

	INODAYA Hospitals - Kakinada		Documentation code: INH/AAC.Doc.No-30
	Policy on Imaging Services Quality assurance		Prepared Date: 11/11/2025
	Reference: AAC.ga. NABH Standards – 6 th Edition		Issue date: 11/11/2025
	Issue No: 01	Review NO: 0	Review Date: 10/11/2026

AAC ga: POLICY ON QUALITY ASSURANCE

1. POLICY:

To maintain all medical equipment's to the appropriate standards as prescribed by equipment manufacturer, so as to ensure that all medical equipment's to be used to provide the best health care services to patients, should be safe, efficient, effective, reliable and long lasting.

2. PURPOSE:

This Policy is intended for the maintenance of medical equipment that ensures:

- a. Maximum availability and reliability of equipment's
- b. Minimum downtime and Maximum Uptime
- c. Maximum return on investment
- d. Prevention of wastage of consumables and spares
- e. Extended useful life of equipment's
- f. Readiness of the equipment for emergency use whenever required

- #### 3. Distribution:
- Radiology, Quality Assurance Team, Hospital management, Management Policy makers Procurement Stores, Finance, Clinical, Technical, Maintenance, Administration, Patients Suppliers.

4. DEFINITION:

The complex equipment that is used for diagnosis, treatment and monitoring purpose. A set of activities conducted to keep an equipment in optimum working condition and consists of periodic inspection, preventive maintenance, and corrective maintenance.

5. SCOPE:

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This policy is applicable to the radiology department. This shall apply to all investigation procedures.

6. RESONSIBILITY:

Management, Biomedical engineer, Maintenance, Purchase dept, Who all are using the equipment.

7. PROCEDURE:

Medical Equipment: The complex equipment that is used for diagnosis, treatment and monitoring purpose. The different uses can be classified as below:

I. Diagnostic – Used in estimation of body potentials, blood values, imaging and laboratory equipment.

II. Therapeutic – Used with radiation energy, prosthetic and orthopedic

Equipment used in resuscitation, special treatment and surgical support including the gas supply system.

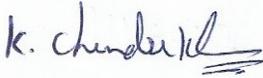
III. Monitoring of body parameters and analysis of hospital environment.

IV. General – Equipment used in routine patient care, CSSD etc.

V. Medical Equipment may be used for medical research and education.

Types of Equipment's: Two Types as given below

I. Major Equipment's: - required to be Tendered/Proprietary Item

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II. Minor Equipment's/Instruments: - which can be obtained by Local Purchase

The tasks to be performed at hospital level are related to:

- (i) inventory & documentation
- (ii) Commissioning & acceptance
- (iii) Monitoring of use & performance
- (iv) Maintenance of the equipment

7 (1). Inventory and Documentation

* It should be mentioned in the Tender Enquiry Document while floating the tender that manufacturer/supplier has to provide CMC (for all the major equipment(s)) for at least three to five years after expiry of warranty period.

Inventory provides information to support different aspects of medical equipment management.

The inventory of Medical Equipment's should be maintained department wise at store level for the equipment's:

- Purchased In the Hospital
- Purchased through Procurement Agency (if any)

The inventory record includes the following details:

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Ms. Chandrakala	Dr. Gowtham Krishna	Mrs. G. Lakshmi Lavanya
Biomedical Engineer	Medical director	Chief executive Officer

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1. Reference ID
2. Equipment Name
3. Company/Make (with contact details)
4. Serial no.
5. Date of Indent
6. Tender No. /Local Purchase
7. NOA no. (With date)
8. Cost per unit
9. Date of issue of CRC (Consignee receipt certificate)
10. Date of Installation
11. Date of issue of FAC (Final acceptance certificate)
12. Warranty Period
13. Maintenance of Equipment
 - a. In-House
 - b. External Agency/Manufacturer Level
14. After warranty maintenance contract with period and charges*
15. Spare parts/ consumable inventory

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16. Current status of functioning of equipment's

The record should be maintained in table form as given in Annexure-I

The inventory must be updated (at least Half Yearly) when:-

- additional equipment has been procured or equipment is replaced by new one
- equipment has been condemned and is no longer in use
- the equipment has been transferred to another location

To ensure that all medical equipment is appropriately maintained, an inventory of this type of equipment must also be kept and maintained under the control of head of the department.

