NABL 135

National Accreditation Board for Testing and Calibration Laboratories (NABL)

Specific Criteria for Accreditation of Medical Imaging – Conformity Assessment Bodies

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AMENDMENT SHEET

S. No.	Page No.	Clause No.	Date of Amendment	Amendment	Reasons	Signature QA Team	Signature CEO
1	5	-	01.08.2019	Deletion of the text	Internal review	-Sd-	-Sd-
2	9	4	20.07.2020	Type of legal identity document specified in line with NABL 131	Harmonized requirements in all NABL documents.	-Sd-	-Sd-
3	9	4		Reference to NABL 201 removed	NABL 201 is withdrawn by NABL		
4	9	4		Removal of 4 days training requirements	Policy Decision		
5	10	4		Reference to NABL 133 removed	Internal review		
6	13	5.1		Term 'Authorized signatory' is replaced with 'personnel responsible for report, review and release of results'	Policy Decision		
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PREFACE

I extend my warmest thanks to all members of Technical Committee for their hard work and outstanding contributions in bringing out this issue of Specific Criteria. I sincerely appreciate the enthusiasm invested by members of NABL to ensure the utility of this document.

I further wish to thank immensely all the stakeholders for their valuable inputs which enabled us to go this extra mile.

My heartfelt thanks to the Chairman, NABL for his constant inspiration and able guidance during this entire endeavor.

CEO, NABL

CONTENTS

ABBREVIATIONS

AERB	-	Atomic Energy Regulatory Board
APAC	-	Asia Pacific Accreditation Cooperation
BARC	-	Bhabha Atomic Research Centre
BMW	-	Bio Medical Waste
CT	-	Computed Tomography
DEXA	-	Dual Energy X-Ray Absorptiometry
EQA	-	External Quality Assessment
ILAC	-	International Laboratory Accreditation Cooperation
ISO	-	International Organization for Standardization
kV	-	Kilovolt
LIS	-	Laboratory Information System
mA	-	Milliampere
MCI	-	Medical Council of India
MI-CAB		Medical Imaging-Conformity Assessment Body
MRA	-	Mutual Recognition Arrangement
MRI	-	Magnetic Resonance Imaging
NABL	-	National Accreditation Board for Testing And Calibration Laboratories
NIST	-	National Institute of Standards and Technology
OPG	-	Oral Pentomo Gram
PC-PNDT	-	Pre-Conception and Pre-Natal Diagnostic Techniques
PET	-	Position Emission Tomography
PET-CT	-	Position Emission Tomography – Computed Tomography
PET-MR	-	Position Emission Tomography – Magnetic Resonance
PT	-	Proficiency Testing
QC	-	Quality Control
RF Power	-	Radio Frequency Power
RSO	-	Radiological Safety Officer
SD	-	Standard Deviation
SOP	-	Standard Operating Procedure
SNR	-	Signal to Noise Ratio
SPECT		Single Photon Emission Computed Tomography
TAT	-	Turnaround Time
USG	-	Ultrasonography (Ultrasound)
WHO	-	World Health Organization
CTDI	-	Computed Tomography Dose Index

1. INTRODUCTION

Medical facilities accreditation activities are operated by National Accreditation Board for Testing and Calibration Laboratories (NABL), involving assessment team and accreditation committee as recommending authorities.

The requirements in this document are based on the International Standard, ISO 15189:2012 - "*Medical laboratories – Requirements for quality and competence*". It stipulates the requirements for competence and quality that are particular to medical laboratories as well as useful and appropriate for Medical Imaging facilities. The MI-CAB's compliance to requirements of the standard and its technical competence are assessed by NABL for accreditation.

The specific criteria document must be used in conjunction with ISO 15189:2012. It provides an interpretation of the later document and describes specific requirements. Further, the MI-CAB shall additionally follow national, regional, local laws and regulations as applicable.

2. SCOPE

The scope of accreditation is applicable to the following groups of Medical Imaging discipline:

I. Projectional Radiography & Fluoroscopy
   a. X Rays, Bone Densitometry (DEXA), Dental X Ray-OPG, Mammography etc
   b. Fluoroscopy

II. Computed Tomography (CT)

III. Magnetic Resonance Imaging (MRI)

IV. Ultrasound and Colour Doppler

V. Nuclear medicine
   a. SPECT
   b. PET CT
   c. PET MRI

VI. *Basic Diagnostic Interventional Radiology Procedures (Image guided Core Biopsy and/or Needle Aspiration e.g. Fine Needle Aspiration Cytology)
   ***For only such IR procedures that will be carried out by Radiologists*

Accreditation shall be considered only for those facilities for which the organization itself is equipped and competent to carry out consistently

3. DESCRIPTION OF MI-CAB

The requirements given in this document are applicable to all MI-CAB applying for NABL accreditation regardless of the level at which they function e.g. attached to a clinical Medical Imaging facility / stand-alone / Hospital based facility.

The classification of medical imaging to be based on following categories:

a) Category A: MI-CAB using Ionized radiation
b) Category B: MI-CAB using Sonography
c) Category C: MI-CAB using Magnetic Resonance
d) Category D: MI-CAB using Nuclear Medicine
e) Category E: MI-CAB using Interventional Radiology
f) Category F: MI-CAB having any combination of above categories.

