"ASSESS THE COMPLIANCE OF NUCLEAR MEDICINE DEPARTMENT TO NABH STANDARDS"

A Dissertation submission in partial fulfilment of the requirements
for the award of

Post-Graduate Diploma in Health and Hospital Management

by

Dr. Kanika Sharma

International Institute of Health Management Research

New Delhi - 110075

May, 2013

SUMMER PLACEMENT IN NATIONAL HEART INSTITUTE

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Certificate of Internship Completion **Date:** 30/4/13

TO WHOM IT MAY CONCERN

This is to certify that Dr. KANIKA SHARMA has successfully completed her 3 months internship in our organization from January 11, 2013 to April 30, 2013. During this internship she has worked on COMPLIANCE OF NUCLEAR MEDICINE DEPARTMENT TO NABH STANDARDS under the guidance of me and my team at IINMAS. During the time of internship she was found hardworking, sincere and dedicated. We wish her good luck for her future assignments

A Pandey
(Signature)

Dr. A PANDEY **(Name)**

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Certificate of Approval

The following dissertation titled **"Compliance of Nuclear Medicine department to NABH standards"** is hereby approved as a certified study in management carried out and presented in a manner satisfactory to warrant its acceptance as a prerequisite for the award of **Post- Graduate Diploma in Health and Hospital Management** for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation

Name	Signature
DR. BRIJENDER SINGH DHILLON	2/5/13

Certificate from Dissertation Advisory Committee

This is to certify that **Dr.Kanika Sharma** a graduate student of the **Post-Graduate Diploma in Health and Hospital Management** has worked under our guidance and supervision. She is submitting this dissertation titled **"Compliance of Nuclear Medicine department to NABH standards"** in partial fulfilment of the requirements for the award of the **Post- Graduate Diploma in Health and Hospital Management**.

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

Faculty Mentor	Organizational Advisor
Designation	Designation CENTRE HEAD
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FEEDBACK FORM

Name of the Student: Dr KANIKA SHARMA

Dissertation Organisation: IINMAS, NHI

Area of Dissertation: Nuclear medicine Department

Attendance: 80%

Objectives achieved: Efficiently met.

Deliverables: Compliance of nuclear medicine dept to NABH standards (Project)

Strengths: Communication Skills, Sincere.

Suggestions for Improvement: Time management.

Signature of the Officer-in-Charge/ Organisation Mentor (Dissertation)

Date: 30/4/13
Place:

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I would like to extend my heartfelt gratitude towards all the personnel at "National Heart Institute" who helped me get through this project.

This project would never have been possible without those who went out of their way to help me.

I start expressing my sincere gratitude to **Dr. Awadhesh Pandey** who gave me the opportunity to work in this renowned organization.

Sincere thanks to all staff at all levels, for helping me at each and every step of my work. Heartiest gratitude to them for making my stay and work at this place a memorable one.

Last but not the least I would like to thank my institution, my faculty members and my mentor **Ms**. **Kirti Udayai** without whose guidance this project would have been a distant reality.

Kanika Sharma

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Part – I

INTERNSHIP REPORT

1.1 NATIONAL HEART INSTITUTE

National Heart Institute, brain child of doyen of Cardiology in India, Dr. S. Padmavati, was inaugurated in 1981 by the then Prime Minister of India, Mrs.Indira Gandhi, as the Clinical Research and Medical Care Delivery wing of All India Heart Foundation, with the aim of providing State-of-art Modern Cardiac Care Technology to the financially impoverished section of the society. It was intended to be a self sufficient, stand alone facility and therefore it was decided that people with paying capacity should also be taken up and the surplus generated from them be channelized for the treatment of the poor.

The National Heart Institute is the Research & Referral tertiary care Heart Hospital of the All India Heart Foundation, which acts as a nucleus for diagnosis and treatment of heart ailments and allied diseases and is equipped with state of the art equipments. Surgical services include all kinds of closed and open Heart Surgeries like Coronary Artery Bypass Surgery, off pump bypass surgery (beating heart surgery), valve repair & replacement surgeries, aortic / carotid

surgeries, congenital heart surgeries including blue babies and minimally invasive (Key hole) surgeries. It has modern Cath lab facilities where procedures like Angiographies, Angioplasties, Stenting of the Coronary arteries, valvotomies correction of birth heart defects and closure of holes of the heart, Electrophysiological studies, Radio Frequency ablation, Rotablation, Intra-vascular ultrasound, pacemaker and internal defibrillator implantation are carried out. Highly qualified staff trained in India & abroad, with extensive experience in Cardiology & Cardiac Surgery service these areas.

Apart from indoor treatment, the Institute also provides comprehensive medical check-up, i.e. Executive health check-ups, at nominal rates with a view to ensuring good physical conditioning and health of all individuals. Cardiac patients with other ailments are also admitted to this hospital, as specialists for diseases other than heart are available round the clock for consultation and treatment.

The Institute has been recognized for open heart surgeries, coronary artery bypass surgery, angiography and angioplasties and other specialized cardiac treatment by the Central Govt. Health Scheme (CGHS), Employees State Insurance (ESI), and Employee Contributory Health Scheme (ECHS), besides the Governments of Himachal Pradesh, Haryana, Madhya Pradesh, Mizoram and Govt. of NCT of Delhi. Ministry of Defense, Office of the Director General of Armed Forces Medical Services and Directorate General of Medical Services Naval Headquarters has recognized NHI for treatment of their employees and their families. 122 Public sector bodies, almost all the TPAs and International Organizations like World Health Organization & UNICEF are also empanelled with the National Heart Institute.

Keeping in tune with its ethos of service to the humanity, National Heart Institute carries out regular Community outreach programmes (heart camps) and also ‘Executive Health Checks’ and ‘Recruitment Checks’ to detect cardiac problems early and take remedial action.

National Heart Institute is recognized by National Boards for post doctoral training and runs an active teaching and training programme in the specialties of Cardiology & Cardiovascular & Thoracic Surgery. It also carries out research in all facets of Cardiology & Cardiac Surgery. National Heart Institute is recognized as a Collaborative Centre of WHO in Preventive Cardiology since 1983. It is an affiliate of the World Hypertension League and Heart Beat International. National Heart Institute lays special emphasis on "Lifestyle

Disorders" and caters to outdoor consultation, education and counseling on Diabetes, obesity, cholesterol related diseases, thyroid disorders, alcohol and smoking. Indoor care for Diabetes & Lifestyle disorders are taken care of the hospital has a department of Pulmonologist and Sleep Medicine which is equipped with sophisticated machines and is manned by dedicated Pulmonologists, Thoracic Surgeons and Physiotherapists.10% indoor beds are earmarked for poor patients having monthly income of Rs.4000/- and below and the hospital regularly provides free treatment to such patients and lots many at subsidized rates. The hospital also runs free OPDs for two hours on all working days. In collaboration with Heartbeat International; the hospital provides free Cardiac Pacemakers for needy patients.

1.2 Nuclear medicine department in National Heart Institute has been outsourced to **IINMAS.**

Indian Institute of Nuclear Medicine and Scanning has 6 centres at Delhi, Chandigarh, Amritsar, Jalandhar, Dehradun & Vishakhapatnam headed by Dr.Awadesh Panday. The Delhi centre was started in September 2009.

1.2(a) Location: Within premises of the hospital but outside the hospital building adjacent to the canteen & pharmacy.

1.2(b) Lay-out: The department comprises of –

- Scan room
- Console room
- Reception/Front desk
- Doctors lounge
- Patient waiting area

- Reserve room
- Radio-pharmaceutical lab

1.2(c) Employees: 1 Centre head

1 Manager Operations

3 Management trainees

2 Technicians (shift duty)

1 Class IV employee

1 Driver

1.2(d) Types of nuclear scan:

- Bone Scan
- Stress Thallium
- Muga (Stress/Rest)
- DTPA / Renal dynamic study
- DMSA
- Captopril Renal Scan

1) DRCG
2) HIDA
3) GI-Bleed
4) GE Reflux
5) VQ Scan
6) Gallium Scan
7) EC Scan
8) Brain Spect
9) Thyroid scan
10) Para-thyroid scan

Radio-Iodine ablation therapy

1.2(e) Process flow of the department:

Patient enters the department

↓

Registration/Billing + History taking

↓

Injection of radiopharmaceutical to the patient

↓

Waiting time for radiopharmaceutical to be absorbed into the body (different for different scans)

↓

Scanning of patient

↓

Report generation within 2hrs after completion of scan

1.3 TASKS:

1.3(a) To prepare the department for NABH mid-inspection to be held in January end or beginning of February tentatively.

1.3(b) Routine tasks:

Patient registration
Patient history taking
Camera handling
Console machine operation
Taking nuclear medicine scans
Processing of scans
Reporting of scans

Elusion (preparation of radioactivity)

Labeling (preparation of radiopharmaceuticals)

Injecting radiopharmaceuticals to patients (IV injections)

Visits to ECHO lab for Stress Thallium patients.

1.4 Reflective learning

The learning that I extracted from the experience not only enriched me in terms of providing knowledge as to how an established private hospital runs but also gave me insights into my ownself,imparting priceless lessons of patience, dedication and importance of good behavioral communication.

