AMALA COLLEGE OF NURSING

(An undertaking of Amala Cancer Hospital Society)
Amala Nagar P.O., Thrissur-680 555, Kerala, India.
Website : www.amalanursingcollege.org

First Cycle NAAC Accreditation 2022

CRITERION 8

B3 NURSING COLLEGE

8.1.3 Students exposed to quality of care and patient safety procedures followed in teaching hospital

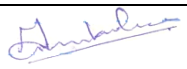
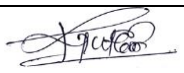
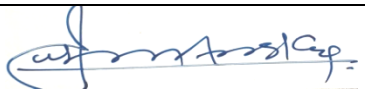
Quality manual

Submitted to

THE NATIONAL ASSESSMENT AND ACCREDITATION COUNCIL

AMALA INSTITUTE OF MEDICAL SCIENCES

AMALA NAGAR, THRISSUR

Document Name:		**QUALITY IMPROVEMENT MANUAL**
Document No.		**AIMS /DM / QCO - 71**
Issue No:		**05**
Issue date:		**05/05/2020**
Revision No.		**02**
Revision Date		**31/01/2022**
No. of Pages		**65**
Prepared By:	**Name**	**Mr. Manikandan R**
	Designation	**Quality Co-ordinator**
	Signature	
Approved By	**Name**	**Fr. Deljo Puthoor CMI**
	Designation	**Accreditation Co-ordinator**
	Signature	
Issued By	**Name**	**Fr.Julious Arakkal CMI**
	Designation	**Director**
	Signature	

AMENDMENT SHEET

Sl. No.	Section no & Page no	Details of the Amendment	Reasons	Signature of the preparatory authority	Signature of the approval authority

Prepared By	Approved By	Issued By
Mr. Manikandan R Quality Co-ordinator	Fr. Deljo Puthoor CMI Accreditation Co-ordinator	Fr.Julious Arakkal CMI Director

CONTROL OF THE MANUAL

The authority over control of this manual is as follows:

Preparation	Approval	Issue
Quality Coordinator	Accreditation Co-ordinator	Director

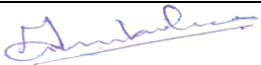
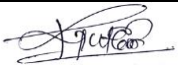
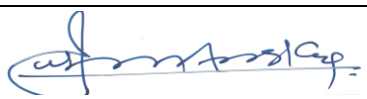
The procedure manual with original signatures of the above on the title page is considered as 'Master Copy', and the photocopies of the master copy for the distribution are considered as 'Controlled Copy'. The Master copy will be sealed as 'Master Copy' and Controlled copies will be sealed as 'Controlled copy'.

Distribution List of the Manual:

Sl. No.	Designation
1.	Director
2.	Associate Director
3.	Quality Control Department

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable mode.

The holder of the copy of this Manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

Prepared By	Approved By	Issued By
Mr. Manikandan R Quality Co-ordinator	Fr. Deljo Puthoor CMI Accreditation Co-ordinator	Fr.Julious Arakkal CMI Director
		

Quality Department is responsible for issuing the amended copies to the copy holders, the copyholder should `acknowledge the same and he /she should return the obsolete copies to the officer.

If amendment regarding any point is required, the person who prepared the manual should contact the Quality Coordinator, prepare the amendment and get approval from approval authority. It should be attached to the Master copy and details to be entered in its amendment sheet. Quality Coordinator is responsible for issuing copy of amendment(s) to the controlled copyholder and he/she should acknowledge the same. Quality Coordinator should also enter the amendment details in the amendment sheets provided in the controlled copy.

The manual is reviewed once a year and is updated as relevant to the hospital policies and procedures. Review and amendment can happen also as corrective actions to the non conformities raised during the self assessment or assessment audits by NABH. The authority over control of this manual is as follows:

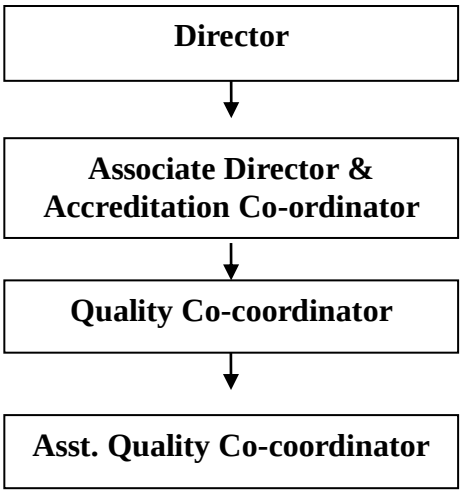
CONTENTS

1.0. INTRODUCTION

Continuous quality improvement program shall be implemented by Quality Control Team. The quality improvement programme shall be supported by the Hospital management. Amala Institute of Medical Sciences is committed to provide Quality Services to all the stake holders and has different committees to coordinate and monitor the services provided. Continuous quality improvement programmes are monitored by core committee by regular internal quality audits, physical checks, data analysis, random sample checks etc.

The quality improvement programme is reviewed periodically through Quality Committee and identify opportunities for improvement are identified. It's have identified key performance indicators to monitor the clinical structures, managerial structures, process and outcomes. All the key indicators shall be reported every month to the management and on later stage amendments shall be made in discussion with the core committee members. Proper awareness to all employees is provided through proper training programmes. Hospital conducts Internal Quality Audit every six months to ensure that all employees are strictly adhering to policies, procedures and work instructions/SOPs related to them.

2.0. DEPARTMENTAL HIERARCHY:



3.0. STAFFING PATTERN

Sl. No	Designation	Working Hours	Number of Staff
1.	Accreditation Coordinator	8	1
2	Quality Co-ordinator	8	1
3	Asst. Quality Co-ordinator	8	2

4.0. DUTIES AND RESPONSIBILITIES:

Quality Coordinator

Reporting to: Associate Director

- Quality Assurance in various sections of the hospital like Hospital Services, Patient Care, Medical investigations, Medication Management, Medical Records, Hospital infection Control, Administration, Training Programs, HR…etc as per NABH Accreditation norms
- Coordination of NABH Accreditation activities.
- Monitoring & ensuring hospital policies, processes, procedures and records as per NABH Norms.
- Review and correction of manuals, forms and formats based on NABH standards in coordination with Associate Director.
- Analyse the regulations related with hospital Quality Assurance and report them to the Associate Director.
- Coordination, Supervision and Administration of Quality department Staff in their duties.
- Conducting internal audit in various departments and evaluation of effective implementation of quality assurance programs of the hospital by professionals and technical & non technical staffs.
- Coordination of collection, processing and compilation of necessary data and reports from various departments for quality Assurance purpose and presenting them in appropriate forums
- Evaluation of incident reports, Adverse Drug event reports, Customer feedback forms and quality indicators and giving corrective action suggestions to Management
- Suggesting necessary training requirements of staffs in various Departments to management.

- Supervision of overall performance of the quality assurance of the hospital and hospital premises.
- The quality control professional may design, review and evaluate the work of hospital staff-professional, technical or clerical, for the effectiveness of quality assurance programs.
- Patient records may be reviewed to determine the need for admission, continued hospital stay and level of care by the staff.
- Analysis of Customer feedback forms and informing the Management

Asst. Quality coordinator

Reporting to: Quality Coordinator

- Ensure documentations regarding Policies, processes & Procedures mentioned in NABH standards in coordination with Quality Coordinator
- Create, review and correct all manuals, records, forms & formats and displays based on NABH standards in coordination with Associate Director and Quality Coordinator.
- Make necessary amendments in all manuals once in a year (Which can be fixed in different months to avoid workload in a month).
- Ensure NABH standards concerned to O.Ts, ICUs, and Ward staff/Nursing Department through proper guidance.
- Ensure proper patient movement and coordination between OT Staff, ICU/Ward staff, attenders and patient bystanders.
- Monitoring, reporting & ensuring the implementation of the concerned NABH standards.
- Ensure clinical audits in stipulated time period in all departments in coordination with Associate Director & Quality Coordinator.
- Ensure the completeness of files as per NABH norms.
- Ensure the fulfillment of OT criteria for the entry of patient before patient movement from ward/ room.
- Ensure the internal & external quality assurance is done properly.
- Ensure the quality of outsourced laboratory & imaging services are as per NABH norms in coordination with concerned Department.
- Ensure monthly collection and submission of Quality indicators from all departments by concerned persons.

- Proper entry of data collected from all departments and making them to presentable form
- Evaluation & follow up of incident forms in coordination with Quality Co-ordinator.
- Making time table for meeting of all committees & verification.
- Evaluation of Customer feedback forms in coordination with Quality Coordinator.
- Convene meeting of the quality team once in a week in consultation with Associate Director
- Monitoring, reporting & ensuring the implementation of NABH standards.

4.0. POLICIES AND PROCEDURES:

Quality Policy:

We are committed to provide world class health care by continually improving processes in creating an ideal work environment and providing safe and ethical medicines to our patients with loving care, to attain the goal of patient satisfaction.

Quality Objectives:

- To provide efficient and timely medical care to all patients with a human touch.
- To continuously monitor and deliver hospital services
- To provide continual and regular training to the skilled employees.
- To constantly improve the level of performance of all the key processes in the organization, especially of our ward staff, and to the traditional ethical values in the practice of medicines and patient care by all members of the hospital
- To build an effective feedback system

Service Standards

1. **Compassionate care**

- We deliver service in a manner that reflects compassion, empathy and caring. Compassion is demonstrated by listening to, accepting and responding to the distinct needs of each patient in each interaction.
- Exercise care when discussing patient information. We never discuss information about a patient in public areas of the hospital (elevators, stairwells, hallways and cafeterias).
- Demonstrate empathy by showing sensitivity to our patients' and families' needs including those of an emotional and spiritual nature.
- Include customers in discussions and decisions about their treatment and plan of care.

2. Effective communication and education

- The purpose of communication is to provide clear, accurate information and to achieve mutual understanding by active listening and open, respectful dialogue.
- Acknowledge patients and families by smiling, making eye contact and offering assistance.
- Use language and terms the customer can understand and offer an interpreter when needed.
- Listen attentively to the customer and check for understanding.

3. Responsiveness

- By anticipating the needs of others and responding in a prompt manner, we consistently provide a high level of service, increasing the trust and confidence others have in us.
- Approach patients or visitors who appear lost and offer to assist them.
- Escort patients, families and visitors to their destination or to the person they need to see, if possible.
- Respond to customers in a timely manner, informing them of any delays or changes that may affect them.

4. Accountability

- We take responsibility to know, understand and perform in a professional and competent manner and we extend ourselves.
- Provide explanations to customers of the services/treatments they are going to receive.
- Take ownership of complaints or requests and follow through to resolution.
- Take care of equipment and facilities and report all problems immediately.
- Maintain a professional appearance and demonstrate pride in our work and our jobs.

5. Teamwork

- We work collaboratively, valuing the specific and necessary contributions of each member of the healthcare team.
- We work together with a shared goal of achieving excellence in addressing patient needs.
- Encouraging participation from all team members (the team consists of all patients, families, physicians and co-workers).
- Offering to help co-workers before being asked and asking for support when we need it.
- Working with others collaboratively in problem solving and decision making.
- Initiating, promoting and adapting to change and the process of continuous improvement.

