Accreditation Standards for Medical Imaging Services

2nd EDITION

December 2019

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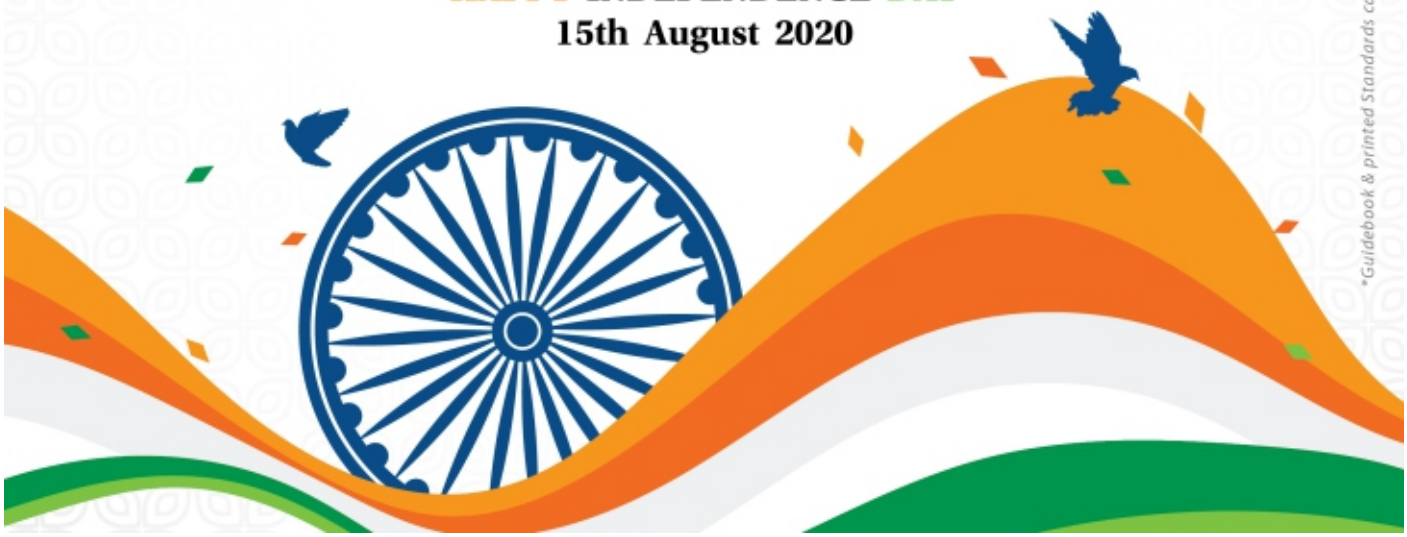

*Guidebook & printed Standards can still be bought at nominal fee

National Accreditation Board for Hospitals and Healthcare Providers (NABH)

Accreditation Standards for Medical Imaging Services

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FOREWORD

National Accreditation Board for Hospitals and Healthcare Providers (NABH), is in its 15th year of creating an ecosystem of quality in healthcare in India. NABH standards focus on patient safety and quality of the delivery of services by the hospitals and healthcare providers in the changing healthcare environment. Without being prescriptive, the objective elements remain informative and guide the organisation in conducting its operations with a focus on patient safety.

Over the years, successive NABH standards have brought about not only paradigm shifts in the healthcare organisation's approach towards delivering the healthcare services to the patient but have equally sensitised the health care workers and patients about their rights and responsibilities.

It is my privilege and pride to release and dedicate this 2nd edition of NABH Accreditation Standards for Medical Imaging Services (MIS) to all healthcare workers. This edition is unique in its approach and has been based entirely on the suggestions made by various stakeholders. For the first time, the objective elements have been categorised into Core, Commitment, Achievement and Excellence.

This edition of NABH Standards for MIS has adapted the format and methodology used in NABH Accreditation Standards for Hospitals which is a globally recognised and approved format. The standards have seven chapters which consists a total of 214 objective elements out of which 34 are in Core category which will be mandatorily assessed during all assessments, 157 are in commitment category which will be assessed during the final assessment, 17 are in achievement category to be assessed during surveillance and 06 are in excellence category which will be assessed during re-accreditation.

This objective methodology will aid the healthcare organisations for a stepwise progression to mature quality system at the end of accreditation cycle. The scoring methodology has been modified to a graded scheme to help smooth implementation of the standards. Bibliography for reference has been added at the end of all chapters which will provide organisations with a resource for taking quality beyond the requirements of the objective elements.

The standards along with the document on Key Performance Indicators have been made available free of charge as a downloadable document on NABH website. I sincerely hope that all healthcare organisations will benefit from the collective efforts of technical committee of NABH and practical suggestions of thousands of quality champions from India and abroad.

NABH remains committed to its mission of taking quality safety and wellness to the last man in the line.

Jai Hind

Dr. Atul Mohan Kochhar
CEO, NABH

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About NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of the Quality Council of India (QCI), set up to establish and operate accreditation programs for healthcare organisations. NABH has been established with the objective of enhancing the health system & promoting continuous quality improvement and patient safety. The board, while being supported by all stakeholders, including industry, consumers, government, has full functional autonomy in its operation.

NABH provides accreditation to hospitals in a non-discriminatory manner regardless of their ownership, size, and degree of independence.

International Society for Quality in Healthcare (ISQua) has accredited NABH.

Vision: To be apex national healthcare accreditation and quality improvement body, functioning at par with global benchmarks.

Mission: To operate accreditation and allied programs in collaboration with stakeholders focusing on patient safety and quality of healthcare based upon national/international standards, through process of self and external evaluation.

NABH ACTIVITIES

NABH Accreditation Programmes: NABH offers accreditation to Hospital, Blood Bank, Eye Care, Small Healthcare Organisations/Nursing Homes, Oral Substitution Therapy Centres, Community Health Centres/Primary Health Centres, AYUSH (Ayurveda, Homeopathy, Unani, Siddha and Yoga & Naturopathy) hospitals, Wellness Centres, Medical Imaging Services, Dental Centres, Allopathic Clinics, Ethics Committees and Panchkarma Clinics.

NABH Certification Programmes: NABH offers certification to Medical Laboratory, Nursing Excellence, Emergency Department, Medical Value Travel Facilitator (MVTF), Entry Level for Hospitals, Entry Level for Small Healthcare Organisation, Entry Level AYUSH Hospitals and Entry Level AYUSH Centres.

NABH International: NABH has started its operations overseas under NABH International (NABH I). It offers all accreditation programs as being offered in India. The program is unique as in addition to the accreditation standards it requires compliance with local regulatory requirements.

Training & Education: NABH conducts Education/Interactive Workshops, Awareness Programmes, and Programme on Implementation (POI).

Scope and Purpose of the Standards

SCOPE OF THE STANDARDS

These standards are applicable to any Medical Imaging Service (MIS) centre provided, the MIS fulfils the following requirements:

- The MIS is currently in operation as a healthcare provider.
- The organisation commits to comply with NABH standards and applicable legal/statutory/regulatory requirements.

These standards are to be used by the whole organisation and not for a specific service within the organisation. Organisations may have different services and it is equally applicable to all services and both public and private hospitals.

PURPOSE OF THE STANDARDS

The aim of the standards is to achieve an acceptable level of performance with a view to:

- Improve public trust and community confidence that the organisation is concerned for patient safety and the quality of care;
- Ensure that they listen to patients and their families, respect their rights, and involve them in the care process as partners;
- Ensure that they provide a safe and efficient work environment that contributes to staff satisfaction and improves overall professional development;
- Provide an objective system of empanelment by insurance companies and other third parties;

In addition, these standards can also be used to:

- Guide the efficient and effective management of an MIS;
- Guide the organisation in the delivery of patient care services and in their efforts to improve the quality and efficiency of those services;
- Review the important functions of an MIS;
- Provide an opportunity to explore compliance expectations of standards and the additional requirements related to safety and regulation.

How to read the standard?

The standard focuses on the key points required for providing patient-centred, safe, high-quality care. The interests of various stakeholders have been incorporated into the standard. They provide a framework for quality assurance and quality improvement. The focus is on patient safety and quality of patient care. It sets forth the basic standards that organisations must achieve to improve the quality of care.

The requirements have been divided into seven chapters.

1. AAC - Access, Assessment and Care of Patient
2. IPI - Imaging Procedures and Interpretation
3. FMS - Facility Management Services
4. EMM - Equipment, Material, and Medications
5. HRM - Human Resource Management
6. MQS - Management of Quality and Safety
7. IMS - Information Management System

Every chapter begins with an 'intent'. The intent states the broad requirements of what the organisation needs to put in place and implement to improve the quality of care. This is followed by the 'summary of standards' which lists all the standards of that chapter. The standards and objective elements are explained after the summary. A list of references is provided at the end of all chapters.