4. MANAGEMENT REQUIREMENTS

Organization and Management Responsibility

An MI-CAB must produce relevant evidence of legal identification which can be any of the following:

Type of Legal Identity	Document(s) to be submitted
Proprietorship	Bank passbook/ Account statement and PAN of the CAB
Limited Liability Partnership	Registration certificate under The Limited Liability Partnership Act, 2008
Company	Registration certificate under The Companies Act, 1956 or 2013
Societies/ Trust	Registration certificate under Societies Registration Act, 1860/ Registration under The Indian Trusts Act, 1882
Government	Gazette or Government Notification or self-Declaration on Letter head by Head of the organization

Organization shall also be required to comply with legislative and statutory requirement/s as mandated by local / regional / national regulatory and/or civic bodies.

Imaging equipment falling under the ambit of **PC-PNDT Act** shall be required to comply with the provisions of the Act, as applicable in respective states/UTs.

Due to statutory and legal requirement, an MI-CAB operating at more than one location within a district having the same legal identity shall be considered as multiple entities for the purpose of accreditation

The accreditation certificate for a Medical Imaging – Conformity Assessment Body (MI-CAB) is non-transferable and shall be valid only for premises for which it is issued.

Qualification norms for MI-CAB Director / Head (howsoever named)

MI-CAB Director/ Head (Howsoever named) shall have the overall responsibility of operations of the MI-CAB. For review, evaluation and release of results, he may delegate selected duties/ responsibilities to qualified personnel.

The MI-CAB Director / delegated personal shall also fulfill the other requirements of ISO 15189:2012.

In case, where more than one person designated as MI-CAB Director, one of them should be available to ensure that she / he is responsible for overall operations and shall be available for consultancy wherever necessary as per statutory/regulatory requirement.

Requirements for Quality Manager

Quality Manager shall be well versed with ISO 15189. She / He should be a full-time employee, and can be delegated with additional responsibilities. Facility shall also ensure the availability of deputy quality manager (when ever required) with requisite qualification and experience as applicable for Quality Manager.

Service Agreements

The users of MI-CAB shall be explicitly informed about the non-accredited status of diagnostic services requested while entering into contract. This may be done by providing separate lists of accredited and non-accredited diagnostic services to users. A copy of accredited scope shall also be made available for reference

Examination by Referral Medical Imaging Facility

Referral Medical imaging Facility is an external facility to which the management chooses to refer a subject for imaging/ examination or when routine imaging procedures/ examinations cannot be carried out. This differs from the diagnostic imaging services that may include public health, forensics or a central (parent) facility to which sending the subject is required by structure or regulation.

NABL allows referral for second opinion for the services of Medical imaging. Referral may also be required for confirmation of imaging findings. The referral Medical Imaging facility has to be NABL accredited, if available or equivalent status.

The imaging procedures in any group may be referred to another accredited MI-CAB at the time of temporary incapacity of services to be provided due to unforeseen circumstances such as breakdown of equipment, disasters, strikes etc.

Note: NABL allows this relaxation only under exceptional situations and it is advised that the privilege provided to the MI-CAB is not misused.

Referral Medical Imaging Facilities and consultants shall be selected as per the criteria laid down by the MI-CAB

MI-CAB shall maintain records pertaining to lists of services and the names & addresses of the referral centers from which services are obtained. The information is kept both in the ‘referral’ file and the ‘subject’ file.

The referring center shall give prior intimation to the users about the Imaging procedures being referred.

The referring center shall produce the original report of the referral center or transcribe the report without alterations of clinical interpretation with additional remarks (if required) and specify the name of the referral center, identify the imaging services performed and the results obtained by any such referral center. Records pertaining to this shall also be made available.
Note: The Medical Imaging facility shall produce MOU (with referral) which may be maintained in a simple form.

Advisory Services

Stand-alone MI-CAB shall communicate with their clients (subject / clinicians) with regard to the choice of imaging procedures under different clinical conditions, whenever required or sought. Communication may be through direct contact, email and / or documentation. Hospital-attached medical imaging facility personnel are encouraged to participate in clinical rounds and meetings. The records of the above shall be maintained.

Control of Records

The MI-CAB shall decide the retention time of records in accordance with national, regional and local regulations. For the imaging equipment covered under PC-PNDT Act, all records (including images) of all the patients and relevant statutory requirements such as form 'F' for pregnant patients are to be maintained for a minimum of 2 years. If any legal case against the MI-CAB is pending then the concerned records shall be maintained till the same case is disposed off.

Note:

1. *The records can be maintained as physical copies (instrument printouts or as photocopies) or electronically.*
2. *Every effort should be made to retain the records. If, however, they are returned to the patient, this must be documented.*

Evaluation and Audits

The MI-CAB shall ensure that pre-imaging examination and post-imaging processes are also covered during its internal audit along with the other processes.

The MI-CAB shall incorporate salient quality indicators for monitoring its performance. This shall describe the evaluation of various aspects of a MI-CAB's function such as but not limited to the following:

- Availability of Referral History
- Patient preparation
- Analysis and reporting of results (Critical imaging finding reporting)
- Turnaround time (outpatient and inpatient)
- Complaints
- Feedback (referral, staff and user)
- Equipment downtime
- Performance in PT / EQA scheme/ external validation/Peer-review audit rates

Risk Management

Risk Management is a proactive concept that involves practices such as identification of risk, quantification and evaluation of risk and consideration of measures that can be used to eliminate or control risk in a medical imaging facility.
This includes management of the MI-CAB obligated to provide adequate facilities, staff, resources, financial support and equipment, thus helping professionals and nursing practitioners reduce the odds of harm's occurring.