The above information in tabulated form shall be kept at Management level and should approve for Purchase or any repairs, or change of equipment.

- Maintenance contract - the process for fresh maintenance contract (AMC/CMC) of the equipment should be initiated 3(three) Months before the expiry of the Warranty period/AMC/CMC. The necessary concurrence from the Management and finance department of the Institution required for renewal of contract/fresh contract shall be taken well in advance so that equipment remains functional and downtime is minimized. Also, the service provider should be located preferably within the city limits.

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- Insurance - If the Costly Equipment's are not covered under AMC/CMC, then they should be got insured so that if any breakdown occurs the expenditure incurred for the same can be claimed from the Insurance Provider.

7 (2). COMMISSIONING AND ACCEPTANCE OF THE EQUIPMENT:

The competent authority should ensure installation and commissioning of the equipment by manufacturer/supplier. The process should be monitored by in-house technical staff so that any technical matters can be noted and recorded in the Maintenance Register (Annexure- II). This occasion also provides an excellent opportunity for in house technical staff to gain familiarity with the new item and its operation. Ideally, in-house technical staff should also attend the operator's training session.

It is particularly important to bear in mind that normally the manufacturer/ supplier's warranty starts the day equipment is installed in the hospital. If equipment is not going to be used for some time after delivery, special arrangements must be made with the supplier to define the warranty period. Such an agreement should preferably be made in the purchase order. Final Acceptance Certificate (FAC) to the supplier should not be issued before the satisfactory performance has been confirmed by the in house technical staff.

Regarding equipment with like CT/MRI Scanner, CSSD etc., the details will be handed over by the agency to the store manager or Medical Superintendent or authorized person in the presence of Head of the Department and in-house staff.

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7 (3). MONITORING OF USE AND PERFORMANCE:

It is important that user should make a safe use of the equipment and also continuously monitor the performance of the equipment. User should also keep a direct link with manufacture/supplier/service provider and observe any supplier's technical services. Such services should be recorded in the Maintenance Register

Many equipment will require daily/weekly inspection and simple maintenance. This type of maintenance is vital for the continuous, safe, effective and reliable operation of medical equipment so as to get accurate and reliable results.

Daily/Weekly Inspection and Maintenance includes:

- a. Visual Inspection
- b. Performance Tests
- c. Calibration
- d. Checkout etc.

These tasks can and must be carried out by the users as per the manufacturer's instructions and suitable documentation should also be maintained for the same. Any discrepancies if found, should be brought into the notice of the controlling authority for necessary corrective action.

7 (4). MAINTENANCE OF THE EQUIPMENT:

Proper maintenance of medical equipment is essential to obtain sustained benefits

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and to preserve capital investment. Medical equipment must be maintained in working order and periodically calibrated for effectiveness and accuracy of the results.

The Maintenance consists of:

- a. Planned Preventive Maintenance
- b. Breakdown Maintenance

a. Planned Preventive Maintenance (PPM)

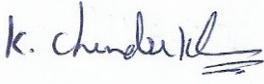
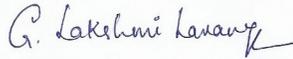
Planned Preventive Maintenance involves maintenance performed to extend the life of the equipment and prevent its failure. Planned Preventive Maintenance is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, calibration, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. In special cases the user may change the frequency to accommodate local environmental conditions.

Planned Preventive maintenance will be a statutory requirement for most of the medical equipments. It will enhance the efficiency, effectiveness and reliability of medical equipment and must be carried out at appropriate frequency as suggested by the manufacturer/ service provider.