Part – II

Dissertation report "ASSESS COMPLIANCE OF NUCLEAR MEDICINE DEPARTMENT TO NABH STANDARDS"

CHAPTER 1: INTRODUCTION

1.1 Nuclear medicine is a medical specialty involving the application of radioactive substances in the diagnosis and treatment of disease. In nuclear medicine procedures, radionuclide are combined with other elements to form chemical compounds, or else combined with existing pharmaceutical compounds, to form radiopharmaceuticals. These radiopharmaceuticals, once administered to the patient, can localize to specific organs or cellular receptors. This property of radiopharmaceuticals allows nuclear medicine the ability to image the extent of a disease process in the body, based on the cellular function and physiology, rather than relying on physical changes in the tissue anatomy.[1]

Nuclear Medicine is a branch of medical science where radionuclides are used for diagnosis and treatment of human diseases. Discovery of artificial radioactivity and development of nuclear reactors and particle accelerators have played a significant role in radiotracer technology. Nuclear medicine imaging and non-imaging procedures provide important information about functional status of the body organs. Radionuclides are also used for therapy of malignant and non-malignant conditions. A lot of progress has taken place over the past few years in therapeutic nuclear medicine. With the use of suitable radiopharmaceuticals targeted therapy is also possible. In nuclear medicine imaging, radiopharmaceuticals are taken internally, for example intravenously or orally. Then, external detectors (gamma cameras) capture and form images from the radiation emitted by the radiopharmaceuticals. This process is unlike a diagnostic X-ray where external radiation is passed through the body to form an image.[2]

Giving larger radiation exposures can reduce the noise in an image, and make it more photographically appealing, but if the clinical question can be answered without this level of detail, then this is inappropriate. The radiation dose from nuclear medicine imaging varies greatly depending on the type of study. The effective radiation dose can be lower than, or comparable to, or can far exceed the general day-to-day environmental annual background radiation dose. The end result of the nuclear medicine imaging process is a "dataset" comprising one or more images. In multi-image datasets the array of images may represent a time sequence (i.e. cine or movie) often called a "dynamic" dataset, a cardiac gated time sequence, or a spatial sequence where the gamma-camera is moved relative to the patient. SPECT (single photon emission computed tomography) is the process by which images acquired from a rotating gamma-camera are reconstructed to produce an image of a "slice" through the patient at a particular position. A collection of parallel slices form a slice-stack, a three dimensional representation of the distribution of radionuclide in the patient.[1]

In Nuclear Medicine (NM), the diagnostic and therapeutic procedures using unsealed radioisotopes shall be carried out only in a facility approved by the **Atomic Energy Regulatory Board (AERB)**. The approved nuclear medicine facility should not be located in the residential building and shall comply with all the regulatory requirements as specified in the AERB safety code on nuclear medicine facilities.[3]

The various stages of approval of nuclear medicine facility by AERB are given as follows:

1. Site and Layout Plan Approval
2. Application for Authorization for Commissioning of the Facility
3. Pre-commissioning Inspection.
4. Approval for Commissioning / Routine Operation.
5. Decommissioning.

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.[4]

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 are also provided.

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

1.2 PROBLEM STATEMENT:

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.[5]

It has been estimated (UNSCEAR, 2000) that worldwide there are about 2000 million x-ray studies, 32 million nuclear-medicine studies and over 6 million radiation therapy patients treated annually, and the numbers are constantly increasing.

The use of radiation for medical diagnostic examinations contributes over 95 % of the manmade radiation exposure and is only exceeded by natural background as a source of exposure (UNSCEAR, 2000)[6.]

NHI got NABH accreditation in August 2011. The mid-term inspection was to be held in the end of January or beginning of February. Nuclear medicine department is AERB approved but not NABH accredited. In pursuit of this the management directed us to prepare the department for NABH audit.

1.3 RATIONALE:

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[4].

1.4 REVIEW OF LITERATURE:

A. Theories and Practice of Radiation Safety in Nuclear Medicine

Alan Vespie, MED, CNMT, RT (N) Safety issues in nuclear medicine are numerous and may involve hazardous material issues, infection control, patient care, and radiation safety. Although all these safety issues are relevant in the daily duties of nuclear medicine technologists, radiation safety issues are perhaps the most pervasive and hence, most influential in the duties of technologists. This article will serve as a refresher course for experienced technologists, a study aid for technologists in training and an educational tool to the layperson. The topics covered will include the nature of radioactivity, the biological

effects of radiation, and finally, radiation safety precautions the nuclear medicine technologist can take to minimize radiation exposure. The three most important methods for reducing radiation exposure are time, distance, and shielding. Regarding time, the technologist should minimize time spent near radioactive sources. However, because patients are themselves a source of radiation, special care needs to be taken to minimize exposure without alienating the patient. This means that technologists need to learn to work quickly, efficiently, and accurately. Repeating one's work may be annoying to the technologist, patient, and physician, but it also increases the amount of exposure time. Strive to perform procedures correctly the first time. If practical, rehearse new or infrequently performed tasks before working with the radioactivity.

B. **Radiation protection in Nuclear Medicine: a review on present situation in Sri Lanka**

Manjula Hettiarachchi Senior Lecturer in Nuclear Medicine, Faculty of Medicine, University of Ruhuna, Karapitiya, Galle.

The principles followed in the radiation safety measurement ensure that workers and members of the public are not exposed beyond the specified limits as directed by the competent authority, follow the ALARA (As Low As Reasonably Achievable) principle, ensure safe handling and security of the radiopharmaceuticals, patient protection and waste management along with handling radiation emergencies. This is to ensure safety of persons handling radiation sources for medical applications, patients undergoing medical procedures, persons connected with the patient living with him and members of public unrelated to medical use of radiation. Following steps have been taken to ensure Maximum safety:

- Distribute the responsibilities among the occupational personal: Occupational personals (radiation safety officer (RSO), radiation safety supervisor (RSS), technical and other staff) are assigned with job descriptions and responsibilities along with radiation protection concept.

- Classification of areas: Units classify three areas in view of reducing the risk of radiation hazard as ALARA by proper instructions on billboard, labeling (Caution! Radiation Area, Caution! Radioactive Material, Caution! Controlled Area, etc).General patients and the attendants are seated in separate areas from the injected patients (Supervised area); Only

those who needed imaging and uptake are allowed to enter ‘Controlled area’ and no one is allowed to enter ‘Restricted area’ without proper authorization.

- Immediate notification to the competent authority in case of any inadvertent spillage and contamination after ensuring all appropriate decontamination measures.

Radioactivity survey on all working areas could be conducted once a week and documented.

C. **A comparative study of radiation safety practices at selected hospitals in the UK and USA**.White DR, Showalter CK, Hamilton DR.

The radiation safety practices in a group of 25 UK and USA hospitals have recently been assessed. This took the form of detailed inspections of some 62 medical radiation departments, including Diagnostic X-ray, Radiotherapy, Nuclear Medicine and Pathology/Research (Radionuclide) Departments. Empirical expressions called "Radiation Safety Indices" were devised to evaluate the incidence of personal doses and radiological incidents occurring from 1977-82 and to characterise the safety facilities, procedures, supervision and educational techniques in each department. An outline is given of national legislative material and voluntary codes of conduct, together with the results of the departmental inspections. The computed indices are presented graphically and an analysis given of apparent national trends.

1.5 OBJECTIVES

General objective:

General objective of the study is to assess compliance of Nuclear medicine department with respect to NABH standards.

Specific objectives:

1. To prepare a checklist to assess compliance of the nuclear medicine department to

NABH standards.

2. To find out the gaps & suggest recommendations for non-compliance factors.
3. To implement the recommendations in confirmation with the management.

CHAPTER 2: METHODOLOGY

2.1 Study Area: Nuclear medicine department, NHI

2.2 Study period: 11th Jan2013- 30th April 2013

2.3 Sample design: Descriptive and Cross sectional study

2.4 Data collection Tools: Checklist

2.5 Techniques: Observation

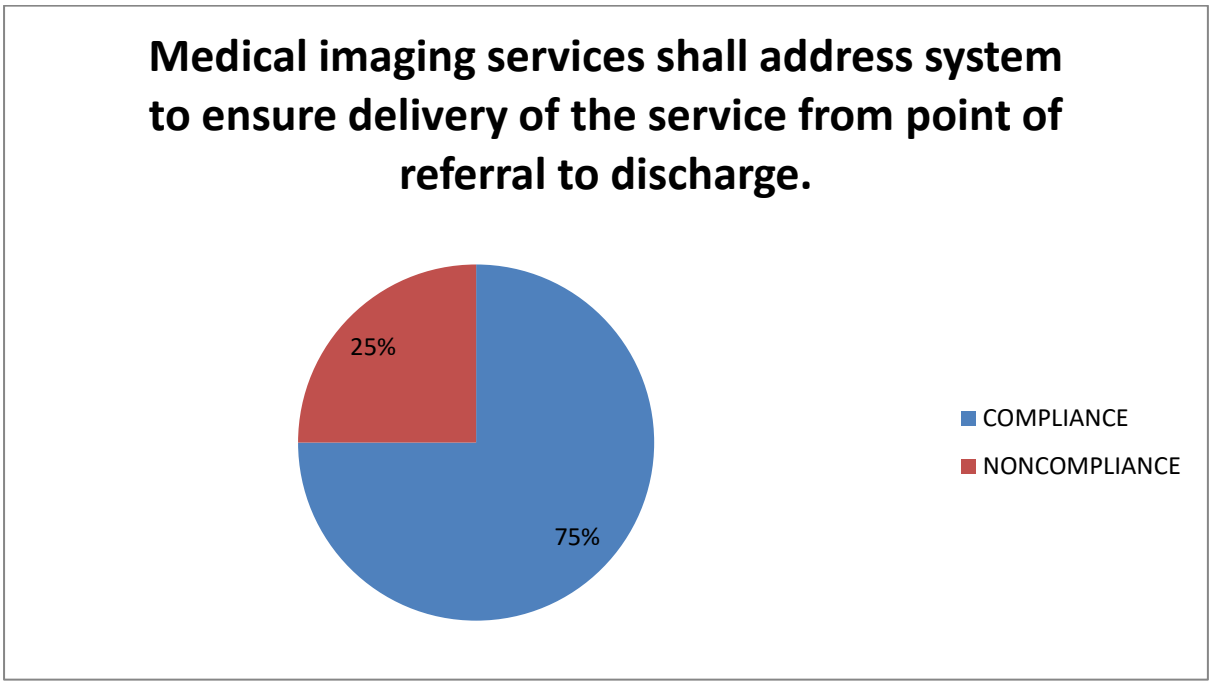
Interview of staff

Screening of documents of the department

CHAPTER 3: RESULTS & FINDINGS:

