GENERAL INFORMATION BROCHURE
FOR ACCREDITATION OF
MEDICAL IMAGING SERVICES

2010
Definition of Medical Imaging Services (MIS)

Medical Specialty that uses X-rays, gamma rays, high frequency sound waves, magnetic fields or isotopes to produce images of organs and other internal structure of the body. The specialty aims to detect & diagnose disease as well as to carry out interventional procedures to confirm the diagnosis and treat certain diseases and abnormalities.

Introduction

In recent decades medical imaging has experienced a technological revolution. Clinical advantages of these services are enormous and affect critical decision making at every stage of patient management. However they could represent unnecessary cost to health care systems in the country and could be hazardous if the quality provided is less than optimal. Hence to assess the quality and safety of medical imaging services and to represent a method for monitoring of quality standards, basic accreditation program needs to be implemented in the country for Medical Imaging Services. These standards reflect the expectation of good imaging radiology and nuclear medicine services from the view point of the service providers, that of patients; the referrers; as well as of safety regulatory bodies like AERB and PC-PNDT.

This document is a product of rigorous one year development process during which they have been through a number of iterations. The current standards reflect the professional judgment of the expert panels of radiologist, nuclear medicine physicians and medical imaging services providers. The standards have been externally evaluated by the panel of Radiologists as well as been subjected to a full public consultation exercise prior to their finalization. The process of formulating these standards is evolutionary and dynamic, and shall be kept updated as required.

These set of standards, cover all Medical Imaging Services including conventional radiation based diagnostic radiology as well as a wide variety of specialized techniques including Ultrasound scans, Doppler studies, Bone densitometry, CT, MRI, PET-CT, SPECT, Radionuclide imaging and therapy, Interventional procedures etc.
Introduction to Accreditation Program for Medical Imaging Services

A Medical Imaging Department in the Hospital or an Imaging centre must maintain certain standard of services (statutory or otherwise); as well as, strive for continuous improvement in the quality of services they provide. Close collaboration with clinical colleagues, verification of result as well as proper maintenance and calibration of the equipment are also a part of quality management in the department of medical imaging.

Standards for NABH Accreditation for Medical Imaging Services are divided into 6 chapters containing 23 standards and 95 objective elements. These standards provide general guidelines pertaining to all diagnostic and interventional imaging services. Specific guidelines for X-ray, Fluoroscopy, USG, CT scan, MR and Nuclear Imaging etc. are then provided in Section 2 (Guidance to the standard) of the document.

The standards are grouped into six chapters as follows:

CHAPTER 1 Control of Services
CHAPTER 2 Control of Imaging Processes and Procedures
CHAPTER 3 Control of Personnel
CHAPTER 4 Control of Equipment
CHAPTER 5 Control of Documents and Record
CHAPTER 6 Risk Control and Safety

For queries and further information:

Website: www.qcin.org

Contact:

Dr Zainab Zaidi
Assistant Director
NATIONAL ACCREDITATION BOARD FOR HOSPITALS & HEALTHCARE PROVIDERS (NABH)
Quality Council of India
Email: zainab@nabh.co
Medical Imaging Services Accreditation

What is Accreditation?

Accreditation is a public recognition by a National Healthcare Accreditation Body, of the achievement of accreditation standards by a Medical Imaging Service, demonstrated through an independent external peer assessment of that organization’s level of performance in relation to the standards.

Confidence in accreditation is obtained by a transparent system of control over the accredited center and an assurance given by the accreditation body that the accredited center constantly fulfills the accreditation criteria.

How Accreditation Assists in Improving Safety?

- Measures organizations’ compliance against standards of excellence: Quality & Safety
- Promotes teamwork - mobilizes teams & clinicians towards safety: More aware and participative in patient safety, own and team safety
- Increased capacity for managing quality improvement & Safety
- Improved communication, collaboration and team building
- Higher level of integration of services
- Provides organizations with critical path to achieve improvement
Benefits of Accreditation

Benefits for Patients

Patients are the biggest beneficiary among all the stakeholders. Accreditation results in high quality of care and patient safety. The patients are serviced by credential medical staff. Rights of patients are respected and protected. Patients satisfaction is regularly evaluated.