Each equipment on the inventory will show whether it is

- a. maintained in-house
- b. maintained by external agency or manufacturer.

The conditions for preventive maintenance required for medical equipment can vary due to factor such as type of equipment, age of the equipment, frequency of use

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of the equipment, etc.

The record of Planned Preventive Maintenance should be maintained department wise and must include following details:-

1. Reference ID as per inventory
2. Equipment Name
3. Company/Make
4. Serial No.
5. Date of Installation
6. Warranty Period
7. Under AMC/CMC
8. Frequency of Preventive Maintenance/Calibration
 - a. as per manufacturer guidelines
 - b. presently being followed
9. Preventive Maintenance/Calibration Done On
10. Preventive Maintenance/Calibration Due On
11. Expenditure with cost and details
12. Remarks with Functional Status

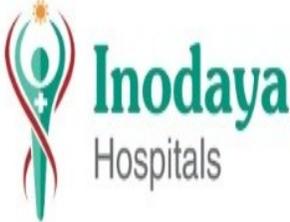
The record should be maintained in table form as given in Annexure-II.

Here is given the frequency of Planned Preventive Maintenance (PPM) of some of the medical equipment as a guideline.

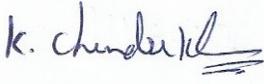
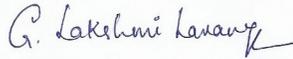
Table showing broad based basic frequency of Planned Preventive Maintenance of some of the equipments is as given below:

- S.No. Equipment Name Frequency*
- 1 X-Ray (Complete System) Quarterly
 - 2 CT Scanner (Complete System) Quarterly
 - 3 4 Cath Lab System Quarterly
 - 5 C-Arm Machine Quarterly

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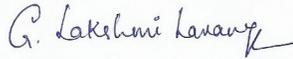
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- 6 Heart & Lung Machine Quarterly
- 7 Arterial Blood Gas analyzer Quarterly
- 9 Electrosurgical Unit Quarterly
- 10 Autoclave Quarterly
- 11 Ultrasonic Washer Quarterly
- 12 Dental X-Ray Machine Quarterly
- 13 Ultrasound Machine Half Yearly
- 14 IABP (Intra aortic balloon pump) Half Yearly
- 15 Echocardiography Machine Half Yearly
- 16 TMT Machine Half Yearly
- 17 PFT Machine Half Yearly
- 18 Patient Monitor Half Yearly
- 19 Cardiac Monitor Half Yearly
- 20 ECG Machine Half Yearly
- 21 Defibrillator Half Yearly
- 22 Anesthesia Machine Half Yearly
- 23 Ventilator Half Yearly
- 24 OT Table Half Yearly
- 25 OT Light Half Yearly
- 26 Suction Machine Half Yearly
- 27 Insufflators Half Yearly
- 28 Endoscope/Laparoscope Half Yearly
- 29 Syringe & Infusion Pump Half Yearly
- 30 Infant Warmer Half Yearly
- 31 Phototherapy Unit Half Yearly
- 32 Fetal Doppler Half Yearly
- 33 Patient Bed Half Yearly
- 34 Pulse Oximeter Half Yearly
- 35 ACT Machine Half Yearly
- 36 Tourniquet System Half Yearly