WHAT IS A STANDARD?

A standard is a statement of expectation that defines the structures and processes that must be substantially in place in an organisation to enhance the quality of care. The standards are numbered serially, and a uniform system is followed for numbering. The first three letters reflect the name of the chapter and the number following this reflects the order of the standard in the chapter. For example, AAC.1. would mean that it is the first standard of the chapter titled 'Access, Assessment and Care of patient'.

WHAT IS AN OBJECTIVE ELEMENT?

It is that component of standard which can be measured objectively on a rating scale. Acceptable compliance with objective elements determines the overall compliance with a standard. The objective element is scored during assessments to arrive at the compliance. The objective element is numbered alphabetically in a serial order. For example, AAPC.1.c. would mean that it is the third objective element of the first standard of the chapter titled 'Access, Assessment, and Care of patient'.

WHAT IS AN INTERPRETATION?

The interpretation provides guidance on what the organisation needs to do to ensure that the requirement(s) of the objective element is met. Where applicable, it provides references and suggests a specific methodology that the organisation needs to adhere to. The word 'shall/should' or 'will/would' is used to reflect a mandatory requirement. The interpretation also lists out desirable aspects for the organisation to implement, and the word 'can/could' is used to reflect this. During scoring, the desirable aspects are not considered, and they are only used to reflect on the overall achievement of the standard, which is reflected in the assessment report. At places, the interpretation would not be specific and would have used the words like 'adequate/appropriate'. This has been done keeping in mind the diverse nature of healthcare delivery and adhering to the intent of this standard which is to improve the quality of healthcare and at the same time, be feasible. The expectation is that whenever such a phrase has been used in the interpretation/objective element, the organisation shall base its practice on evidence-based/best practice. In some places, the interpretation has listed out examples. The examples are only illustrative in nature, and the organisation has the liberty to decide what/how to implement. However, the requirement of the objective element would have to be adhered.

CORE STANDARD

Certain standards in the standard have been designated as Core Standard. These are standards that the organisation should have in place to ensure the quality of care or the safety of people within the organisation. CORE has been used to identify such standards.

LEVELS

The rest of the standards have been divided into three levels, namely commitment, achievement, and excellence. This has been done keeping in mind the fact that quality is a journey and that accredited organisations need to improve constantly. Most of the objective elements would be at the commitment level, and these would form the basis for accreditation at the end of the final assessment. The level of compliance with the standards placed at the achievement and excellence level would also count towards continued accreditation.

In the standard, certain objective elements require mandatory system documentation. The same have been identified by the * (asterisk) mark.

Scoring

The objective elements stated in the standards are scored during the assessment. The same is also used for scoring during the self-assessment. The scoring is to be done using a five-point scale. When applying a score, use the following rationale to determine the level of compliance.

Score	Rationale
1	**No compliance** • No systems in place and there is no evidence of working towards implementation • None or little (≤ 20%) of the samples meet the requirement(s) of the objective element • Non-conformity exists
2	**Poor compliance** • Elementary (limited) systems in place and there is some evidence of working towards implementation • Minimal (between 21-40%) of the samples meet requirement(s) of the objective element • Non-conformity exists
3	**Partial compliance** • Systems are partially in place, and there is evidence of working towards implementation • Some (between 41-60%) of the samples meet the requirement(s) of the objective element • Non-conformity exists
4	**Good compliance** • Systems are in place, and there is evidence of working towards implementation • The majority (between 61-80%) of the samples meet the requirement(s) of the objective element • Non-conformity could exist
5	**Full compliance** • Systems are in place, and there is evidence of implementation across the organisation • Almost all (between 81-100%) of the samples meet the requirement(s) of the objective element • No Non-conformity

The basis for scoring shall be implementation. However, if there is inadequate/inappropriate system documentation, the score could be downgraded by one.

NOT APPLICABLE (NA) CRITERIA

There could be a few standards/objective elements that may not be applicable to some organisations. A standard/objective element may be described as not applicable when the statement/content of the element would never occur in the organisation. The organisation has to identify such standard/objective element before the assessment and inform the NABH secretariat of the same. During the assessment, the assessment team shall discuss the same with the organisation and a final list shall be arrived at.

Abbreviations

ACR-RADPEER	American College of Radiology - RADPEER
AERB	Atomic Energy Regulatory Board
ALARA	As Low As Reasonably Achievable
CPR	Cardio-Pulmonary Resuscitation
CT	Computerised Tomography
FNAC	Fine Needle Aspiration Cytology
ISO	International Organization for Standardization
MIS	Medical Imaging Services
MRI	Magnetic Resonance Imaging
MTP	Medical Termination of Pregnancy
NABH	National Accreditation Board for Hospitals & Healthcare Providers
OPD	Out-Patient Department
PC-PNDT	Pre-Conception and Pre-Natal Diagnostic Testing
PET	Positron Emission Tomography
PMS	Preventive Maintenance Service
RCA	Root Cause Analysis
TAT	Turn Around Time
TLD	Thermo Luminescent Dosimeter
USG	Ultrasonography
WHO	World Health Organisation

Chapter 1

Access, Assessment and Care of Patient (AAC)

INTENT OF THE CHAPTER

Patients are well informed of the imaging services that an organisation provides. Only requests of those imaging procedures, which can be performed with the available resources and expertise are accepted by the organisation.

There is a well-defined registration process to ensure continuity of care. Information required for the performance of appropriate imaging, prioritization of scheduling, and interpretation is readily available.

The organisation defines the patient and family's rights and responsibilities. The staff is aware of these rights and is trained to protect them. Patients are informed of their rights and educated about their responsibilities. The organisation promotes the privacy, dignity, and security of patients and staff. The organisation promotes patient-focused service delivery. A documented process for obtaining patient consent exists for informed decision-making about their care. Patients and families have a right to seek and get information and education about the procedures in a language and manner that is understood by them.

The organisation is prepared to handle imaging emergencies. The patient transportation is safe and secure. Facilities for handling life-threatening events are available. Safe anaesthesia and sedation practices are followed.

Summary of Standards	
AAC.1.	The organisation defines and displays the scope of medical imaging services that it provides.
AAC.2.	The organisation has a well-defined registration and admission process.
AAC.3.	The organisation protects patient and family rights and informs them about their responsibilities during care.
AAC.4.	The organisation has written guidance for obtaining informed consent from the patients to enable informed decision making about their care.
AAC.5.	Emergency imaging services are guided by applicable laws and regulations and written guidance.
AAC.6.	Patient transportation and ambulance services are guided by applicable laws, regulations and written guidance.
AAC.7.	Written guidance exists for the care of patients requiring cardio-pulmonary resuscitation.
AAC.8.	Written guidance exists for the care of patients undergoing anaesthesia and procedural sedation.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

AAC.1.	**The organisation defines and displays the scope of medical imaging services that it provides.**

Objective Elements

Commitment	a.	The scope of medical imaging services being provided are clearly defined and prominently displayed.*
Commitment	b.	Patients are accepted only if the organisation can provide the required medical imaging services.
Commitment	c.	The staff is oriented to the medical imaging services.

Standard

AAC.2.	**The organisation has a well-defined registration and admission process.**

Objective Elements

CORE	a.	The organisation uses written guidance for registering the patient and a unique identification number is generated for each patient at the end of the registration.*
Commitment	b.	All attempts are made to ensure that the unique identification number is maintained for each patient on all subsequent visits.
Commitment	c.	The organisation has a mechanism to capture all the required information about the procedure requested, the relevant clinical and lab details, and information about prior imaging before performing the procedure.
Commitment	d.	The organisation has a mechanism in place to ensure that the imaging is appropriate for the patient and the clinical indication.
Commitment	e.	The organisation has a mechanism in place for scheduling and prioritization according to the patient's condition and urgency of diagnosis.

Standard

AAC.3.	**The organisation protects patient and family rights and informs them about their responsibilities during care.**

Objective Elements

Commitment	a.	Patients and families are informed of their rights and responsibilities in a format and language that they can understand.
Commitment	b.	The information about specific procedures are available to patients and accompanying persons in relevant formats and languages including the local language.
Commitment	c.	The patients and (or) attendants are informed about the expected costs prior to imaging.
Commitment	d.	Imaging services provided are uniform for a given health problem in all settings.
Commitment	e.	The privacy and dignity of the patient is preserved without any discrimination.
CORE	f.	Confidentiality of patient information will be maintained.
Commitment	g.	The patient and family have a right to seek an additional opinion.

