

Standards for Hospitals/Nursing
Homes/Day Care Centres for
Empanelment under WBHS 2008

INTRODUCTION

For a patient, paramount importance is placed on Safety, Respect to his rights, Evidence based treatment reflecting the current knowledge and skills and a Transparent billing system.

To ensure that a Health Care Organisation (HCO) is performing in this desired fashion, it is essential that its Structures and Processes are robust and Outcomes are measured and analysed.

Compliance with the Clinical Establishment Act and other statutory provisions ensures that the structures are robust. Processes important for patient safety are to be identified and based on current 'best practices' while outcomes are measured by a continual Quality Assurance Programme.

This manual tries to identify the more important processes and outcomes which must be addressed so that Patient Safety, Respect to patient's rights, Evidence based treatment and a Transparent billing system is not compromised in any way.

THIS MANUAL CLOSELY FOLLOWS THE NABH'S STANDARD FOR HEALTH CARE ORGANISATION IN STYLE AND CONTENT. THIS ASSISTANCE FROM NABH IS GRATEFULLY ACKNOWLEDGED.

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CHAPTER 1

ACCESS, ASSESSMENT AND CONTINUITY OF CARE (AAC)

AAC.1. THE ORGANIZATION DEFINES AND DISPLAYS THE SERVICES THAT IT CAN PROVIDE.

Objective Element

- The services being provided are clearly defined.
- The defined services are prominently displayed.
- The staff is oriented to these services

AAC.2. THE ORGANIZATION HAS A WELL-DEFINED REGISTRATION AND ADMISSION PROCESS.

Objective Element

- Standardized policies and procedures are used for registering and admitting patients
- Patients are accepted under the scheme only if the organization is capable for providing the required service
- The policies and procedures also address managing patients during non availability of beds
- The staff is aware of these processes

AAC.3. THERE IS AN APPROPRIATE MECHANISM FOR TRANSFER OR REFERRAL OF PATIENTS

Objective Element

- Policies guide the transfer of stable patients to another facility who require services for which the organization is not adequately equipped
- Hospital arranges, if required, transportation for patients referred to another facility
- Procedures identify staff responsible during transfer
- The organization gives a summary of patient's condition and the treatment given

AAC.4. DURING ADMISSION THE PATIENT AND /OR THE FAMILY MEMBERS ARE EDUCATED TO MAKE INFORMED DECISIONS

Objective Element

- The patients and/or family members are explained about the proposed care
- The patients and/or family members are explained about the expected results
- The patients and/or family members are explained about the possible complications
- The patients and/or family members are explained about the expected costs.
- The patient and/or family members are explained about the expected escalation of costs for treatment whenever there is a change of setting of the patient

AAC.5. PATIENTS UNDERGO AN ESTABLISHED INITIAL ASSESSMENT AND REGULAR REASSESSMENTS

Objective Element

- The organization defines the content of the assessments for the patients.
- The organization determines who can perform the assessments.
- The organization defines the time frame within which the initial assessment is completed.
- The initial assessment for in-patients is documented within 12 hours or earlier. The

initial assessment results in a documented plan of care.

- All patients are reassessed at least once daily.
- Staff involved in direct clinical care document reassessments.
- Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.

AAC.6. LABORATORY AND IMAGING SERVICES ARE PROVIDED AS PER THE REQUIREMENTS OF THE PATIENTS

Objective Element

- Scope of the laboratory and imaging service, if available, is defined and documented by the organization.
- Adequately qualified/trained personnel perform and/or supervise the investigations.
- Policies and procedures guide collection, identification, handling, safe transportation and disposal of specimens.
- Laboratory/imaging reports are available within a defined time frame.
- Critical results are intimated immediately to the concerned personnel.
- Laboratory tests/ imaging services not available in the organization are outsourced to WBGHS empanelled/ organization(s) based on their quality assurance system.

AAC.7 PATIENT CARE IS CONTINUOUS IN NATURE

Objective Element

- During all phases of care, there is a qualified individual identified as responsible for the patient's care.
- Information about the patient's care and response to treatment is shared among medical, nursing and other care providers.
- Information is exchanged and documented during each staffing shift, between shifts, and during transfers and referrals between health care providers.

- The patient's record (s) is available to the authorized care providers to facilitate the exchange of information.
- Policies and procedures guide the referral of patients to other departments/specialties not available in the organization.

