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BOARD FOR TESTING AND
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SPECIFIC CRITERIA *for* RADIOLOGICAL TESTING LABORATORIES

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AMENDMENT SHEET

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10							

Contents

S.NO.	SECTION	PAGE NO.
	Amendment Sheet	i
	Contents	ii
1	Introduction	1
2	Classes of tests	2
3	Criteria for accreditation	6
4	Safety	11
5	Classification for testing laboratories	12

1. Introduction

Laboratories accreditation activities are administered under the direction of National Accreditation Board for Testing & Calibration Laboratories (NABL) and involving Technical Committees and Accreditation Committees as recommending bodies. NABL assessment system is based on the basis of ISO/ IEC 17011 and APLAC / ILAC requirements.

This document on "Specific Criteria for Radiological Testing Laboratories" is one of a series of supplementary booklets of the document ISO/ IEC 17025: 2005 "General Requirements for the Competence of Testing and Calibration Laboratories".

Radiological is one of the following fields in which NABL currently gives accreditation.

Fields of Testing

- Biological Testing
- Chemical Testing
- Electrical Testing
- Electronics Testing
- Fluid Flow Testing
- Mechanical Testing
- Non-Destructive Testing
- Optical and Photometry Testing
- Radiological Testing
- Thermal Testing
- Forensic Laboratories

The aim of radiological imaging practices both in medicine and industry is to obtain good quality images at optimal doses. Diagnostic information may be missed in images of poor quality and this may necessitate retakes or repeat diagnostic procedures. This could result in unnecessary doses to personnel and public and overloading of the machine in industrial and medical radiological testing procedures, and in addition result in larger doses to patients in medical procedures. In radiation therapy, the aim is to give as accurate a dose as possible to the tumour and spare the normal tissues. Other types of radiological equipment in industry include nucleonic gauges industrial irradiators, etc.

The information contained in this document must be read alongwith the document ISO/ IEC 17025: 2005.

2. Classes of Tests

A laboratory for testing radiological materials and equipment should be capable of performing the following:

Testing or radiation sources
Testing of radiological equipment and nucleonic gauges
Testing of radiation monitors

A laboratory may be accredited for testing of particular type of radiological equipment (such as industrial or medical radiological equipment, nucleonic gauges) or all types of radiological equipment as per AERB codes. Radiological equipment considered here is radiation generating equipment or the one containing radiation sources. Open radiation sources are not covered.

2.1 Radiation Sources

These include radiation sources emitting neutrons, alpha, beta, and gamma radiation used for X-ray machines and accelerators. Activity of the sealed source may vary from few microcuries for a laboratory source to a few kilocuries for teletherapy sources or more for industrial irradiation units. The X-ray machines may range from diffraction, diagnostics to therapeutic machines and industrial X-ray machines.

Radiation sources will have to be tested for the following:

2.1.1 Identification of the Source

2.1.1.1 Identification of the nature of radiation by use of spectrometers and/or other suitable techniques.

2.1.1.2 Determination of the energy of the radiation emitted

a. Using suitable spectrometric method, in case of low activity sources.
b. Using appropriate absorbers for high activity sources.

2.1.2 Dose Output of the Source

Determination of dose output with the help of dosemeters/ monitors pre-calibrated against primary/ secondary standards.

2.1.3 Surface contamination

Sources should be checked for surface contamination by employing appropriate techniques.

2.1.4 Mechanical Integrity

Rigorous testing employing Bubble test, Drop test etc. should be performed at the source manufacturing stage as per the Atomic Energy Regulation Board codes. Test for mechanical integrity of the sealed radiation source for routine handling should be done by adopting suitable procedures.

2.2 Radiological Equipment

These may include interlocking, fluoroscopic/screening equipment, diaphragm/ timer controls, collimators, patient couch, radiographic cameras, manipulators, tongs, transport containers, labels on the equipment/containers, dark room accessories, radioisotopic gauges etc.

2.2.1 Operational Test and Appropriateness

Functional test of the equipment and accessories and tallying with the functional checklist based on manufacturer's specifications.

2.2.2 Radiation leakage test, Shielding adequacy checks, radiation leakage around the equipment in beam ‘OFF’ as well as ‘ON’ position. The radiation level should conform to the stipulated levels laid down by the competent authority.