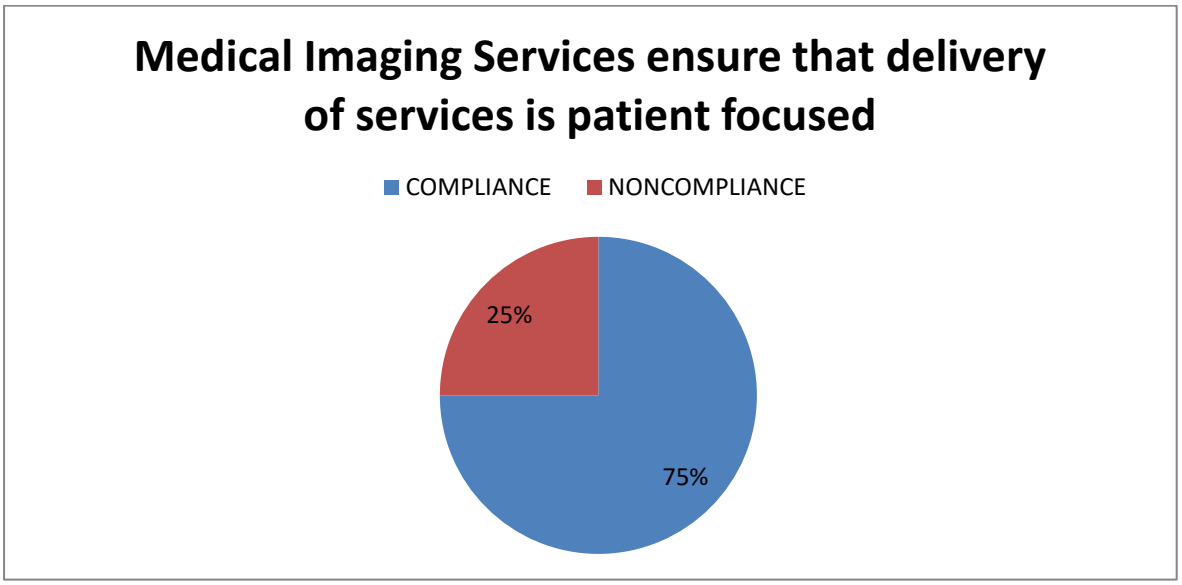
Figures:

Fig.3 a)



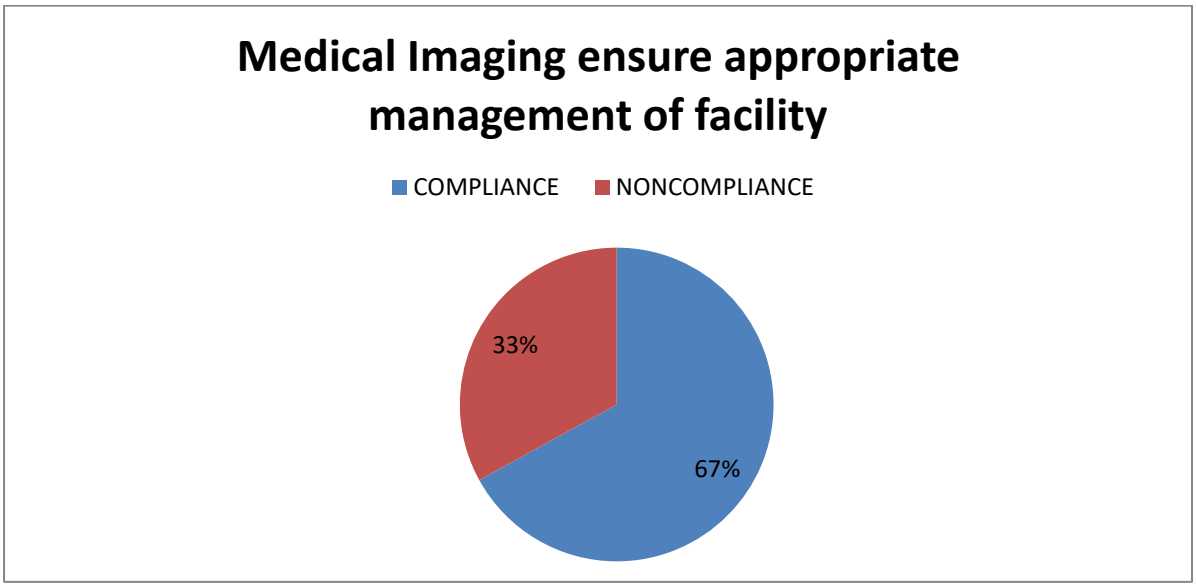
On the basis of analyzing the checklist for assessment of compliance to the set norms by NABH it was found that there is 75% compliance in delivering the services to the patient from point of referral to discharge. 25% non compliance was seen that there was no written protocol for imaging processes. It was also seen that time frame to manage imaging pathways from receiving of referral to discharge was not documented.

Fig.3 (b)



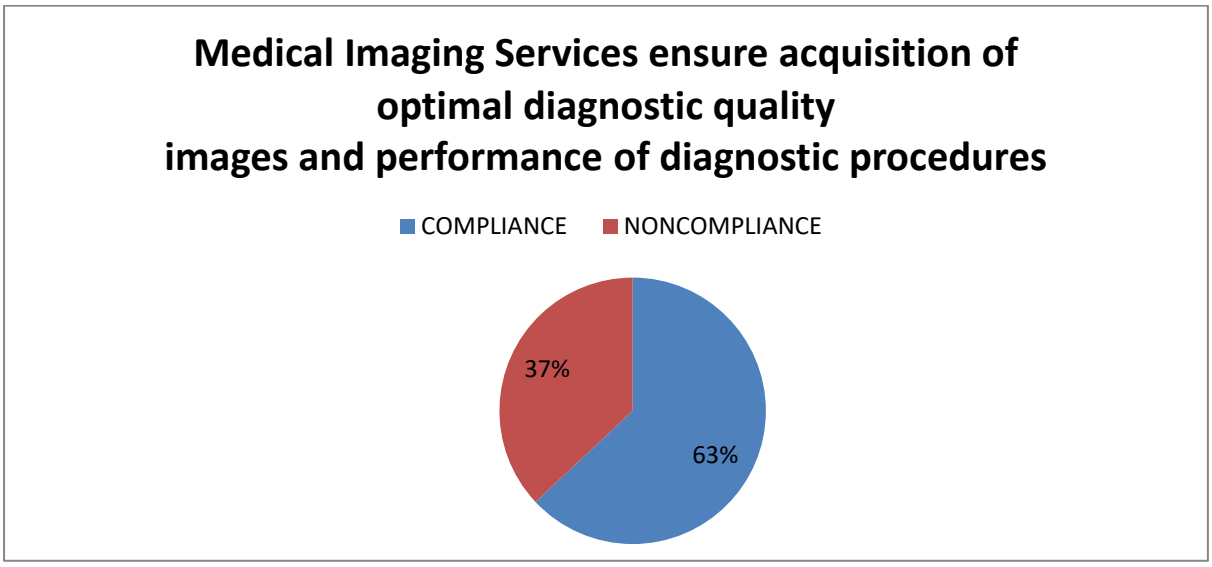
Further it was evaluated that 75% compliance is seen in the delivery of services being patient focused. It was observed that no information about specific procedure was displayed for patients and attendants in relevant format and language. Also patient's feedback is not taken which contributes to 25% noncompliance in the delivery of services.

Fig.3(c)