Standard

AAC.4.	**The organisation has written guidance for obtaining informed consent from the patients to enable informed decision making about their care.**

Objective Elements

CORE	a.	Written guidance incorporates the list of situations where informed consent is required and the process for taking informed consent.*

CORE	b.	Informed consent includes information regarding the procedure, its risks, benefits, alternatives in a language that the patient/guardian can understand.
Commitment	c.	The written guidance describes who can give consent when the patient is incapable of independent decision-making.*
CORE	d.	Informed consent is taken by the person performing the procedure or by a staff member of the team.

Standard

AAC.5.	**Emergency imaging services are guided by applicable laws and regulations and written guidance.**

Objective Elements

Commitment	a.	The organisation shall have written guidance for the identification of emergencies.*
Commitment	b.	Written guidance is used for the triaging of patients for prioritization of maging.*
Commitment	c.	Written guidance is used for handling emergency patients in the premises and during imaging.*
Commitment	d.	Written guidance is used for handling and management of medico-legal cases.*
Commitment	e.	There is an identified area in the organisation to receive and manage emergency patients.

Standard

AAC.6.	**Patient transportation and ambulance services are guided by applicable laws, regulations and written guidance.**

Objective Elements

Commitment	a.	Written guidance exists to ensure safe and timely transportation of patients within, to, and from the imaging services.*

Achievement	b.	There is adequate access and space for the ambulance(s) and/or patient transport vehicle(s).
CORE	c.	The ambulance and/or patient transport vehicle(s) adhere to statutory requirements and are manned by trained personnel as per the existing laws and regulations.
Commitment	d.	The ambulance(s) and/or patient transport vehicle(s) are appropriately equipped.

Standard

AAC.7.	**Written guidance exists for the care of patients requiring cardio-pulmonary resuscitation.**

Objective Elements

Commitment	a.	Written guidance exists for the uniform use of resuscitation throughout the organisation.*
Commitment	b.	During cardio-pulmonary resuscitation, assigned roles and responsibilities are complied with.
Commitment	c.	Staff providing direct patient care are trained and periodically updated in emergency life support and cardio-pulmonary resuscitation.
Commitment	d.	An appropriately equipped crash cart or a resuscitation tray is maintained.
Commitment	e.	The events during any emergency life support and cardiopulmonary resuscitation are documented and analysed.
Commitment	f.	The organisation has a mechanism for the transfer of patients to an appropriate acute care facility when required.

Standard

AAC.8.	**Written guidance exists for the care of patients undergoing anaesthesia and procedural sedation.**

Objective Elements

Commitment	a.	Written guidance exists for the selection of patients for anaesthesia/sedation, its administration and monitoring.*
CORE	b.	Informed consent for administration of anaesthesia, procedural sedation is obtained.
Commitment	c.	Competent and trained persons administer anaesthesia and sedation.
Commitment	d.	The patient is appropriately monitored on predefined parameters before, during, and after the procedure till the discharge.
Commitment	e.	The equipment required for procedural sedation and anaesthesia services is available.
Commitment	f.	Equipment and workforce are available to manage patients who have gone into a deeper level of sedation than initially intended.

Chapter 2

Imaging, Procedures and Interpretations (IPI)

INTENT OF THE CHAPTER

All images are acquired in accordance with agreed protocols by qualified and competent staff working within their defined scope of practice. Images are of optimal diagnostic quality according to current best practices.

The Imaging studies are interpreted onsite as well as in teleradiology, using the agreed format and language developed by competent staff working within their defined scope of practice. The aim is to deliver an accurate and effective radiological and clinical interpretation of the images.

Interventional procedures are conducted in accordance with agreed protocols by competent staff working within their defined scope of practice.

The generation, verification, and amendments of reports are within a defined timeframe and in accordance with the defined protocols. Turnaround time for communication of reports is defined and monitored.

There is a process of recall and amendment of reports with errors.

Functioning and use of teleradiology services are monitored.

The involvement of MIS in research activities follows all regulatory guidelines.

Summary of Standards	
IPI.1.	Written guidance exists for conducting imaging procedures to acquire images of optimal diagnostic quality.
IPI.2.	Written guidance exists for the care of patients undergoing diagnostic and therapeutic interventional procedures.
IPI.3.	The organisation has written guidance on the content of the imaging reports and discharge documents.
IPI.4.	The organisation has written guidance for communication of the imaging results and discharge documents.
IPI.5.	Teleradiology services address all issues pertaining to reporting and communication.
IPI.6.	All research activities and clinical trials are carried out as per written guidance.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

IPI.1.	**Written guidance exists for conducting imaging procedures to acquire images of optimal diagnostic quality.**

Objective Elements

Commitment	a.	Appropriately qualified and trained personnel plan and perform imaging studies.
Commitment	b.	The written guidance for image acquisition for all examinations is developed based on current best practices.*
Commitment	c.	The protocols are appropriate for the specific age, gender, clinical indications, anatomical part, and modality.
Achievement	d.	The protocols are implemented, and protocol deviations are documented.
Commitment	e.	The protocols include appropriate post-processing and quantification as appropriate for the clinical indication.
Achievement	f.	The protocols for image acquisition for all examinations are reviewed at a defined periodicity for improvement and adaptation of the current best practices and guidelines.
Commitment	g.	Written guidance exists to prevent events like a wrong patient, wrong site, wrong side, and wrong imaging procedure.*
Commitment	h.	Protocols include assessment and monitoring of patients before, during, and after the imaging procedure.
Commitment	i.	The quality of diagnostic images and completeness of the procedures are checked through written guidance.*
Commitment	j.	Staff are appropriately oriented and trained for these.

Standard

IPI.2.	Written guidance exists for the care of patients undergoing diagnostic and therapeutic interventional procedures.

Objective Elements

Commitment	a.	Adequately qualified and trained staff members perform and assist the procedures.
Commitment	b.	The protocols for all diagnostic and therapeutic interventional procedures are developed and documented.*
Commitment	c.	Patients undergoing an interventional procedure shall have a pre-procedural assessment and a provisional diagnosis is documented prior to the procedure.
CORE	d.	Informed consent is obtained by a member of the performing team prior to the procedure and the same is documented.
Commitment	e.	Written guidance exists to prevent adverse events like wrong site, wrong patient and wrong interventional procedure.*
CORE	f.	Radiation safety procedures are followed.
Commitment	g.	Written guidance for infection prevention and control are followed.*
Commitment	h.	Appropriate facilities and equipment, appliances, and instrumentations are available in the procedure area.
Commitment	i.	Appropriate sedation/anaesthesia, clinical and emergency support is available before, during, and after the interventional procedure.
Commitment	j.	A procedure note is documented prior to transfer out of patient from the facility.
Commitment	k.	The outcomes of diagnostic and therapeutic interventional procedures are monitored.

Standard

IPI.3.	**The organisation has written guidance on the content of the imaging reports and discharge documents.**

Objective Elements

Commitment	a.	An imaging report or a discharge document are provided to the patients for each procedure.
Commitment	b.	Results are reported in a standardized manner using the current best practices and guidelines.
Commitment	c.	The report contains the patient's demographic details including unique identification number
Commitment	d.	The report contains the details of the procedure performed, medication and sedation administered, details of any adverse event, and any other treatment given.
Commitment	e.	The report contains findings, diagnosis or differential diagnosis.
Achievement	f.	The report ensures that the current clinical indication for the imaging study is addressed and all attempts are made to collate findings with the previous imaging findings as well as clinical details.
Achievement	g.	The imaging report or discharge document contains advice for any further investigation, follow-up imaging advice, medication, and other instructions as appropriate in an understandable manner.
Achievement	h.	There is written guidance to address recall/amendment of reports when required.*

Standard

IPI.4.	**The organisation has written guidance for communication of the imaging results and discharge documents.**

Objective Elements

Commitment	a.	There is written guidance on communication of routine, urgent and critical imaging findings with a defined turnaround time for each of them.*

Commitment	b.	A list of conditions requiring critical and urgent communication is defined.
Commitment	c.	The reports are communicated to the patient and/or referring clinician within the appropriately defined timeframe based on the clinical indication and urgency.
Achievement	d.	Imaging tests and/or reporting outsourced to other organisation(s) follow the same turnaround time and critical reports requirements.
Commitment	e.	The organisation has a mechanism to ensure that the right report is communicated to the right patient and the right physician at the right time.