6. Respect

- We value the unique qualities and needs of individuals and are committed to understanding and appreciating the diversity of cultures, opinions and experiences that patients, families and hospital staff bring to our environment.
- Respect the customer‟s knowledge of their medical condition.
- Show concern for the customer‟s privacy by closing the door before asking personal questions.
- Demonstrate awareness of cultural differences and respect for other people‟s opinions and experiences.

NABH

National Accreditation Board for Hospitals & Health Care Providers

- An Autonomous body for accreditation of health care services in India.
- Part of Quality Council of India.

NABH Accreditation = Quality + Safety

Aims

- Patient Safety
- Employee Safety
- Environment & Community Safety

NABH Norms (5th Edition)

10 Chapters

100 Standards

651 Objective elements

Patient Centred chapters		Management Centered chapters	
1	Access Assessment & Continuity of Care (AAC)	6	Patient Safety and Quality Improvement (PSQ)
2	Care of Patients(COP)	7	Responsibilities of Management (ROM)
3	Management of Medication (MOM)	8	Facility Management & Safety (FMS)
4	Patient Rights & Education (PRE)	9	Human Resource Management (HRM)
5	Hospital Infection Control (HIC)	10	Information Management System (IMS)

Patient-Safety Programme

- **Patient Safety** is a health care discipline that emerged with the evolving complexity in health care systems and the resulting rise of patient harm in health care facilities. It aims to prevent and reduce risks, errors and harm that occur to patients during provision of health care.

This patient-safety programme includes

- **Committee** – Safety committee to review the programme and conducting quarterly
- **Manual** – have a safety manual Updating yearly
- **Patient safety and Clinical Safety officer**: is the designated individual(Dr. Dijoe, Associate Prof, Orthopaedics Dept.) for coordinating and implementing the patient-safety programme.

- **Adapts and implements international patient-safety goals (IPSG)**.

  Organization is monitoring patient safety indicators includes IPSG goals, which includes

  - Initial assessment
  - Incidence of Communication errors including handovers
  - Incidence of Patient identification errors
  - Incidence of medication errors
  - Compliance to Hand hygiene practice
  - Compliance rate to medication prescription in capitals.

- **Review process**: The patient-safety programme is a continuous process, reviewed once in three months through safety committee and Quality Committee and updated at once in a year. Any Identify the opportunities for improvent shall be reviewd annually and document in the safety committee. If not identify any opportunities , the same shall be documented.
- This review includes facility inspection process/internal audit, patient safety incidents, risk management and analysis of key safety indicators.
- Training – Training is being given regarding the programme through Induction, CNE, CTP
- Incident analysis –to identify the patient safety events and do RCA, CAPA. This ranges from near miss, no harm to sentinel event.
- Clinical audit-to review and identify for further improvement.
- Patient safety audit-is being done twice an year along with internal audit.
- Patient safety risk assessment: is being done and implementing risk-reduction activities. Organization conducts proactive analysis by using tools like HIRA, FMEA in both clinical and non-clinical prossess

Continuous Quality Improvement

A QI **program** is a set of focused activities designed to monitor, analyze, and **improve** the **quality** of processes in order to **improve** the healthcare outcomes in an organization. This involves collection of data on structures, processes and outcomes in all areas especially high risk areas. The collected data is analyzed for further improvement in the system and make adequate changes in the systems and practices in the hospital.

Purpose of continuous quality improvement is to -

- Monitor patient and staff satisfaction

- Monitor of quality indicators
- Monitor of Adverse Drug reactions and medication errors
- Monitor patient safety indicators
- Monitor of medical audit results
- Ensuring mock drill twice in a year.
- Ensuring facility safety round twice a year in patient care areas and once a year in non- patient care areas

Goals of Continuous quality Improvement -

- To utilize an interdisciplinary hospital-wide team approach to Quality improvement activities
- To maintain a Quality improvement team to be responsible for each key function and will evaluate the need for Quality improvement activities for the function on an ongoing basis by reviewing policies and procedures relating to that function and make necessary revisions as well as to establish priorities for measuring Quality to initiate Quality improvement measures in a prioritized manner.
- To improve patient care guidelines relating to operative and other procedures, in a collaborative effort.
- To utilize a standard format for documenting and reporting all Quality measures hospital-wide
- To collect data on staff views regarding Quality improvement activities
- To establish priorities for Quality improvement activities
- To develop a formal tool for prioritizing Quality improvement activities
- To strive to raise the benchmark in all aspect of service delivery and meet the quality standard expected for the same.

Structure for Quality Improvement:

Hospital has developed a structure for carrying out processes related to Quality Improvement in the hospital.

- The quality improvement programme is developed, implemented and maintained by a multi-disciplinary committee.
- Staff are made aware of the structure of the quality assurance program in the hospital through various training programmes like Orientation, CNE, CTP etc

- The Quality improvement programme has been reviewed by the quality committee on monthly basis.
- The quality improvement programme is a continuous process and updated at least once in a year and is being documented in the Quality Improvement Manual.

This Quality improvement programme is as follows:

- Quality Improvement Manual;in which the programmes have been documented.
- Hospital Committees;Conduction committees as per schedule.
- Tracing Quality indicators: collecting, reviewing, analyzing the deviations and improvement opportunities and presented in the Quality committee.
- Incident Analysis (RCA, CAPA)
- Mock drills – Conducting twice an year
- Internal audit –Conducting one in 6 months
- clinical audits - Conducting one in 3 months
- Trainings – Induction, Ongoing training

The quality assurance programs are designed for areas are like Laboratory, Imaging, Operation theatre environment and the ICU services

Documentation system:

Hospital has developed its documentation on policies, procedures, programmes, guidelines etc. These have been developed by committee personnel of the hospital, reviewed by heads of the departments, recommended by Quality Coordinator and have been approved by Director.

Hospital Quality Committee

Purpose

Quality Management committee shall be responsible for continuous quality improvement initiatives.

Fr. Julious CMI, Director – Chairman

Fr. Deljo Puthoor CMI, Associate Director –Vice Chairman
Mr. Manikandan R, Quality Co-ordinator- Secreatry

Members

1. Fr. Jaison Mundanmany CMI, Associate Director
2. Fr. Shibu PuthenPurackal CMI, Assistant Director.
3. Fr. Antony Mannumel CMI, Assistant Director
4. Dr. Betsy Thomas, Prof OBG & Medical College Principal
5. Dr.Rajesh Anto, Medical Superintendent
6. Dr. SureshKumar, Prof and HOD Neuro Surgery dept
7. Dr. Dijoe, Patient Safety Officer,Ortho dept.
8. Dr. Lisha, Pulmonary Medicine
9. Dr. Jobin, Emergency Medicine
10. Mr. Saiju, Chief Operating Officer
11. Mr. Franco, Joseph, CFO
12. Sr. Likitha, Chief Nursing Officer(CNO)
13. Mr. Piljo, HR Manager
14. Mr. Jijo Lazarus T, Civil Engineer
15. Mr. Jose A. Mekkattukulam, Electrical Engineer
16. Mr. Jomon, Biomedical Engineer
17. Mr. S. Sivakumar, Chief Medical Physist & RSO
18. Ms. Lucy, Purchase officer
19. Sr. Rubin, Pharmacy in-charge
20. Ms. Leela, Central Store in-charge
21. Ms. Litty, ICN incharge
22. Ms. Stephy, MRD In-charge
23. Sr. Lisanto, Radiology in-charge
24. Sr. Elizabeth, Blood Bank in-charge
25. Mr. Saneesh, MSW HOD
26. Ms. Reena, Chief Dietician
27. Mr. Renny Security In-charge
28. Mr. Nikhil, Fire Safety Officer

Structure of Committee and roles

Chairperson

The committee shall be headed by Chairperson elected by members whom shall overlook the functioning of the committee and system

Secretary

Elected secretary shall be responsible for coordination of meetings, documentation of minutes and communication of decisions to respective members.
They shall also coordinate with quality department regarding the functioning of committee.

Frequency of meeting

Once in a month

Responsibilities and functions

- Planning of the quality management system
- Establishment, monitoring and review of quality indicators
- Ensuring the availability of resources as required by the quality management system
- Conducting management reviews
- Reviewing non-conformances related to services
- Reviewing internal audit reports
- Analysis of data on process and service measurements
- Analysis of patient satisfaction data and complaints
- Ensuring timely corrective and preventive actions
- Ensuring continual improvement of the quality management system.

Quality Coordinator/Accreditation Coordinator:

The hospital has designated an Accreditation coordinator, who has overall responsibility of coordinating the work of NABH accreditation. His / her responsibility will include:

- To issue various documents to departments from time to time
- To keep a record of all the documentation of the hospital, in relation to accreditation

- ❖ To delegate the activities in departments and ensure its timely completion
- ❖ To regularly receive feedbacks from departments regarding status of their work related to accreditation preparation
- ❖ To plan and execute regular assessment of the hospital in accordance with accreditation standards
- ❖ To coordinate all such activities required for quality assurance and continuous monitoring of the hospital

Departmental coordination:

Each department of the hospital has been appointed with one in charge / coordinator. The responsibility of these coordinators will be

- ❖ To receive and retain all the documents and official correspondence related to accreditation from time to time
- ❖ To inform and orient the staff of their department on policies and procedures developed for their department
- ❖ To ensure the completion of all the work assigned to their department for NABH accreditation preparation
- ❖ To organize regular training programmes for staff of their department

Quality Circle/Link Person

A quality circle is a group of workers who do the same or similar work, who meet regularly to identify, analyze and solve work-related problems. In Amala they called as Link doctor for co-ordinating doctor's team, link nurse for co-ordinating nurses and link person for co-ordinating other department.

Structure

The members of various departments constitutes the Quality Circle which includes

- Doctors
- Nursing
- Operations
- Quality

- HR
- HIC
- Biomedical Engineering
- Maintenance –Civil and Electrical
- Radiotherapy
- Purchase dept
- Pharmacy
- MSW
- Central Store
- MRD
- Radiology
- Blood Bank
- Nutrition clinic
- Lab

Frequency of meeting: Periodical/ quarterly

Responsibilities and functions

1.Know the Hospital/ policy by read the dept Manual

2. Supports the In-charge.

3. Participation in the Quality Improvement Programme.

4. Proper Incident Reporting System- through One Amala i-Apps.

5. Gives Suggestions and feedback - through One Amala i-Apps.

6. Motivator in your dept.

Quality Improvement Program

Lab Quality Assurance Program (Ref: Lab Manual)

The hospital laboratory ensures that all patient samples are tested using appropriate technology based analyzer by competent personnel. The Lab adheres to standards of ISO 9001 for monitoring the quality standards, continual improvement and patient safety. The in-charge ensures that all personnel of the department are knowledgeable about the contents of departmental manual & procedures including changes relevant to the scope of their testing activities. Technical specifications for glassware, chemicals, Kits & Reagents used for testing are determined and followed while placing purchase order to procure these items. The specifications are used for conducting inspections of items delivered by the suppliers. Only approved & standard glassware, analytical grade chemicals, approved kits, reagents are used for testing. Only Analytical Grade chemicals are used during in-house preparation of standards and reagents. The name of the reagent and date of preparation of the reagent are indicated clearly for reagents prepared in-house. The chemicals, reagents and kits are stored at the temperature and humidity conditions specified in the product insert or as specified by the manufacturer. The expiry date of the reagents and kits are verified before use. Equipments, Micropipettes and Temperature measuring devices are calibrated in-house or through external agency at intervals as specified in Equipment calibration Plan and the details are recorded in the Equipment Calibration Record maintained in the department. Amala Hospital follows the criteria for assuring the quality of examination procedures mentioned in Clause 5.6 of the NABL Manual 112: Specific Criteria for Accreditation of Medical Laboratories.