Benefits for Medical Imaging Service

Accreditation to a Medical Imaging Service stimulates continuous improvement. It enables Medical Imaging Service in demonstrating commitment to quality care. It raises community confidence in the services provided by the hospital. It also provides opportunity to healthcare unit to benchmark with the best.

Benefits for Medical Imaging Service Staff

The staff in an accredited Medical Imaging Service is satisfied lot as it provides for continuous learning, good working environment, leadership and above all ownership of clinical processes. It improves overall professional and skill development of Radiologists, Nuclear Physicians and Para Medical Staff.

Benefits to paying and regulatory bodies

Finally, accreditation provides an objective system of empanelment by insurance and other third parties. Accreditation provides access to reliable and certified information on facilities, infrastructure and level of care.
About NABH

National Accreditation Board for Hospitals and Healthcare Providers (NABH) is a constituent board of Quality Council of India (QCI), set up to establish and operate accreditation programme for healthcare organizations. NABH has been established with the objective of enhancing 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 Medical Imaging Service in a non-discriminatory manner regardless of their ownership, legal status, size and degree of independence.

Structure of QCI

The National leader in raising the bar for healthcare Quality and Safety

National Accreditation Board for Hospitals & Healthcare Providers (NABH)

National Accreditation Board for Education and Training (NABET)

National Accreditation Board for Testing and Calibration Laboratories (NABL)

National Accreditation Board for Certification Bodies (NABC)

National Board for Quality Promotion (NBQP)
NABH is operating accreditation program for following Services:

Specifically address:
- Patient Rights
- Access and Care of patients
- Infection Control
- Patient Safety
- Management

The Indian National Standards (NABH) have been benchmarked with international Accreditation standards (USA, UK, Australia):

- Hospitals
- Small HCOs
- Blood Banks
- NABH for Pathology Services
- Standards for Community Health Centers
- Standards for Imaging and Wellness Centres

Recently launched AYUSH & Wellness Centre Standards
Organizational Structure

National Accreditation Board for Hospitals and Healthcare Providers (NABH)

- Appeals Committee
- Accreditation Committee
- Technical Committee
- Secretariat
- Panel of Assessors & Experts
Organizational Structure

Accreditation Committee
The main functions of Accreditation Committee are as follows:
- Recommending to board about grant of accreditation or otherwise based on evaluation of assessment reports & other relevant information.
- Approval of the major changes in the Scope of Accreditation including enhancement and reduction, in respect of accredited hospitals.
- Recommending to the board on launching of new initiatives related to accreditation.

Technical Committee
The main functions of Technical Committee are as follows:
- Drafting of accreditation standards and guidance documents
- Periodic review of standards
- Recommending to the board on launching of new initiatives

Appeals Committee
The Appeal Committee addresses appeals made by the hospitals against any adverse decision regarding accreditation taken by the NABH. The adverse decisions may relate to the following:
- refusal to accept an application,
- refusal to proceed with an assessment,
- corrective action requests,
- changes in accreditation scope,
- decisions to deny, suspend or withdraw accreditation, and
- any other action that impedes the attainment of accreditation.
Organizational Structure

NABH Secretariat
The Secretariat coordinates the entire activities related to NABH Accreditation to Medical Imaging Service.

Panel of Assessors and Experts
NABH has a panel of trained and qualified assessors for assessment of Medical Imaging Service.

- **Principal Assessor**
  The Principal Assessor is overall responsible for conducting the pre-assessments and final assessments of the Medical Imaging Service.

- **Assessors**
  NABH has empanelled experts for assessment of Medical Imaging Service. They are trained by NABH on Medical Imaging Service accreditation and various assessment techniques. The assessors are responsible for evaluating the Medical Imaging Service's compliance with NABH Standards.
NABH Standards for Medical Imaging Service

NABH Standards for Medical Imaging Service prepared by technical committee contains complete set of standards for evaluation of Medical Imaging Service for grant of accreditation. The standards provide framework for quality of care for patients and quality improvement for Medical Imaging Service with the goal to improve diagnostic accuracy and safety, as well as, enhancing the overall patient experience. The standards help to build a quality culture at all level and across all the function of Medical Imaging Service.

Standards for NABH Accreditation for Medical Imaging Services are divided into 6 chapters. These standards provide general guidelines pertaining to all diagnostic and interventional imaging services. Specific guidelines for X-ray, Fluoroscopy, USG, CT scan, MR and Nuclear Imaging etc. are then provided in Section 2 of the document.