Therefore, MI-CAB shall ensure that:

- Documented procedures for identification, assessment, management and minimizing the potential risks arising due to handling of patient (having varied physical, mental and medical condition) and imaging procedures are being followed.
- Have facility for treatment of patient in case of adverse contrast reaction including antidote, emergency drugs, suction apparatus, anaesthetic equipment for resuscitation, oxygen supply etc in designated areas. Risk due to handling of radioactive material/Biomedical waste and the patient administered with radiopharmaceutical should be identified, assessed, managed and minimized.

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5. TECHNICAL REQUIREMENTS

5.1. Personnel

The personnel employed in MI-CAB shall be sufficiently qualified, experienced and trained in imaging procedures as specified by regulatory body/s time to time. The roles and responsibilities of personnel shall be adequately defined to cater the need of each designated area/division of MI-CAB.

In all cases, it is the responsibility of MI-CAB to abide by the National/Regional/State/Local regulatory requirements/Acts/ Rules/Legal orders/Court Decisions/Orders issued by Government/Statutory Bodies as applicable and effective from time to time.

The qualifications of Medical imaging facility's Director / Head or the person designated to be responsible for Medical Imaging procedure in such facilities of MI-CABs shall meet the requirements as specified by the regulatory bodies(such as MCI). She / He shall have the overall responsibility of Technical / Advisory / Scientific operations of the MI-CAB.

However, for the purpose of release of report and other technical operation, responsibilities may be delegated to qualified personnel.

Personnel responsible for report, review and release of results

All personnel responsible for report, review and release of results (signing of test reports) shall fulfill at all times the minimum eligibility criteria specified in the prevalent statutory and regulatory provisions for different modalities/ groups in scope of accreditation.

Medical Physicist / Radiological Safety Officer (RSO)

MI-CABs involving radiological operations and radiation sources shall appoint suitably qualified and experienced person as Radiological Safety Officer as per prevalent norms of AERB and other relevant statutory requirements

 # Imaging Procedure specific statutory requirements regarding experience are required to be followed wherever applicable.

The RSO shall have roles & responsibilities as per the Atomic Energy Radiation Protection Rules, 2004. He may be designated to supervise day-to-day work with ionizing radiation to ensure use of good radiation practice by following- Selection, maintenance and installation planning of equipment, Calibration and quality assurance, training to staff and radiation safety, management program including radiation waste disposal as per prevalent norms of regulating authority.

PC-PNDT Registered MI-CAB

All radiologists/ sonologists / doctors using USG machines need to have their names entered in the PC-PNDT certificate or on a separate sheet that must be displayed along with the PC-PNDT registration certificate. These doctors should be qualified to perform ultrasound according to their degree/ diploma certificate recognized by Medical council of India or any other authoritative Body formed by Govt of India for the purpose mentioned aforesaid.

Note 2: NABL is a voluntary accreditation body and has no statutory powers. Checking of compliance to the regulatory requirements falls under the purview of respective/applicable regulator.

5.2. Accommodation and Environmental Conditions

The MI-CAB shall have adequate space for efficient functioning, a pleasant ambience and conditions to avoid cross contamination.

The MI-CAB shall have effective separation for incompatible activities.

Note: MI-CAB shall ensure adequate space for patient reception, changing rooms, patient preparation, workbenches, equipment and storage of volatile & inflammable reagents and bio-hazardous materials. Radiation safety aspects shall be taken care of as per requirements of the regulatory agency (AERB).

MI-CAB shall implement the layout plan, shielding requirements, class requirement, storage, waste management and environmental conditions as per type approval and applicable safety codes/guidelines of AERB.

The MI-CAB shall have adequate lighting, power plugs and uninterrupted power supply. Use of exposed cables should be kept to a minimum. The MI-CAB shall ensure that adequate uninterrupted power supply is available so that there is no compromise/loss of stored data. All computers, peripherals, equipment and communication devices shall be supported in such a way that service is not likely to be interrupted. In the event of a power failure or any emergency breakdown, the MI-CAB shall have procedures in place to ensure the integrity of contrast media/ intermediate drug / reagents / consumables/ radiopharmaceuticals or whatsoever used in the procedure of MI-CAB.

Gas cylinders and other auxiliaries if any, shall be kept secured to prevent unintended movement.

MI-CAB shall ensure clean, hygienic, dedicated and clearly marked areas for reception, patient waiting and patient preparation, pre-examination and patient Toilet facility. MI-CAB shall ensure that only authorized personnel get access to the dedicated areas. CAB shall also ensure the availability of appropriate patient clothing at the time of Imaging, if required.

X-ray/Fluoroscopy

- MI-CAB shall ensure clearly demarcated areas for processing, developing of the radiography film apart from the x-Ray machine room, scanning room, changing area, control room and reporting area.
- MI-CAB shall ensure vibration free and flat surfaces/statures and other arrangement to obtain the radiography images with non-repeated radiation exposure to patient.

