

NABL 123



National Accreditation Board for Testing and Calibration Laboratories (NABL)

Specific Criteria for Calibration Laboratories in Radiological Discipline

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AMENDMENT SHEET

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PREFACE

This document clarifies NABL's stand on the accuracy and measurement capability levels. NABL intends to uphold its policy of granting accreditation to laboratories as per their requirements of accuracy and measurement capability.

These criteria are applicable to laboratories, which perform repetitive calibrations in various parameters and desire accreditation from NABL.

These criteria provide guidelines for use by laboratories and those who are associated with the programme of accreditation of calibration laboratories e.g. experts, assessors, officials engaged with day-to-day activities of accreditation. These criteria cover all areas/ fields of calibration.

This document provides the laboratories with necessary information on the requirements for assessment/ surveillance and to assist them in carrying out internal audit of their system.

The information in this document has been compiled in two parts.

PART – I

General Guidelines for Accreditation of Calibration Laboratories

This part contains relevant information on general requirements of a laboratory engaged in Calibration in the field of Radiological Measurements. The laboratory seeking accreditation must comply with the requirements of ISO/ IEC 17025: 2005 and this document.

PART – II

Specific Criteria for Accreditation of Calibration Laboratories

This part provides information on special requirements of the laboratories, which are specific to the parameters covered in the respective fields

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PART – I

GENERAL GUIDELINES FOR ACCREDITATION OF CALIBRATION LABORATORIES

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1.0 SCOPE

1.1 Calibration laboratories are accredited by NABL after it is demonstrated that a laboratory complies with the requirements of international standard ISO/IEC 17025: 2005. In view of generic nature of the standard the requirements stated there in, need to be further redefined in specific fields of calibration. This specific criteria lays down those specific requirements in the field of radiological calibration. This part of the document thus amplifies the generic requirements for radiological calibration and supplement the requirements of ISO/IEC 17025:2005. Laboratories seeking NABL accreditation in the field of radiological calibration must also comply with the requirements stated in this part.

1.2 Calibration and Measurement Capability (CMC) is one the parameters that is used by NABL to define the scope of an accredited calibration laboratory, the others being parameter/quantity measured, standard/master used, calibration method used and measurement range. The CMC is expressed as” the smallest uncertainty that a laboratory can achieve when calibrating the best existing device”. It is an expanded uncertainty estimated at a confidence level of approximately 95% corresponding to a coverage factor $k=2$.

Note: Refer NABL 143 on NABL policy on Calibration and Measurement Capability (CMC) and uncertainty in calibration

The laboratory’s ability to achieve their claimed CMC shall be evaluated based on its performance during the on-site assessment and by review of proficiency testing results, wherein the laboratory has participated.

1.3 The definition of CMC implies that within its accreditation a laboratory is not permitted to report a smaller uncertainty of measurement than the CMC endorsed on its scope of accreditation. This means that the laboratory shall be required to state a uncertainty not better than that corresponding to the CMC whenever it is established that the actual calibration process adds significantly to the uncertainty of measurement. The CMC is applicable only to the results for which the laboratory claims its status as accredited laboratory. It is therefore a realistic means for customers to select and compare accredited laboratories’ capabilities.

1.4 All the parameters for which accreditation is sought must be expressed in S.I. Units, wherever applicable.

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2.0 CRITERIA FOR ACCREDITATION

Accreditation of a calibration laboratory will require assessment in respect of organization, staff, equipment and traceability of its calibration, laboratory accommodation and environmental conditions, safety, handling of calibrated equipment and equipment under calibration, measurement capability and recording system, etc., as per ISO/ IEC 17025: 2005 General Requirements for the Competence of Testing and Calibration Laboratories. Some explanatory notes of this document are given in the following clauses.

3.0 ORGANISATION

3.1 The Calibration Laboratory shall be organized in such a way that all staff members are aware of both the extent and the limitations of their area of responsibility. This organization shall specify and document the responsibility and authority of the Head of the Calibration Laboratory/ Technical Manager/ Quality Manager with direct access to the top management. All personnel will perform or verify work affecting the quality of calibrations as per general guidelines and specific criteria laid down for the accredited parameters. The calibration laboratory shall be organized in such a way so as to ensure the integrity and training of its staff and operations for ensuring unbiased Calibration.