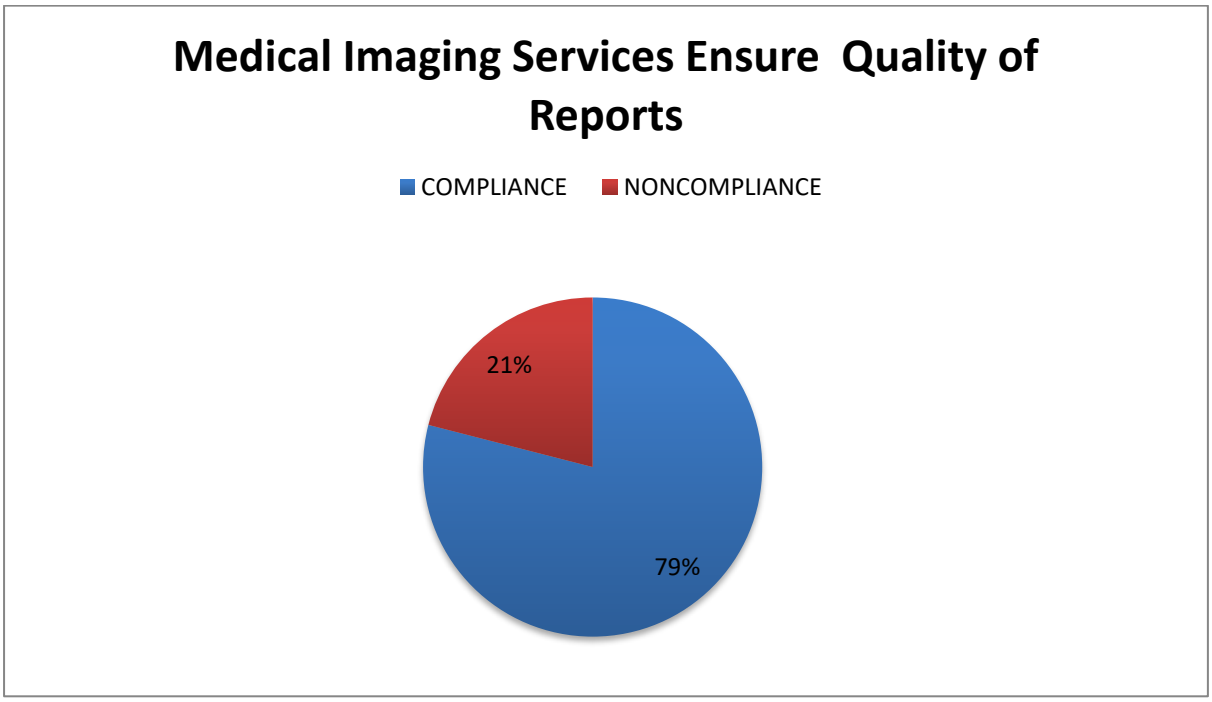
67% compliance level was found in ensuring appropriate management of facility. 33% lack was observed as a provision for low-dose active patient waiting has not been made in the Department. The approved active waiting patient waiting area is used as general waiting area also. The approved dose administration room is being used for general purpose & the dose administration is found to be carried out in the Imaging room. There is no separate Decontamination room for radioactive waste disposal, it is being kept in RP laboratory for decay and delay.

Fig.3 (d)



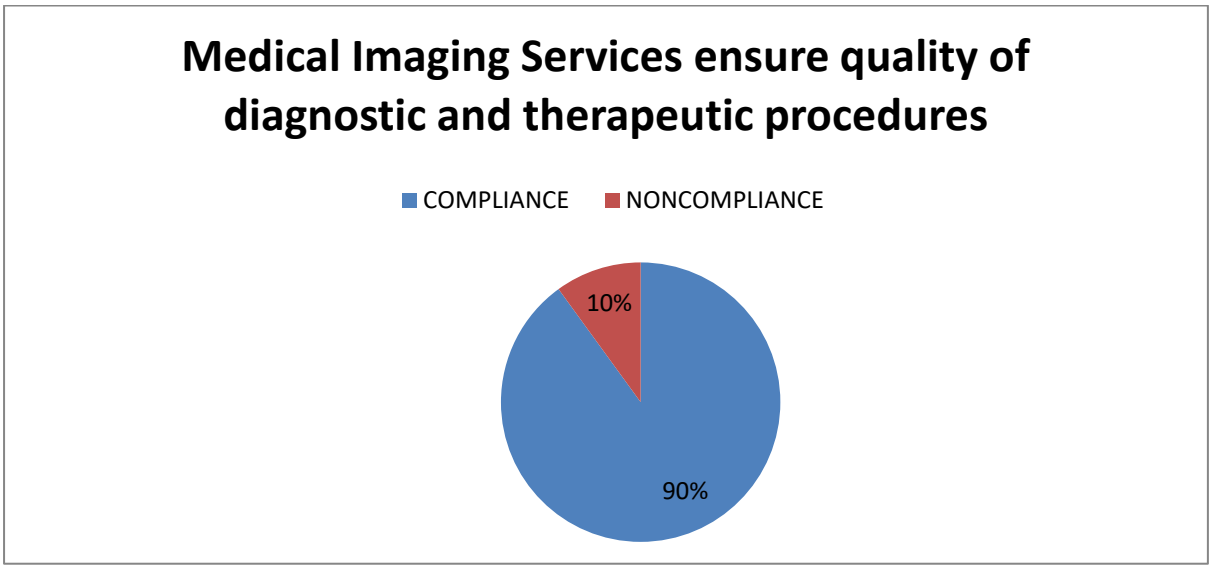
There is only 63% compliance towards ensuring acquisition of optimal diagnostic quality images and performance of diagnostic procedures. 37% non compliance is observed as the protocols for image acquisition for all examinations are not documented. No feedback on images and procedures is done through documented process of internal verification & external validation.

Fig.3 (e)



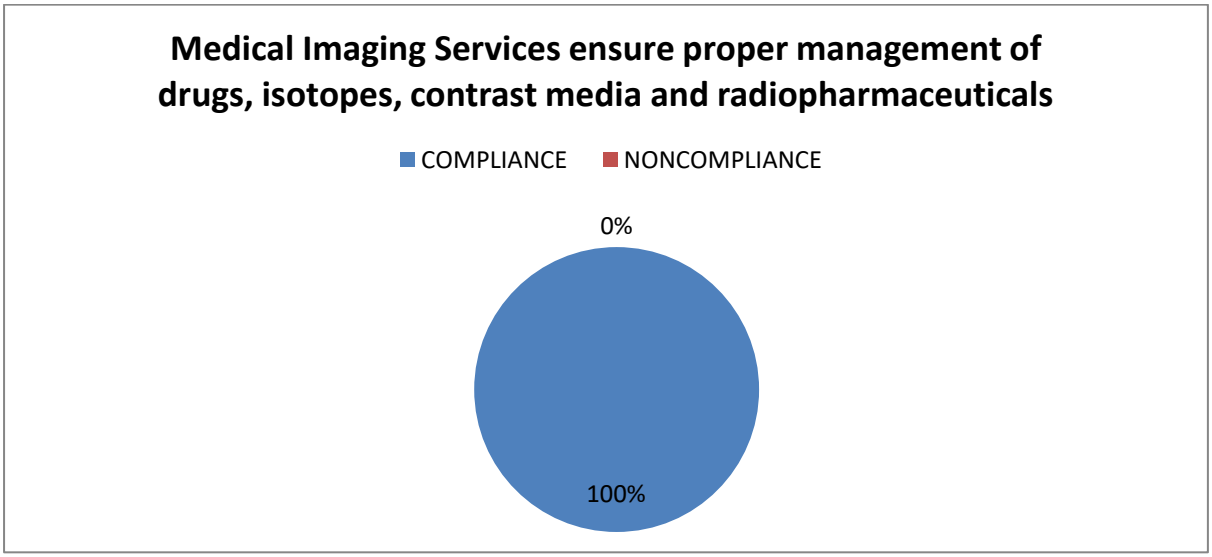
The main reason for noncompliance is not ensuring analysis of feedback from Referrer/Professional colleagues on the content and quality of reports through defined & documented process.

Fig.3 (f)



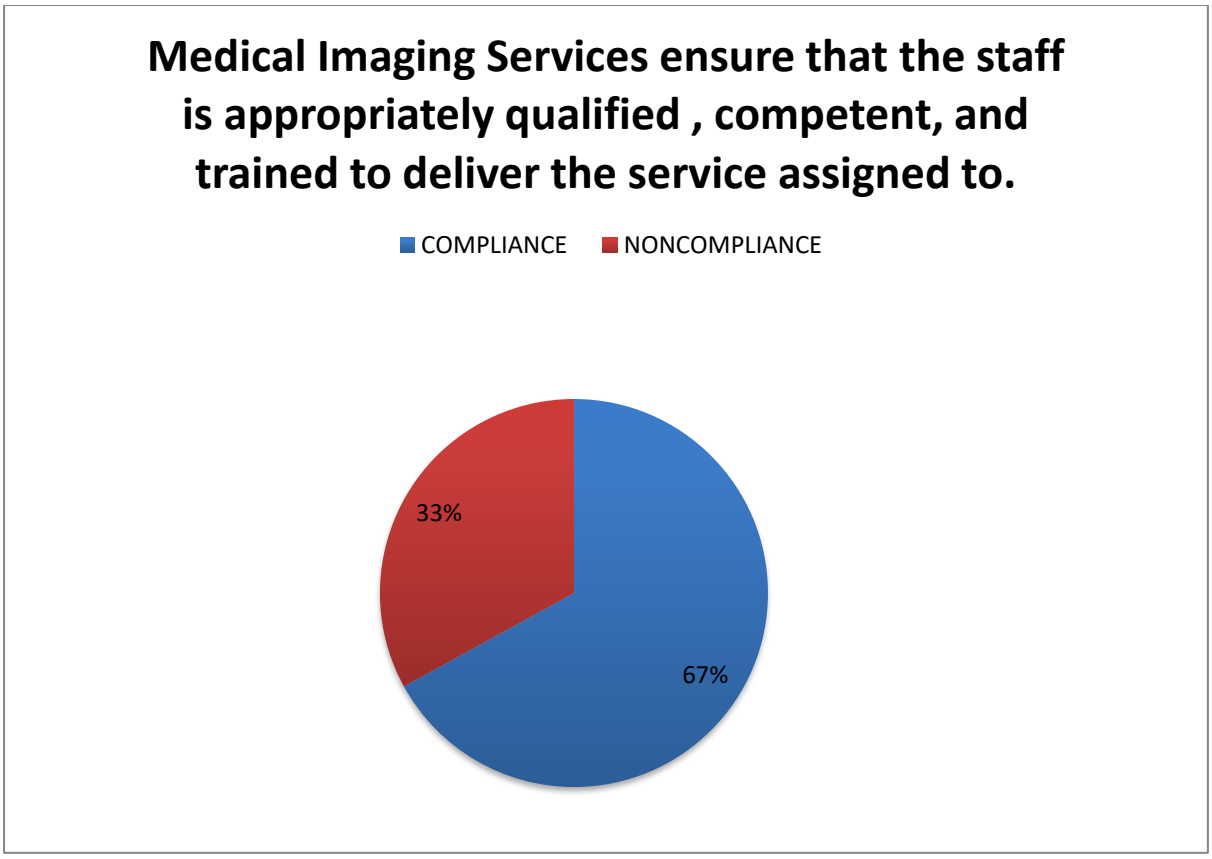
10% non compliance was found in ensuring quality of diagnostic and therapeutic procedures as the protocols for all diagnostic and therapeutic interventional procedures were not defined and documented.