Standard

IPI.5.	**Teleradiology services address all issues pertaining to reporting and communication.**

Objective Elements

CORE	a.	Teleradiology services are provided under a documented agreement between the provider and consumer of the services.
Commitment	b.	All clinical, lab and prior imaging information is available to the teleradiology services provider.
Commitment	c.	Appropriately qualified and trained personnel interpret the imaging studies.
Commitment	d.	Appropriate equipment is used for the acquisition, communication, display, and storage of images.
Commitment	e.	Results are reported in a standardized manner consistent with the organisational standards.
Achievement	f.	Written guidance exists to address recall/amendment of teleradiology reports when required.*

Standard

IPI.6.	**All research activities and clinical trials are carried out as per written guidance.**

Objective Elements

CORE	a.	All research activities and clinical trials, in compliance with regulatory, national, and international guidelines are carried out as per the written guidance.*
Commitment	b.	The organisation has access to an appropriate ethics committee or internal review board to oversee all research activities or clinical trials.
Commitment	c.	The ethics committee has the power to discontinue a research activity or clinical trial when risks outweigh the potential benefits.
CORE	d.	Patients' informed consent is obtained before entering them into research activities/clinical trials in accordance with the prevalent laws and regulations.
Commitment	e.	Patients are informed of their right to withdraw from the research activity/clinical trial at any stage and also of the consequences (if any) of such withdrawal.
Excellence	f.	The organisation contributes to national and international research.

Chapter 3

Facility Management Services (FMS)

INTENT OF THE CHAPTER

Appropriate signage guides the visitors. The organisation provides safe water, electricity, medical gases, and vacuum systems as required by the scope of services.

Regular facility inspection rounds are conducted, and appropriate actions are taken to ensure safety.

The organisation works towards the provision of a safe and secure environment for patients, their families, staff, and visitors. This includes risk mitigations as well as environmental safety.

The organisation plans for managing emergencies within the facilities.

The organisation plans for the safe management of hazardous/ radioactive materials in the facility and environment.

Summary of Standards	
FMS.1.	The organisation's environment and facilities operate in a planned manner to ensure operational efficiency and promote environmental friendly measures.
FMS.2.	All facilities are appropriately maintained to ensure uninterrupted services.
FMS.3.	The organisation has a mechanism to provide a safe and secure environment.
FMS.4.	The organisation has plans for fire and non-fire emergencies within the facilities.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

FMS.1.	**The organisation's environment and facilities operate in a planned manner to ensure operational efficiency and promote environmental friendly measures.**

Objective Elements

Commitment	a.	Facilities are appropriate to the scope of services of the organisation.
Commitment	b.	Up-to-date drawings are maintained which detail the site layout, floor plans, and fire-escape routes.
Commitment	c.	The provision of space shall be in accordance with the current good practices (Indian or international standards) and directives from government agencies.
Commitment	d.	There are appropriate internal and external sign postings in the organisation in a language understood by patient, families, and the community.
CORE	e.	Potable water and electricity are available round the clock.
Commitment	f.	Medical gases are procured, handled, stored, distributed, used and replenished in accordance with written guidance.*

Standard

FMS.2.	**All facilities are appropriately maintained to ensure uninterrupted services.**

Objective Elements

Commitment	a.	There are designated individuals (with appropriate equipment) responsible for the maintenance of all the facilities.
Commitment	b.	Alternative sources for electricity and water are provided as a backup for any failure/shortage especially for the equipment and the organisation regularly tests these alternative sources.
Commitment	c.	There is a maintenance plan for all facilities and furniture.

Achievement	d.	Response times are monitored from reporting to inspection and implementation of corrective and preventive actions.
Excellence	e.	The organisation takes initiatives towards an energy-efficient and environmental-friendly facility.

Standard

FMS.3.	**The organisation has a mechanism to provide a safe and secure environment.**

Objective Elements

Commitment	a.	MIS coordinates the development, implementation, and monitoring of the facility safety plan.
CORE	b.	Patient-safety devices & infrastructure are installed across the organisation and inspected periodically.
Commitment	c.	Operational planning identifies areas which need to have extra security and describes access to different areas in the organisation by staff, patients, and visitors.
CORE	d.	Written guidance exists for the disposal of waste and scrap material.*
Commitment	e.	Facility inspection rounds to ensure safety are conducted.
Commitment	f.	Inspection reports are documented and corrective and preventive measures are undertaken.

Standard

FMS.4.	**The organisation has plans for fire and non-fire emergencies within the facilities.**

Objective Elements

CORE	a.	The organisation has plans and provisions for early detection, abatement, and containment of fire and non-fire emergencies.

Commitment	b.	The organisation has a documented safe-exit plan in case of fire and non-fire emergencies.*
Commitment	c.	Staff is trained for their role in case of such emergencies.
Achievement	d.	Mock drills are held at least twice a year.
Commitment	e.	There is a maintenance plan for fire-related equipment and infrastructure.

Chapter 4

Equipment, Material and Medications (EMM)

INTENT OF THE CHAPTER

The organisation ensures appropriate procurement, installation, operation, maintenance, quality assurance, and replacement of all imaging equipment as well as the ancillary equipment and consumables. These are performed in accordance with the prevailing laws and national guidelines.

The organisation has documented policies and procedures that guide the availability, safe storage, prescription, dispensing, and administration of contrast media, radiopharmaceuticals, and other medications.

The emergency medications are standardized throughout the organisation, readily available, and replenished in a timely manner. Safe use of high-risk medication like narcotics, chemotherapeutic agents, and radioisotopes are guided by written guidance.

The organisation ensures monitoring of patients after administration of medications including contrast media and radiopharmaceuticals.

There are procedures for reporting and analyzing adverse events and medication errors.

Written Guidance exists for the use of devices for interventional radiology as well as the therapeutic use of radiopharmaceuticals.

Sound practices govern the availability and use of all materials, supplies and devices required as per the scope of services.

Summary of Standards	
EMM.1.	Written guidance exists for the management of all equipment.
EMM.2.	Written guidance exists for the procurement, storage, and usage of medication.
EMM.3.	Written guidance exists for the safe and rational use of contrast media and medications.
EMM.4.	The organisation is governed by written guidance for diagnostic/therapeutic usage of radiopharmaceuticals.
EMM.5.	Written guidance exists for the use of medical supplies and consumables, stents, coils, and other implantable and ablative medical devices.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

EMM.1.	**Written guidance exists for the management of all equipment.**

Objective Elements

Commitment	a.	The organisation plans for equipment in accordance with its services and strategic plan.
Commitment	b.	Equipments are inventoried with proper equipment history and logs.
CORE	c.	The installation of the equipment is safe and commensurate with the applicable laws.
CORE	d.	The operation of the equipment is safe and compliant with the applicable laws.
Commitment	e.	Appropriate calibration and quality assurance of the equipment is performed at a defined periodicity.
Commitment	f.	Written guidance exists for operational and maintenance (preventive and breakdown) plan of all equipment.*
Commitment	g.	Equipment cleaning and disinfection adheres to transmission-based precautions at all times.
Achievement	h.	The organisation identifies and plans for obsolescence, condemning, and decommissioning of the equipment.
Commitment	i.	Qualified and trained personnel inspect, test, and maintain equipment and utility systems.

Standard

EMM.2.	**Written guidance exists for the procurement, storage, and usage of medication.**

Objective Elements

Commitment	a.	Written guidance exists for procurement and stocking of contrast media, radiopharmaceuticals, and other medications commensurate with the scope of services.*

CORE	b.	Written guidance exists for the storage of medication in a clean, safe and secure environment.*
Commitment	c.	Sound inventory control practices guide the storage of the medications.
Commitment	d.	Written guidance exists for the usage of multidose formulations and their discard.*

Standard

EMM.3.	**Written guidance exists for the safe and rational use of contrast media and medications.**

Objective Elements

Commitment	a.	Written guidance exists for use of contrast media and other medications, which is commensurate with current best practices.*
Commitment	b.	Contrast media and other medications are handled and administered by those who are permitted and trained to do so.
CORE	c.	There is a mechanism to identify patients who are at high risk for adverse events following the administration of contrast media and other medications.
Commitment	d.	Written guidance exists for monitoring of patients during and after administration of contrast media and other medications.*
CORE	e.	Written guidance exists for managing adverse drug reactions, and other adverse drug events.*

Standard

EMM.4.	**The organisation is governed by written guidance for diagnostic/therapeutic usage of radiopharmaceuticals.**

Objective Elements

Commitment	a.	Written guidance governs the safe transport, storage, preparation, handling, distribution, administration, and disposal of radiopharmaceuticals.*

CORE	b.	The written guidance for handling radiopharmaceuticals are in consonance with laws and regulation.*
Commitment	c.	This includes the management of radioactive spills and personnel contamination.
Commitment	d.	The patients at higher risk of adverse reactions to specific drugs, isotopes, and radiopharmaceuticals are identified, assessed, and managed.
Commitment	e.	Staff, patients, and visitors are educated on safety precautions and the management of adverse events.
Commitment	f.	The protocols followed in the holding area used for nuclear medicine patients are defined and implemented.
Commitment	g.	All patients are provided with a comprehensive discharge summary.