Quality Control:

The internal and external quality control procedure that is performed in the Department is documented. HOD ensures that the Internal Quality Control samples are introduced along with patient samples in the routine laboratory workload and processed in the same manner as patient specimens by technicians who

routinely perform patient testing. Amala Hospital adopts mutual consent standards or methods which are clearly established in the peer reviewed journals and text books, specified, characterized and mutually agreed upon by all parties concerned. Amala Hospital documents statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer like product inserts, operating manuals, etc.

Internal Quality Control:

Assayed internal Quality Control samples are run before processing patient samples/ after major equipment break down/ after maintenance procedures/ whenever a new batch of reagent strips are used and the results are recorded in the Internal Quality Control Register of the respective department.

The Quality Control values are checked for the acceptable range specified in the product insert.

If the Quality Control is not within the acceptable range specified, the reagents are checked and changed if necessary/ Quality Control sample is checked/the equipment is recalibrated and Quality Control is run to obtain a Quality Control value that is close to the target value and within the specified range. Department Head/ in-charge analyses the results for any undue deviation and takes necessary corrective and preventive action if any and record the same in Internal Quality Control Register (IQCR).

External Quality Control scheme (EQAS):

EQAS for clinical biochemistry and hematology are available.

Inter Laboratory Comparison [ILC]:

ILC is done with NABL accredited Laboratory once in three months for all parameters. The results are sent to the external agency for analysis after approval by the authority. The results received from the external agency are analyzed for any undue deviations, if any and necessary corrective and preventive actions are taken if the deviation is beyond the acceptable range and the details of action taken are recorded in the Inter Lab Comparison Register.

Proficiency Testing:

The Quality Manager tests the proficiency of the technicians in performing a particular test by giving a random sample for testing. The results are analyzed and corrective and preventive actions are taken if required.

Assuring the quality examination procedures:

Amala Hospital has designed internal quality control systems that verify the attainment of the intended quality of results. Amala Hospital has control systems which provide staff members with clear and easily understood information on which base the technical & medical decisions. Special attention is paid to the elimination of mistakes in the process of handling samples, requests, examinations, reports, etc. Amala Hospital determines the uncertainty of results, which are relevant and possible. Uncertainty components, which are of importance, are taken into account. Amala Hospital has calibration programme for measuring systems and verification of trueness are designed and performed so as to ensure that results are traceable to SI units or by reference to a natural constant or other stated reference.

Where none of these are possible or relevant, other means for providing confidence in the results are applied including:

- Participating in inter-laboratory comparison programme/EQAS with an NABL accredited laboratory for all parameters in scope of accreditation.
- Using suitable reference materials (internal quality control, standards / calibrators with traceability) certified to indicate the characterization of the material.
- Performing examination or calibrations by another procedure, whenever it is not possible to carry out inter laboratory comparison

- Performing ratio or reciprocity-type measurements, which are expressed as measurement of uncertainty (Mu ±). Mu ± for various tests is calculated and monitored every month from the internal quality control values.
- Adopting mutual consent standards or methods, which are clearly established in the peer, reviewed journals and textbooks, specified, characterized and mutually agreed upon by all parties concerned.
- Documenting statements regarding reagents, procedures or the examination system when traceability is provided by the supplier or manufacturer.

AIMS participates in inter laboratory comparisons such as those organized by external quality assessment schemes. AIMS management monitors the results of external quality assessment and participates in the implementation of corrective actions when control criteria are not fulfilled. AIMS participates in Proficiency Testing as per clause 5.6 of NABL 112 "Specific Criteria for Accreditation of Medical Laboratories". AIMS participates in Proficiency Testing and analyses the results and takes the necessary corrective and preventive action, which is documented, in Inter-Lab comparison. AIMS ensures that as far as possible, the external quality assessment programme which provides clinically relevant challenge that mimics patient samples and validate the entire examination process including pre and post examination processes. AIMS conducts split sample testing by technicians who routinely perform the test, when such proficiency testing or inter laboratory comparisons are not available and documents the results in Split sampling Proficiency Testing Register.

Whenever a formal inter-laboratory comparison programme is not available, AIMS has developed a mechanism for determining the acceptability of procedures by exchanging samples with other laboratories. The laboratory management monitors the results of both the laboratories and records the same. If there is any deviation necessary, corrective and preventive action are taken and recorded. AIMS verifies the comparability of results throughout the clinically appropriate intervals, whenever the examinations are performed using different procedures or equipment. AIMS perform the verification of comparability of

results once in a month. AIMS do not perform tests at any site other than its permanent facility. AIMS documents, records and as appropriate, expeditiously acts upon results from these comparisons. AIMS acts on the problems or deficiencies that are identified and records the actions taken and retain the same.

Maintenance:

Break down Maintenance:

Automated Equipment is under Annual maintenance contract (AMC), unless it is in warranty period. The AMC provider is usually the Manufacturer or his nominated service provider. Whenever any equipment is found defective it is removed from the use and a label indicating the status of the equipment is displayed.

The service provider is intimated and followed up to ensure that the equipment is serviced. The details of Equipment failure are recorded in Equipment History Record. In case of any replacement of components, the details are also entered in Equipment History Record. After the service is completed the equipment is tested and validated before being commissioned into use.

Preventive Maintenance:

AIMS also maintains Preventive Maintenance Schedule for every equipment. Preventive maintenance to all the machines in the list of equipment is done and breakdown found is recorded in the Equipment Breakdown Record. If any Equipment is in the warranty period, then the preventive maintenance schedule is developed as per the warranty agreement. Maintenance procedures for equipments are developed and documented wherever required and maintenance is carried as per the documented procedures. In case of breakdown of any equipment in the list of equipment, the concerned person operating the equipment intimates Service engineers. Service engineer analyze the reason for the departure from the specific limits on previous tests and institute the control of non-conforming process. Manufacturer's instructions, operator manuals or other documentation are used to establish requirements, for compliance with relevant standards or to specify requirements for periodic calibration, as appropriate, to fulfill part of this requirement. After the Preventive maintenance, the Equipment is tested and validated before being used.

Routine Maintenance:

Routine maintenance of equipment is undertaken by the Lab technician in the Laboratory. Lab technician use the instruction Manuals and other direction provided by the Manufacturer while carrying out routine maintenance.

Calibration:

Equipment Calibration Record indicates the calibration requirement of equipment as specified by the Manufacturers. In-charge of the Laboratory ensures that no equipment is used unless calibrated as mentioned in the Equipment Calibration Record. Calibration status of equipment is indicated on the Equipment Calibration Record and also on the equipment with a label.

Internal Calibration:

In-charge ensures that only qualified and trained Technicians calibrate the equipment, which are internally calibrated. Manufacturer directions for internal calibration are closely followed while calibrating the equipments. After the calibration, the equipment is tested and verified for its performance and the readings reported by the equipments are compared with the acceptable range of readings prescribed by the Manufacturer. In case of any deviations from the acceptable range the equipment is re-calibrated and verified again. The readings of verifications after calibration are recorded on the Equipment Calibration Record with the traceability of the master equipment used and then the equipment is declared fit for use. The fitness status is displayed on the Equipment. The calibration certificates are available in the Equipment History Record.

External Calibration:

Whenever the Equipment is removed from the Lab and sent for the external calibration, the movement of the equipment is recorded on the Equipment History Record. After the External calibration when the Equipment is received, it is tested, verified and validated before being put in use. The calibration certificate issued by the External Agency is received and maintained with the Equipment History Record.

Computers and office Equipments:

When computers or automated examination equipments are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory ensures that**:**

- Computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility.
- The integrity of data is protected by providing a password to the users.
- Computers and automated equipment are maintained to ensure proper functioning and are provided with environmental and operating conditions necessary for maintaining the integrity of data, and
- Computer programme and routines are adequately protected to prevent access, alteration or destruction by casual use or unauthorized persons.

Corrective Actions:

This procedure is applicable for the following areas in all departments:

- Sample Rework/ Retesting of retained sample
- Complaints/ Suggestions/ Feedback received from patients/ physicians/ outside labs & hospitals
- Non Conformances related to results of Internal Quality Control
- Non Conformances related to results of External Quality Control/ feedback received on External Quality Assurance Scheme from outside agencies
- Non conformances related to consumables, chemicals, kits & reagents & Quality problems due to incoming materials.
- Non-conformances noted and arising during actual testing of samples.

Corrective actions are initiated based on non-conformances reported or noted during routine testing of patient samples, Sample rework, results of Internal Quality Control , proficiency test results, Complaints and suggestion received from patients, feedback from referral doctors, Feedback on EQAS Programme/ Results of Inter Lab Comparison, non-conformance reports generated during internal as well as external audits. The details of any nonconformance raised/ observed during the internal audit are recorded by the Auditor in duplicate in the Non-Conformance Report and signature is to be obtained from the auditee. One

copy is to be retained by Quality Officer for follow up**.** Other copy is to be given to the auditee of the respective department.

Disposition details, root cause for nonconformity and corrective actions planned or proposed are to be outlined within one week from the date of receiving the Non-conformity Report by the Auditee with target date and authorized by the Quality Officer. The proposed corrective action is to be verified by Quality Manager. If the proposed corrective action is adequate, the follow up copy is retained by the Quality Officer and by the Auditee. If the proposed corrective action is not adequate, it is to be sent to the concerned department for the revised corrective actions. After the implementation of the corrective action as per the target date, a re-audit is to be organized by the Quality Officer to verify the effectiveness of corrective actions implemented. The nonconformity report is to be closed if implementation of corrective action is found satisfactory and is to be signed off by the auditee and auditor in both the copies. Both the copies are to be forwarded to Quality Officer for review and authorization. After the review Quality Officer has to send one copy to the Director. The other copy is to be retained by the Quality Manager.

Preventive Action:

Applicable to:

- Retest/ resample
- Clients/ patients complaints
- Quality problems due to incoming materials
- Test work non-conformances.
- Internal Quality Control
- External Quality Control

The preventive actions are based on bench marking with similar organizations, analysis of data, including trend and risk analysis, proficiency-testing results, new technology, and problems in similar situations, etc. Technical Manager of the Respective Departments evaluates the identified areas and draws up action plans for the

implementation of the preventive actions and records the same in the Preventive Actions. Technical Manager/ Lab Technician is responsible for the implementation of the agreed preventive action. The proposed preventive action is to be given to the Quality Coordinator. Based on the target date indicated, implementation of the preventive action is to be verified and the preventive action report is to be closed on both the copies after review by Quality Coordinator. The results of the corrective action are submitted for laboratory management review by the Quality Coordinator. The effectiveness of the preventive action taken is reviewed in the Management Review Meeting.