Fig.3 (g)



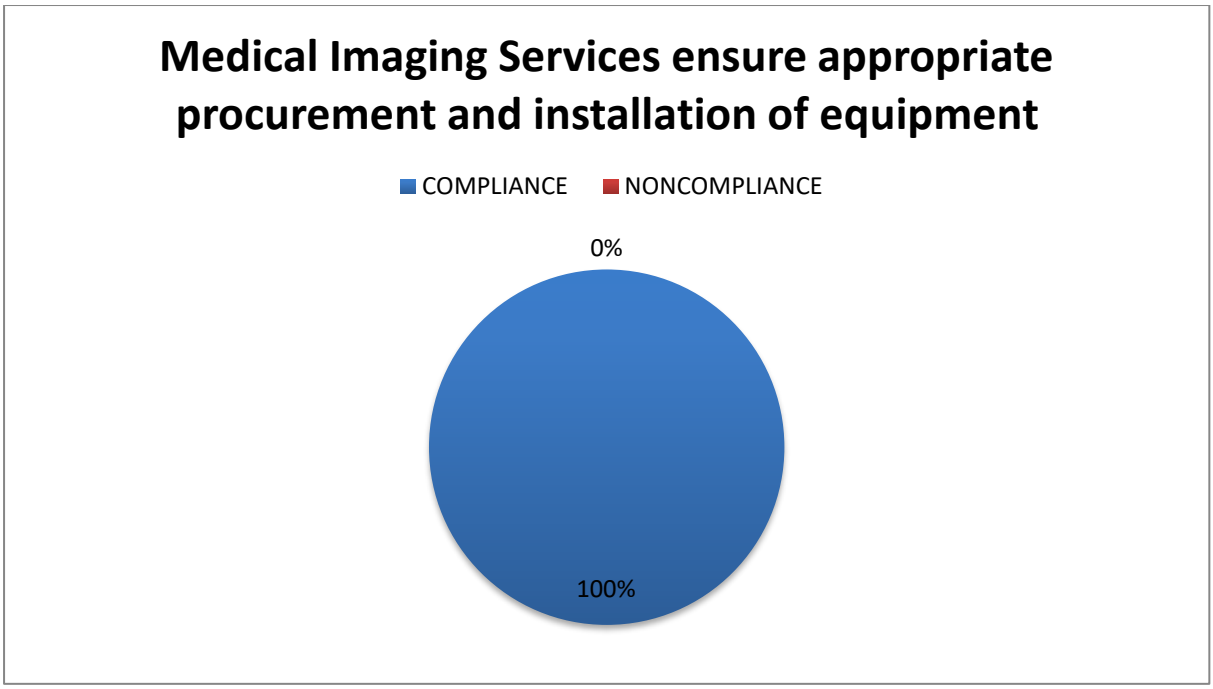
100% compliance was observed in ensuring the protocols for administration of drugs, isotopes, and contrast media and radio pharmaceuticals to the patients.

Fig3 (h)



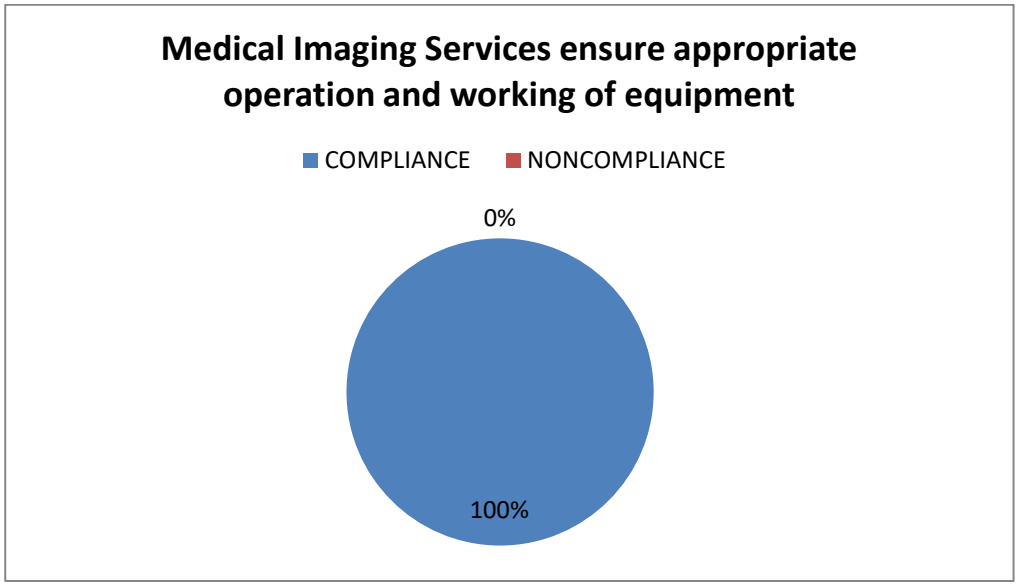
There is 33% non compliance level seen in documentation and implementation of policies and procedures for selection, recruitment, retention and succession planning of staff.

Fig.3 (I)



There was 100% compliance observed in procurement & installation of equipments. All documentation was up-to-date.

Fig.3 (j)



It was seen that policies and procedures for operation and calibration of equipment were defined and implemented and also records were maintained.

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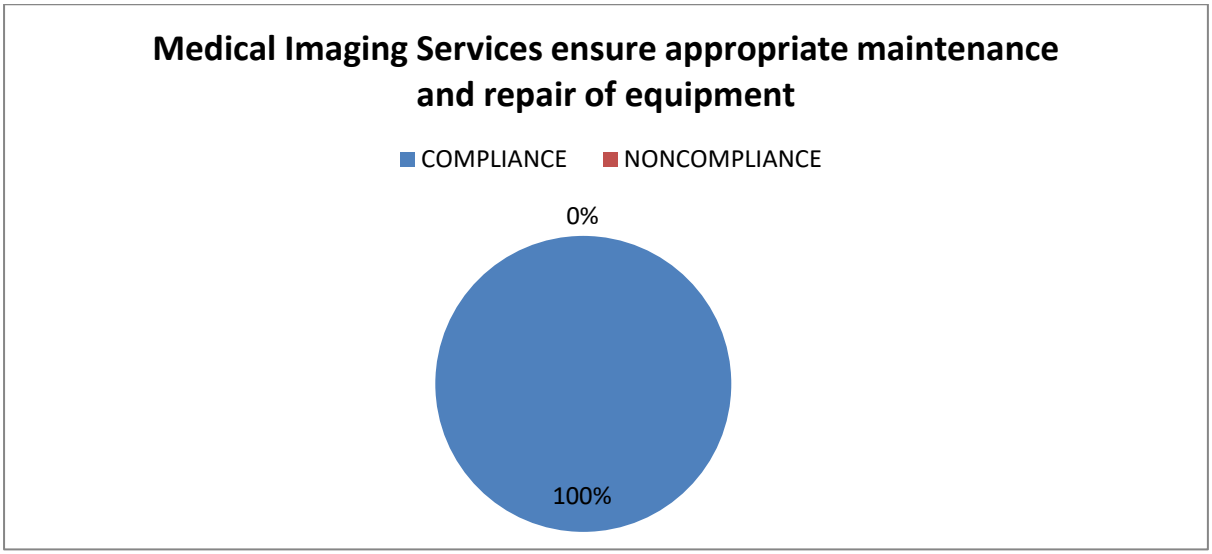
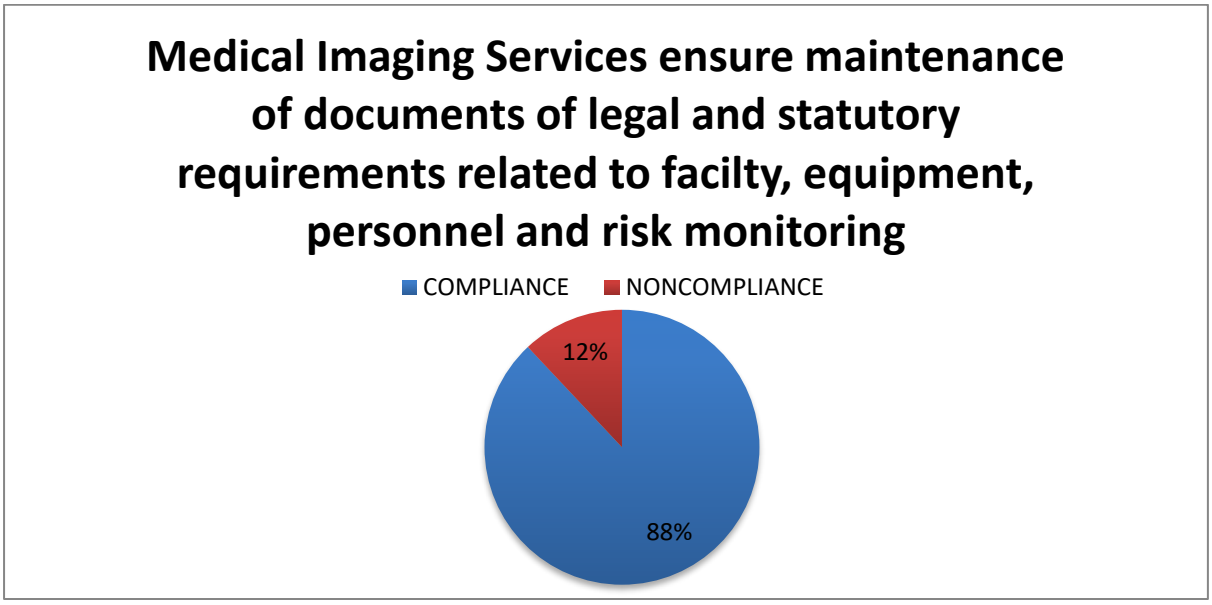
Fig.3 (k)