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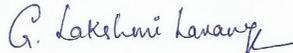
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- 37 Blood and Fluid Warmer Half Yearly
- 38 Electromyogram Machine Half Yearly
- 39 Electroencephalogram Machine Half Yearly
- 40 Bi-Pap Machine Half Yearly
- 41 Humidifier Half Yearly
- 42 Holter System Half Yearly
- 43 Pace Maker Half Yearly
- 44 Bubble CPAP (Continuous positive airway pressure) System Half Yearly
- 45 Infant Resuscitator Half Yearly
- 46 Microwave Diathermy Half Yearly
- 47 Hot Pack Unit Half Yearly
- 48 Traction Unit Half Yearly
- 49 Continuous Passive Motion System Half Yearly
- 50 Cold Pack unit Half Yearly
- 51 Ultrasonic Tens System Half Yearly
- 52 Hemodialysis Machine Half Yearly
- 53 Continuous renal replacement therapy (CRRT) Machine Half Yearly
- 54 Donor Couches Half Yearly
- 55 Microscopes Half Yearly
- 56 Centrifuge/Cryofuge Half Yearly
- 57 Hot Plate Half Yearly
- 58 Cell Counter Half Yearly
- 59 Cell Separator Half Yearly
- 60 PH Meter Half Yearly
- 61 Refrigerator Half Yearly
- 62 Deep Freezer Half Yearly
- 63 Bio-safety Cabinet Half Yearly
- 64 Water Bath Half Yearly
- 65 Laminar Flow Half Yearly
- 66 Urine Analyzer Half Yearly

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- 68 Micropipettes Half Yearly
- 69 Weighing Balance Half Yearly
- 70 Plasma Thawing Bath Half Yearly
- 71 Platelet Agitator Half Yearly
- 72 Tube Sealer Half Yearly
- 73 ELISA Reader Half Yearly
- 74 Immuno Assay System Half Yearly
- 75 Microtome Half Yearly
- 76 Refractometer Half Yearly
- 77 Ophthalmoscope Half Yearly
- 78 Slit Lamp Half Yearly
- 79 Keratometer Half Yearly
- 80 Auto Perimeter Half Yearly
- 81 Image Capturing system Half Yearly
- 82 Dental Chair Half Yearly
- 83 Dental Sterilizer Half Yearly
- 85 Lithotripsy Machine Half Yearly
- 86 Lithotripsy Table Half Yearly
- 87 Uroflowmeter Half Yearly
- 88 ENT Examination Unit Half Yearly
- 89 Harmonic Scalpel System Half Yearly
- 90 Chest Vibrator Half Yearly
- 91 Fibrillator Half Yearly
- 92 VDRL Rotator Half Yearly
- 93 Hormone Analyzer Half Yearly
- 94 Air Sampler Half Yearly
- 95 Wax Bath Half Yearly
- 96 Surgical/Operating Microscope Half Yearly
- 97 Phaco-emulsification Machine Half Yearly
- 98 Tissue Flotation Bath Half Yearly

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99 Vortex Mixer Half Yearly
100 Transport Incubator Half Yearly

For above and rest of the Medical Equipment, advice of manufacturer/supplier/ service provider should also be taken into consideration.

Note: -

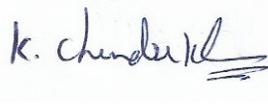
1. Preventive Maintenance of all the equipments whether in use or not shall be done periodically as advised by manufacturer/supplier, so that functioning status of the equipment could be known and equipment is readily available whenever its use is needed.
 2. In critical care areas like Casualty, ICU, OT etc., if the number of equipments are less (one or two), then authority may look into that a standby active unit should be kept ready so that patient does not suffer in case the equipment in use goes out of order.
 3. Life of equipment and quality of testing : Ensure usage of good quality consumables for prolonging life of equipment and maintaining quality of testing.
- * Service report after every repair or schedule service (PPM) should be taken by the user in which all the details like warranty on spare parts need to be added and same should be updated in the inventory register as well as in the Maintenance Register. If any deficiency is observed, the same may be communicated to service provider and Head of the institution for necessary action.

b. Breakdown Maintenance

Breakdown Maintenance is a task performed to identify, isolate, and rectify a fault so that the out of order equipment, machine, or system can be restored to an operational condition.

All medical equipment in use should be free from any fault or defect and all repair work should be carried out to accepted standards by competent person(s).

Faulty or defective equipment shall not be used regardless of how minor is the

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problem and must be reported in the first instance to the manufacturer/supplier/agency hired for maintenance of the equipment as soon as possible.