3.2 A Deputy Head/ Technical Manager may also be nominated to take over the responsibility in the absence of the Laboratory Head. In case there is no Deputy-in-charge, the authorities concerned may appoint a suitable person to look after the laboratory, under intimation to NABL. The laboratory shall also clearly define authorized signatory for the calibration certificates/ reports issued by the laboratory.

4.0 MANAGEMENT SYSTEM

4.1 The calibration laboratory shall have a Quality Manual which shall be maintained up-to-date and available for scrutiny, in compliance with ISO/ IEC 17025: 2005 and NABL requirements, with emphasis on following information:

- a) A quality policy statement, including objectives and commitments by the top management.
- b) A statement on the organization of the calibration laboratory.

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- c) Names, qualifications and experience of the persons responsible for managerial, and scientific/ technical activities.
 - d) A clearly defined charter of responsibility showing the relationship between management and support services.
 - e) Scope and operation together with information on measurement capability and traceability of calibration of all measuring instruments to national measurement standards.
 - f) The reference of document number on detailed calibration procedures adopted in the laboratory, which should be compiled in the form of a manual for the use of calibration staff.
 - g) The reference list of all national/ international standards being referred to or used in the performance of calibration work (copies of such standard specifications should be available in the laboratory for the use of calibration staff.)
 - h) All amendments made in any of the documents must be dated and listed in the Quality Manual and brought to the notice of NABL.
- 4.2 The calibration facilities established in accordance with the general guidelines and specific criteria shall be audited periodically and reviewed by or on behalf of the management to ensure the continued effectiveness of the system.
- 4.3 The calibration laboratory shall clearly specify, document and make known to the customers, the administrative and other procedures to be followed for getting calibration done from the laboratory. The procedure for redressal of technical complaints should also be clearly specified and documented.
- 4.4 The laboratory shall have authorized signatories for approving and issuing calibration certificates for each calibration parameter as mentioned in the scope of accreditation. Any officer competent to evaluate calibration results critically and occupying a position involving responsibility for the adequacy of calibration results is eligible for approval by NABL as an authorized signatory of endorsed calibration documents. Consequently approved authorized signatories must demonstrate understanding of these requirements.

5.0 PERSONNEL

5.1 Technical Personnel

5.1.1 Qualification required for carrying out calibration activity:

The following are the specific requirements. However, qualification and experience will not be the only criteria for the required activity. They have to prove their skill, knowledge and competency in their specific field of calibration activity.

- a) B.E / B.Tech or M.Sc. (degree with 3 months experience in Basics of Radiological Calibration.
- b) B.Sc or Diploma with 6 months experience in Basics of Radiological Calibration.
- c) ITI with 1 year of experience in Basics of Radiological Calibration.

5.1.2 Training and experience required:

- a) Training may be external / internal depending on the expertise available in the field. Effectiveness of training action needs to be ensured.
- b) Competence of the trainer in case of internal training needs to be ensured.
- c) Training in Radiological Calibration and in Uncertainty Measurements.
- d) For Technical Manager, Training in Radiological Calibration and in Uncertainty Measurements, CMC including statistical analysis is mandatory.
- e) Experience and competence in Radiological Calibration.
- f) Sufficient knowledge about handling of reference equipment, maintenance, traceability, calibration procedure and effect of environmental conditions on the results of calibration.
- g) During training calibration activity should be done under supervision.

5.2 Authorized Signatory:

5.2.1 Qualification required for interpretation of results and signing the calibration certificates:

The following are only guidelines. However, qualification and experience will not be the only criteria for the required activity. They have to prove their skill, knowledge and competency in analysis and interpretation of calibration results.

- a) B.E / B.Tech or M.Sc degree with 6 months experience in Radiological Calibration.
- b) B.Sc. or Diploma with 1 year experience in Radiological Calibration.

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5.2.2 Training and experience required:

- a) Training may be external / internal depending on the expertise available in the field. Effectiveness of training needs to be ensured.
- b) Competence of the trainer in case of internal training needs to be ensured.

6.0 ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

6.1 Vibrations

The calibration area shall be adequately free from vibrations generated by central air-conditioning plants, vehicular traffic and other sources to ensure consistent and uniform operational conditions. The laboratory shall take all special/ protective precautions like mounting of sensitive apparatus on vibration free tables and pillars etc., isolated from the floor, if necessary.

6.2 Acoustic Noise

Acoustic noise level in the laboratory shall be maintained to facilitate proper performance of calibration work. A threshold noise level of 60 dBA is recommended unless otherwise stated.