The standards are grouped into seven chapters as follows:

CHAPTER 1 Control of Services
CHAPTER 2 Control of Imaging Processes and Procedures
CHAPTER 3 Control of Personnel
CHAPTER 4 Control of Equipment
CHAPTER 5 Control of Documents and Record
CHAPTER 6 Risk Control and Safety
Assessment Criteria

A Medical Imaging Services willing to be accredited by NABH must ensure the implementation of NABH standards in its organization.

The assessment team will check the implementation of NABH Standards in organization. The Medical Imaging Services shall be able to demonstrate to NABH assessment team that all NABH standards, as applicable, are followed.

Medical Imaging Services (MIS) participating in accreditation program will be expected to provide following types of evidence:

- Statutory requirements for imaging services and facility.
- Approved documents that identify relevant service policy, protocols and/or strategies that set out, the service plans to deliver each standard statement and objective element therein.
- Evidence that demonstrate that the Medical Imaging service is implementing these policies, protocols and/or strategies.
- Practical demonstration of randomly selected procedures
- Evidence that demonstrates that the service is monitoring its performance regularly in the implementation of its policies, protocols and strategies
Preparing for NABH Accreditation

Medical Imaging Services management shall first decide about getting accreditation for its center from NABH. It is important for a Medical Imaging Services to make a definite plan of action for obtaining accreditation and nominate a responsible person to co-ordinate all activities related to seeking accreditation. An official nominated should be familiar with existing Medical Imaging Services quality assurance system.

Medical Imaging Services shall procure a copy of standards from the NABH Secretariat against payment. Further clarification regarding standards can be got from NABH Secretariat in person, by post, by e-mail or on telephone.

The Medical Imaging Services looking for accreditation shall understand the NABH assessment procedure. The Medical Imaging Services shall ensure that the standards are implemented in the organization.

The Medical Imaging Services can download the application form for NABH Accreditation from the web-site. The applicant Medical Imaging Services must have conducted self-assessment against NABH standards at least 3 months before submission of application and must ensure that it complies with NABH Standard for Medical Imaging Services.
Preparing for NABH Accreditation

1. Obtain a copy of NABH Standard for Medical Imaging Services (From NABH office)
2. Get accustomed to the standard & implement them (By organization)
3. Obtain a copy of Application Form (From NABH web site)
4. Fill and submit the Application (to NABH Secretariat)
5. Pay the Application fee
NABH Accreditation Procedure

1. Appln. for accreditation + Self-Assessment by MIS (By Medical Imaging Services)
2. Acknowledgment and Scrutiny of application (by NABH Secretariat)
3. Pre - Assessment visit (By Assessment Team)
4. Final Assessment of Medical Imaging Services (By Assessment team)
5. Review of Assessment Report (by NABH Secretariat)
6. Recommendation for Accreditation (by Accreditation Committee for MIS)
7. Approval for Accreditation (by Chairman, NABH)
8. Issue of Accreditation certificate (by NABH Secretariat)

Feedback
To Medical Imaging Services
And
Necessary Corrective Action Taken By Medical Imaging Services
NABH Accreditation Procedure

Application for accreditation:
The Medical Imaging Services shall apply to NABH in the prescribed application form. The application shall be accompanied with the following:
- Prescribed application fee as detailed in the application form
- Signed copy of ‘Terms and Conditions for Maintaining NABH Accreditation’, available free on the web-site
- Filled in Self Assessment Toolkit, available free on the web-site.
- Quality/ Medical Imaging Services Manual (as per NABH standards) and other NABH relevant documents i.e. different policies and procedures of the Medical Imaging Services

Self-Assessment toolkit is for self-assessing itself against NABH Standards. The self assessment shall be done by the Medical Imaging Services in a stringent manner and if at the time of pre-assessment it is found that there is a significant difference between the self assessment and the pre-assessment report then the organization shall apply for final assessment not earlier than six months from the date of completion of pre-assessment.

The applicant Medical Imaging Services must apply for all its facilities and services being rendered from the specific location. NABH accreditation is only considered for Medical Imaging Services entire activities and not for a part of it.