2.3 Radiation Monitors

Radiation monitors to be tested may be of a wide variety. Dose rate monitors may have ranges from 1 uSv/h to 1 Sv/h or even higher. Integrated doses may be measured from 1mSv to 2Sv, or more. The radiation energy will vary from a few KeV right up to several MeV. The desired accuracy of the monitors will depend upon the specific uses.

The tests on Radiation Monitors will include:

2.3.1 Appropriateness

Check the suitability of the monitor and its range for the purpose in view.

2.3.2 Accuracy and Reproducibility

Test for accuracy and reproducibility as a

a. Secondary standard (+ 5%)

b. Routine monitor (+20%)

2.3.3 Response Time

Determine response time and check the suitability of the monitor for the purpose on hand.

2.3.4 Directional and Energy Dependence

Check the monitor for directional and energy dependence. These should be within +20%

2.3.5 Paralysis

Check that the monitor does not get paralysed when placed in an intense radiation field.

2.3.6 Calibration

Ensure that the monitors are calibrated against primary/secondary standards within the range of interest.

2.3.7 Temperature and Pressure

Correct for temperature and pressure dependence.

VARIOUS RADIOLOGICAL TESTS

GROUP	SUBGROUP
Radiation Monitors	Area survey instruments
	Fixed monitors
	Personnel monitoring dosemeters
	Control monitors
	Environmental radiation monitors
	Therapy level dosemeter
Radiation Sources	Diagnostic X-ray machines
	CT scanners
	Simulators
	Therapy X-ray machines
	Industrial X-ray machines
	Cobalt machines
	Caesium machines
	Medical Accelerators
	Brachytherapy after loading systems
	Industrial Accelerators
	Accelerators used in research
	Diffraction X-ray machines
	Dental X-ray machines
	X-ray machines used in consumer product testing
	X-ray machines for baggage checking
	Neutron generators
	Beam welding equipment
	Electron Industrial irradiators
	Isotopic sources used in industrial gauges
	Isotopic sources used in medical brachy therapy
Radiological Equipment and Nucleonic Equipment	Medical gamma camera
	Medical spectrometer
	RIA counter
	Liquid scintillation counter
	Industrial gamma radiography
	Radiography camera
	Thickness gauges
	Gamma switches
	Nucleonic weighing machines
	Smoke detectors containing sources
	Nucleonic level gauges
	Nucleonic moisture and density gauges
	Industrial irradiators

3. Criteria for Accreditation

The object of the assessment is to determine if the laboratory complies with the criteria defined by NABL.

The application of these criteria to testing services operating in the field of radiological testing is explained in the following paragraphs:

3.1 Personnel

3.1.1 The emphasis of NABL assessments in the field of radiological testing is an assurance that effective technical control is being exercised over all testing procedures. The Board needs to be satisfied that testing services have at least one person who has the competence, time and authority to achieve adequate technical control of its operations. A large testing service may need more than one such person.

3.2 Training and Experience

As the staff is the key to the standard of performance of a testing service, assessments are directed primarily at appraisal of staff.

The radiological testing staff is classified into three categories:

a. Officers exercising technical control - those who are responsible for control of radiological tests (head of the laboratory).
b. Officers who, under direction, can take responsibility for performance of specific routine tests (technical staff).
c. Technologists/ technician who perform routine technical and non-technical duties, working under close supervision.

The officers a. & b should have the following experience and training.

i. Sound knowledge of, and adequate training / experience in use of, applicable radiological testing techniques and electronics instrumentation.
ii. Knowledge of relevant materials, manufacturing processes and service conditions.
iii. Adequate training/ experience and ability in interpretation of data from relevant radiological tests.

iv. Adequate training/ experience in use of relevant codes and standards and ability to prescribe suitable procedures in the absence of appropriate codes and standards.
v. Ability to prepare routine and critical reports.
vi. Ability to control quality of performance of radiological tests.

3.3 Qualification of Personnel

3.3.1 Officers exercising Technical Control

These officers must have authority and time for effective control of the radiological testing operations that they supervise. They should have either of the following qualification:

a. Degree in electrical/ mechanical/ electronics/ instrumentation engineering / technology or equivalent.
b. Postgraduate in medical physics or physics with specialization in electronic instrumentation or equivalent.
c. Diploma in radiological physics (1year course) conducted by BARC.