User department should:

1. Record details of the defect(s).
2. Attach label to the faulty equipment(s).
3. Contact Service engineer of manufacturer/supplier/hired agency by telephone number/fax/email supplied and keep a record of the same.
4. Ensure that information regarding breakdown is passed to all staff, including any shift changes and head of the institution.

All the breakdowns occurring in the department should be maintained on record and must include following details:-

1. Reference ID as per inventory
2. Equipment Name
3. Company/Make
4. Serial No.
5. Date of Installation
6. Warranty period
7. Under AMC/CMC
8. Breakdown Date and Time
9. Breakdown Details (Technical fault or other reasons)
10. Date and Time of Rectification
11. Total Time Taken (Rectification Time – Breakdown Time)
12. Rectification Details with expenditure including cost (if any)
13. Remarks with functional status

The record should be maintained in the table form as given in Annexure-II

Note: - The replacement of the defective part(s) should be done at the earliest feasible after taking the necessary concurrence from the finance department and sanction from the Competent Authority. The reason(s) for the delay if any, should be recorded.

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7(5). Equipment Audit

Equipment audit is a periodic evaluation system to measure the quality of performance of the medical equipments.

At any given point of time, a substantial number of equipment in the hospital may be non-functional. The reasons for the same could be:

1. Want of Minor repairs
2. Lack of Preventive Maintenance
3. Lack of corrective Maintenance
4. Lack of essential Spares
5. Electrical Faults
6. Unfavorable environmental conditions
7. Mishandling of equipment by untrained and unskilled manpower
8. Purchase of equipment without justifiable demand etc.
9. False Reporting, Willful Damage and Overuse than rated

For this, there is a need for periodic evaluation of the quality of performance of the equipment in a hospital. If such an audit is performed, it will be an advantage to all ESI Hospitals so that not only better utilization of medical equipment is ensured but also it contributes to the improvement in the quality of health care to beneficiaries and judicious use of resources.

The Equipment Audit should be done by a committee (Equipment Audit Committee) at Hospital Level on half yearly basis.

The Equipment Audit Committee should consist of:

1. Managing director
2. The Medical Superintendent/designated medical officer of the hospital
3. The head of the concerned department
4. Head of maintenance (If Posted)

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5. Representative from Administration
6. Representative from Finance Department
7. Hospital Store In-charge
8. Nursing Superintendent.

Focus of the Audit is to:

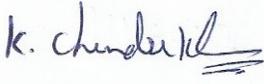
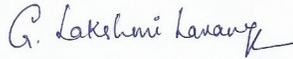
1. Check the current status of the medical equipment
2. Analysis of the records such as Breakdown Register, Preventive maintenance Register
3. Questioning the user about the usage and performance of the equipment.
4. Suggesting measures to optimally utilize the equipment for quality health services.

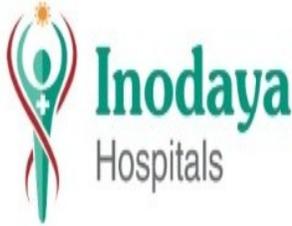
7(6). Training and Development

For the safety of the patient and the user, proper training is critical for both the user and the technical staff. Training and education is not a one-time activity but a continuous process, When ever new instrument installed related employees should go under training. If new employee joins during orientation program they should be trained by the Equipment related HOD.