Scrutiny of application:
NABH Secretariat receives the application form and after scrutiny of application for its completeness in all respect, acknowledgement letter for the application shall be issued to the Medical Imaging Services with a unique reference number. The Medical Imaging Services shall be required to quote this reference number in all future correspondence with NABH.
Pre-Assessment:
NABH appoints a Principal Assessor/ Assessment Team who is responsible for pre assessment of Medical Imaging Services. NABH forwards the application form, documents, procedures, Self assessment toolkit to the Principal Assessor/ Assessment Team.

Objective of Pre-assessment:
- Check the preparedness of the Medical Imaging Services for final assessment
- Review the scope of accreditation and ascertain the requirement of the number of assessors and the duration of the accreditation
- Review of the documentation system of the Medical Imaging Services
- Explain the methodology to be adopted for assessment.

The Principal assessor shall submit a pre-assessment report in the format specified in the document ‘Pre-Assessment Guidelines & Forms’. Copy of the report is handed over to the organization after the assessment and original sent to NABH Secretariat.

The Medical Imaging Services shall be required to pay the requisite Annual fee before the final assessment.
Final Assessment:
The Medical Imaging Services is required to take necessary corrective action to the non-conformities pointed out during the pre-assessment. The final assessment involves comprehensive review of Medical Imaging Services functions and services. NABH shall appoint an assessment team. The team shall include Principal assessor (already appointed) and the assessors. The total number of assessors appointed shall depend on the scope of services. The date of final assessment shall be agreed upon by the Medical Imaging Services management and assessors. Assessment shall be conducted on Medical Imaging Services department and services.

Based on the assessment by the assessors, the assessment report is prepared by the Principal assessor in a format prescribed by NABH.

The details of non-conformity (ies) observed during the assessment are handed over to the Medical Imaging Services by the Principal assessor and detailed assessment report is sent to NABH.
Scrutiny of assessment report

NABH shall examine the assessment report. The report is taken to the accreditation committee. Depending on the score and compliance to standard would decided the award of accreditation or otherwise as per details given below.

Issue of Accreditation Certificate

NABH shall issue an accreditation certificate to the Medical Imaging Services with a validity of three years. The certificate has a unique number and date of validity. The certificate is accompanied by scope of accreditation.

The applicant Medical Imaging Services must make all payment due to NABH, before the issue of certificate.

All decision taken by NABH regarding grant of accreditation shall be open to appeal by the Medical Imaging Services, to chairman NABH.
Surveillance and Reassessment

Accreditation to a Medical Imaging Services shall be valid for a period of three years. NABH conducts surveillance of the accredited Center in one accreditation cycle of three years. The surveillance visit will be planned during the 2nd year i.e. after 18 months of accreditation.

The Medical Imaging Services may apply for renewal of accreditation at least six months before the expiry of validity of accreditation for which reassessment shall be conducted.

NABH may call for un-announced visit, based on any concern or any serious incident reported upon by an individual or organization or media.
Financial Term and Conditions

General information brochure : Free of cost
Application form for Medical Imaging Services : Free of cost
Self assessment toolkit : Free of cost
NABH Standards for Medical Imaging Services accreditation : Rs. 1000/-

Application fee and NABH Accreditation charges:

<table>
<thead>
<tr>
<th>Practice Category (based on no. of modalities present)</th>
<th>Assessment Criteria</th>
<th>Accreditation Fee</th>
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<tbody>
<tr>
<td></td>
<td>Pre-assessment</td>
<td>Assessment</td>
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<tr>
<td></td>
<td>One man day</td>
<td>Two man days (2x1)</td>
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<tr>
<td>Small Practice, 1 modality</td>
<td>One man day</td>
<td>Two man days (2x1)</td>
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<tr>
<td>Medium Practice, 2 modalities</td>
<td>One man day</td>
<td>Two man days (2x1)</td>
</tr>
<tr>
<td>Large Practice, 3 or more than 3 modalities</td>
<td>Two man days (2x1)</td>
<td>Four (2x2) man days</td>
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NOTE: The man days given above for pre-assessment, final assessment and indicative and may change depending on the facilities and size and
Notes on Accreditation fee:

- The accreditation fee does not include expenses on travel, lodging/boarding of assessors. These expenses are to be borne by the hospital on actual basis.
- The application fee includes pre-assessment charges.
- The first annual fee is payable after pre-assessment visit and before assessment visit.
- 10% discount will be admissible in case Medical Imaging Services pay for the accreditation fee for three years in one installment.