The following table depicts the broad procedures:

Process	Requirements	Responsibility
Determination of potential nonconformities and their causes	Trend analysis on patient complaints and feedback Analysis of audit summaries	Quality Coordinator
Evaluation of the need for action to prevent occurrence of non-conformities	Analyze whether systemic or process non-conformity Discussion with section in charge or consultant of the Respective Departments	Quality Coordinator & Technical Manager
Determining and implementing action needed	Action plans with specified targets	Quality Coordinator & Technical Manager
Recording results of action taken	Action taken reports Corrective and Preventive action logs	Technical Manager & Quality Coordinator
Reviewing preventive actions taken	Management Review process	Quality Coordinator

Quality Assurance in Imaging Services

Ref: RADIOLOGY MANUAL

Prepared By	Approved By	Issued By
Mr. Manikandan R Quality Co-ordinator	Fr. Deljo Puthoor CMI Accreditation Co-ordinator	Fr.Julious Arakkal CMI Director

The Quality Assurance programme is established as per the AERB Guidelines. The programme shall address verification and validation of the imaging methods. Quality of services shall address safety of staff and patients, timeliness of results, accuracy and validity of results The programme shall address surveillance of imaging results by the Head of the Radiology Department. In order to ensure the quality of the imaging results, occasionally the imaging may be repeated and the results compared with earlier ones. If variations are noted the machines are to be recalibrated. The surveillance shall be conducted periodically atleast once a month with a sample size from both OP and IP patients.

The programme shall address periodic calibration and maintenance of all equipment. Imaging machines/equipments are covered by Annual Maintenance Contracts. Regular and preventive maintenance work is done on all the sensitive equipments in the imaging department. The periodical servicing of the equipments done by authorized service engineers of the equipment supplying company is documented to assure its good working condition. Verification and validation of imaging methods shall be documented. The corrective and preventive actions taken on the non-conformities shall be documented.

Quality Assurance In Radiotherapy

QA (Qaulity Assurance) programme

Meaning

Any planned and systematic action necessary to provide adequate confidence that the component or procedure will perform satisfactorly in compliance with the safety standards as specified by the competent authority including quality control.

Different mode of QA 's **;**

Daily, Monthly, Annual and in between in case there is major break down, QA will be done as per protocol.

Storage of source :

In brachytherapy, IR -192 source of activity 10Ci is capable to be stored as per AERB regulations (any no of source).

- Disposal

a. Disposal of the source to be done after the activity is reduced to less than 2Ci, NOC has to be obtained from AERB; customs clearance and arrangement for transport will be done by company (Nucletron).

b. After the disposal the intimation will be given within 7days to AERB

Mould used in linac

Meaning of mould :

Immobilisation device for daily treatment execution with reproducability.

- Individual moulds like head and neck, pelvis etc will be used with the help of base plate and neck rest.

AERB approvals :

All the approvals are availbale in the radiotherapy

Approval of layout plan of radiotherapy facility

- Authorization to import Medical Linear Accelerator
- Layout approval for HDR brachytherapy.
- Type approval of Medical Linear Accelerator
- Type approval of remote control HDR V3 from nucletron
- Licence for Linac, HDR, Exact Trac
- Permission to use HDR V3
- Commissioing approval of Linac -DBX accelerator

- Authorization of Exact Trac -X Ray -6D simulator for IGRT
- Commissioing approval of Exact Trac -X Ray -6D simulator for IGRT
- Authorization to import Brachytherapy source
- RSO approved by AERB

***Transport of Patients in and out after brachytherapy treatment*.**

Patient posted for brachytherapy before entering the brachy room, patient surveyed with survey meter and after the treatment the same procedure will be followed.

Community Based Activities

1. To conduct cancer awareness programmes by way of radio and TV programmes

2. To sensitise public to come for treatment at an early stage of cancer

3. To publish brochures and pamphlets regarding cancer and to conduct cancer screening programmes

Future plans:

1.To develop basic and clinical research esp. cervix, breast and Head and neck malignancies.

2. To upgrade present Linac to have radiosurgery and electron therapy.

3. To establish medical physics and radiobiology labs- which will provide platform for research

4. To encourage staff to do clinical research and trials and register for Ph.D

5. To conduct annual CME's for Post Graduates

Quality Assurance in OT

Ref:

- GOT` MANUAL
- CVTS OT MANUAL
- SSOT MANUAL

A quality assurance programme shall be followed for the surgical services which includes surveillance of the operation theatre environment.

Sl. No	Quality objective	Performance indicator	Responsibility	Measurement criteria	
				Criteria	Frequency
1.	Service quality	Staff availability (surgeon, anesthetist, nurse, supportive staff)	OT in charge	Duty roaster Monthly	
		OT Utilization rate, equipment down time	OT in charge	OT register	Monthly
		Medication administration (Name of the drug, Dosage, route, frequency)	In charge nurse	Anesthesia Record	Monthly
2.	Monitoring of infection rates OT environment	Post operative complications like surgical site infections, complications	OT In charge nurse	Patient case sheet	Monthly
		Rate of air exchange, cleaning and disinfection	OT in charge nurse	OT	Monthly
3	Internal Audit	OT functions	OT in charge nurse	Checklist	Once in 6 months
4	OT Quality Indicator tracing	Collecting, analyzing and monitoring the QI	OT in charge nurse	Checklist	Monthly
5	Prophylactic antibiotic administration				
6	Surgical safety checklist adherence				

Surveillance activities of each and every OT shall include:

- Daily monitoring of humidity.
- Daily monitoring of temperature.
- Daily cleaning and carbolisation of OT after every operative case.
- Weekly monitoring the efficacy of the OT fumigations.
- Monthly monitoring of pressure differentials within the OT.
- Monthly monitoring of the AHU filters and AC ducts.
- Half-yearly monitoring of integrity of filters – HEPA.

Surveillance of Operation Theatres:

The HCO undertaking surgery have a specific protocol for operating room procedures, including specific requirements for surgical hand washing routines and handling of sharps.

When individuals are being admitted to hospital or presenting at an emergency unit, a detailed medical and surgical history will be collected from them or their careers to identify conditions that may require additional precautions. All articles used in an operation will be sterile. The principles of sterile aseptic technique must be applied to all operating room procedures. The principle of 'confine and contain' will be applied at all times for all patients. Sterile drapes must be used for the patient; staff must wear full sterile operating room personal protective clothing. Patients should inform their doctor of their infectious status. Preoperative testing of patients should be on clinical indication. All staff in the surgical team should be vaccinated against hepatitis B. Surgical staff should not perform exposure-prone procedures if they are considered actively infectious with human immunodeficiency virus, hepatitis B virus or hepatitis C virus .Staff with dermatitis or skin wounds should be excluded from the operating team**.** Operating lists should allow sufficient time for adequate infection control activities, including routine cleaning and the appropriate disposal of clinical waste. The operating room should be cleaned as soon as practicable after surgery, including the correct disposal of sharps

and clinical waste and cleaning of all surfaces. Reusable instruments should be immersed in warm water and detergent as soon as possible after use and must then be thoroughly cleaned in a designated clean-up area before sterilization.

OT Specifications and Air-conditioning (As per NABH Guidelines):

OT Size: Standard OT size of 20' x 20' x 10' (Height below the false ceiling level is considered). Occupancy: Standard occupancy of 5-8 persons at any given point of time inside the OT is considered. Equipment Load: Standard equipment load of 5-7 kW considered per OT. Ambient temperature & humidity at each location is considered while designing the system.

Requirements of Super-Specialty OT:

Air Changes Per Hour: Minimum total air changes should be 25 based on international guidelines although the same will vary with biological load and the location. The fresh air component of the air change is required to be minimum 5 air changes out of total minimum 30 air changes. If HCO chooses to have 100% fresh air system than appropriate energy saving devices like Heat Recovery Wheel, Run around Pipes etc should be installed.

Air Velocity: The vertical down flow of air coming out of the diffusers should be able to carry bacteria carrying particle load away from the operating table. The airflow needs to be unidirectional and downwards on the OT table. The air velocity recommended as per the international and national guidelines is 90-120 FPM at the Grille/ Diffuser level.

Positive Pressure: There is a requirement to maintain positive pressure differential between OT and adjoining areas to prevent outside air entry into OT. The minimum positive pressure recommended is 15 Pascal (0.05 inches of water) as per ISO 14644 Clean Room Standard.

Air handling in the OT including air Quality: Air is supplied through Terminal HEPA filters in the ceiling. The minimum size of the filtration area should be 8' x 6' to cover the entire OT table and surgical

team. The minimum supply air volume to the OT (in CFM) should be compliance with the desired minimum air change. The return air should be picked up/ taken out from the exhaust grille located near the floor level (appx 6 inches above the floor level). The air quality at the supply i.e. at grille level should be Class 100/ ISO Class 5 (at rest condition). Class 100 means a cubic foot of air must have no more than 100 particles measuring 0.5 microns or larger.

Temperature and Humidity: The temperature should be maintained at 21 +/- 3 Deg C inside the OT all the time with corresponding relative humidity between 40 to 60% though the ideal Rh is considered to be 55%. Appropriate devices to monitor and display these conditions inside the OT may be installed.

Air Filtration: The AHU must be an air purification unit and air filtration unit. There must be two sets of washable flange type pre filters of capacity 10 microns and 5 microns with aluminium / SS 304 frame within the AHU. The necessary service panels to be provided for servicing the filters, motors & blowers. HEPA filters of efficiency 99.97% down to o.3 microns or higher efficiency are to be provided in the OT and not in the AHU.

Requirements of General OT:

Air Change Per Hour: Minimum total air changes should be 20 based on international guidelines although the same will vary with biological load and the location. The fresh air component of the air change is required to be minimum 4 air changes out of total minimum 25 air changes.

Air Velocity: The vertical down flow of air coming out of the diffusers should be able to carry bacteria carrying particle load away from the operating table. The airflow needs to be unidirectional and downwards on the OT table.

Positive Pressure: There is a requirement to maintain positive pressure differential between OT and adjoining areas to prevent outside air entry into OT. The minimum positive pressure recommended is 15 Pascal (0.05 inches of water) as per ISO 14644 Clean Room Standard.

Air handling in the OT including Air Quantity: Air is supplied through HEPA filters in the AHU. The minimum size of the air supply area should be 6' x 4' to cover the entire OT table and surgical team. The minimum supply air volume to the OT (in CFM) should be compliant with the desired minimum air change. The return air should be picked up/ taken out from the exhaust grille located near the floor level (approx 6 inches above the floor level). The air quality at the supply i.e. at grille level should be Class 1000/ ISO Class 6 (at rest condition). Class 1000 means a cubic foot of air must have no more than 1000 particles measuring 0.5 microns or larger.

Temperature and Humidity: The temperature should be maintained at 21 +/- 3 Deg C inside the OT all the time with corresponding relative humidity between 40 to 60% though the ideal Rh is considered to be 55%. Appropriate devices to monitor and display these conditions inside the OT may be installed.

Air Filtration: The AHU must be an air purification unit and air filtration unit. There must be two sets of washable flange type pre filters of capacity 10 microns and 5 microns with aluminium / SS 304 frame within the AHU. The necessary service panels to be provided for servicing the filters, motors & blowers. HEPA filters of efficiency 99.97% down to o.3 microns or higher efficiency may be provided in the AHU.

General Guiding Notes:

The AHU of each OT should be dedicated one and should not be linked to air conditioning of any other area.

During the non-functional hours, AHU blower will be operational round the clock (may be without temperature control).

VFD devices may be used to conserve energy.

- Window & split A/c should not be used in any type of OT because they are pure re circulating units and have convenient pockets for microbial growth which cannot be sealed.
- The flooring, walls and ceiling should be non-porous, smooth, and seamless, without corners and should be easily cleanable repeatedly.