CT & MRI

MI-CAB shall ensure: -

1. Scanning unit
   - Control, reporting and equipment rooms
   - Patient changing area
2. Sub waiting areas - Access to patient amenities and patient preparation and monitoring, if required
3. Support areas including bays for linen, hand washing and utility.,

Magnetic Resonance Imaging (MRI)

1. Procedure must take into consideration potential interactions of the magnetic field with ferro-magnetic objects in the environment of the scanner. Consideration must also be given for potential hazards posed by objects implanted within the patient as well as within personnel in the area.
2. Policies must include**:**
   a. Exclusion of the general population outside the 5 Gauss line with appropriate warning signs, and
   b. Procedures to screen patients and all other personnel entering the MRI examination room for intracranial aneurysm clips, cardiac pacemakers, intra-ocular foreign bodies and other contraindicated devices.
3. MRI safety education & training must be provided for all staff accessing the MRI area.
4. An MR facility may be expected to adequately provide for at least the following specialist facilities relevant to the accommodation of the MR Imaging equipment:
   a. Definition of 5 gauss line,
   b. Controlled access to the imaging room and appropriate signage,
   c. Temperature and humidity control for computing equipment,
   d. Detection of Helium boil-off, Oxygen depletion
   e. Communication with the patient during examination
5. All equipment including patient transfer trolley in the MRI imaging facility shall be MRI compatible.
6. Quenching protocols in case of emergency

Ultrasound and Color Doppler

- MI-CAB shall ensure that the all the provisions of PC- PNDT act are complied..

PET/ SPECT

MI-CAB shall ensure: -

1. Scanning room
   - Control, reporting and computer module equipment rooms
   - Patient changing area
2. anaesthesia arrangements wherever necessary (e.g. pediatric). Patient Injection Facility and waiting area before imaging (e.g. after injection of radiotracer)
3. Radio tracer handling and preparation room, fume hood and Laminar flow wherever required.
4. Radiopharmaceutical activity measurement area
5. Sub waiting areas - Access to patient amenities and patient preparation and monitoring, if required
6. Support area including bays for linen, hand washing and utility.,
7. Toilet facility exclusively for Radio-active patient
8. Radio-active waste storage room with radioactive waste management plan.

5.3. MI-CAB Equipment, Reagents and Consumables

MI-CAB shall:

- Ensure procurement and installation of medical equipment only from the manufacturers/suppliers registered with regulating agencies for that purpose.
- Have valid service contract for all imaging equipment at all time.
- Manage and monitor appropriate operation and working of the equipment to deliver the service.
- Manage and monitor appropriate maintenance and repair of the equipment to deliver the service.
- Manage and monitor appropriate replacement of existing equipment & planning for new equipment for continuation and expansion of service. – May requirement.

Verification of all imaging equipment is required for quality assurance from competent authority of the MI-CAB. Verification of all ancillary automated or semi-automated system is required. This may be conducted through manufacturer prescribed method or any other standard protocols.

The MI-CAB shall check each lot of consumables used in imaging procedures as per the established guidelines followed internationally (First satisfactorily exposed film/test print).

Storage, Handling & Labeling

All contrast, radiopharmaceuticals and other consumables, shall be labeled and stored as recommended by the manufacturer/regulatory bodies. The label shall contain information like: name and characteristics of content, quantity, activity, concentration, date received / prepared, date of opening, storage requirements and expiry dates wherever applicable.

Similarly, radiopharmaceuticals and oral contrast prepared in-house shall have the name & signature of individual who prepared the reagent, storage requirements, date of preparation & expiry.

Calibration:

Policy on calibration and traceability of measurements shall be as per NABL 142: *NABL Policy on Traceability of Measurement Results*. The equipment shall be calibrated, as applicable, from NABL accredited calibration laboratories or accredited agencies recognized by Govt. of India. For further details regarding calibration and applicable standards, may refer NABL 126: *Specific Criteria for Calibration of Medical Devices.*

A manufacturer's calibration certificate is not valid unless it contains an accepted procedure and traceability (as per NABL 142).

It must be stressed that the calibration intervals depend upon ruggedness of the equipment, frequency of use, quality & periodicity of maintenance and life of the equipment. Wherever required, MI-CAB shall produce a compliance/performance testing report for the equipment from the recognized/accredited quality assurance agencies.

All equipment must be calibrated following preventive maintenance, breakdown and repairs or more frequently as recommended by the manufacturers.

At the time of installation of new equipment, the Installation report, acceptance testing report/ QA report /Performance testing report should be documented.

Refer Annexure 1 for the parameters to be checked during performing testing of MI equipment (Number of parameters may vary depending on equipment technology)

CT/ MRI

Advance MRI machines are integrated with auto calibration that helps to avoid collecting external sensitivity map and need for separate calibration scans.

Further, MI-CAB may use the "phantom" for calibrating MRI machines that is traceable to international system of units (SI). Traceable MRI calibrations are expected to enable accurate, quantitative measurements of tumors and other disease markers that can be reproduced across many different patients, scanners and clinics over time—and potentially reduce medical costs.

For Computed Tomography, Test phantoms of a standardized human shape or test objects of a particular shape, size and structure, having traceability to SI units, shall be used for the purposes of calibration and evaluation of the performances of CT scanners. It should include parameters but not limited to CT number; uniformity; linearity; noise; spatial resolution; low contrast resolution; slice thickness; positioning of couch etc. For Imaging & dosimetry, CTDI or suitable phantom shall be used

The frequency of the calibration should not exceed one year.

Ultrasound/Color Doppler

MI-CAB ensure that the methods for calibrating ultrasound equipment and techniques for evaluating the consistency of operation of A-, B- and M-mode pulse-echo ultrasound apparatus should be used by the appropriate personal. Equipment parameters to be included in these procedures include system sensitivity and noise level, time gain compensation, A-mode display linearity, B- and M-mode grey scale, longitudinal and lateral resolution, depth calibration, B-mode position alignment, initial and strong-interface dead zones and power output.