Standard

EMM.5.	**Written guidance exists for the use of medical supplies and consumables, stents, coils, and other implantable and ablative medical devices.**

Objective Elements

Commitment	a.	The use of medical supplies, consumables, and devices is rational, safe, and commensurate with the current best practices.
Commitment	b.	Medical supplies and consumables are stored appropriately and are available where required.
Commitment	c.	Written guidance governs the reuse and re-sterilization of devices.*
Commitment	d.	A discharge summary is provided in case of any implant procedure including the details of the implant.
Commitment	e.	Patients and family are educated about the implanted prosthesis and medical device including their maintenance and precautions.

Chapter 5

Human Resource Management (HRM)

INTENT OF THE CHAPTER

Human resources are an asset for the effective and efficient functioning of a Healthcare Organisation. The goal of human resource management is to acquire, provide, retain, and maintain competent people in the right numbers to meet the needs of the patients and community served by the organisation.

The management of staff is effective, fair, consistent, and supportive. Management of staff should comply with current legislation and current best practice. To ensure high-quality care to patients, the organisation works to ensure that the staff is acquired in the right numbers and skill-mix to meet the needs of the patients and community served by the organisation.

All the staff is supported to maintain, improve and widen the scope of their competencies. The organisation must ensure fair and consistent handling of all complaints and grievances from staff within a defined timeframe.

The organisation ensures that there is a well-documented performance appraisal system in the organisation, and it is used as a tool for further development.

The organisation should plan to have ongoing professional training/in-service education to enhance the competencies and skills of the staff continually covering all aspects of safety.

The staff is aware of the human resource policies which are applicable to them.

Summary of Standards	
HRM.1.	Written guidance exists for human resource planning.
HRM.2.	The organisation has a documented training program for the staff.
HRM.3.	The organisation has a documented human resource management process.
HRM.4.	There is documented personal information for each staff member.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

HRM.1.	Written guidance exists for human resource planning.

Objective Elements

Commitment	a.	The organisation maintains an adequate number and mix of staff to meet the needs of the organisation.
Commitment	b.	There is written guidance for the recruitment and selection of staff.*
Commitment	c.	Job specification and job description are defined and documented for each category of staff.*
Commitment	d.	The credentials, skills, and training of the staff are verified wherever possible.
Commitment	e.	The organisation verifies the antecedents of the potential employee with regard to criminal/negligent background.
Commitment	f.	There is a defined process of privileging for all healthcare providers for the services assigned to them.
Commitment	g.	There are clearly defined roles and supervisory requirements for the students, trainees and volunteers.

Standard

HRM.2.	The organisation has a documented training program for the staff.

Objective Elements

CORE	a.	Every staff member is made aware of the organisation's policies and procedures through induction training at the time of joining.
Commitment	b.	Written guidance for training and development exists for the staff.*
Commitment	c.	Retraining occurs at a defined periodicity, and also when job responsibility changes and/or new equipment is introduced.

Commitment	d.	Staff are trained on the risks as applicable to the organisation's environment at a defined periodicity.
CORE	e.	Staff are also trained on occupational safety aspects
Excellence	f.	Evaluation of training effectiveness is done by the organisation.

Standard

HRM.3.	**The organisation has a documented human resource management process.**

Objective Elements

Commitment	a.	The MIS carries out periodic appraisal and competency evaluation as per written guidance.*
Excellence	b.	The organisation encourages and promotes competency development
CORE	c.	The organisation has documented disciplinary and grievance handling policies and procedures.*
Commitment	d.	There is a provision for appeals in all disciplinary cases.
Commitment	e.	There is a provision for health check-ups; health and other benefits to the staff.

Standard

HRM.4.	**There is documented personal information for each staff member.**

Objective Elements

Commitment	a.	A personal file is maintained for each staff member.
Commitment	b.	The personal files contain information regarding the staff's qualifications, background, and health status.
Commitment	c.	All records of in-service training and education are contained in the personal files.

Commitment	d.	The personal file shall include information on the credentialing and privileging of staff members for performing all imaging-related procedures.
Commitment	e.	Personal files contain the results of all evaluations.

Chapter 6

Management of Quality and Safety (MQS)

INTENT OF THE CHAPTER

The responsibilities of the management and the leaders at all levels are defined. The organisation complies with all applicable regulations and ensures ethical management in all activities of the organization.

Leaders ensure that patient safety and risk management are an integral part of patient care and hospital management.

The standards encourage an environment of patient safety and continual quality improvement. The patient safety and quality programme should be documented and involve all areas of the organisation and all staff members. The management monitors the quality of imaging, interventional procedures, and image interpretation and promotes continuous improvement at all levels. The management monitors the managerial indicators and turnaround times and promotes continual improvement at all levels.

The safety program is structured and incorporates all aspects of patient and staff safety. It involves safety related to radiation as well as non-radiation imaging. A culture of safety encourages the free sharing of errors with the intent to learn from them. Pro-active safety, as well as safety audits, are included.

Summary of Standards	
MQS.1.	Roles of management is defined.
MQS.2.	The organisation has a structured quality improvement program.
MQS.3.	The organisation identifies and monitors the quality of imaging studies and reports.
MQS.4.	The management ensures patient and staff safety in the organisation.
MQS.5.	There is an established risk control and safety program in the imaging services.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

MQS.1.	**Roles of management is defined.**

Objective Elements

Commitment	a.	Management defines the organisation's vision, mission, and values.
Commitment	b.	Management chooses leaders and establishes an organogram in the organisation.
CORE	c.	Management is aware of current applicable laws and ensures that the organisation adheres to them.
CORE	d.	Management ensures the acquisition of all relevant licenses and their updation.
Achievement	e.	Management ensures ethical management of all patient services that the organisation provides.
Commitment	f.	The management ensures that all policies and protocols are developed and documented to guide the functioning of the organisation.

Standard

MQS.2.	**The organisation has a structured quality improvement program.**

Objective Elements

CORE	a.	A continual quality improvement program is developed, documented, and implemented throughout the organisation.*
Commitment	b.	The program is periodically reviewed and updated at least once a year.
Commitment	c.	The organisation conducts regular audits for timeliness and efficiency of services.
Commitment	d.	The organisation identifies and monitors priority key performance indicators (clinical, managerial, and infrastructural) in the organisation.
Commitment	e.	The MIS has an established system of periodic audits.

Commitment	f.	The program includes a system to obtain feedback from patients and visitors on all aspects of services.
Achievement	g.	There is a system of periodic review to ensure that feedback is utilized to improve services.

Standard

MQS.3.	**The organisation identifies and monitors the quality of imaging studies and reports.**

Objective Elements

Commitment	a.	The organisation monitors the appropriateness of imaging.
Commitment	b.	The organisation monitors image quality and completeness of imaging for a given indication and clinical context.
Achievement	c.	The organisation monitors re-dos of imaging procedures and recalls of reports.
Commitment	d.	The organisation conducts regular audits for the completeness of reports.
Commitment	e.	The program addresses periodic internal/ external peer reviews.
Achievement	f.	The program addresses surveillance of imaging results with clinical correlation and follows up wherever possible.
Commitment	g.	The program includes a system to obtain feedback from referring colleagues.
Achievement	h.	There is a system of periodic review to ensure that feedback is utilized to improve services.

Standard

MQS.4.	**The management ensures patient and staff safety in the organisation.**

Objective Elements

CORE	a.	A comprehensive safety program is developed and implemented throughout the organisation as per written guidance.*

Commitment	b.	The program is periodically reviewed and updated at least once a year.
Commitment	c.	The organisation conducts regular audits for patient safety program
CORE	d.	The program addresses the safety of staff, patients and visitors from violence, aggression, and abuse.
Achievement	e.	The organisation implements an incident management system.
Excellence	f.	The organisation shall have a process for informing various stakeholders in case of a near-miss/adverse event/sentinel event.

Standard

MQS.5.	**There is an established risk control and safety program in the imaging services.**

Objective Elements

Commitment	a.	The radiation safety program is documented and developed by the radiation safety committee of the organisation.*
Commitment	b.	This program is implemented and overseen by an appropriately designated radiation safety officer and is aligned with the organisation's safety program.
CORE	c.	Radiation signages are prominently displayed in all appropriate locations.
Commitment	d.	Patients are appropriately screened for safety/risk prior to undergoing imaging on a particular modality.
Commitment	e.	Staff personnel and patients are provided with appropriate radiation protection devices.
Commitment	f.	Personal radiation monitoring devices are provided to all the radiation workers.
Commitment	g.	The safety program also addresses the risk associated with MRI.
Commitment	h.	The safety program also addresses ultrasound services.
Commitment	i.	The safety program also addresses the risk associated with the use of ablative and therapeutic devices during diagnostic & interventional procedures.