The tasks to be performed By Hospital Employees:

1. Biomedical engineer and Maintenance manager should be planning, managing and implementing the maintenance of medical equipment.
2. Hospital regarding Inventory, Planned Preventive Maintenance (PPM) and Breakdown. The information received will be kept hospital-wise as well as equipment-wise in the format given.
3. Analyzing the above information for Quality Management of Medical equipments being used. This will be done through assessment and analysis of:

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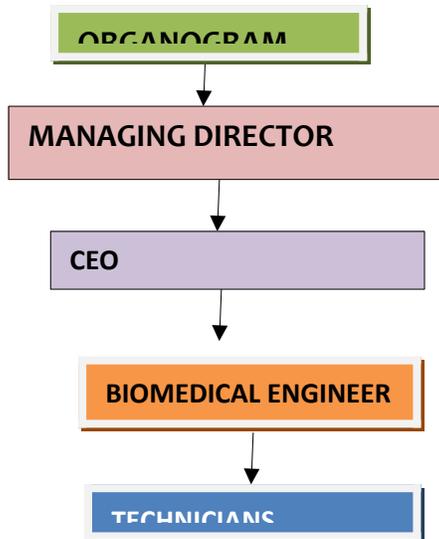


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a. Downtime of Major Equipments such as in OT, ICU, Imaging, Dialysis and Laboratory etc. It needs to be compared quarterly.

Formula: - Total Breakdown time= $\frac{\text{Downtime of equipment}}{\text{Total Uptime}} \times 100$

b. Maintenance Cost Index*=
Maintenance Cost Formula:- $\frac{\text{Total Uptime}}{\text{Capital Cost}} \times 100$



INVENTORY REGISTER

<i>k. Chandrakala</i> Prepared by:	<i>Gowtham Krishna</i> Verified By	Approved by: <i>G. Lakshmi Lavanya</i>
Ms.Chandrakala	Dr. Gowtham Krishna	Mrs.G.Lakshmi Lavanya
Biomedical Engineer	Medical director	Chief executive Officer

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Note: - Inventory register should be updated half yearly for current status of functioning of the equipment, with name and signature of the concerned person by whom equipment has been checked.

Necessary actions should be taken if required so that equipment is nearly always available for the right use.

MAINTENANCE REGISTER

Equipment Name with Reference ID:	Company/Make:
Serial No.:	Date of Installation:
Warranty Period (Date of Expiry):	Under AMC/CMC (with cost):
Average Life (as per manufacturer):	Frequency of Planned Preventive Maintenance (as per manufacturer):
Contact details of the company (manufacturer/supplier):	Location:
Contact details of External Contractor (if any):	

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AAC 10: POLICY ON IMAGING SERVICES QUALITY ASURANCE CORRECTIVE ACTION AND PREVENTIVE ACTION

8. POLICY:

Corrective Action Request is a systematic approach to request investigation of a problem that already happened and request root cause analysis and resolution from Employees to prevent recurrence

9. PURPOSE:

- To provide guidance to carry out proper Root Cause Analysis (RCA) with suitable quality tools
- To ensure responded RCA able to meet Key sight expectation

10. Distribution: Radiology, Quality Assurance Team, Hospital management, Clinical, Technical.

11. DEFINITION:

Action to eliminate the cause of problem or non compliance and preventive action not to happen in the future.

12. SCOPE:

This procedure covers all corrective and preventive actions identified when nonconformity is encountered/anticipated through internal audits, customer complaints on Hospital Management or Radiology scope and any event that could affect the QMS.

13. RESONSIBILITY:

Radiographer, Radiology technicians, Management, Biomedical engineer, Maintenance,.

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6.1 The Quality Management Representative is responsible for ensuring the proper implementation of this procedure.

6.2 The Department HOD / Top Management/ QMR ensure that appropriate actions are carefully reviewed, approved, and implemented without undue delay to eliminate the causes of nonconformities. They are also responsible for ensuring the effectiveness of actions taken.

6.3 The Initiator is responsible for conducting follow-up activities to verify the completeness and the effectiveness of the actions taken.