3.3.2 Officers responsible for specific routine tests i.e. persons who, under direction, take responsibility for performance of specific routine tests should have either of the following:

a. Degree in science with physics as one of the subjects
b. Diploma in electrical/ mechanical/ electronics/ instrumentation Engineering.

At least one such staff member must have (i) a diploma in radiological physics (1year course) conducted by BARC or (ii) M.Sc in medical physics.

3.3.3 Technologist

The laboratory technologist or equivalent shall have higher secondary certificate in science / ITI and at least one year experience or training in a relevant laboratory.

3.4 Authorized Signatory

The role of NABL approved signatory is to ensure the reliability and adequacy of the test document. The minimum requirement for an Authorized Signatory shall be a Graduate in Science with physics as one of the subjects / Diploma in electrical/ mechanical/ electronics/ instrumentation engineering or equivalent from a recognized university with

at least 5 years experience in relevant field, or Post-graduate in physics / specialization in relevant subject / equivalent or Degree in electrical/ mechanical/ electronics/ instrumentation engineering / technology or equivalent from a recognized university or Diploma in radiological physics (one year course conducted by BARC) with at least 2 years experience in relevant field.

Note: The Assessment team may however recommend Authorized Signatory who does not meet the above specified minimum experience requirement with specific recommendations to NABL, after adjudging the competence of the Authorized Signatory during on-site assessment.

An approval may be limited to specific tests, or may be granted for all tests for which the testing service is registered.

The criterion of "competence in critical evaluation of test results" may extend signatory approval well down the staff scale. When radiological reports are required, it is obviously necessary for the officer in charge on site to be an approved signatory.

3.5 Accommodation

Areas of appropriate size may be provided as under:

3.5.1 One room or nearly 300 sq. feet for setting up various counting systems.

This should have low background radiation and be preferably air-conditioned.

3.5.2 Area of nearly 600 sq. feet for equipment testing purpose. The room should be well shielded since high activity sources would be handled in this room. A suitable partition should be provided so as to serve the purpose of a control room.

3.5.3 There should be appropriate space of area 100 sq. feet for storing radiation sources under lock and key.

3.5.4 Area of about 300 sq. feet for data record-cum office. These areas may not be exclusive for testing activity.

3.6 Equipment and facilities

A testing service must be fully equipped for performance of all tests for which accreditation is sought. If tests are performed to codes or standards which define particular items or types of equipment, it become mandatory. All equipment must be maintained in good condition.

Fixed and mobile laboratories must provide adequate accommodation for performance of tests. Adequate storage facilities must be available for equipment and records.

3.7 Operating a Testing Service

3.7.1 Test Procedures

Sound management is essential if a testing service is to operate at a satisfactory standard. Particular attention should be given to the following aspects of management:

There must be clearly defined and recognizable lines of authority and responsibility within the organization, each officer being aware of both the extent and limitations for each job. Records of field jobs must include evidence of checking of records and reports of senior staff during supervisory visits.

All field work must be under effective technical control.

3.7.2 Records System

An adequate records system is essential. It must contain sufficient information on each test to permit a repeat performance.

Identification of each test article, the client's instructions, the test procedure, all test data and the test results must be recorded. All records, including radiographs, must be traceable to the article under test.

When records such as work sheets and viewing sheets are checked, they must be signed or initiated by the checking officer as an indication that this has been done. Signed copies of test documents and all related records must be retained for not less than five years after completion of the work involved.

Radiographs must remain the property of the testing service. If required, radiographs may be taken by the client and there should be record/ signature to that effect and if the client is not taking them, these should be kept for 5 years.

3.7.3 Interim and Final Reports

There are many circumstances in which clients must have an immediate report of results of non-destructive testing examinations. Irrecoverable decisions are frequently made on the basis of these immediate reports. This has led to the practice of issuing, in some circumstances, "interim" and "final" reports.

When a testing service is required to issue interim and final reports, the NABL endorsement must not be applied to the final report unless the corresponding interim reports have also been endorsed.

4. Safety

The laboratory must ensure adequate and appropriate standards of safety in the case of

4.1 Civil Structure

4.2 Electrical

4.3 Radiation

4.4 Fire

5. Classification of Testing Laboratories

A single laboratory may not be equipped for accreditation of all types of radiological equipment/ materials. Testing laboratories may be classified under the following categories:

5.1 Medical

5.2 Industrial

5.3 Medical and Industrial

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