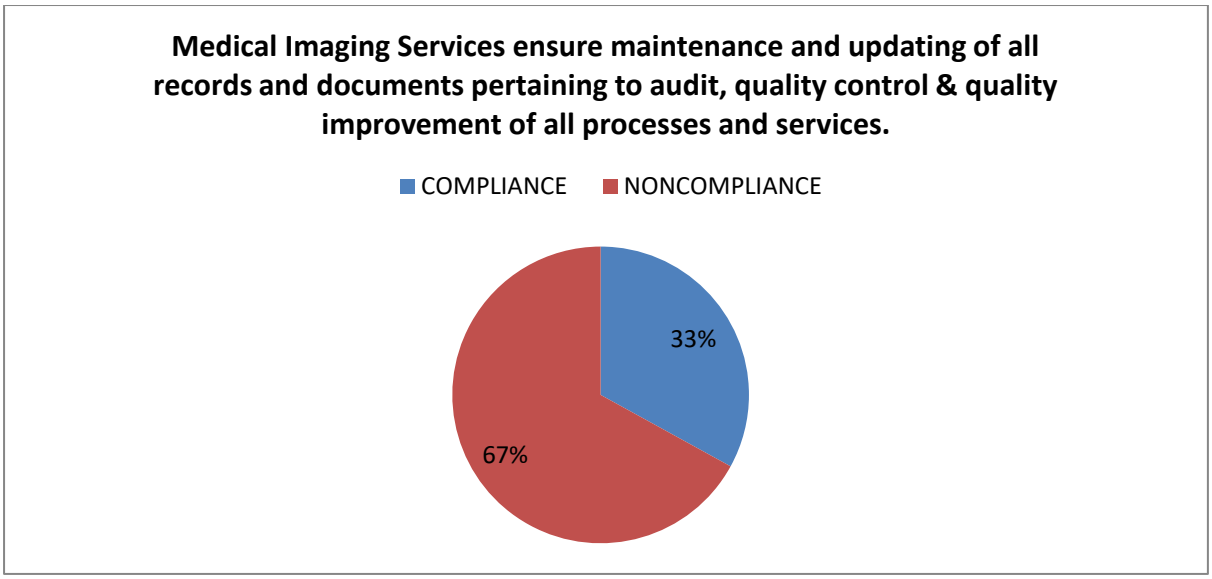
It was observed that equipment downtime management and monitoring was documented and implemented.

Fig.3 (l)



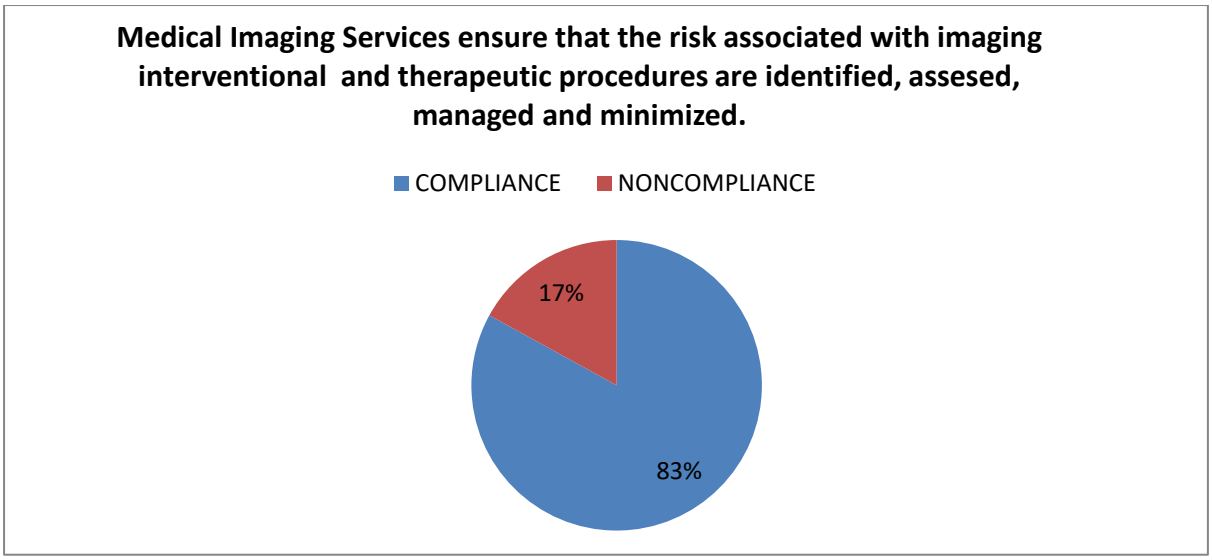
Documentation for legal and statutory requirements related to all staff and risk monitoring were not maintained. But still 88% compliance level was achieved in maintenance f legal and statutory requirements related to facility, equipment, personnel and risk monitoring.

Fig.3 (m)



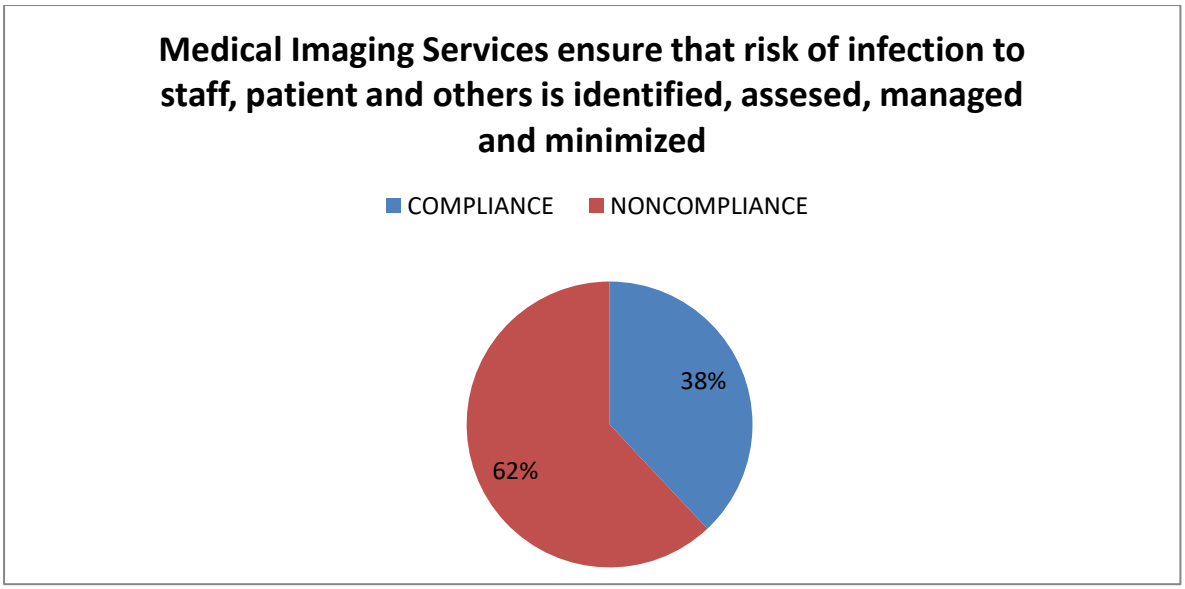
67% compliance was received in maintenance and updation of all records and documents pertaining to audit, quality control & quality improvement of all processes. Roles and responsibilities for maintenance and updating of all records and documents pertaining to audit, quality control & quality improvement of all processes and services were not implemented. Policies and procedures for audit, quality check, verification and validation were also not implemented. There was no documentation related to quality improvement.

Fig.3 (n)



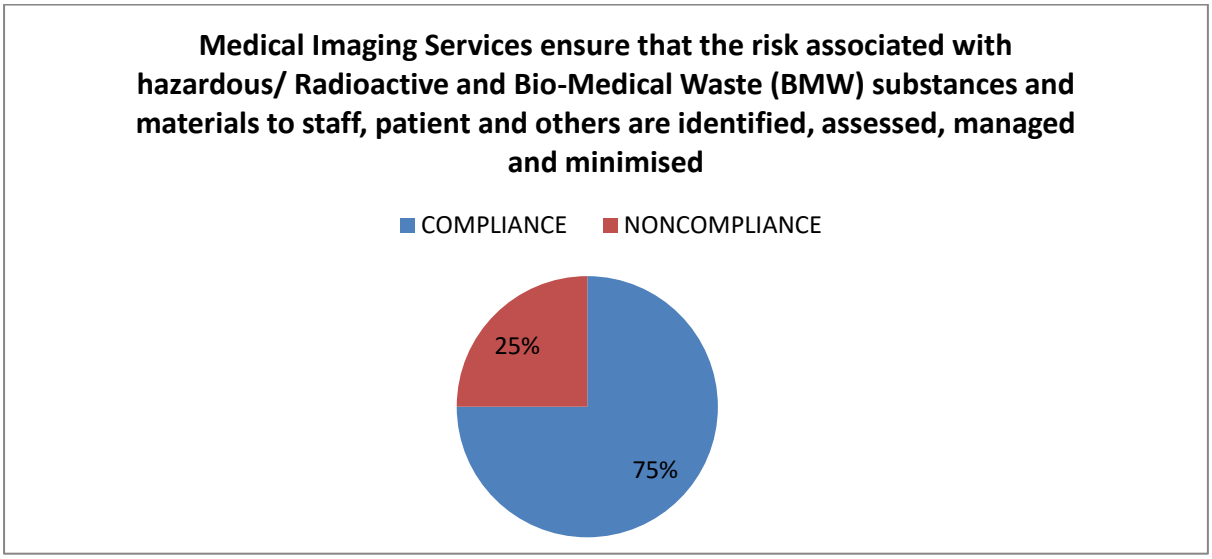
83% compliance was found in managing, assessing and minimizing the risks associated with imaging and therapeutic procedures as roles & responsibilities for all levels of risk management in all areas of imaging were not implemented. There is no separate waiting room for patients and their attendants. Technicians were unaware of the principle of ALARA. Also the technicians did not wear lead apron everytime while handling radioactivity.