- The material should be chosen accordingly. Validation of system to be done as per ISO 14664 standards and to be necessarily include:
    - Temperature and Humidity check;
    - Air particulate count;
    - Air Change Rate Calculation;
    - Air velocity at outlet of terminal filtration unit / filters;
    - Pressure Differential levels of the OT with respect to ambient / adjoining areas;
    - Validation of HEPA Filters by appropriate tests like DOP etc.

Maintenance of the system: It is recommended that periodic preventive maintenance be carried out in terms of cleaning of pre filters at the interval of 15 days. Preventive maintenance of all the parts is carried out as per manufacturer recommendations.All the engineering controls shall be monitored on a daily basis and registers shall be maintained to record the aspects such as temperature, humidity,

Quality Assurance Programme in ICU:

Ref:

- MICU MANUAL **AIMS / DM /MICU - 46**
- CICU MANUAL **AIMS / DM /CICU - 12**
- RICU MANUAL **AIMS / DM /RICU - 74**
- CVS ICU **AIMS / DM / CVSICU - 16**
- CCU MANUAL…. **AIMS / DM / CCU – 10**
- PICU MANUAL- …**AIMS / DM / PICU - 65**
- NICU MANUAL- **AIMS / DM / NICU – 53**
- SICU MANUAL- **AIMS / DM / SICU – 78**

- PSICU MANUAL- **AIMS / DM / PSICU – 67**
- NSICU MANUAL- … **AIMS / DM / NSICU - 50**
- SSICU MANUAL- **AIMS / DM / SSICU- 76**
- ONICU MANUAL- … **AIMS / DM / ONICU - 58**

QUALITYASSURANCE OF SURGICAL SERVICES

Ref:

- MANUAL-GEN SURGERY- ….AIMS/DM/GSO-29
- MANUAL-ORTHOPAEDICS- … AIMS /DM/ORO-60
- MANUAL-OBG- AIMS / DM / GYO - 57
- MANUAL-OPTHALMOLOGY- AIMS / DM / OPO - 59
- PLASTIC SURGERY AIMS / DM / PSO – 66
- SURGICAL ONCOLOGY AIMS / DM / SOO – 79
- NEURO SURGERY DEPT. MANUAL AIMS / DM / NSO - 52

All the patients who are to undergo surgery have full details of their medical condition in their case records. Depending on his medical condition the patient may need either elective or emergency surgical procedures. The elective procedure could either be minor in nature or major. Emergency surgical procedures though usually major, could also be minor in nature. Surgical patients have the preoperative assessment and the provisional diagnosis documented prior to the surgery .Before either elective or emergency procedures, the surgeon examines the patients and makes an assessment of his/her condition based on the clinical presentation of the case, signs and symptoms, and results of the investigations. A provisional diagnosis is made and this is documented in the patient's case notes before he is taken up for surgery. This is done mainly to avoid adverse events like wrong site, wrong patient and wrong surgery etc. All patients admitted for elective major surgery should undergo the following tests: Blood Hb., blood grouping & Rh typing, Random blood sugar estimation,

blood urea, serum creatinine, HIV, HbsAg and HCV(if serology test done before 3 months then need not do again). They should also have ECG and chest X-ray taken.(Optional)

Elective minor cases need to have the following tests done: Hb, Random blood sugar, HIV and HbsAg. They should also have their ECG and chest X-ray taken, Preoperative initial assessment has to be done for all patients undergoing elective major and emergency operations. If the surgeon comes across any abnormal findings in the pre operative tests, it has to be documented in the patient's records and this has also to be informed to the patient's relatives. Patients with obvious ECG changes or patients with history of cardiac problems should be seen by the cardiologist before being taken up for surgery. The patient should be informed by the cardiologist of the potential cardiac risks during or after surgery. Patients with poor renal function or chronic renal disease should have consultation with the nephrologists. The bystanders or relatives must be informed by the nephrologists about the possible postoperative or intra operative complications.

Apart from the general consent which is obtained routinely from all in-patients, patients undergoing surgery should be informed about the procedure, its probable outcome, and its possible outcome and its probable complications if any. Following this, informed consent from the patient is taken. The name of the surgical procedure, site of surgery and complications of surgery should be written in capital letters. Patients with cardiac or renal problems should be given their informed consent in his/her handwriting and signed with a witness other than a hospital staff. One of the witnesses should be the ward nurse in charge.

The patient is prepared for surgery as follows:

- The patient should not take anything orally at least 6 to 8 hours before the actual surgery.
- The patient's weight is recorded.
- The skin of the operation site is prepared by shaving the hair and cleaning with antiseptic.
- Bowel preparation is done by giving enema.
- Artificial dentures and jewellery are removed (and receipt given or handed over to authorized people), Nail polish is cleaned.

- The patients dress is changed to a clean one.
- Patients ID tag is checked and patient is identified.
- The patients depending on their physical condition are shifted to the OT by wheel chair or trolleys.
- A Staff nurse from the ward accompanies the patient with the case sheet to the OT. The OT nurse takes over the patient after checking the case sheet and making identification and documents.
- Here after the OT staff is responsible to take care of the patient till he/she leaves the recovery room.
- Patient is shifted to Operation Theater in sterile gown/dress supplied by the CSSD.
- All type of surgeries performed in this hospital are by well qualified, experienced surgeons who have had extensive training and expertise in their particular fields. Complex surgeries are sometimes performed by a team of doctors, each dealing with his /her specialty.
- Prior to surgery the case file shall be reviewed, the condition of the patient shall be checked and surgical safety checklist before induction of anaesthesia, before skin Incision and before the patient leaves the operating room shall be completed by the surgeon and anesthesiologist. The WHO Safe Surgery Checklist is being followed.

After the surgery is completed, before the patient is transferred back to the ward, the surgeon writes down and documents a brief operative note and post operative plan of care. The anesthesiologist on his/her part also notes down the details of the anaesthesia procedure starting with the pre-medication, induction till the end of anaesthesia, ex-tubation etc. All the events during the stages of anaesthesia are recorded and documented. The anesthesiologist will follow the patient in the recovery room and the surgical ICU/ward till the patient fully recovers from anaesthesia. As a quality assurance programme, the OT and its surrounding areas like the recovery room, CSSD etc are under the strict supervision by the infection control nurse and OT Supervisor and the hospital infection surveillance team who ensures absolute sterility of the operation areas so as to avoid the risk of transmission of infection. The plan also includes monitoring of surgical site infection rates. All the post operative patients shall be screened for the same. The hospital infection control team conducts regular

documented surveillance which includes monitoring of surgical site infections. Culture swabs are taken from infected or suspected wound sites to analyze them with the aim to prevent or reduce the risk of hospital associated infections.

Quality Indicator Collection Details

Procedure for collection of data, interpretation and analysis of quality indicators:

Collection of Data: Reports of all key indicators as decided by the management will be submitted to the quality coordinator before 5th of every month by the Head of each department. All the data will be collected in the standardized format.

Analysis of Data: All the data will be assessed in the form of Structure, process and the outcome.

Structure: Structure includes the facilities provided to the staff. Formula used for calculation. Training or awareness of the set formulas / quality improvement programme.

Process: Strict adherence of developed procedures in the daily work routine. In case of deviations, same will be documented in the quality indicator reporting form with proper reasoning.

Outcome: Based on the reports received, trend analysis will be done and the same will be reported to the chairman/ Management.

The analysis of indicators shall be done on monthly basis by the Quality Committee.

- The compliance in 90 % or more is considered as excellent
- The compliance in 80 % or more is considered as good.
- The compliance in 70 % or more is considered as acceptable
- The compliance rate less than 70% needs to be investigated

Trend Analysis:

The outcomes of the Quality Care Indicators are analyzed every month and a comparative statement is made on the progress for each month. The progress report is forwarded to the management. In case of negative progress, if any, corrective action report shall be made by the Core Committee in discussion with the concerned Department Head and the same shall be submitted to the Management.

Validation of quality indicators

- The data which is collected is validated from time to time and in response to queries or when an unexplained trend occurs.
- The data which is prepared from the user department has been cross checked and countersigned by the department HOD/In-charge and forwarded to QC department. Validation meeting/ review meeting shall be conducted periodically with that department/through Quality meeting or other committees.
- Appropriate tools like RCA, Fish bone diagram etc are used for data analysis and interpretation. After the analysing, the data results are communicated with the department through meetings/trainings, Link group/quality circle group and thereby used as a tool for further improvement.
- We are tracing 65 QIs- (56 NABH QIs (30 + 26) and additionally 9 Amala QIs) as monthly and presented in various committees.

Sl. no	Quality indicator	Formula	Units	Frequency of data collection/monitoring	Remarks
1.	Time taken for Initial Assessment of Indoor patients and emergency patients	Sum of time taken for the assessment/– total number of patients	Minutes	Monthly	Data collection through checklist by QC and Nursing team. (ED data by QC team and Nursing initial assessment by Nursing tem)
2.	Number of reporting errors / 1000 investigations	Number of reports with errors/ number of tests performed* 1000	/1000 tests	Monthly	Data will be provided from concerned Lab and Radiology departments.

3.	Percentage of adherence to safety precautions by employees working in diagnostics	Number of staff adhering to safety precautions / Number of staff audited.	Percentage	Monthly .	Data collection through checklist done by ICN/Quality department/RSO.
4.	Medication error rate	Total number of Medication errors / Total number of opportunities of Medication errors *100	Percentage	Monthly	Data collection through incident reports and chart audit by QC team/Clinical Pharmacist.
5.	Error prone abbreviations	Number of medication charts with error prone abbreviations/number of medication charts reviewed*100	Percentage	Monthly	Data collection through incident reports and chart audit by QC team/Clinical Pharmacist.
6.	Percentage of in patients developing adverse drug reactions.	Number of patients developing adverse drug reactions./number of in patients *100	Percentage	Monthly	Data collection by Pharmacovigilance and through incident reports and chart audit.
7.	Percentage of unplanned return to OT	Number of unplanned return to OT/No. of patients who underwent surgeries in the OT*100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.
8.	Percentage of surgeries where the organization procedure to	number of surgeries where the procedure was followed/ number of surgeries performed*100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month and through chart audit by QC team.

	prevent adverse events like wrong site, wrong patient and wrong surgery have been adhered to.				
9.	Percentage of transfusion reactions	Number of transfusion reactions / Number of units transfused *100	Percentage	Monthly	Data captured at BLOOD BANK and will submit to quality at every month.
10.	Standardized mortality ratio for ICU Mortality rate	Actual deaths in ICU/predicted deaths in ICU Number of deaths/number of discharges and deaths *100	Percentage	Monthly	Data captured by QC team by APACHE 2 score entry, the data will available through I-Apps. Data captured at medical records departments and will submit to quality at every month.
11.	Return to emergency within 72 hours with similar presenting complaints.	Return to emergency within 72 hours with similar presenting complaints/number of patients who have come to emergency.*100	Percentage	Monthly	Data captured by casualty relations officer and submit to quality every month.
12.	Incidence of hospital associated pressure ulcers after admission	Number of patients who develop new/worsening pressure ulcers /total Number of IP	/1000 patient days	Monthly	Data captured by infection control nurses and presented in HICC.