Commitment	j.	Occupational health hazards are adequately addressed.
CORE	k.	Biomedical and hazardous waste is collected and disposed off in a safe manner and as per the applicable guidelines.

Chapter 7

Information Management System (IMS)

INTENT OF THE CHAPTER

Information is an important resource for the effective and efficient delivery of healthcare. The provision of healthcare and its continued improvement is dependent to a large extent on the information generated, stored, and utilized appropriately by the organisation. The data and information meet the organisation's needs and support the delivery of quality care and service.

Written guidance is in place for storage of imaging and other records; and for maintaining confidentiality, integrity, and security of records, data and information.

Teleradiology services defined the specific storage and statutory requirements and deletion of the data after completion of the retention period.

Summary of Standards	
IMS.1.	The information needs of the patients, visitors, staff, management, and external agencies are met using an appropriate information management system.
IMS.2.	The organisation has an imaging record for every patient.
IMS.3.	Written guidance exists for maintaining confidentiality, integrity, and security of records, data, and information.

*This implies that this objective element requires documentation

STANDARDS AND OBJECTIVE ELEMENTS

Standard

IMS.1.	The information needs of the patients, visitors, staff, management, and external agencies are met using an appropriate information management system.

Objective Elements

Commitment	a.	The information needs of the organisation are identified.
Commitment	b.	Information management and technology acquisitions are commensurate with the identified information needs.
Commitment	c.	Written guidance defines the use of remote access to patient data and images in a safe and secure manner.*
Commitment	d.	The organisation contributes to external databases in accordance with the law and regulations.
Excellence	e.	The organisation or its members actively participates in scientific and educational deliberations.
Commitment	f.	The organisation has an effective process for document control.
Commitment	g.	Written guidance exists for storing and retrieving data.*

Standard

IMS.2.	**The organisation has an imaging record for every patient**

Objective Elements

Commitment	a.	Every imaging record includes a unique identifier for each patient which is maintained for each patient on all subsequent visits.
Commitment	b.	Organisation policy identifies those authorized to make entries in imaging records.
Commitment	c.	The mandatory contents of the imaging record are identified and documented.*
Commitment	d.	Information on the invasive procedures performed is incorporated in the medical record.

Standard

IMS.3.	Written guidance exists for maintaining confidentiality, integrity, and security of records, data, and information.

Objective Elements

CORE	a.	Written guidance exists for maintaining confidentiality, security, and integrity of records, data, and information.*
CORE	b.	Written guidance exists for the safeguarding of data/records against loss, destruction, tampering, and unauthorised use.*
Commitment	c.	Request for access to information in the medical imaging records by patients/physicians and other public agencies are addressed consistently.
Commitment	d.	The staff is aware of these.

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Glossary

The commonly-used terminologies in the NABH standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

Accreditation	Accreditation is a self-assessment and external peer review process used by healthcare organisations to accurately assess their level of performance in relation to established standards and to implement ways to improve the healthcare system continuously.
Accreditation assessment	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
Advance life support	Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.
Adverse drug reaction	A response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.
Adverse event	An injury related to medical management, in contrast to complications of the disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems).
Basic Life support (BLS)	Basic Life support (BLS) is the level of medical care which is used for patients with life-threatening illnesses or injuries until the patient can be given full medical care
Breakdown	Activities which are associated with the repair and servicing of site infrastructure, buildings, plant or equipment within the site's agreed building capacity allocation which have become inoperable or unusable because of the failure of parts.
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.
Cardio Pulmonary esuscitation (CPR)	The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilators or respirators, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

Competence	Demonstrated ability to apply knowledge and skills (para 3.9.2 of ISO 9000: 2015). Knowledge is the understanding of facts and procedures. Skill is the ability to perform a specific action.
Computerized Tomography	A computerized tomography (CT) scan combines a series of X-ray images taken from different angles around the body and uses computer processing to create cross-sectional images.
Confidentiality	Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as the privacy of information related to his/her healthcare records.
Consent	1. The willingness of a party to undergo examination/procedure/ treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to make an informed decision of his/her healthcare. 2. In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India, the legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.
Credentialing	The process of obtaining, verifying and assessing the qualification of a healthcare provider.
Correction	Action to eliminate the detected non-conformity (Reference: ISO 9000:2015)
Corrective action	Action to eliminate the cause of a non-conformity and to prevent recurrence. (Reference: ISO 9000:2015)
Data	Data is a record of the event.
Discharge summary	A part of a patient record that summarises significant clinical findings, procedures performed, treatment rendered, patient's condition on discharge and any specific instructions given to the patient or family (for example follow-up medications).
Employees	All members of the healthcare organisation who are employed full time/part-time and are paid suitable remuneration for their services as per the laid-down policy.
Failure Mode and Effect Analysis (FMEA)	A method used to prospectively identify error risks within a particular process. visitors, relatives and staff.

Grievance handling procedures	The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
Hazardous waste	Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include the biological waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.
Incident Reporting	It is defined as written or verbal reporting of any event in the process of patient care that is inconsistent with the deserved patient outcome or routine operations of the healthcare facility.
In-service education/ training	Organised education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.
Indicator	A statistical measure of the performance of functions, systems or processes over time. For example, hospital-acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.
Intent	A brief explanation of the rationale, meaning and significance of the standards laid down in a particular chapter.
Inventory control	The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure an adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
Job description	1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job. 2. A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes job specifications that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.
Job specification	1. The qualifications/physical requirements, experience and skills required to perform a particular job/task. 2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.

Maintenance	The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function. (Reference: British Standard 3811:1993)
Magnetic Resonance Imaging(MRI)	A non-invasive diagnostic technique that produces computerized images of internal body tissues and is based on nuclear magnetic resonance of atoms within the body induced by the application of radiowaves
Mammography	A non-invasive radiological procedure used to take pictures of the breasts inorder to diagnose any abnormality/pathology or cysts.
Medical equipment	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.
Mission	An organisation's purpose. This refers to the overall function of an organisation. The mission answers the question, "What is this organisation attempting to accomplish?" The mission might define patients, stakeholders, or markets served, distinctive or core competencies or technologies used.
Monitoring	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g.monitoring of growth and nutritional status, air quality in the operation theatre. It requires careful planning and the use of standardised procedures and methods of data collection.
Patient Medical Imaging Record	A document which contains the chronological sequence of events that a patient undergoes during his stay in the healthcare organisation. It includes demographic data of the patient, assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary.
Objective	A specific statement of a desired short-term condition or achievement includes measurable end results to be accomplished by specific teams or individuals within time limits. (Reference: American Society for Quality)
Objective element	It is that component of standard which can be measured objectively on a rating scale. Acceptable compliance with the measurable elements will determine the overall compliance with the standard.
Occupational health hazard	The hazards to which an individual is exposed during the course of the performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards.
Optimal diagnostic Quality image	Images which provide necessary and sufficient diagnostic information to provide an accurate diagnosis

Patient Satisfaction	Patient satisfaction is a measure of the extent to which a patient is content with the healthcare which they received from their healthcare provider. Patient satisfaction is thus a proxy but a very effective indicator to measure the success of healthcare providers.
Performance appraisal	It is the process of evaluating the performance of staff during a defined period of time with the aim of ascertaining their suitability for the job, the potential for growth as well as determining training needs.
Policies	They are the guidelines for decision-making e.g. admission, discharge policies, antibiotic policy, etc.
Preventive maintenance	It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect the mand to prevent or eliminate any degradation in their operating conditions. The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item.
Privileging	It is the process for authorising all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.
Procedure	1. A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2015). 2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
Process	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000: 2015).
Positron Emission Tomography (PET scan)	A non-invasive radiological procedure producing a sectional view of the body constructed by positron-emission tomography by using a radioactive tracer/isotope.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	1. Degree to which a set of inherent characteristics fulfil requirements(Para 3.1.1 of ISO 9000: 2015). Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000: 2015). Requirements are a need or expectation that is stated, generally implied or obligatory (Para 3.1.2 of ISO 9000:2015). 2. Degree of adherence to pre-established criteria or standards.