5.4. Pre-examination Processes

Relevant clinical history is necessary for most specialized tests. Request forms should be designed so that the requesting physician provides this information. MI-CAB shall ensure that all relevant clinical & imaging records (previous as well as current), should be available with the patient so that examination protocol scan be tailored and correct contextual interpretation provided.

MI-CAB shall identify the situation where documented informed consent is required.

MI-CAB will ensure that the pre-examination instruction shall be provided to patient specific to the imaging procedure as applicable.

MI-CAB shall inform patient about the possible radiation hazard and management, resulting due to use of radiopharmaceutical.

Example:
"The MR scanning sequence begins by screening the patient for metallic foreign bodies and devices such as pacemakers, dentures that may represent a contraindication to imaging. The patient's important health conditions, including allergies, should also be reviewed. Patient shall be checked physically and electronically before entering zone III of MRI suite. Informed consent is obtained for the procedure including the administration of medium e.g. Gadolinium, if ordered. The technologist shall explain about the scanning procedure requirements. Thus, prepared for the study, the patient is led into the scanner room for the scan itself.

Before CT scan, patient should be checked for any allergy to contrast media. If allergic, choose appropriate alternative procedure."

5.5. Examination Processes

MI-CAB shall ensure to use imaging procedures through established and standard protocols, monograms etc. In case of modification in the protocol MI-CAB shall obtain consent from the patient.

MI-CAB shall have documented SOPs describing the performance of all procedures. These SOPs shall include the following necessary information but not limited to:

a. Patient management

b. Imaging procedures appropriate to specific clinical condition
c. Deviations from standard imaging protocols
d. Operation of equipment
e. Quality control procedures
f. Necessary remedial action e.g. adverse event management
g. Records to be kept, and
h. Safety issues

MI-CAB should have mechanism to identify the sources and calculate Measurement uncertainty in reported values.

5.6. Ensuring Quality of Examination Results

The MI-CAB shall design the internal quality control procedure as per the established practices and appropriate to its size & scope.

External Quality Assessment (EQA) / Proficiency Testing (PT):

Facilities are encouraged to participate in as broad a range of PT activities as practicable, but at least once in a year for each group, measurement or related activity covered by the scope of accreditation, where such programs are available.

MI-CAB may refer NABL 163: *Policy for participation in Proficiency testing activities, document.*

The MI-CAB shall:

1. participate in EQA / PT/ Alternate approach (as mentioned below) in at least one group prior to gaining accreditation
2. have a 4-year plan to cover entire accredited/ proposed scope
3. participate in an EQA program in case of change in equipment and extension of scope

The MI-CAB shall document corrective actions taken based on the EQA/PT/alternate approach-evaluation report.

Participating in EQA / PT must be integrated within the routine workload and analyzed in rotation by personnel who routinely perform the imaging procedure. In case of radiological film received as EQA samples, they are to be reported by appropriate levels of staff involved in the department without sharing of data. They should then collectively discuss the results before they are dispatched.

Where formal PT programs are not available for any activities or do not provide sufficient coverage, facilities must investigate other means of assuring the quality and performance of the activities for which they seek or hold accreditation.

Note: *Repeat study shall be done only with informed consent*

Alternative approaches

For those tests where a formal EQA is not available, the MI-CAB shall adopt alternative approaches to validate performance. Such alternative approaches are:

- Examination of radiological film/subject by different qualified personal (within the MI-CAB)
- Use of reference methods & materials, where available
- Exchange of films to study with other accredited facilities preferably.

When the MI-CAB exchanges films with other facilities as an alternative approach to EQA participation, following needs to be addressed:

a. In case of comparison between 2 facilities, one will function as the “reference MI-CAB” against which the other will be compared. This is to be documented as a MoU.
b. When there are several facilities, compare the result against the “reference MI-CAB”- The results obtained shall be compared qualitatively and/or statistically up to the extent possible.

Internal and/or external peer review shall be done by the in-house radiologists and radiologists of other centers who have a memorandum of understanding. Five Percent of the total monthly workload for each modality in the scope of services including radiography, mammography, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasonography (USG) and Doppler may be taken up for blind peer review. The review may be further categorized as concordant and discordant according to the diagnostic accuracy, quality of images and appropriateness of the technique (sample size and spectrum, that is to be covered within a year, shall represent all types of procedures carried out for each group in the scope of accreditation. Exception is allowed in the case of those procedures where peer review/sharing of images is prohibited under the existing statutory laws and acts.
The results of discordant imaging finding, if observed, may further classified as clinically significant and non-significant. For clinically significant discordant imaging finding, MI-CAB shall carry out and document the adequate root cause analysis.

5.7. Post-Examination Processes

Disposal of Bio Medical Waste (BMW):

The MI-CAB shall follow national, state and local guidelines for Bio-Medical Wastes (Management and Handling) Rules**,** 1998 or latest applicable made under the Act and as amended from time to time.

The MI-CAB shall have a documented contract with a licensed BMW Management Contractor or common waste management facility as per the local, regional or national guidelines. The MI-CAB shall follow the protocols laid by the contractor regarding segregation of waste. This shall

also be displayed in colored posters at different sites of BMW generation for ready reference of the staff.