		days *1000			
13.	Catheter associated Urinary Tract Infection Rate	Number of Urinary Catheter associated UTIs in a month / Number of Urinary Catheter days in that month *1000	/1000 urinary catheter days	Monthly	Data captured by infection control nurses and presented in HICC.
14.	Ventilator associated pneumonia Rate	Number of ventilator associated pneumonias in a month / Number of ventilator days in the month *1000	/1000 ventilator days	Monthly	Data captured by infection control nurses and presented in HICC.
15.	Central line associated blood stream infection rate	Number of central line associated blood stream infections in a month/no.of central line days in that month *1000	/1000 central line days	Monthly	Data captured by infection control nurses and presented in HICC.
16.	Surgical Site Infection Rate	Number of surgical site infections in a given month/ Number of surgeries performed in that month *100	/100 surgical procedures	Monthly	Data captured by infection control nurses and presented in HICC.
17.	Compliance to hand hygiene practice	Total no. of hand hygiene actions performed / Total no.of hand hygiene opportunities *100	Percentage	Monthly	Data captured by infection control nurses and presented in montly HICC.
18.	Percentage of cases who received appropriate prophylactic antibiotics within the	Number of patients who did received appropriate prophylactic antibiotic/number of patients who underwent surgeries	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month and through chart audit by QC team.

	specified time frame.	in the OT *100			
19.	Percentage of re-scheduling of surgeries	Number of cases re-scheduled/ number of surgeries planned*100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.
20.	Turnaround time for issue of blood and blood components	Sum of time taken /total number of blood and blood components cross matched/reserved	Minutes	Monthly	Data captured at BLOOD BANK and will submit to quality at every month.
21.	Nurse-Pt ratio for ICU& ward	No. of nursing staff/No. of occupied beds	Ratio	Monthly	Data captured by HR dept and will submit to quality at every month
22.	Waiting time for outpatient consultation	Sum total patient – in time for consultation/tptal number of out patients	Minutes	Monthly	Waiting time from OPD collected by OP staff.
23.	Waiting time for diagnostics	Sum total patient reporting time/number of patients reported in diagnostics.	Minutes	Monthly	Waiting time from diagnostics collected by Radiology staffand submit to QC every month
24.	Time taken for discharge	Sum of time taken for discharge/number of patients discharge	Minutes	Monthly	Data collected by QC staff from Admission discharge register by checklist as monthly.

25.	Percentage of medical records having incomplete/ improper consent	Number of medical records having incomplete/ improper consent / Number of discharges and death *100	Percentage	Monthly	Data captured at medical records departments and will submit to quality at every month. Live chart audit also performed by quality team and analyzed in monthly basis. Incomplete consent means, If any of the essential elements/ requirement of consent is missing. Improper consent means, if any consent obtained is invalid/void (consent obtained from wrong person/ consent obtained by wrong person etc.)
26.	Stock out rate of emergency medications	Number of stock outs of emergency drugs/Number of drugs listed as emergency drugs in hospital formulary *100.	Percentage	Monthly	Data captured at pharmacy and store, will submit to quality at every month.
27.	Number of variations observed in mock drill	Total number of variations in a mock drill	Number	Monthly	Data captured by QC team after conducting Mock Drills.
28.	Patient fall rate(falls per 1000 patient days)	Number of falls month /total number of patient days*1000	/1000 patient days	Monthly	Data capturing by incident reports.
29.	Percentage of near misses	Number of near misses reported/number of incidents reported *100	Percentage	Monthly	Data capturing through incident reports by QC team.
30.	Incidence of needle stick	Number of parentral exposures in IP	/1000 days	Monthly	Data capturing through incident reports by HIC team.

	injuries	/number of inpatient days *1000			
31.	Appropriate handovers during shift change	total no of handovers done appropriately/ total no of handover opportunities*100	Percentage	Monthly	Nursing hand over data captured by Nursing team and will submit to quality at every month.
32.	Compliance rate to medication prescription in capitals.	Total number of prescriptions in capital letters/total number of prescriptions*100	Percentage	Monthly	Data capturing through medical record audit.
33.	Percentage of re-dos	Number of re-dos/number of tests performed*1000	/1000 tests	Monthly	Data will be provided from concerned Lab and Radiology departments.
34.	Percentage of modification of anesthesia plan for the month	Number of cases where anesthesia plan is modified for that month/ Total number of patients given anesthesia for that month *100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.
35.	Percentage of unplanned ventilation following anesthesia	Number of unplanned ventilation following anesthesia/ Number of patients given anesthesia	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.
36.	Percentage of Adverse Anesthesia Events for a given period of time	Number of Adverse Anesthesia events for a given period of time/ Number of patients given anesthesia for a given period of time *100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.

37.	Anesthesia related mortality rate for a given period of time	Number of patients died because of anesthesia for a given period of time/ Number of patients given anesthesia for a given period of time *100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.
38.	percentage of cases which the planned surgery changed intra operatively	Number of cases in which the planned surgery is changed intra operatively/ number of surgeries performed*100	Percentage	Monthly	Data captured at operation theatre and will submit to quality at every month.
39.	Percentage of wastage of blood and blood products	Number of units of blood and blood products wasted in a month / Number of units of blood and blood products collected in a month *100	Percentage	Monthly	Data captured at BLOOD BANK and will submit to quality at every month.
40.	Percentage of case sheets wherein screening for nutritional needs has been done	Case sheets with nutritional assessment / Number of discharged case sheets *100	Percentage	Monthly	Data collection through chart audit by QC team.
41.	Percentage of cases wherein nursing plan is documented	Number of case sheets with nursing care plan documented/ total number of patients *100	Percentage	Monthly	Data collection through chart audit by Nursing tem.

42.	Return to ICU within 48 hours	Number of returns to ICU within 48 hours/number of discharges/transfers in the ICU *100	Percentage	Monthly	Data captured by ICU in-charges and submit to quality every month.
43.	Re-intubation rate.	Number of re-intubations within 48 hours of extubation/number of intubations*100	Percentage	Monthly	Data captured by ICU in-charges and submit to quality every month.
44.	Number of drugs and consumables purchased by local purchase (within and outside formulary	a) Number of drugs/items purchased by local purchase within formulary/ number of drugs/items in hospital formulary list *100 b) Number of drugs/items purchased by local purchase within formulary/ number of drugs/items in hospital formulary list *100	Percentage	Monthly	Data captured at pharmacy and store, will submit to quality at every month.
45.	Percentage of consumables rejected before preparation of Goods Receipt Note	Total quantity rejected before GRN/ Total quantity received before GRN *100	Percentage	Monthly	Data captured at pharmacy and store, will submit to quality at every month.
46.	Number of variations from the procurement process	Number of variations from the defined procurement process/ total number of items	Percentage	Monthly	Data captured at Purchase Pharmacy department and will submit to quality at every month.

		procured*100			
47.	Percentage of employees provided pre-exposure prophylaxis	Number of employees provided with Pre-exposure prophylaxis / Number of employees who were due to be provided with Pre-exposure prophylaxis *100	Percentage	Monthly	Data captured by infection control nurses and human resources department and will submit to quality at every month.
48.	Bed occupancy rate average length of stay	Number of inpatient days in a given month/number of available bed days in that month *100 Number of inpatient days in a given month/ number of discharges and deaths *100	Rate	Monthly	Data captured by Operations dept and will submit to quality at every month.
49.	OT & ICU utilisation rate	OT Utilisation time in hours/resource hours *100 Number of bed utilised days/bed days available *100	Percentage	Monthly	OT utilisation rate captured at operation theatre and will submit to quality at every month. ICU utilisation rate captured by QC/Operations dept.
50.	critical equipment down time	Sum of down time of all critical equipment in hours in a month	Hours	Monthly	Data captured by Biomedical Engineering dept and will submit to quality at every month
51.	Out patient satisfaction index	Average score achieved/maximam possible score *100	Percentage	Monthly	Data capturing through OP feed back forms.

52.	In patient satisfaction index	Average score achieved/maximam possible score *100	Percentage	Monthly	Data capturing through IP feed back forms.
53.	Employee satisfaction index	Average score achieved/maximum possible score*100	Percentage	Monthly	Data collection through checklist by HR/QC/Software.
54.	Employee attrition rate	Number of employees who have left during the month/ number of employees at the beginning of month+newly joined staff*100	Percentage	Monthly	Data captured at HR department and will submit to quality at every month
55.	Employee absenteeism rate	Number of employees who are on unauthorised absence / number of employees *100	Percentage	Monthly	Data captured at HR department and will submit to quality at every month
56.	Number of sentinel events reported collected and analysed within defined time frame.	Number of sentinel events analysed within the time frame/number of sentinel events reported/collected *100	Percentage	Monthly	Data capturing through incident reports by QC team.
57.	Percentage of Medical Records not having discharge summary	Number of medical records without Discharge Summary / Total number of discharges / LAMAs / deaths in that month *100	Percentage	Monthly	Data captured at medical records departments and will submit to quality at every month.
58.	Percentage of missing records	Number of missing records / number of medical records	Percentage	Monthly	Data captured at medical records department and will submit to quality at every

		*100			month.
59.	Incidence of patient identification errors	Number of patient identification error/no.of incidents reported *100	Percentage	Monthly	Data capturing through incident reports/rounds by QC team.

Amala QI

SL.NO	QUALITY INDICATOR	FORMULA	FREQUENCY OF DATA COLLECTION/ MONITORING	REMARKS
1)	Donor waiting Time	Total time taken for donor/ total no of donor (at blood bank)	Monthly	Data captured at BLOOD BANK and will submit to quality at every month.
2)	Rate of primary CS	No of primary cs/ total no of live birth excluding repeated C S*100	Monthly	Data captured by QC team by LR register.
3)	Average time taken from Consulting ED MO to ward &ICU (Hrs)	Total time taken from ED MO consultation to ward/ No.of patients shifted from ED	Monthly	Data captured by QC team by ED register.
4)	Percentage of Occurrence of ADI	No. of ADI/ No. of IP days*100	Monthly	Data captured by QC team by incidents/chart audit.
5)	Total No. and Timely response to maintenance request.	Total number of request came through i-Apps and closed on time.	Monthly	Data captured by QC team through the Software.