6.3 Illumination

The calibration area shall have adequate level of illumination. Where permissible, fluorescent lighting is preferred to avoid localized heating and temperature drift. The recommended level of illumination is 450-700 lux on the working table with glare index of 19 for the laboratory.

6.4 Environmental Conditions and Monitoring

The environmental conditions for the activity of the laboratory shall be such as not to adversely affect the required accuracy of measurement. Facilities should be provided whenever necessary for recording temperature, pressure and humidity values prevailing during calibration. The atmospheric conditions maintained in the laboratory during calibration should be reported in the calibration report/ certificate.

The laboratory shall specify limits on the environmental conditions to be achieved in the laboratory. The condition shall appropriate to the level of accuracy required for the calibration undertaken by the laboratory.

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Standard Environmental Condition for the Radiological Calibration Laboratory shall be as follows:

- a) Temperature $25^{\circ}\text{C} \pm 3^{\circ}\text{C}$; and
- b) RH 45% to 75%

The environmental condition shall be monitored at appropriate intervals and Calibration stopped when the environmental condition falls outside the specified limits.

6.5 **Entry to the Calibration Area**

As far as possible, only the staff engaged in the calibration activity shall be permitted entry inside the calibration area.

7.0 **EQUIPMENT**

Each calibration laboratory should have measurement standards or equipment of required accuracy in respect of each parameter covered by it in order to be able to realize and to substantiate the corresponding measurement capability claimed. Stability of the standards, accuracy of the values realized through them and repeatability, should be regularly monitored.

Any bias resulting from ageing of standards should be precisely determined. Instructions for operating each standard and equipment/ instrument should be readily available for use by the laboratory staff members.

7.2 The standards/ measuring equipment of the laboratory should be calibrated at regular intervals, with higher accuracy standards. The calibration certificates, performance history sheets in respect of the reference secondary/ working standards and measuring equipment should be held safely by the laboratory.

7.3 Proper record shall be maintained for each standard and equipment with the following information:

- a) Name of the equipment
- b) Manufacturers name and address
- c) Type, range, identification and serial number
- d) Date of procurement and commissioning
- e) Details of Calibration

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- f) Details of maintenance and repairs
- g) Performance history with dates
- h) Availability of service manual

7.4 Details of periodic calibration schedule of new and old standards and measuring equipment should be worked out in consultation with higher accuracy laboratory and this schedule should be observed.

7.5 Details of re-calibration of used, serviced and repaired equipment should also be available and proper precautions shall be observed to identify equipment, which are not in service.

7.6 Any alterations in the observations/ data shall be signed by the calibration staff and duly authenticated. Instructions to this effect should be printed on data sheet used for writing observations/ data in the laboratory.

8.0 RANGE, UNCERTAINTY OF MEASUREMENT AND TRACEABILITY

8.1 The level of uncertainty of measurement of the standards to be maintained by a laboratory and the measurement capabilities to be generated by it in respect of various parameters shall be as demonstrated during assessment.

8.2 All the Standard Equipment of the Laboratory shall be calibrated periodically as per the requirements of NABL 142

8.3 In the event when the levels of uncertainty of measurement and measurement capability of an accredited laboratory are revised, the laboratory shall be required to intimate NABL secretariat and undergo surveillance/ reassessment as applicable.

9.0 CALIBRATION CERTIFICATE/ REPORT

9.1 The result of calibration carried out by the calibration laboratory, shall be presented in a comprehensive manner, using a standard format which shall unambiguously and objectively present the measurement results and all relevant information in order to facilitate easy comprehension and usage.

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- 9.2 The calibration report/ certificate shall include the following additional information:
- a) Date of receipt of the item and date of completion of the calibration work
 - b) Environmental conditions maintained during the measurements
 - c) Signature and title of authorized person (authorized signatory) accepting responsibility for the report and date of issue
 - d) A statement of the accreditation measurement capability relevant to the job under calibration
 - e) A symbol of NABL or statement or both clarifying the status of accreditation of the laboratory.
 - f) The Uncertainty of measurement
 - g) An evidence that the measurements are traceable to National/ International Standards through unbroken chain of Accredited Laboratories.
- 9.3 The calibration report/ certificate shall not contain any recommendation on the calibration interval except where this has been agreed with the client. This requirement may be superseded by legal regulations.