MI-CAB shall ensure the management and handling of radio-active wastes as per Atomic Energy Waste Disposal Rule: 1987 made under the provisions of the Atomic Energy Act, 1962(33 of 1962) and the rules made there under and as amended from time to time by AERB.

Despite the move towards digital, many facilities still use analog x-ray machines. Hazardous chemicals used in Analog machines/any imaging procedure must be dealt with and handled in a manner that is not only compliant, but protects users and the environment.

For radiology X-ray departments, medical waste management plans must also include managing analog x-ray waste.

X-ray Fixer

X-ray fixer, or x-ray fixer solution neutralizes any developer remaining on the film, removes undeveloped silver halides, and hardens the emulsion. It may contain high concentrations of silver, typically 3,000 to 8,000 mg/l of silver. Because of this silver content, used x-ray fixer must be managed as a hazardous waste. Used fixer shall not be poured down the drain or disposed of as regular solid waste.

X-ray Developer

X-ray developer contains hydroquinone, which is a highly toxic substance. It is a skin irritant, and when exposed improperly, persons can develop symptoms such as dizziness, headache, nausea, vomiting, lack of oxygen in the blood, and any dust that gets in the eyes can lead to impaired vision, among other injuries. Only UNUSED developer is toxic; once it has been used, it is safe to dispose of in the sink or toilet.

X-ray Film

Used x-ray film also contains silver, just like x-ray fixer. If the concentration is high enough, it is considered hazardous waste and must be treated as such. It is best disposed of through silver recycling.

Lead Aprons and Gowns

The contaminated and/or toxic protective equipment, shall not belong to the regular trash and shall be managed separately for the propose of waste management.

Radio-pharmaceutical Waste:

There should be proper arrangements for isolation, collection and treatment of radioactive waste (excreta of radioactivity injected patients, contaminated wears and materials , if any) Radioactive materials no longer required must be labeled and disposed off as per Atomic Energy Waste Disposal Rule, 1987 to avoid an environmental hazard.

The MI-CAB shall ensure the compliance of Atomic Energy (Safe disposal of Radioactive waste) Rules, GSR-125, 1987. The Director/Head of MI-CAB shall obtain an authorization from the

Competent Authority for disposal of radioactive waste and dispose of the same under the supervision of RSO of the facility by suitable means and modes.

5.8. Reporting of Results

In addition to the compliance of clause 5.8.3 of ISO 15189:2012, the report shall also include the following

- Detail of radiopharmaceuticals administered, including type and dose of isotope, the time and means of administration, and the identity of the person or persons responsible for the administration.
- Where necessary, an explanation of any modifications to the procedure as identified in the practice's procedure manual.
- Adverse reaction to the radiopharmaceuticals administered.
  Correlation with previous imaging details/other relevant clinical details if available

Identification by name and signatures of the person authorizing release shall be included in the test report in accordance with Cl.5.8.3 of ISO 15189:2012.

Biological reference range shall be mentioned in the report wherever applicable

5.9. Release of Results

The MI-CAB shall establish and display critical limits for imaging procedure which require immediate attention for patient management. Test results within the critical limits shall be communicated to the concerned clinician after proper documentation.

MI-CAB shall maintain record of three types of report for routine, urgent and critical finding. For critical findings the MI-CAB shall maintain records for communication to concerned person.

<u>Interim report</u>
Practically all hospital MI-CAB and many stand-alone MI-CABs operate round the clock (24X7). After routine working hours, the MI-CAB may not have authorized personnel on duty. Hence, The MI-CAB shall have the following arrangements in place. If feasible, authorized personnel should be posted to supervise and authorize release of urgent test images that are required for immediate management of the patient. If there is no authorized personnel on duty, the report will be "Interim" (only images) and can be shared with referring clinician on specific request. The final report shall be released as per defined policy for release of report.

<u>Revised report</u>
If a report is revised, a hard or soft copy of the original and revised reports, together with the reason for revision, shall be recorded and maintained.

MI-CAB shall ensure confidentiality of report including teleradiology facility.

5.10. MI-CAB Information Management

Results generated shall be communicated to the customers / users through a computerized or paper-based information system which manages workflow, quality and audit trail for the images processed in the MI-CAB. The MI-CAB shall have a documented procedure to ensure that the confidentiality of patient information is maintained at all times including tele radiology reporting.

Information system management

a. When there is a comprehensive computerized information system, all function from accession to reporting shall be verified after installation.
b. The general process should involve:
    i. Input patient data and save demographics and clinical information.
    ii. retrieve the same data
    iii. capture screen print
    iv. compare with data on paper form or in a paperless system
    v. sign and file with date
c. There shall be a half-yearly review during which the above process is repeated for a minimum of 10 different types of images / tests.
d. Interfaces: Interfaces between hardware (analyser) and information system or between software systems shall be verified to ensure that the interface transmits data in the intended manner and that there is no misfiling of results in the database or in-appropriate formatting of the report.
e. Rule based systems for automated selection and reporting of results, shall be verified.
f. If there is major change in any of the components of the information system, the effect on the entire workflow for a selected sample shall be demonstrated to have no deleterious effect.
g. Security and confidentiality: There shall be rule based authenticated access into the information system and there shall be procedures to inactivate users who are no longer authorized to access these systems. There shall be a facility to demonstrate an audit trail to link the activity undertaken by a user with relation to patient data or software change.
h. Redundancy (Back-up), manual procedures for down times and disaster recovery systems along with SOPs should be in place and certified by appropriate (local) information technology authority.