AAC.8. THE ORGANIZATION HAS A DOCUMENTED DISCHARGE PROCESS

Objective Element

- The patient's discharge process is planned
- Policies and procedures exist for coordination of various departments and agencies involved in the discharge process (including medico-legal cases)
- Policies and procedures are in place for patients leaving against medical advice
- A discharge summary is given to all the patients leaving the organization (including patients leaving against medical advice)
- Discharge summary contains the reasons for admission, significant findings and diagnosis and the patient's condition at the time of discharge.
- Discharge summary contains information regarding investigation results, any procedure performed, medication and other treatment given
- Discharge summary contains follow up advice, medication and other instructions in an understandable manner.
- Discharge summary incorporates instructions about when and how to obtain urgent care
- In case of death the summary of the case also includes the cause of death
- Patient records also contain a copy of the discharge /case summary

CHAPTER 2

PATIENT RIGHTS AND EDUCATION (PRE)

PRE.1. THE ORGANIZATION PROTECTS PATIENT AND FAMILY RIGHTS DURING CARE

Objective Element

- Patient and family rights are documented
- Patients and families are informed of their rights in a format and language that they can understand
- Staff is aware of their responsibility in protecting patients rights
- Violation of patient rights is reviewed and corrective/preventive measures taken

PRE.2. A DOCUMENTED PROCESS FOR OBTAINING PATIENT AND / OR FAMILIES CONSENT EXISTS FOR INFORMED DECISION MAKING ABOUT THEIR CARE

Objective Element

- General consent for treatment is obtained when the patient enters the organization
- Patient and/or his family members are informed of the scope of such general consent
- The organization has listed those procedures and treatment where informed consent is required
- Informed consent includes information on risks , benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand

PRE.3 PATIENT AND FAMILIES HAVE A RIGHT TO INFORMATION ON EXPECTED COSTS

Objective Element

- There is uniform pricing policy in a given setting
- The tariff list is available to patients
- Patients are educated about the estimated costs of treatment
- Patients are informed about the estimated costs when there is a change in the patient condition or treatment setting including treatment not within the scope of the scheme

PRE.4 THERE IS A WELL DEFINED GRIEVANCE REDRESS MECHANISM

Objective Element

- Mechanism exist for patients/ family members to lodge complaints
- Complaints are responded to within a specified time period
- Complaints are analysed and corrective action is taken

CHAPTER 3

CARE OF PATIENTS (COP)

COP.1. UNIFORM CARE OF PATIENTS IS GUIDED BY THE APPLICABLE LAWS AND REGULATIONS

Objective Element

- Care delivery is uniform when similar care is provided in more than one setting
- The care and treatment orders are signed, named, timed and dated by the concerned doctor
- The care plan is countersigned by the clinician in-charge of the patient within 24 hours
- Evidence based medicine and clinical practice guidelines are adopted to guide patient care whenever possible

COP.2. EMERGENCY SERVICES ARE GUIDED BY POLICIES, PROCEDURES, APPLICABLE LAWS AND REGULATIONS

Objective Element

- Policies and procedure for emergency care are documented
- The patients receive care in consonance with the policies
- Staff is familiar with the policies and trained on the procedures for care of emergency patients
- Ambulances with adequate facilities are made available on demand

COP.3. POLICIES AND PROCEDURES DEFINE RATIONAL USE OF BLOOD AND BLOOD PRODUCTS

Objective Element

- Documented policies and procedures are used to guide rational use of blood and blood products
- Blood and blood products are procured from licensed blood bank
- Informed consent is obtained for transfusion of blood and blood products
- Transfusion reactions are analysed for preventive and corrective actions

COP.4. POLICIES AND PROCEDURES GUIDE THE CARE OF PATIENTS IN THE INTENSIVE CARE AND HIGH DEPENDENCY UNITS

Objective Element

- Adequate staff and equipment are available
- Defined procedures for situation of bed shortages are followed
- Infection control practices are followed
- The unique needs of end of life patients are identified and cared for
- There is a policy for the use of ventilator support for end of life care

COP.5. POLICIES AND PROCEDURES GUIDE THE CARE OF OBSTETRICAL PATIENTS

Objective Element

- The organization defines the scope of obstetric services
- Persons caring for high risk obstetric cases are competent
- The organization ensures care of neonates of high risk pregnancies either in house or ensures requisite expertise is available from other facility

COP.6. POLICIES AND PROCEDURES GUIDE THE CARE OF PEDIATRIC PATIENTS

Objective Element

- Those who care for children have age specific competency
- Patient assessment includes detailed nutritional, growth, psychosocial and immunization assessment
- Policies and procedures prevent child/ neonate abduction and abuse
- The children's family members are educated about nutrition, immunization and safe parenting and this is documented in the medical record