10.0 PROFICIENCY TESTING (clause 5.9 of ISO/IEC 17025:2005)

- 10.1 Laboratories shall follow NABL 163 (Policy for Participation in Proficiency Testing Activities) and NABL 164 (Guidelines for inter-laboratory comparison for calibration laboratories where formal PT programmes are not available) for participation in PT/ILC programmes.
- 10.2 In order to assure validity of calibrations undertaken and demonstrate its technical competence, a laboratory will be required to participate, from time to time, in Proficiency Testing Programmes. The laboratory shall remain prepared to participate in the Proficiency Testing Programme through inter-laboratory, inter-comparison schemes wherever it is technically feasible. In case any abnormalities, in terms of En number are detected through these inter-comparisons, appropriate corrective action will be taken, the standards/ equipment shall be replaced/ repaired and re-calibrated with a higher accuracy standard. Reports on such inter-comparisons should be documented with reference.

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PART – II

SPECIFIC CRITERIA FOR ACREDITATION OF CALIBRATION LABORATORIES IN THE FIELD OF RADIOLOGICAL MEASUREMENTS

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1.0 SCOPE OF ACCREDITATION

- 1.1 An accredited laboratory shall be classified as calibration laboratory for the accredited parameters in the field of Radiological Measurements in accordance to its measurement capability.
- 1.2 A calibration laboratory seeking accreditation to offer calibration services in the field of Radiological Measurements will generally carry out calibration in the parameters, listed below:
- i. Dosimeter (X-rays & Gamma rays)
 - ii. Area Survey Meter

2.0 SPECIAL REQUIREMENTS OF LABORATORY

- 2.1 The calibration laboratory shall make arrangement for regulated and uninterrupted power supply. The recommended regulation level is ± 1 % or better on the calibration bench.
- 2.2 Relevant IS specifications (IS:1248, IS:4722) regarding total harmonic content and variation in supply frequency should be followed. Voltage stabilizers of low harmonic content should be used to comply with this requirement.
- 2.3 Adequate arrangements shall be made by the laboratory so as to ensure temperature gradient not exceed in 1.5 deg C per hour inside the laboratory in case of power failure.
- 2.4 The laboratory shall use if necessary, isolation transformers and filters etc. to ensure minimization of ground current and effects of mains hum interference.
- 2.5 The power supply to the calibration laboratory shall be directly obtained from the substation as far as possible and shall not be on the same feeder line which is supplying power to workshops and other production areas which require operation of heavy duty machines.
- 2.6 Electrical mains earthing shall be provided in accordance with relevant specifications IS: 3043. This shall be periodically checked and stray couplings minimized.
- 2.7 Special care shall be taken about the location of magnetic field sources like, transformers, looped wires, ferrous materials etc., in order to minimize magnetic interference in the measurements.

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- 2.8 Adequate screening of the laboratory against electromagnetic interference shall be done if necessary. By pass filters should also be provided to minimize conducted interference effect on the electronic equipment. Special shielding chambers should be provided in the laboratory for measurements, particularly when signal to noise is a disturbing factor for accurate measurements.
- 2.9 The reference standards shall be maintained at temperatures specified for their maintenance in order to ensure their conformity to the required level of operation and traceability. The laboratory should have specific facilities required for carrying out the calibrations of parameters chosen.
- 2.10 The laboratory shall be sealed against dust and external air pressure. Wherever required positive air pressure shall be maintained inside the laboratory.
- 2.11 Adequate protective measures, like use of transient suppressors etc. shall be taken by the laboratory to ward off high current spikes and transients emanating from switching off and on the heavy machines, surges in power lines and other such reasons from reaching the electronics equipment in general and computer based systems involving data storage facilities in particular.

3.0 SAFETY PRECAUTIONS

- 3.1 Relevant fire extinguishing equipment for possible fire hazards shall be available in the corridors or convenient places in the laboratory. Adequate safety measures against electrical/ chemical fire hazards must be available at the work place. Laboratory rooms/ areas where highly inflammable materials are used/ stored should be identified. Access to relevant fire equipment should be assured near these rooms/ areas.
- 3.2 Specifications SP.3.1 – 1986, a special publication in the form of a wall chart, giving the method of treatment in case of electric shock, should be followed. The chart should be placed near the power supply switchgear and at other prominent places as prescribed under Indian Electricity Rules 1956.
- 3.3 Means shall be provided for Safety against radiation hazards in the laboratory. Special warning and protection devices shall be available for the safety of workers.

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