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Annexure 1

Table 1: Recommended calibration and performance checks of equipment commonly used in MI-CAB in compliance to AERB requirements wherever applicable

S. No	Type of test	Frequency of Check	Parameters to be Checked
General Radiography: Plain film			
1	Reject Film Analysis	Monthly	No. of reject films/ images &reasons for reject
2	Light beam diaphragm test	Monthly	Alignment of light beam
3	kVp accuracy / consistency test	Yearly	kVp output by X-ray generator
4	mAs accuracy / consistency test	Yearly	mAs output by X-ray generator
5	View box check	Weekly	Check for marks
		Yearly	Clean diffuser panel and view box
6	System - sensitometry	Daily	Run calibration strip and set the Calibration values
7	Imaging quality	Monthly	Review for artifacts
Mammography			
1	Optical Density Test	Daily	Optical Density
2	Processor Sensitometry test	Daily	Speed Index (SI)
			Control Index (CI)
			Value of Base + Fog (BF)
3	ACR Phantom Image test	Weekly	Film background OD
			Contrast
			Test object Score
			Density Difference
4	Reject Analysis	Monthly	Percentage of rejects over total film use
5	AEC Calibration Test	Quarterly	Optical Density
6	Screen Film Contact	Six-Monthly	Poor contact will seen as darker area
7	Darkroom Fog Test	Six-Monthly	Optical Density Difference
8	Compression Force Test	Six-Monthly	Compression force
9	Densitometer Calibration Check	Six-Monthly	Optical Density
10	Screen Uniformity Test	Yearly	Standard Deviation of Optical Density
			Difference in Max. and Min Optical Density
11	View-box check	Weekly	Check for marks
		Yearly	Luminance
Ultrasound			
1	Ultrasound machine and all transducer	1. On commission and change of	Physical and mechanical inspection
			Image uniformity and artifact survey

S. No	Type of test	Frequency of Check	Parameters to be Checked
		transducer Physical and mechanical inspection 2. At routine servicing at least twice in a year	Contrast resolution(also referred to as anechoic object imaging)
			Ring down or dead zone
2.	Ultrasound machine and all transducer	On commission and change of transducer	Geometric accuracy (also referred to as distance accuracy)
			System sensitivity (also referred to as depth of penetration / visualization)
			Spatial resolution a) Axial b) Lateral
3.	Ultrasound machine display	1. On commission and change of transducer 2. At routine servicing at least twice yearly	Fidelity of US machine display monitor
4	Ultrasound machine display	On commission and change of transducer	Fidelity of hardcopy or display device used for primary interpretation (e.g. PACS).
Nuclear Medicine			
1	Gamma Camera	Daily	Photo peak & Energy window setting
		Daily	Uniformity (Extrinsic or Intrinsic)
		Weekly	Centre of Rotation (COR) (Only for SPECT gamma cameras)
		Quarterly	Spatial Resolution
		quarterly or when necessary	Energy & Uniformity correction tables
		At acceptance testing	Sensitivity
		At acceptance testing	Count rate characteristics
2	Dose calibrator	Daily	Constancy with long half-life radionuclides
		Semi-annually	Linearity response to 99mTechnetium(^{99m}Tc)
3	PET/CT	Daily	CT quality
		Daily	PET
		Daily	PET & CT bed/couch alignment test
Densitometry			
1	DEXA	Daily	Repeatability of the phantom's BMD results
Magnetic Resonance Imaging (MRI)			
1	MRI scanner	Weekly	General Condition of the system
		Quarterly	Centre Frequency and Transmitter Gain
		Quarterly	Geometric Distortion
		Annually	High Contrast Resolution

S. No	Type of test	Frequency of Check	Parameters to be Checked
		Annually	Low Contrast Resolution
		Weekly	Film Quality Control
		Annually	Magnetic Field Homogeneity
		Annually	Slice Position Accuracy
		Annually	Slice Thickness Accuracy
		Annually	Radiofrequency Coil Checks
		Annually	Inter-Slice Radiofrequency Interference
		Annually	Soft-Copy Displays (Monitors)
		Six Monthly	MRI contrast injectors
Computed Tomography (CT)			
1	CT Scanner	Daily	Visual Inspection: • All panel switches, lights & technique indicators • Radiation exposure warning light at control and entrance doors • X-ray activation indicator on equipment • Aural communication • CCTV camera & monitor (Patient pre-procedure area) • Protocols/technique chart
		Daily	Warm up and Air-calibration
		Daily	• CT Number for water • Homogeneity test & standard deviation • Noise • Image uniformity • Artifact evaluation
		Half yearly during Preventive maintenance service	Table position accuracy
			Co-incidence of internal scan plane lights and scan plane
			Distance Measurement accuracy
		Yearly	Image scan width
			Low contrast resolution
			High contrast resolution
			X-ray generator: Tube potential (kVp)
			X-ray generator: Exposure time accuracy
			CT contrast injector