Fig.3 (o)



From the above graph it can be observed that there was 62% non compliance in assessing and managing infection to staff, patient or others. No documented roles and responsibilities were found regarding infection control. No staff member was seen wearing gloves while injecting patients. Protocols and procedures for needle stick injuries and their precautions were not known.

Fig.3 (p)



Above graph shows 75% compliance level was achieved. Roles and responsibilities for control of hazardous/radioactive and Bio- Medical Waste (BMW) substances and materials were not implemented. Technicians were unaware of BMW disposal. Decontamination room was shown to be under construction & RP lab is being used for disposal purpose. Procedures to manage risk associated with accidental spillage of hazardous / radioactive materials is not displayed.

CHAPTER 4: LIMITATIONS OF THE STUDY

1. Time constraint.

2. Observation bias of assessor while filling up of checklist.

CHAPTER 5:

5.1 CONCLUSION

Overall there was 76% compliance of nuclear medicine department to NABH standards. Certain legal requirements needed to be implemented. Documentation part needed to be improved Recommendations were given based on the checklist to the management & some were implemented in confirmation with the management.

5.2 RECOMMENDATIONS

Report was given to the management regarding all non-compliance factors. Following recommendations were given:

1. Provision for low-dose active patient waiting has to be made in the Department.
2. No public occupancy shall be allowed in the active patient waiting area.
3. The area designated for dose administration has to be used for the same purpose & it shall not be used for any general purpose which will result in public occupancy in the active area.
4. Radioactive waste shall not be accumulated in the Hotlab & has to be disposed off timely by ensuring radiological safety.
5. Emergency procedures in case of radioactive spillage & misadministration are required to be pasted at appropriate place in the NM facility.
6. RSO employed should be present in the department during working hours.

7. Trainee shall be provided with personnel monitoring device to work in a controlled area.

8. Training of staff regarding importance of following radiation safety & infection control practices, ALARA principle & BMW disposal.

9. Strict implementation & monitoring of radiation safety & infection control practices.

10. All incomplete documentations to be completed like Inventory logbook, disposal logbook, area monitoring register, employee safety register, HIS enteries.

11. Displays regarding Patients right & responsibilities, BMW management, infection control practices should be present in the department.

12. Catalogue for patients for various procedures should be made available to them in relevant format & language.

13. Patient feedback & also from Referrer/Professional colleagues on the content and quality of reports should be taken.

5.3 IMPLEMENTATION

The following steps were then undertaken in confirmation with the management as a part of preparation of Nuclear medicine department for NABH audit:

Following documentation was completed:

1. Radiopharmaceutical log book from Jan'12-Jan'13
2. Bio-Medical Waste disposal log book
3. Inventory log book from Jan'12-Jan'13
4. Employee safety manual
5. QC Gamma camera & collimation register
6. Area monitoring register
7. HIS entries

- Crash cart audit
- Signage Displays
- TAT preparation
- Area monitoring along with RSO with Gieger Muller meter of Nuclear medicine department, X-ray lab, Cath lab

- Infection control and Biomedical Waste Disposal and Coding. Also, training of the staff regarding BMW and Spillage management.

6. REFERENCES:

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4. General information brochure for accreditation of medical imaging services 2010. National Accreditation Board for Hospital & Healthcare providers (http://*www.nabh.co/main/mis/pop/GIB.pdf*, accessed on 2 May 2013)

5. *NHS Improvement The best of clinical pathway redesign Practical examples delivering benefits to patients 2011 (http://www.improvement.nhs.uk/documents/bestofclinicalpathwayredesign.pdf*,accessed on 2 May 2013)

6. *European commission guidelines on clinical audit for medical radiological practices (diagnostic radiology, nuclear medicine and radiotherapy) European commission radiation protection no 159 (http://ec.europa.eu/energy/nuclear/radiation_protection/doc/.../159.pdf)*

7. Self assessment toolkit of Imaging centres – National Accreditation Board for Hospitals & Healthcare providers. (http://nabh.co/main/mis/Self_Assessment_Toolkit.xls, accessed on 18 Jan 2013)

7. ANNEXURE:

SELF ASSESSMENT TOOLKIT[7]

	Elements		Documentation (Yes/ No)	Implementation (Yes/ No)	Evidence (cross reference to documents / manuals etc.)	Scores (0/ 5/ 10)	Total Score	Compliance rate
Chapter 1: CONTROL OF SERVICES (CS)								
Medical Imaging Services shall address system to ensure delivery of the service from point of referral to discharge.								
	a	Roles and responsibilities of each area of service delivery are defined.	Y	Y	MANUAL	10		
	b	Medical Imaging Services ensure justification of referrals according to patients condition, urgency of diagnosis and radiation risk.	N	Y		5		
	c	Medical Imaging Services ensure that protocols for imaging pathways and processes are defined, documented, implemented and monitored.	N	Y		5		
	e	Timeframe to manage imaging pathways from receiving of referral to discharge from the Medical Imaging Services is defined, documented, implemented and monitored.	N	N		0	20	50 %
Medical Imaging Services ensure that delivery of services is patient focused.								
	a.	Roles and responsibilities of staff managing each area of service to the patient (information, delivery of service and care, safety, privacy) are defined.	Y	Y	MANUAL	10		
	b.	Medical Imaging Services ensure that the information about specific procedure is available to patients and attendants in relevant format and language.	N	Y		5		
	c.	Medical Imaging Services ensure that patient and attendants are informed	Y	Y	PRICE LIST	10		

		about expected cost prior to imaging.						
	d.	Medical Imaging Services ensure safety of patients, attendants and their belongings while in the facility.	Y	Y	SAFETY MANUAL	5		
	e.	Medical Imaging Services ensure safe transport of the patients within, to and from the facility whenever required.	Y	Y		5		
	f.	Medical Imaging Services ensure privacy and dignity of the patient without any discrimination.	Y	Y	CONSENT FORMS	10		
	g.	Medical Imaging Services ensure that patients feedback is utilised to improve the service delivery system.	N	N		0		
	h.	Medical Imaging Services ensure that staff is aware about patients rights and responsibilities.	N	N		0	**45**	**56 %**
Medical Imaging Services ensure appropriate management of facility and environment.								
	a.	Roles and respons ibi l i t ies of management of each area of facility are defined	Y	Y	MANUAL	10		
	b.	Medical Imaging Services ensure vsignage in appropriate language and format to guide the patient and attendant to and within the facility.	N	N		0		
	c.	Medical Imaging Services ensure that design and construction of the facility is in accordance with the legal requirements pertaining to the equipment and the services offered.	Y	Y	PERMIT LETTER	10		
	d.	Medical Imaging Services ensure that design and construction of the facility supports specific needs of the patient population (including children andthose with special needs) and staff.	N	N		10		
	e.	Medical Imaging Services ensure that access to particular areas is restrictedaccording to specific needs and risks with proper barrier and signage.	Y	Y	SIGNAGE	10		
	f.	Medical Imaging Services ensure that water, electricity, ventilation and medical gases & vacuum installation in all area of service is maintained with provision of alternate sources.	N	Y		5	**45**	**75 %**