COP.7. POLICIES AND PROCEDURES GUIDE THE ADMINISTRATION OF ANESTHESIA

Objective Element

- There is a documented policy and procedure for the administration of anaesthesia
- All patients for anaesthesia have a pre-anaesthesia assessment by a qualified individual
- The pre-anaesthesia assessment results in formulation of an anaesthesia plan which is documented
- An immediate preoperative re-evaluation is documented.
- Informed consent for administration of anaesthesia is obtained by the anaesthetist
- During anaesthesia monitoring includes regular and periodic recording of heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, airway security and potency and level of anaesthesia
- Each patient's post-anaesthesia status is monitored and documented
- A qualified individual applies defined criteria to transfer the patient from the recovery area
- All adverse anaesthesia events are recorded and monitored
- The person administering parenteral sedation is different from the person monitoring the patient's vital signs

COP.8. POLICIES AND PROCEDURES GUIDE THE CARE OF PATIENTS UNDERGOING SURGICAL PROCEDURES

Objective Element

- Surgical patients have a preoperative assessment and a provisional diagnosis documented prior to surgery
- An informed consent is obtained by the operating surgeon prior to the procedure
- Documented policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong surgery
- Persons qualified by law are permitted to perform the procedures that they are entitled to perform
- A brief operative note is documented prior to transfer out of patient from recovery area
- The operating surgeon documents the post-operative plan of care
- The Operation theatre is adequately spaced, equipped and monitored for infection control practices.

COP.9. POLICIES AND PROCEDURES GUIDE NUTRITIONAL THERAPY

Objective Element

- Patients receive food according to their clinical needs
- There is a written order for the diet
- Nutritional therapy is planned and provided in a collaborative manner
- When families provide food, they are educated about the patients diet limitations
- Food is prepared, handled, stored and distributed in a safe manner

CHAPTER 4

MANAGEMENT OF MEDICATION (MOM)

MOM.1 POLICIES AND PROCEDURES GUIDE THE ORGANIZATION OF PHARMACY SERVICES AND USAGE OF MEDICATION

Objective Element

- The hospital formulary consisting of a list of medication appropriate for the patients' and organization's resources is developed
- There is a defined process for acquisition of these medications
- There is a process to obtain medications not listed in the formulary
- Documented policies and procedures govern procurement and usage of implantable prosthesis

MOM.2. POLICIES AND PROCEDURES GUIDE THE STORAGE OF MEDICATION.

Objective Element

- Medications are stored in a clean, well lit and properly ventilated environment
- Temperature sensitive medications are stored in a refrigerator whose temperature is regularly monitored
- Vaccines are stored in a refrigerator specially constructed for that purpose and not in a domestic refrigerator
- Sound inventory control practices guide storage of the medications
- Sound alike and look alike medications are stored separately
- Emergency medications are available all the time
- Emergency medications are replenished in a timely manner when used

MOM.3. POLICIES AND PROCEDURES GUIDE THE PRESCRIPTION OF MEDICATIONS

Objective Element

- The organization determines who can write orders
- Orders are written in a uniform location in the medical records
- Medication orders are clear, legible, dated, named and signed
- Policy on verbal orders is documented and implemented
- The organization defines a list of high risk medication
- High risk medication orders are verified prior to dispensing

MOM.4. THERE ARE DEFINED PROCEDURES FOR MEDICATION ADMINISTRATION

Objective Element

- Medications are administered by those who are permitted by law to do so
- Patient is identified prior to administration
- Medication, dosage, route and timing is verified from the order prior to administration
- Medication administration is documented
- Policies and procedures govern patient's medications brought from outside the organization
- A proper record is kept of the usage, administration and disposal of narcotic drugs and psychotropic substances

MOM.5. PATIENTS ARE MONITORED AFTER MEDICATION ADMINISTRATION

Objective Element

- Patients are monitored after medication administration and this is documented
- Adverse drug events are defined and reported within a specified time frame

MOM.6. POLICIES AND PROCEDURES GUIDE THE USE OF MEDICAL GASES

Objective Element

- Documented policies and procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases.