Table 2: Requirement for digital imaging devices

S/N	Type of test	Parameters to be Checked
1	AEC devices	i. To perform calibration before use ii. Annual check on the calibration status
2	Imaging plates	Regular maintenance shall be performed and each imaging plate has an unique identification number.
3	Compression	i. Labelled if irreversible compression has been applied and the compression ratio. ii. Ensure no loss of clinically significant information. iii. Consistent presentation of images on workstation is essential.
4	PACs	i. Sufficient bandwidth to deliver expected volumes of images in a timely fashion. ii. Adequate error checking capability. iii. Fast and easy navigation between new and old studies. iv. Window level and adjustment tools. v. Hanging protocols that address the selection of image series and display format shall be flexible and tailored to user preferences with proper labelling and orientation. vi. Calculate and display accurate linear measurements and pixel value determination as appropriate for the modality – e.g. HU for CT studies.
5	Display	At the start of use and annual performance check: i. Evaluated for significant pixel defects. ii. Pixel pitch about 0.200 mm and no larger than 0.210 mm. iii. Reference to ISO 9241 on the guidelines on maximum number of pixel defects. iv. Documentation of allowed pixel defects should be provided by manufacturer.
6	Display resolution	i. Resolution shall be at least 2.5 lp/mm ii. Diagonal display distance is about 80% of the viewing distance. iii. At 2/3 m this corresponds to a diagonal size of 53 cm. iv. An aspect ratio, width to height of 3:4 or 4:5 is recommended. v. all display monitors used for primary interpretation shall be tested monthly.
7	Luminance	At ambient: i. Luminance shall be less than 1/4thof the luminance of the darkest gray level. ii. Contrast response of diagnostic monitors should be within 10% of the GSDF– gray scale display function over the full LR
		At minimum luminance: i. Luminance shall be at least 1.0 cd/m2 for diagnostic interpretation
		A maximum luminance: i. Ratio of L max to L min shall be greater than 250. ii. L max of diagnostic monitors shall be at least 350 cd/m^2 with L min of 1.0 cd/m^2.
8	White point	CIE daylight standard D65 white point shall correspond to colour temperature of about 6500 degrees F.

Annexure 2

PATIENT MANAGEMENT

1. All patients should have access to appropriate information to make an informed decision including:
   a. Pre-procedure preparation and/or instructions, and
   b. Post-procedure and/or discharge instructions.
2. Patient waiting areas should be located and, if necessary shielded, so that exposure from radiation sources is as low as reasonably achievable.

Sedation and Anesthesia

- The MI-CAB shall ensure that sedated patients are discharged in the care of a responsible adult after appropriate recovery, with appropriate instructions concerning driving, operation of equipment, Medication etc.
- The MI-CAB should also have guidelines at designated place for identification of patients not suitable for intravenous sedation in the absence of an anaesthetist.

Patient Identification

- MI-CAB shall have adequate procedures to ensure that every report and image are correctly identified to the patient.
- Patient identification and details shall be verified and handed over to the patient/authorised person.
- Discrepancies in the request/ referral forms must be identified and a record should be maintained of the outcome.
- Records relating to any given patient shall be uniquely identified through all stages of the procedure. Such records shall include worksheets, checklists, films, etc. Identification may be achieved by use of a unique session number, patient's full name, identification number, date of birth, bar codes or any other laboratory adopted method.

Patient Needs Assessment

- The written or electronic request, originated from clinician shall provide adequate information to show the necessity of the examination and enable appropriate interpretation of result.
- Information relevant to the studies may include allergies, pregnancy status and previous studies. Additional specific information shall be obtained and recorded prior to patients undergoing imaging procedures.

Patient Infection Control

a. Use of multi dose contrast media or radiopharmaceuticals shall be permissible under strict aseptic conditions complying with the prevalent laws
b. Use of new needles and syringes for re-entering vials even for the same patient's use shall be ensured.
c. Discarding of any contrast media or radiopharmaceuticals beyond their expiration time shall be ensured.

Patient Safety

- Female patients of childbearing age shall be queried if they are pregnant.
- If they are or are suspected to be pregnant, the specialist shall decide whether to proceed with the procedure. If the specialist decides to proceed, the patient shall be advised of the risk involved and documented evidence shall be available.

Diagnostic Mammography

The average glandular dose as determined by the doctor must not exceed 2mGys (200 mrads) per view, using the RMI-156 phantom or another equivalent constitution specific doses.

Fluoroscopy

a. A log of screening times for all fluoroscopic examinations shall be kept.
b. An appropriately equipped emergency cart shall be immediately available to treat serious adverse reactions and for resuscitation in case of respiratory or cardiac arrest within the MRI suite.

Nuclear Medicine

a. Appropriate procedures regarding pregnant and breast-feeding patients shall be observed, including warning signs, verbal enquiry and the issue of special instructions to the patient when required.

Regarding Occupational Safety, it is recommended that MI-CAB may refer OHSAS 18001:2007 (Occupational Health & Safety Management / SS 506 part 1:2004 (Occupational safety and health (OSH) management system).

Patient Preparation for Interventional Radiology

- Adequate provision must be made for patient preparation and observation post-procedure. This may be within the radiology department, a short stay unit or in the hospital ward.
- Personnel, equipment and facilities shall be available for emergency resuscitation.

References

1. ISO 15189: 2012 Medical laboratories–Requirements for quality and competence

2. Bio-medical Waste (management & handling) Rules

3. OHSAS 18001:2007 (Occupational Health & Safety Management / SS 506 part 1:2004 (Occupational safety and health (OSH) management system).

4. The Pre-Conception and Pre-Natal Diagnostic Techniques (Prohibition of Sex Selection) Act 1994 (PC-PNDT)

5. Atomic Energy Act,1962

6. Atomic Energy Radiation Protection Rules, 2004.

7. Atomic Energy (Safe Disposal of Radioactive Wastes) Rules, 1987

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