notify the Council of any material modifications to the calibration system, alterations to accreditation status or its recognized equivalent, and any substantive changes to the service provision, including but not limited to changes in key personnel or operational location.

7. Regulatory Inspections and Performance Review

7.1 Regulatory Inspections

a) Regulatory inspections shall be conducted in every five years to ensure continued compliance with approval conditions.
b) Random inspection shall be conducted as appropriate to check the noncompliance.

7.2 Performance Reviews

a) Review feedback from customers or stakeholders who have used the calibration services.
b) Address any non-conformances or complaints promptly and initiate corrective actions if necessary.

8. Renewal of Approval

a) A renewal application shall be submitted by the institute 03 months prior to the expiry of the approval, along with the updated documentation, calibration procedures, and equipment.
b) Renewal process may include a regulatory inspection described in section 7.
c) Fee for the renewal of approval determined by the Council should be paid by the institute.

9. Revoke/Suspension

9.1 Grounds for Revocation/Suspension

Approval may be revoked or suspended if the laboratory:

a) Fails to comply with current criteria for recognition.
b) Does not follow documented procedures, policies, or quality system requirements.
c) Provides calibration services that are inaccurate, misleading, or outside approved scope.
d) Fails to take corrective action after deficiencies are identified during inspections, reviews, or interlaboratory comparisons.
e) Engages in practices that compromise impartiality, confidentiality, or integrity of results.

9.2 Revocation/Suspension Process

a) Revocation or suspension shall be communicated in writing by the Council.
b) The notice may specify the reasons, scope affected, and effective date.
c) The laboratory may be required to stop offering affected calibration services immediately.
d) Records of revocation/suspension shall be maintained by both the laboratory and the authority.

9.3 Duration and Conditions

a) Suspension may be temporary until corrective actions are implemented and verified.
b) Revocation is permanent unless the laboratory reapplies and demonstrates full compliance.
c) Reinstatement requires documented evidence of corrective actions and a successful review/assessment.

9.4 Client Notification

a) The laboratory shall notify clients if suspension or revocation affects services already provided or pending.
b) Certificates or reports issued during non-compliance may be invalidated.

10. Appeal Process

10.1 Right to Appeal

a) Applicants denied approval have the right to appeal the decision.
b) Appeals shall be submitted in writing within 30 days from notification.

10.2 Submission Requirements

a) The appeal shall clearly state the grounds for contesting the decision.
b) Supporting documents, evidence, or clarifications shall be included.
c) Appeals shall be signed by an authorized representative of the applicant.

10.3 Review Panel

a) Appeals shall be reviewed by a panel of experts independent of the original decision makers.
b) The panel shall evaluate whether procedures, criteria, and evidence were applied fairly and correctly.
c) Additional information may be requested from the applicant during the review.

10.4 Decision Process

a) The panel shall deliberate and issue a final decision.
b) The decision shall be communicated to the applicant in writing, with reasons provided.
c) The final decision is binding and concludes the appeal process.

10.5 Possible Outcomes

a) Approval Granted: If the appeal is successful, approval is reinstated or granted.
b) Approval Denied: If the appeal is unsuccessful, the denial stands.
c) Conditional Approval: In some cases, approval may be granted subject to corrective actions or conditions.

11. Record-Keeping by the Council

a) All approval-related documents (applications, evaluations, certificates, inspection reports, appeals) may be maintained for a minimum of 10 years.
b) A comprehensive list of approved institutions shall be published on the official website of the Council to ensure transparency and provide relevant information to the public.

12. Definitions

a) **Calibration** : The process of adjusting or verifying the accuracy of radiation measuring equipment against a known standard.
b) **Approval** : Official recognition that an institution is competent to perform and certify radiation equipment calibration.
c) **Certification**: The formal attestation by an approved body that radiation measuring equipment meets the required specifications and is traceable to national or international standards.

13. References

a) IAEA Safety Standards, *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards, General Safety Requirements Part 3 (GSR Part III)*
b) NIST Special Publication 250-44, *Radiation Processing Dosimetry Calibration Services and Measurement Assurance Program*
c) Procedure for testing lab, Rules & procedures for accreditation of testing laboratories, Sri Lanka Accreditation Board (SLAB) for conformity assessment
d) ISO/IEC 17025, General Requirements for the Competence of Testing and Calibration Laboratories
e) Safety Reports Series 16, *Calibration of radiation protection monitoring instruments https://www-pub.iaea.org/MTCD/Publications/PDF/P074_scr.pdf,*

14. Payment Criteria

14.1. For New Applications:

Application processing fee for any institute is Rs. 2,400.00
The approval fee for any institute (for 05 years) is Rs. 600,000.00

Steps of Payment		
Step 1	On site inspection fee	20% of the approval fee
Step 2	Follow-up inspection fee (if applicable)	20% of the approval fee
Step 3	Outstanding balance of the total approval fee	60% or 80% of the approval fee as appropriate

14.2. For Renewal Applications:

Steps of Payment		
Step 1	Application processing fee	Rs. 2,400.00
Step 2	Renewal of approval fee	Rs. 600,000.00