6)	Percentage of patient shift attended within the time frame(30 minutes)	Number of shifts attended by staff within 30 minutes/Total number of CMC shifts*100	Monthly	Data captured by Operations dept team through the Software and will submit to quality at every month..
7)	Phlebitis Rate	Total Phlebitis reported/Total cannula days	Monthly	Data captured by HIC team by checklist

QI presentation division(Clinical and managerial)

Sl No.	Type of QI	QIs	Presented by
	Appropriate patient assessment	Initial assessment –IP and ED –doctors and nurses	Dr. Dijoe
		Care plan documentation by doctors	
		Nutritional screening by nurses	Nursing dept
		Nursing care plan documentation by nurses.	Nursing dept
	Safety and quality-control programmes of all the diagnostic services.	Number of reporting errors/1000 investigations.	Dr. Robert, Radiology
		Percentage of re-dos.	
		Percentage of reports co-relating with clinical diagnosis.	
		Percentage of adherence to safety precautions by employees working in diagnostics.	
	Safety and quality-control programmes of all the Lab services	Number of reporting errors/1000 investigations.	Dr. Sreeja and Sr. Helen
		Percentage of re-dos.	
		Percentage of reports co-relating with clinical diagnosis.	
		Percentage of adherence to safety precautions by	

		employees working in Lab.	
	Medication management	Incidence of medication errors.	Quality team
		Percentage of admissions with adverse drug reaction(s).	
		Percentage of medication charts with error prone abbreviations.	
		Percentage of patients receiving high-risk medications developing adverse drug event.	
	Monitoring includes use of anaesthesia.	Percentage of modification of anaesthesia plan.	Dr. Paul
		Percentage of unplanned ventilation following anaesthesia	
		Percentage of adverse anaesthesia events.	
		Anaesthesia-related mortality rate.	
	Monitoring includes surgical services.	Percentage of unplanned return to OT.	Dr. Suresh
		Percentage of re-scheduling of surgeries	
		Percentage of cases where the organisation‘s procedure to prevent adverse events like wrong site, wrong patient and wrong surgery have been adhered to.	
		Percentage of cases who received appropriate prophylactic antibiotics within the specified time frame	
	Monitoring includes use of blood and blood components.	Percentage of transfusion reactions. a.	Blood bank
		Percentage of wastage of blood and blood components.	
		Percentage of blood component usage	
		Turnaround time for issue of blood and blood components.	
	Monitoring includes infection control activities.	Catheter Associated Urinary Tract Infection rate.	HIC
		Ventilator Associated Pneumonia rate.	
		Central line associated bloodstream infection rate.	
		Surgical site infection rate.	
	Monitoring	Mortality rate.	

	includes review of mortality and morbidity indicators.	Return to ICU within 48 hours.	Dr. Dijoe
		Return to the emergency department within 72 hours with similar presenting complaints.	
		Re-intubation rate.	
	Monitoring includes patient safety goals.	Incidence of Communication errors including handovers	Nursing, Dr. Dijoe and HIC
		Incidence of Patient identification errors	
		Compliance to Hand hygiene practice	
		Compliance rate to medication prescription in capitals	
	Monitoring includes procurement of medication essential to meet patient needs.	Percentage of drugs and consumables procured by local purchase.	Dr. Lejo and Ms. Lucy
		Percentage of stock outs including emergency drugs.	
		Percentage of drugs and consumables rejected before preparation of goods receipt note.	
		Percentage of variations from the procurement process.	
	Monitoring includes risk management.	Number of variations observed in mock drills.	Quality, HIC, HR
		Incidence of falls.	
		Incidence of hospital associated pressure ulcer after admission.	
		Percentage of staff provided pre-exposure prophylaxis.	
	Monitoring includes utilisation of space, manpower and equipment.	Bed occupancy rate and average length of stay.	Mr. Saiju, COO
		OT and ICU utilisation rate.	
		Critical equipment down time.	
		Nurse-patient ratio for ICUs and wards.	
	Monitoring includes patient satisfaction which also incorporates waiting time for services.	Out-patient satisfaction index.	Quality
		In-patient satisfaction index.	
		Waiting time for services including diagnostics and out-patient consultation.	
		Time taken for discharge	
	Monitoring	Employee satisfaction index.	

	includes employee satisfaction.	Employee attrition rate.	HR
		Employee absenteeism rate.	
		Percentage of employees who are aware of employee rights, responsibilities and welfare schemes.	
	Monitoring includes adverse events and near misses.	Percentage of sentinel events reported, collected and analysed within the defined time frame.	Quality and HIC
		Percentage of near misses.	
		Incidence of blood body fluid exposures.	
		Incidence of needle stick injuries.	
	Monitoring includes availability and content of medical records.	Percentage of medical records not having discharge summary.	Ms. Stefy, MRD
		Percentage of medical records not having codification as per International Classification of Diseases (ICD).	
		Percentage of medical records having incomplete and/or improper consent.	
		Percentage of missing records. b.	

Quality Improvement Tools And Projects Undertaking

- ✓ The organisation undertakes quality improvement projects at a minimum of two.
- ✓ The organization uses appropriate analytical tools such as RCA, Parato etc, statistical tools such as sig sigma, managerial tools such as PDCA.
- ✓ These studies have conducted periodically and presented to the top management.

Clinical audit.

- ➢ The organization shall identify and work on at least four clinical audits in identified priority patient care aspects. These audits are retrospective/concurrent in nature and are performed to improve the quality of patient care
- ➢ Every clinicical department shall conduct one clinical audit per dept per year The parameters could be disease based, based on morbidity (length of stay), process/procedure based etc.
- ➢ The clinical audit team consists of clinicians, administrators and nurses.

- Every month Clinical Audit & Patient Care Audit Committee has been conducted and analyzed the summary of clinical audit.
- Clinical audits are documented . Root-cause analysis (RCA) has been done and remedial measures are implemented.

Quality improvement programme supported by management

- ✓ The management creates a culture of safety.
- ✓ The leaders at all levels in the organisation are aware of the intent of the patient safety and quality improvement programme and the approach to its implementation.
- ✓ Departmental leaders are involved in patient safety and quality improvement. The department shall have their own KPI which are collected, monitored ,analyzed and actively work to achive for that goals.
- ✓ The management makes available adequate resources such as men, money,machine required for patient safety and quality improvement programme.
- ✓ Organisation earmarks adequate funds from its annual budget(for Quality, Patient safety and HIC aspects) in this regard.
- ✓ The management shall identify organization and department level dept level, quality objectives, set targets, monitor them at least once in three months and modify annually.The targets shall be shared with faculty through varios plateform such as One Amala, I-Apps, committees, meetings, trainings, news letters.
- ✓ The management uses the feedback(from staff as annaully through surveys) obtained from the workforce to improve patient safety and quality improvement programme

Prepared By	Approved By	Issued By
Mr. Manikandan R Quality Co-ordinator	Fr. Deljo Puthoor CMI Accreditation Co-ordinator	Fr.Julious Arakkal CMI Director

Prepared By	Approved By	Issued By
Mr. Manikandan R Quality Co-ordinator	Fr. Deljo Puthoor CMI Accreditation Co-ordinator	Fr.Julious Arakkal CMI Director

Incidence Reporting

Amala Institute of Medical Sciences (AIMS) shall have a well-defined system of incidence reporting which shall include:

- Identification
- Reporting
- Review/Root Cause Analysis (RCA).
- Corrective and preventive Action (CAPA).

All incidents shall be captured at quality control Department. Hospital has a well-defined process of collecting incidents through One Amala- iApps/incident report forms and feedback through patient feedback forms. The Quality control Department shall be responsible for the conducting the **Root Cause Analysis** of incidents and feedbacks including complaints received. Based on the analysis, quality control Department suggests the CA / PA for continual improvement of the quality of patient-care services on consultation with management. Patient feedback (negative or positive) and complaints have been conveyed to all HODs in the institution through monthly Quality/Core Committee Meeting which will be conveyed to staff. The reports are documented and kept under the responsibility of Quality Control department.

Incident reporting method:

All types of incidents shall be reported to quality control department within 24 hours of incidents occurrence through One Amala- iApps.

There are 4 categories (Category – 1, Category – 2, Category – 3, Category – 4)

Category – 1 - Near-miss

- A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so.

  Errors that did not result in patient harm, but could have, can be categorised as near-misses.

Category -2 - No -harm

- A No-harm is an event is a patient safety event that reaches the patient, but does not cause harm.

Eg: Documentation error.

Category -3 - Adverse Event

- An injury related to medical management, in contrast to complications of disease. Medical management includes all aspects of care, including diagnosis and treatment, failure to diagnose or treat, and the systems and equipment used to deliver care. Adverse events may be preventable or non-preventable.

Eg: Medication errors

Category -4 - Sentinel Event

- A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or **major and enduring loss of function** for a recipient of healthcare services.
- **Major and enduring loss of function** *refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun.*
- ***The impairment lasts for a minimum period of two weeks*** *and is not related to an underlying condition.*

Eg:

- ❖ Surgery performed on the wrong body part.
- ❖ Surgery performed on the wrong patient.
- ❖ Patient suicide, attempted suicide or deliberate self-harm resulting in serious Disability
- ❖ Nosocomial infection or disease causing patient death or serious disability.

Sentinel Event Reporting

A **Sentinel event** is an unexpected occurrence involving death or serious physical or psychological injury or the risk thereof. Serious injury specially includes loss of limb or function. Such events are called "sentinel" events because they signal the need for immediate investigation and response.

Eg: Suide while a patient is under24/7 surveillance

Unexpected death

Non Conformance/Incident Report process proceedings shall be initiated when an event occurs resulting in:

- Process error in service activities;
- Patient health care deficiencies;
- Noncompliance in preventive processes as per safety norms;
- Employee under performance in any of the above.

The employee/ controlling staff meets an event under one of the above categories shall be responsible for processing incident Report before the end of their scheduled duty shift. If the incident is a potential Sentinel Event, as defined under definition, the individual noting the incident shall notify to their Superior immediately and shall be followed by notification to HOD with parallel notification to Quality Co-ordinator. The Quality Co-ordinator shall pursue event processing further by the defined procedure sequence. There is a defined protocol to determine the necessity for root cause analysis. When root cause analysis is initiated, Quality Co-coordinator shall track it further till corrective/ preventive action is suggested and implemented by HOD. Based on the scope of services provided, intense analysis shall also be based on defined parameters specific in the process. The Quality Co-coordinator shall maintain all records of all Non Conformance /Sentinel Event Reports and their disposition.

Norms for deciding the necessity for root cause analysis:

When Event falls under the following criteria:

- The occurrence involves an unanticipated death or major permanent loss of function;
- The occurrence is associated with significant deviation from the usual processes for providing health care services or managing the organization;
- The event has undermined or has significant potential for undermining the public's confidence in the organization.

Guidelines for root cause analysis:

- Shall focus on organizational system and processes.

- Direct or "proximate" cause of the Sentinel Event and the processes and systems related to its occurrence shall be determined.
- Related systems and processes shall be analyzed.
- Special causes in clinical processes and common causes in organization processes shall be considered in the analysis.
- Possible risk prevention activities shall be considered.

Intense analysis criteria:

When monitoring performance of specific clinical processes, certain events always elicit intense analysis. Based on the scope of services provided, intense analysis shall also be performed on the following:

- Confirmed transfusion reactions;
- Significant adverse drug reactions;
- Significant medication errors and hazardous conditions;
- Major discrepancies, or patterns of discrepancies, between preoperative and postoperative, including pathologic diagnoses, including those identified during the pathologic review of specimens removed during surgical and invasive procedures;
- Significant adverse events associated with anesthesia use;
- Significant infection related issues.

Analysis shall be done by:

- Safety variances involving falls or injuries, material safety handling or damage/lost patient property shall be routed to Safety committee.
- Equipment malfunctions reports shall be routed to Biomedical Dept.
- Utility outages and pest control issues shall be routed to Hospital Support Services.
- All housekeeping related issues shall be referred to Housekeeping.
- All other issues shall be categorized departmental accountability wise and shall be referred to HODs concerned accordingly.

Reports : Summary of events with analysis and on concerns if any shall be submitted to:

- Associate Director – for Management review and recommendations on nonconformance and incidents of clinical & nonclinical (including Hospital support services & safety deficiencies) nonconformance & incidents;

Internal audit

All processes covered by the NABH system will be audited at least once in six months. The auditors are selected from various departments such as Consultants, Nurses, Administration etc and they are given training on NABH standard requirement and the Quality/NABH coordinator maintains a list of qualified auditors eligible to perform the audit. A checklist specifying the parameters to be audited for various functions will be used for conducting the audit.

Planning and Execution audit

Internal auditors including the Coordinator are trained in the techniques of auditing and qualified by training them in internal auditing. The training covers the requirements of NABH standard requirements.