Quality improvement	Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.
Radiation Safety	**Radiation safety** refers to safety issues and protection from radiation hazards arising from the handling of radioactive materials or chemicals and exposure to Ionizing and Non-Ionizing Radiation. This is implemented by taking steps to ensure that people will not receive excessive doses of radiation and by monitoring all sources of radiation to which they may be exposed (Reference: McGraw-Hill Dictionary of Scientific & Technical Terms). In a Healthcare setting, this commonly refers to X-ray machines, CT/PETCT Scans, Electron microscopes, Particle accelerators, Cyclotron etc. Radioactive substances and radioactive waste are also potential Hazards. **Imaging Safety** includes safety measures to be taken while performing an MRI, Radiological interventions, Sedation, Anaesthesia, Transfer of patients, Monitoring patients during imaging procedure etc.
Referring clinician	A person who prescribes diagnostics imaging tests for any diagnostic centre.
Registered Nurse	A professional registered for practice and holding an active license to practice from the State Nursing Council
Risk abatement	Risk abatement means minimising the risk or minimising the impact of that risk.
Risk assessment	Risk assessment is the determination of the quantitative or qualitative value of risk related to a concrete situation and a recognised threat (also called hazard). Risk assessment is a step in a risk management procedure.
Risk management	Clinical and administrative activities to identify, evaluate and reduce the risk of injury.
Root Cause Analysis (RCA)	Root Cause Analysis (RCA) is a structured process that uncovers the physical, human, and latent causes of any undesirable event in the workplace. Root cause analysis (RCA) is a method of problem-solving that tries to identify the root causes of faults or problems that cause operating events. RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.

Safety	The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.
Scope of services	Range of clinical and supportive activities that are provided by a healthcare organisation.
Security	Protection from loss, destruction, tampering, and unauthorised access or use.
Sedation	The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation: **Minimal sedation** (anxiolysis) - A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are not affected. **Moderate sedation**/analgesia (conscious sedation) - A drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. No interventions are needed to maintain a patent airway. **Deep sedation**/analgesia - A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. Patients may need help in maintaining a patent airway.
Sentinel events	A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or **major and enduring loss of function** for a recipient of healthcare services. **Major and enduring loss of function** refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.
Staff	All personnel working in the organisation including employees, "fee-for-service" medical professionals, part-time workers, contractual personnel and volunteers.
Standards	A statement of expectation that defines the structures and process that must be substantially in place in an organisation to enhance the quality of care.
Sterilization	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.

Surveillance	The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.
Turn-around-time	Turnaround Time (TAT) means the amount of time taken to complete a process or fulfil a request.
Ultrasound Form A	Form of application for registration or renewal of registration of a genetic counselling centre/genetic laboratory/geneticclinic/ultrasoundclinic/ imaging centre.
Ultrasound Form B	Certificate of Registration.
Ultrasound Form C	Form For Rejection of Application For Grant/Renewal of Registration
Ultrasound Form D	Form For Maintenance of Records By The Genetic Counselling Centre
Ultrasound Form E	Form For Maintenance of Records By Genetic Laboratory
Ultrasound Form F	Form For Maintenance of Record In Respect of Pregnant Woman By Genetic Clinic/Ultrasound Clinic/Imaging Centre
Ultrasound Form G	Form of Consent
Ultrasound Form H	Form For Maintenance of Permanent Record of Applications For Grant/Rejection of Registration Under The Pre-Natal Diagnostic Techniques (Regulation And Prevention Of Misuse) Act,1994.
Validation	Validation is verification, where the specified requirements are adequate for the intended use.
Verification	Verification is the provision of objective evidence that a given item fulfils specified requirements.
Vision	An overarching statement of the way an organisation wants to be, an ideal state of being at a future point. This refers to the desired future state of an organisation. The vision describes where the organisation is headed, what it intends to be, or how it wishes to be perceived in the future.
Work Place Violence	Incidents where staff are abused, threatened or assaulted in circumstances related to their work, including commuting to and from work, involving an explicit or implicit challenge to their safety, well-being or health. (Adapted from European Commission)

List of Licenses and Statutory Obligations

1. License as per Atomic Energy (Radiation Protection) Rules, 2004 issued by AERB for all radiation equipment.
2. Building Permit (from the Municipal Corporation or appropriate body).
3. No objection certificate from the Chief Fire Officer.
4. License under Bio-Medical Waste Management Rules, 2016
5. License under the Air (Prevention and Control of Pollution) Act, 1981.
6. License under the Water (Prevention and Control of Pollution) Act, 1974.
7. Medical Termination of Pregnancy (MTP) Act, 1971.
8. License under Pre-Natal Diagnostic Techniques Act, 1996
9. Permit to operate lifts under the Lifts and Escalators Act.
10. Drugs & cosmetics Act, 1940.
11. License under Narcotic Drugs and Psychotropic Substacnes Act 1985.
12. License for possession and use of Rectified Spirit
13. Vehicle registration certificates for Ambulances under Motor Vehicle Act, 1988 (if applicable).
14. Electricity Act, 1998.
15. Sales Tax Registration certificate.
16. Permanent Account Number (PAN) under Income Tax Act 1961
17. The Employees' Provident Funds and Miscellaneous Provisions Act, 1952
18. The Employees' State Insurance Act, 1948.
19. Indian Medical Council Act, 1956
20. Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002
21. The Maternity Benefit Act, 1961 and ammedments thereon
22. Minimum Wages Act, 1948.
23. National Building Code of India 2016
24. Negotiable Instruments Act, 1881.
25. Payment of Bonus Act, 1965.
26. Payment of Gratuity Act, 1972.
27. Payment of Wages Act, 1936.
28. Persons with Disability Act, 1995.
29. Protection of Human Rights Act, 1993.
30. Public Provident Fund Act, 1968.
31. Sale of Goods Act, 1930.
32. Tax Deducted at Source (TDS) Act.
33. Sales Tax Act.
34. Scheduled Caste and Scheduled Tribe (Prevention of Atrocities) Act, 1989
35. Companies Act, 1956.
36. Urban Land Act, 1976.
37. The Central Goods and Services Tax Act 2017

Key Performance Indicators

The concept of performance in health services represents an instrument for bringing quality, efficiency and efficacy together. Performance represents the extent to which set objectives are accomplished. Performance is a multidimensional one, covering various aspects, such as evidence-based practice (EBP), continuity and integration in healthcare services, health promotion, orientation towards the needs and expectation of patients and family members.

Key Performance Indicators (KPIs) help to systematically monitor, evaluate, and continually improve service performance. By themselves, KPIs cannot improve performance. However, they do provide "signposts" that signal progress toward goals and objectives as well as opportunities for sustainable improvements.

Well-designed KPIs should help the organisation to do a number of things, including:

- Set performance standards and targets to motivate continual improvement
- Establish baseline information i.e., the current state of performance
- Measure and report improvements over time
- Compare performance across geographic locations
- Benchmark performance against regional and international peers or norms
- Allow stakeholders to independently judge health sector performance.

Medical Imaging Services (MIS) Centres are encouraged to capture all data which involves clinical and support services. The data needs to be analysed and risks, rates and trends for all the indicators have to be demonstrated for appropriate action.

The intent of the NABH KPIs is to have comprehensive involvement of the scope of services for which an MIS has applied for the accreditation program. Standardised definitions for each indicator along with numerator and denominator have been explained. Each MIS can have the data set measure, analyse the aggregated data and appropriate correction, corrective and preventive action can be formulated. Each MIS can also design their own methodology of data collection but a broad guidance note has been given to facilitate organisation's compliance.

A.Mandatory KPI's:

The following indicators needs to be monitored and submitted to NABH secretariat on a quarterly basis by all accredited MIS centres. Incase of any indicators being not applicable for an MIS, it may be indicated as such.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
1	IPI.2.k.	Outcome of Interventional Procedures		Number of patients who achieved the desired outcome of an intervention / Number of patients who underwent interventional procedures	X 100	Percentage	Monthly	Technical and clinical success as desired and complications like infections, etc. can be monitored in this.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
2	IPI.4.e.	Percentage of identity errors in dispatch of reports (right report, right patient, right clinician)		Number of errors / Number of reports dispatched	X 100	Percentage	Monthly	This should be done by prospective audit. The audit shall be done when the reports are being dispatched. A person(s) working at the dispatch desk could be entrusted with this responsibility. It is preferable that the identity of the person auditing is anonymised from the performing team.
3	FMS.1.i.	Critical Equipment Downtime	The term downtime is used to refer to periods when a system is unavailable. Downtime or outage duration refers to a period of time that a system fails to provide or perform its primary function	Sum of downtime for critical equipment in hours in a month		Hour	Monthly	This shall be monitored separately for each critical equipment.
4	EMM.3.d.	Contrast Reaction Rate	Any adverse reaction to the contrast injected shall be considered as a Contrast reaction. It may range from a mild allergic reaction (including chills/rigours) to life-threatening complications.	Number of contrast reactions / Number of patients who received contrast	X 100	Percentage	Monthly	Analysis can be done separately for mild, moderate and severe reactions.
5	EMM.3.d.	Contrast Extravasation		Number of contrast extravasations recorded / Number of patients received contrast using pressure injector		Hour	Monthly	This shall be monitored separately for each critical equipment.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
6	MSQ.2.c.	Turnaround time from completion of imaging till report ready for dispatch	Time taken to be calculated from the time the completion of the imaging procedure till the report is ready for dispatch.	Sum of time taken / Total number of imaging procedures performed		Minutes	Monthly	This shall be monitored separately for Routine, Urgent and Critical Imaging reports. For critical reports end point should the actual dispatch of the reports. This should be monitored separately for each modality and for teleradiology.
7	MSQ.2.g.	Patient Satisfaction Index	Patient satisfaction is defined in terms of the degree to which the patient's expectation are fulfilled. It is an expression of the gap between the expected and perceived characteristics of a service.	Average score achieved / Maximum possible score	X 100	Percentage	Monthly	The sample shall be derived from repeat patients. It is preferable who are coming to the MIS for the first time may not be included as it possible that they would not be in a position to give feedback on some aspects. The organisation could capture satisfaction for various individual parameters (as laid down in its feedback form). The index shall be calculated by averaging the satisfaction of various parameters.
8	MSQ.3.e.	Variations (Significant) in Peer Review of Imaging reports		Total number of significant variations observed in a imaging reports		Number	Monthly	Can be captured separately for each modality.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
9	MSQ.3.f	Percentage of reports correlating with Clinical Diagnosis	This shall be monitored at final diagnosis on follow-up/discharge/surgery)	Number of reports correlating with the final clinical diagnosis Number of reports sampled	X 100	Percentage	Monthly	The sample shall include cases that go for Surgery or Histopathological diagnosis. E.g., Correlation of tumour staging on imaging & on surgery
10	MSQ.3.h.	Patient Satisfaction Index	Referring Clinician satisfaction is defined in terms of the degree to which the referring clinician expectations are fulfilled. It is an expression of the gap between the expected and perceived characteristics of a service.	Average score achieved Maximum possible score	X 100	Percentage	Monthly	The sample shall be derived from regularly referring clinicians. The organisation could capture satisfaction for various individual parameters (as laid down in its feedback form). The index shall be calculated by averaging the satisfaction of various parameters.
11	MSQ.5.f.	Percentage of adherence to radiation safety precautions by staff working in diagnostics including TLD Usage		Number of staff adhering to radiation safety precautions Number of employees sampled	X 100	Percentage	Monthly	This shall be captured by doing an audit on a monthly basis. With template/ checklist covering all aspects of radiation safety precautions
12	MSQ.3.h.	Percentage of imaging records having inappropriate consent	Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risks and benefits, alternative procedure or treatment with their risks and benefits so as to enable the patient to take an informed decision of his/her healthcare.	Number of reports having improper consent Number of consents sampled	X 100	Percentage	Monthly	If any of the essential element/requirement of consent is missing it shall be considered as incomplete. If any consent obtained is invalid/void (consent obtained from wrong person/consent obtained by wrong person etc.) it is considered as improper.

B.Optional Clinical / Managerial Indicators

Although continual monitoring of the following indicators are required in other applicable objective elements, structured monitoring as key performance indicators can be done under MSQ.2.d. as identified priority indicators. Optional indicators should be chosen by the organization depending on its current priority requirement. Once managerial and one clinical indicator may be added to the mandatory KPI's in each cycle. Any other relevant KPI can also be identified and monitored.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
A	Optional Clinical Indicators							
1	AAPC.7.d	CPR Analysis		Total number of variations observed in actual CPR events		Number	Quarterly	
2	AAPC.8.f.	Percentage of Adverse Anaesthesia Events	Adverse Anaesthesia event is any untoward medical occurrence that may present during use of with an anaesthetic product but which does not necessarily have a casual relationship with this treatment	Number of patients who developed adverse anaesthesia eventsNumber of patients who underwent anaesthesia	X 100	Percentage	Monthly	
3	IPI.1.d.	Percentage Compliance to Imaging Protocols		Number of protocol violations/deviations occurred Number of procedures performed using a particular protocol chosen for monitoring	X 100	Percentage	Monthly	Any protocol violation/deviation that occurs based on an internal/external assessment finding shall be considered as happened. Analysis should include justified and unjustified deviations. This should be done for Interventional procedures also.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
4	IPI.3.h	Percentage of Reporting Errors		Number of reporting errors / Number of tests performed	X 100	Percentage	Monthly	This includes reporting errors picked up after dispatch. Reporting errors also include transcription errors. For better analysis, the organisation could capture the data separately for different Imaging modalities (for example, X-Ray/USG/CT/MRI). Further, the organisation could consider capturing data pertaining to reporting errors that were identified and rectified before the dispatch of the reports. This would enable the organisation to improve on its process. Although the indicator is collated on a monthly basis, immediate correction is to be initiated when such instances happen. This shall be monitored separately for each modality.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
5	HRM.2.e.	Incidence of needlestick injuries	Needlestick injury is a penetrating stab wound from a needle (or other sharp objects) that may result in exposure to blood or other body fluids. Needlestick injuries are wounds caused by needles that accidentally puncture the skin.	Number of parenteral exposures / Number of injections given	X 100	Percentage	Monthly	Parenteral exposure means injury due to any sharp.
6	MSQ.3.c.	Percentage of redos of imaging procedures		Number of redos / Number of imaging procedures done	X 100	Percentage	Monthly	This can be done separately for all imaging modalities.
7	MSQ.3.d	Percentage of reports with incomplete details		Number of reports having incomplete information / Number of reports generated	X 100	Percentage	Monthly	The incompleteness will be assessed against a checklist with all the parameters that need to be included in any report. This can be done as a sampling audit for one modality every month.
8	MSQ.2.d.	Adequacy of sample in imaging-guided biopsy / fine needle aspiration cytology procedures		Adequate samples / Total number of imaging-guided biopsies / FNAC's	X 100	Percentage	Monthly	This can be done separately for each modality and in each modality, it may be done for high throughput procedures

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
B	**Optional Managerial Indicators**							
1	MSQ.2.d.	Percentage of identity errors in performing imaging/procedures (right patient, right procedure, right side/site)		Number of errors recorded / Number of sampled imaging procedures.	X 100	Percentage	Monthly	This should be done by prospective audit. The audit shall be done when the imaging procedure is being performed. A person(s) working in the Modality could be entrusted with this responsibility. It is preferable that the identity of the person auditing is anonymised from the performing team. The appropriate sample size will be taken for one modality at a time in a month.
2	MSQ.2.d.	Number of variations observed in mock drills	A mock drill is a simulation exercise of preparedness for any type of event. It could be an event or disaster. This is basically a dry run or preparedness drill. For example, fire mock drill, disaster drill, Code Blue Drill, Global Pandemic preparedness drill.	Total number of variations observed in a mock drill		Number	Monthly	To capture the variation it is suggested that every organisation develop a checklist to capture the events during a mock drill. This shall also include tabletop exercises. This shall be done separately for each type of mock drill
3	MSQ.2.d	Patient Scheduling Time	It is the time from imaging request to the scheduled appointment for imaging	Sum of scheduling time / Total number of patients		Minutes	Monthly	Can be done separately for indoor/outdoor patients and separately for each modality.

S. No.	Standard	Indicator	Definition	Formula		Percentage	Frequency of Data Collation / Monitoring	Remarks
4	MSQ.2.d.	Percentage of rescheduling of planned procedures	Rescheduling of patients planned procedure includes cancellation and postponement of the procedure.	Number of procedures rescheduled / Number of procedures planned	X 100	Percentage	Monthly	This shall be monitored separately for each modality
5	MSQ.2.d.	Equipment Utilisation Time		Equipment utilisation time in hours / Working hours in a month		Hours	Monthly	This can be monitored separately for each equipment.
6	MSQ.2.d.	Percentage Stock out of Emergency Medications, supplies & material	A stockout is an event which occurs when an item listed as an emergency medication/supplies/material by the organisation is not available upon the requested need date in the organisation.	Number of stock-outs of emergency medication / supplies / material Number of emergency medications/supplies/materials listed in the formulary	X 100	Percentage	Monthly	To capture this, organisation should maintain a register in the MIS (stores) wherein all such events are captured. The organisation shall capture the number of instances. In one instance, it is possible that there was stock out of more than one item.
7	MSQ.2.d.	PMS not performed as scheduled		Number of PMS visits missed/delayed / Total number of PMS visits scheduled/planned		Percentage	Quarterly	This can be done separately for each modality

NATIONAL ACCREDITATION BOARD
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