Chapter 2: CONTROL OF IMAGING PROCESSES AND PROCEDURES (CPP)								
CPP.1: Medical Imaging Services ensure acquisition of optimal diagnostic quality images and performance of diagnostic procedures.								
	a	Roles and responsibilities of staff for management of each area of image acquisition and image quality are defined.	N	Y		5		
	b	Medical Imaging Services ensure that protocols for image acquisition for all examination are developed, defined, document ed, communi c a t ed, implemented and monitored.	N	Y		5		
	c	Medical Imaging Services ensure quality of diagnostic images and procedures.	N	Y		5		
	d	Medical Imaging Services ensure analysis of feedback on images and procedures through documented process of internal verification & external validation.	N	N		0	15	38 %
CPP.2: Medical Imaging Services ensure the quality of reports (clinical and technical).								
	a	Roles and responsibilities for staff reporting the images are defined.	Y	Y	MANUAL	10		
	b	Medical Imaging Services ensure that the structure, content and format of report is standardized.	Y	Y	REPORT FORMAT	10		
	c	Medical Imaging Services ensure the generat ion, verification and amendments of reports are within appropriately defined timeframe.	Y	Y	TAT	10		
	d	Medical Imaging Services ensure that all attempts are made so that the imaging interpretation is collated with relevant clinical laboratory and previous imaging details.	Y	Y	HISTORY SHEETS	10		
	e	Medical Imaging Services ensure communication of reports to patient and/or referrer within appropriately defined timeframe.	Y	Y	REPORT REGISTER	10		

	f	Medical Imaging Services ensure appropriate quality of images and reports for teleradiology services	N	Y		5		
	g	Medical Imaging Services ensure analysis of feed back from Referrer/Professional colleagues on the content and quality of reports through defined & documented process.	N	N		0	55	79 %
CPP.3: Medical Imaging Services ensure quality of diagnostic and therapeutic interventional procedures.								
	a	Roles and responsibilities for staff conducting diagnostic and therapeutic interventional procedures are defined.	Y	Y	MANUAL	10		
	b	Medical Imaging Services ensure that the risk, the expected outcome and alternative treatment protocols are explained to the patient, the attendant and the referrer; and same is documented.	Y	Y	HISTORY SHEETS	10		
	c	Medical Imaging Services ensure that protocols for all diagnostic and therapeutic interventional procedures are defined , documented , implemented and monitored.	N	Y		5		
	d	Medical Imaging Services ensure that appropriate sedation/anaesthesia, clinical and emergency support is available before, during and after the procedure.	N	Y		5		
	e	Medical Imaging Services ensure that the outcomes of diagnostic and therapeutic interventional procedures are monitored.	N	N		10	40	80 %
CPP.4: Medical Imaging Services ensure proper management of drugs, isotopes, contrast media and radiopharmaceuticals.								
	a	Roles and responsibilities for staff in the area of drugs, isotopes, contrast media and radiopharmaceuticals are defined.	Y	Y	MANUAL	10		
	b	Medical Imaging Services ensure that protocols for prescription, purchase, storage, supply, handling and labeling of drugs, isotopes, contrast media and radiopharmaceuticals are defined, documented, implemented and monitored.	N	N		0		

	c	Medical Imaging Services ensure that protocols for administration of drugs, isotopes, contrast media and radio pharmaceuticals to the patients including corrective action taken in case of adverse drug/contrast reaction are defined, documented, implemented and monitored.	N	N		0		
	d	Medical Imaging Services ensure that patients at higher risk of adverse reactions to specific drugs, isotopes, contrast media and radiopharmaceuticals are assessed and managed.	N	N		0	10	25 %
Chapter 3: CONTROL OF PERSONNEL (CP)								
CP.1: Medical Imaging Services ensure that the staff is appropriately qualified, competent and trained, to deliver the service assigned to them.								
	a	Roles and responsibilities for ma int enanc e of r e cord and verification of credentials of the staff are defined.	Y	Y	HR FILE	10		
	b	Medical Imaging Services ensure that policies and procedures for selection, recruitment, retention and succession planning of staff are defined, documented and implemented.	N	N		0		
	c	Medical Imaging Services ensure that there is a documented personal record for each staff member.	Y	Y		10	20	67 %
Chapter 4: CONTROL OF EQUIPMENT (CE)								
CE.1: Medical Imaging Services ensure appropriate procurement and installation of equipment.								
	a	Medical Imaging Services ensure that the policies and procedures for the procurement of all equipment and c onsumables are defined, implemented and monitored in a collaborative manner between user and management.	Y	Y	INVOIC E	10		
	b	Medical Imaging Services ensure that the policies and procedures for the installation of equipments are defined, documented, implemented and monitored and record of same is maintained.	Y	Y	DOCUM ENTS	10	20	100 %

CE.2: Medical Imaging Services ensure appropriate operation and working of equipment.								
	a	Roles and responsibilities for each area of the operation and working of all equipment are defined.	N	Y		5		
	b	Medical Imaging Services ensure that the policies and procedures for operat ion and calibration of equipment are defined, documented, implemented, monitored and record of the same is maintained.	N	N		0	5	25 %
CE.3: Medical Imaging Services ensure appropriate maintenance and repair of equipment.								
	a	Roles and responsibilities for maintenance, service and repair of the equipment are defined.	Y	Y	BILLS	10		
	b	Medical Imaging Services ensure that equipment downtimes are monitored and managed within defined timeframe.	N	N		0		
	c	Medical Imaging Services ensure that policies and procedure for maintenance and repair of equipments are defined, documented, implemented and monitored and record of the same is maintained.	N	Y		5	15	50 %
CE.4: Medical Imaging Services ensure appropriate replacement of existing equipment & planning for new equipment for continuation and expansion of service.								
	a	Roles & responsibilities for replacement of existing equipment & planning for new equipment for expansion of service are defined.	Y	Y	BILLS	10		
	b	Medical Imaging Services ensure that equipment replacement and/ or upgradation is planned and implemented in accordance with scope of services and expansion plan.	Y	Y	DOCUM ENTS	10	20	100 %
Chapter 5: CONTROL OF DOCUMENTS AND RECORD (CDR)								
CDR.1: Medical Imaging Services ensure appropriate management of all the documents, images and records pertaining to the patient.								

	a	Roles and responsibilities for generation, maintenance, integration, safety, confidentiality and retrievability of all the documents, images and records pertaining the patient are defined.	Y	Y	MANUAL	10		
	b	Medical Imaging Services ensure that policies and procedures to identify, and classify documents, images and records pertaining to the patient are defined, preferably in computerised format.	N	N		0		
	c	Medical Imaging Services ensure that policies and procedures regarding retent ion, conf ident ial i ty and retrievability of all the documents, images and records pertaining to the patient are implemented and monitored.	Y	Y	CONSENT FORMS	10	20	67 %
CDR.3: Medical Imaging Services ensure maintenance of documents of legal and statutory requirements related to facility, equipment, personnel and risk monitoring.								
	a	Roles and responsibilities for maintenance of documents of legal and statutory requirements related to facility, equipment, personnel and risk monitoring are maintained.	Y	Y	LICENSES	10		
	b	Medical Imaging Services ensure that documents of legal and statutory requirements related to facility, are maintained.	Y	Y	LICENSES	10		
	c	Medical Imaging Services ensure that document of legal and statutory requirements related to equipments are maintained.	Y	Y	LICENSES	10		
	d	Medical Imaging Services ensure that document of legal and statutory requirements related to all staff (including risk monitoring) are maintained.	N	Y		5	35	88 %
CDR.4: Medical Imaging Services ensure maintenance and updating of all records and documents pertaining to audit, quality control & quality improvement of all processes and services.								
	a	Roles and responsibilities for maintenance and updating of all records and documents pertaining to audit, quality control & quality improvement of all processes and services are defined.	N	N		0		

	b	Medical Imaging Services ensure that policies and procedures for audit, quality check, verification and validation are maintained.	N	N		0		
	c	Medical Imaging Services ensure that all documents related to quality improvement are maintained.	N	N		0	0	0
Chapter 6: RISK CONTROL AND SAFETY (RCS)								
RCS.1: Medical Imaging Services ensure that the r isk associated wi th imaging, interventional and therapeutic procedures are identified, assessed, managed and minimised.								
	a	Roles & responsibilities for all levels of risk management in all areas of imaging are defined.	N	N		0		
	b	Medical Imaging Services ensure that the radiation doses are as low as reasonably possible for all patients (ALARP principle) especially for children, women of child bearing age, pregnant women and patients undergoing repeated exposures.	N	Y		5		
	c	Medical Imaging Services ensure that there is a system in place to define, as ses s and manage r i sks of occupational exposure to ionising radiation and record for the same is maintained.	N	Y		5		
	d	Medical Imaging Services ensure that risks of acoustic output and exposure times are defined, assessed, managed and minimized.	N	N		0		
	f	Medical Imaging Services ensure that risk associated with use of ablative, therapeutic devices during diagnostic & interventional procedures are defined, assessed, managed & minimized.	N	Y		5		
	g	Medical Imaging Services ensure that the incidents & errors pertaining to risks as sociated with all the procedures are reported, investigated, recorded, acted upon, analysed, and used to guide and plan the future action.	N	N		0	15	25 %
RCS.2: Medical Imaging Services ensure that the risk of infection to staff, patient and others is identified, assessed, managed and minimised.								

	a	Roles and responsibilities regarding infection control are defined.	N	N		0		
	b	Medical Imaging Services ensure that policies and procedures to identify, assess, manage and minimise the risk of infection to staff, patient and others are defined, documented, implemented and monitored.	N	N		0		
	c	Medical Imaging Services ensure that policies and procedures for decontamination of equipment and environment are defined, documented, implemented and monitored.	N	N		0		
	d	Medical Imaging Services ensure that protocols and procedures for needle stick injuries and subsequent post exposure prophylaxis are defined, documented, implemented and monitored.	N	N		0	0	0
RCS.3: Medical Imaging Services ensure that the risk associated with hazardous/ Radioactive and Bio-Medical Waste (BMW) substances and materials to staff, patient and others are identified, assessed, managed and minimised.								
	a	Roles and responsibilities for control of hazardous/radioactive and Bio- Medical Waste (BMW) substances and materials are defined.	N	N		0		
	b	Medical Imaging Services ensure that policies and procedures to identify, assess, manage and minimise the risk a s soc i a t ed wi th ha z a rdous / radioactive and Bio-medical waste (BMW) substances and materials to staff, patient and others are defined, documented, implemented and monitored.	N	N		0		
	c	Medical Imaging Services ensure that appropriate protective equipment required to decontaminate and manage exposure to hazardous/ radioactive substances are available and maintained.	N	N		0		
	d	Medical Imaging Services ensure that the incidents & errors pertaining to risks associated with hazardous/ radioactive substances and materials	N	N		0	0	0

		are reported, investigated, recorded, analysed, acted upon and used to and plan the future action.							
			TOTAL SCORE:					380	51 %