Audit starts with the opening meeting. All departmental heads shall be informed about the purpose of audit, audit timings and duration of audit etc. Check list based on standards will be used by the auditor. All minor correction shall be suggested then and there by the auditor to the departmental staff. Audit gets over with the closing meeting, over all observations shall be summarized by the chief auditor. Audit observations shall be documented and handed over to the quality department. All the audit reports shall be discussed with the core committee members and the observations noticed will be presented to the Chairman for improvements. The Audit reports shall be forwarded to the concerned Departmental Heads. Corrective and preventive actions will be done by the department staff based on the audit observations. Reports of the corrective and preventive actions will be submitted to the Quality department by the concerned Head of the department.

Audit Report

Prepared By	Approved By	Issued By
Mr. Manikandan R Quality Co-ordinator	Fr. Deljo Puthoor CMI Accreditation Co-ordinator	Fr.Julious Arakkal CMI Director

The non-conformance report is prepared by the auditor. The auditor discusses with auditee and fills up corrective action and target date for effecting corrective action. All non-conformance reports are signed by the concerned auditee as a token of acceptance of the non conformity.

Follow up and corrective action

Auditee takes timely corrective action by conducting the root cause analysis as agreed and recorded in the incident/Accident report and inform the auditor regarding the same. It is ensured that the non conformities are closed by taking appropriate corrective actions at an earlier date without delay.

Auditor makes follow up with auditee and review implementation of corrective action after auditee reports its completion.

Follow up audit is carried out to verify and record implementation and effectiveness of corrective action taken. The Quality Controller monitors the verification of corrective action taken by the auditors with in maximum of one month.

Quality Co-ordinator verifies the effectiveness implementation of corrective actions as recorded by auditor and closes the non-conformance if completion is satisfactory. The results of internal audit are reviewed in the management review meeting.

Internal Communications:

The top management has defined and implemented an effective and efficient process for communicating the Quality Policy, Objectives, Quality management requirements and accomplishments. This helps the hospital to improve the performance and directly involves its people in the achievement of the Quality Objectives. The Management actively encourages feedback and communication from people in the hospital as a means of involving them through the following modes.

- Weekly, fortnightly & monthly meets
- Management Review Meetings
- Team briefings and other meetings.
- Notice Board, Email

Risk Assessment

- Risk is defined as the possibility of something bad happening.
- Risk assessment is a systematic approach to recognising and characterising risks, and evaluating their significance, in order to support decisions about how to manage them

- A risk assessment is a thorough look at your workplace to identify those things, situations, processes, etc. that may cause harm, particularly to people. After identification is made, you analyze and evaluate how likely and severe the risk is. When this determination is made, you can next, decide what measures should be in place to effectively eliminate or control the harm from happening.
- Risks are identified as department wise and the staff shall be aware about this.

Risk Identification

- Brainstorming sessions;
- Occurrence of a event;
- Review of documents.

Why risk assessment is important

- Create awareness of hazards and risk.
- Identify who may be at risk (e.g., employees, cleaners, visitors, contractors, the public, etc.).
- Determine whether a control program is required for a particular hazard.
- Determine if existing control measures are adequate or if more should be done.
- Prevent injuries or illnesses, especially when done at the design or planning stage.
- Prioritize hazards and control measures.
- Meet legal requirements where applicable.

Risk Category

Likelihood of occurrence(L)	Potential severity of the impact(S)	Category(L*S)
5-Very high likelihood(Weekly) 4 -High likelihood(Monthly) 3- Moderate likelihood(Quarterly) 2- Low likelihood(Yearly)	5- Very high impact (Severe injury/death to the patient/very high impact on the system) 4 -High impact(Major injury to the patient/ high impact on the system) 3- Moderate impact(Moderate	High(16-25) Medium(11-15) Low(1-10)

1 -Very low likelihood(No known occurrence)	injury to the patient/ Moderate impact on the system) 2 -Low impact(Minor injury to the patient/ Low impact on the system) 1 -Very low impact(No injury to the patient/impact on the system)	

Matrix

Sl No.	Risks Identified	Likelihood of occurrence (1-5)	Potential severity of the impact (1-5)	Total score (L*S)	High(16-25) Medium(11-15) Low(1-10)	Actions Required	Responsible team

Documentation of manuals:

Quality Manual: This is an outline of hospital policies of Amala institute of medical sciences together with the Mission, Vision and Values of Hospital Quality Policy and Patient Safety priorities. Quality Manual also contains the structure and functions of the continuous quality improvement programme.

Department manuals: Every department maintains a manual describing their scope of service, Organogram, staffing patterns and job descriptions of staffs. The manual will also contain the specific work instructions, SOPs and policies relevant to the department. Responsibility for keeping the manual updated

and implementation rests with the Head of the Department. The responsibility for audit and updating of SOPs –if needed, rests with the NABH coordinator of the hospital.

Quality/NABH Coordinator at Amala institute of medical sciences has the overall authority, responsibility and commitment to communicate, implement, control and supervise the compliance of various departments with the accreditation standards. The roles and responsibility of the Quality/NABH Coordinator include:

- Establishing and maintaining the Quality Improvement and Patient Safety Program.
- Document control.
- Ensuring documentation of all Committee Meetings, Agenda and Minutes through concerned persons.
- Updating Quality Manual and other Quality documents.
- Schedule and conduct Internal Audits.
- Schedule and conduct of Management Review meeting.
- Ensuring corrective and preventive action arising from the above
- Coordinate with NABH in Accreditation related activities.

Document Control:

Documents such as regulations, standards and policies, SOPs, manuals and other relevant documents as well as drawings, software form part of the Hospital Quality Management System. A copy of each of these controlled documents shall be archived for future reference in their respective departments. These documents can be maintained either in printed form or electronic media as appropriately required. The Head of the Department of concerned departments will review & approve all their documents annually. The Head of Quality Dept. issues the finalized document.

The Head of Quality ensures that:

Authorized editions of appropriate documents are available at all locations where operations essential to the effective functioning of the Hospital are performed.

Documents are periodically reviewed and revised where ever necessary to ensure suitability and compliance with applicable requirements.

Invalid or obsolete documents are promptly removed from all prints of issue or use, or otherwise assured against unintended use.

Obsolete documents retained for either legal and / or knowledge preservation purposes are suitably marked or destroyed and the records of these are maintained as a separate register.

Document Changes:

Revision of management systems documents is carried out when necessary by the original author and updated at least once in two years. When alternate persons are designated for review, they shall first familiarize themselves with pertinent background information upon which to base their review and approval. These amendments shall be marked, initialed and dated by the Head of the Department. The amendment shall be brought to the notice of the NABH coordinator and the same shall be reissued

Preventive Actions:

The NABH Coordinator shall be perpetually vigilant and identify potential sources of non-compliance and areas that need improvement. These may include trend analysis of specific markers such as turnaround time, risk analysis and introducing proficiency testing for self-assessment. Where preventive action is required, a plan is prepared and implemented. All preventive actions must have control mechanisms and monitor for efficacy in reducing any occurrence of non-compliance or producing opportunities for improvement.

Corrective Action:

The NABH Coordinator takes all necessary corrective action when any deviation is detected in Quality Management System.

Root Cause Analysis: Deviations are detected by:

- Patient complains/feedbacks.
- Non-compliance receipt of items/sample.
- Non-compliance at Internal/external Quality Audit.

- Management Reviews with the responsible persons from the respective sections.

Selection and Implementation of Corrective Actions: Potential corrective actions are identified and the one that is most likely to eliminate the problem is chosen for implementation. Corrective action is taken into consideration the magnitude and degree of impact of the problem. All changes from corrective action is documented and implemented.

Monitoring Of Corrective Actions: The NABH Coordinator shall monitor the outcome parameters to ensure that corrective actions taken have been effective in eliminating the problem.

Audit Of Patient Care Services

There shall be an established system for the audit of patient care services. The hospital shall have the responsibility for monitoring every aspect of patient care from the time the patient enters the hospital through diagnosis, treatment, recovery, and discharge, in order to continuously improve the effectiveness of performance. The quality improvement programme is the subject of all the staff inside the hospital. The top management of the hospital has ensured that a mix of staff is organizing the quality control programme for the hospital.

Medical records Audit:

Audits shall be carried out regularly for the purpose of improving the quality of medical care. This is done monthly in a structured manner. Medical Record Audit has been constituted, and medical records shall be audited by members of the medical record Audit committee, and shall be analyzed.

The defined process for checking the Inpatient medical records is as follows:

Before the patients are discharged, the files are compiled, checked for completion by concerned nurse in-charge. The discharged patient's records are dispatched to Medical Record department from the discharge counter. The medical record department staff assembles the files, arranges in a specific sequence and rechecks for completeness. The checked record files are then sent to concerned staff including doctors for final, verification and to correct the possible missing. Later the medical record audit team will review

certain percentage of records. The sample chosen shall be having appropriate case mix and sample size shall be unanimously decided by Medical Record Audit Committee. Sample records are selected randomly from all the specialties. The review process is carried out as per the Medical Audit Check list. The reports shall be discussed in Medical Record review Committee for necessary action.

Following components are specially checked for:

- Completion of various components of the medical record.
- Timeliness of entries. Legibility of authorship (name, sign, date and time).
- Adequacy and fulfilling minimum requirements of assessment notes.

Clinical Audit.

The clinical departmental improvement study will be carried regularly. The findings will be presented in the clinical audit committee meeting. The needed corrective and preventive actions will be taken.

Doctors

- The department meeting is held yearly.
- HOD meeting will take place whenever.

Committee Meetings

AIMS has set up various committees, which meet in a defined interval and also documents the minutes of the meetings. The committees are as follows

- Hospital quality/ Core Committee
- Medical Record Audit committee
- Clinical Audit Committee
- CPR analysis Committee
- Infection Control Committee
- Drugs and Therapeutic Committee

- Purchase and Condemnation Committee
- Safety and disaster management Committee
- Transfusion Committee
- Ethics Committee
- Grievance and Redressal Committee
- Committee Against Sexual Harassment

5.0. LIST OF FIES/REGISTERS

Sl No.	List of registers	Register No.	Duration
1.	Committee Meeting Minutes File	AIMS/ QC- 01	2 Years
2.	Event Reports File	AIMS/ QC- 02	2 Years
3.	Quality Indicator Collection Checklist File	AIMS/ QC- 03	2 Years
4.	Mock Drill Reports File	AIMS/ QC- 04	2 Years
5.	Internal Audit Reports File	AIMS/ QC- 05	2 Years
6.	Clinical Audit Reports File	AIMS/ QC- 06	2 Years
7.	Training Records File	AIMS/ QC- 07	2 Years
8.	Department wise Training Records File	AIMS/ QC- 08	2 Years
9.	Patient Safety File	AIMS/ QC- 09	2 Years
10.	CPR Analysis Reports File	AIMS/ QC- 10	2 Years
11.	Indent Book	AIMS/ QC- 11	1 Year
12.	NABH Updates Folder	AIMS/ QC- 12	5 Years
13.	Review Meeting Minutes/Data Folder	AIMS/ QC- 13	3 Years
14.	Live Chart Audit /Discharge Time Collection Checklist	AIMS/ QC- 14	1 Year
15.	Quality Department Folder	AIMS/ QC- 15	3 Years
16.	Circular Folder	AIMS/ QC- 16	2 Years
17.	Reports Folder	AIMS/ QC- 17	2 Years
18.	Patient Care Audit Reports Folder	AIMS/ QC- 18	3 Years
19.	Final Proof Folder -Revised/ New Forms	AIMS/ QC- 19	3 Years