6.4 The Unit Staff may initiate requests for actions upon identification of NC .

6.5 The Radiologist and technical Incharge are authorized to initiate RFA through their Leader.

6.6 The Imaging service Team Leader is responsible to monitor their technician and Whether Documenting or not.

5.7 The Document Controller/Record Custodian shall be responsible in maintaining the Radiology technical team..

14. PROCEDURE:

7.1 Identification of Nonconformities

Nonconformities are identified through or during conduct or as a result of the following:

7.1.1 Project Management;

7.1.2 Daily reports and TAT, Critical values

7.1.3 Evaluation of previous outputs/activities relative to the operations;

7.1.4 QMS audits

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7.1.5 Customer feedback; and,

7.2 Documenting and Reporting of Nonconformities

Identified nonconformities should be recorded on the RFA Form.

7.2.1 Prior to issuance of Report, the form is assigned a Uhid number as follows:

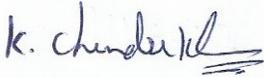
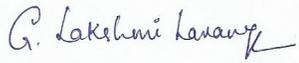
Date, Time, Sign of radiologist print on hospital logo paper, To dept

7.2.2 Radiology report form contains information that includes, but not limited to:

- Description of potential or actual
- nonconformity/nonconformance
- Root-cause analysis, if applicable;
- Disposition/Action Plans;
- Immediate Correction (Band-aid solution or Short-term)
- Corrective/Preventive Actions
- Verification of Disposition/Action Plans
- Individuals responsible for initiating and implementing action;
- Target completion date; and,
- Follow-up action date.

7.3 Corrective and/or Preventive Action Implementation

7.3.1 The individual or unit/group responsible for the identification of nonconformities, its root cause, and implement appropriate action in a timely manner. The identified root cause is recorded in the appropriate section of the Report.

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7.3.2 For actions to be effective, they should be focused on addressing the root-cause rather than the detected NC.

7.3.3 The Department Manager reviews and approves the actions indicated in the RFA, prior to their implementation.

7.4 Verification of Actions Taken

7.4.1 Details of the actions taken and the verification results are written on the follow-up portion of the RFA.

7.4.2 Once the target completion date is due, the IQA Team Leader/Initiator verifies the action taken and records this in the RFA.

7.4.3 If verification necessitates an additional action plan or follow-up, the next follow-up date is agreed upon.

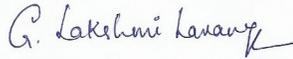
7.4.4 To ensure that needed actions are prevented from unnecessary delays, follow-ups shall be limited to only three times wherein the QMR conducts the third and final follow-up.

7.5 Effectiveness of Actions Taken

7.5.1 Records of review of the effectiveness of actions taken are maintained per department.

7.5.2 Status of actions taken is included in the agenda and is discussed during management reviews.

Policy on Appropriateness and Clinical Correlation

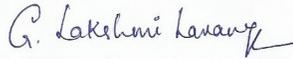
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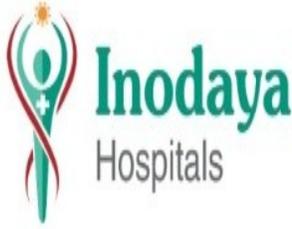
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- The patient who needs to undergo radiological investigation will be given requisition slip on which the need for investigation and provisional expected radiological diagnosis will write.
- The clinical data on the requisition slips and the radiological findings will be captured.
- The program addresses the appropriateness and need for the investigation to be done for the patient.
- CAPA will be done for any deviation in investigation appropriateness.
- The program addresses the correlation between provisional clinical diagnosis and radiological findings and the results were discussed during clinic radiological meetings which were part of Quality meeting.
- The program addresses both external and internal peer reviews of the CT,X ray films for sample size derived by solvent formula [$n = N/(1+Ne^2)$].

Document Revision History

DOCUMENT REVISION HISTORY		
Version	Date of issue	Reason for Revision
Original version - 1	10/03/2022	Prepared 5 th edition
Revised version - 2	05/07/2023	Periodic revision and update

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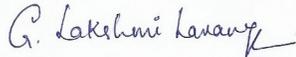
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Revised version - 3		
Revised version - 4		
Revised version - 5		

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