CHAPTER 5

HOSPITAL INFECTION CONTROL (HIC)

HIC 1 THE ORGANIZATION HAS A WELL-DESIGNED, COMPREHENSIVE AND COORDINATED HOSPITAL INFECTION CONTROL (HIC) PROGRAMME

Objective Element

- The hospital infection control programme is documented and is aimed at reducing/ eliminating risks to patients, visitors and providers of care
- The hospital has a multi-disciplinary infection control committee/ infection control team having a designated infection control nurse
- Hand washing facilities in all patient care areas are accessible to health care providers.
- Compliance with proper hand washing is monitored regularly.
- Isolation/ barrier nursing facilities are available.
- Adequate gloves, masks, soaps, and disinfectants are available and used correctly

HIC 2 THE HOSPITAL HAS AN INFECTION CONTROL MANUAL

Objective Element

- The manual identifies the various high-risk areas.
- It outlines methods of surveillance in the identified high-risk areas.
- It focuses on adherence to standard precautions at all times.
- Equipment cleaning and sterilization practices are included.
- An appropriate antibiotic policy is established and implemented.
- Laundry and linen management processes are also included.

HIC 3 THE INFECTION CONTROL TEAM IS RESPONSIBLE FOR SURVEILLANCE ACTIVITIES IN IDENTIFIED AREAS OF THE HOSPITAL.

Objective Element

- Surveillance activities are appropriately directed towards the identified high-risk areas.
- Collection of surveillance data is an ongoing process.
- Verification of data is done on regular basis by the infection control team.
- In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.
- Scope of surveillance activities incorporates tracking and analysing of infection risks, rates and trends.

HIC 4 THERE ARE DOCUMENTED PROCEDURES FOR STERILIZATION ACTIVITIES IN THE HOSPITAL.

Objective Element

- There is adequate space available for sterilization activities
- Regular validation tests for sterilization are carried out and documented.

- There is an established recall procedure when breakdown in the sterilization system is identified.

HIC 5 STATUTORY PROVISIONS WITH REGARD TO BIO-MEDICAL WASTE (BMW) MANAGEMENT ARE COMPLIED WITH.

Objective Element

- The hospital is authorized by prescribed authority for the management and handling of Bio-medical Waste.
 - Proper segregation and collection of Bio-medical Waste from all patient care areas of the hospital is implemented and monitored.
 - The organization ensures that Bio-medical Waste is stored and handed over to authorized contractor within stipulated time limits in a secure manner.
 - Requisite reports are submitted to competent authorities on stipulated dates.
 - Appropriate personal protective measures are used by all categories of staff handling Bio-medical Waste.
-
- Appropriate pre and post exposure prophylaxis is provided to all concerned staff members.

CHAPTER 6

RESPONSIBILITIES OF MANAGEMENT (ROM)

ROM 1 THE RESPONSIBILITIES OF THE MANAGEMENT ARE DEFINED

Objective Element

- All licenses and statutory requirements are fulfilled by the organization
- The organization has a documented organogram and is headed by a suitably experienced individual
- Those responsible for governance ensure that the Government licenses are

periodically renewed.

- The organization complies with the laid down and applicable legislations and regulations

ROM 2 THE SERVICES PROVIDED BY EACH DEPARTMENT ARE DOCUMENTED

Objective Elements

- Scope of services of each department is defined
- Administrative policies and procedures for each department is maintained

CHAPTER 7

FACILITY MANAGEMENT & SAFETY (FMS)

FMS.1. THE ORGANIZATION COMPLIES WITH THE RELEVANT RULES AND REGULATIONS, LAWS AND BYELAWS

Objective Element

- The management is conversant with the laws and regulations and knows their applicability to the organization.
- Management regularly updates any amendments in the prevailing laws of the land.
- The management ensures implementation of these requirements.
- There is a mechanism to regularly update licenses / registrations / certifications.

FMS.2. THE ORGANIZATION'S ENVIRONMENT AND FACILITIES OPERATE TO ENSURE SAFETY OF PATIENTS, THEIR FAMILIES, STAFF AND VISITORS.

Objective Element

- There is a documented operational and maintenance (preventive and breakdown) plan.
- Up-to-date drawings are maintained which detail the site layout, floor plans and fire escape routes.
- The provision of space is at least in accordance with the requirements of the West Bengal Clinical Establishment Act 2003.
- There are designated individuals responsible for the maintenance of all the facilities.
- Maintenance staff, either in house or outsourced, is contactable round the clock for emergency repairs.

- The hospital has a system to identify the potential safety and security risks including hazardous materials

FMS.3 THE ORGANIZATION HAS A PROGRAM FOR CLINICAL AND SUPPORT SERVICE EQUIPMENT MANAGEMENT.

Objective Element

- Qualified and trained personnel operate and maintain the equipment
- Equipment are periodically inspected and calibrated for their proper functioning.
- There is a documented operational and maintenance (preventive and breakdown) plan

FMS.4 THE ORGANIZATION HAS PROVISIONS FOR SAFE WATER, ELECTRICITY.

Objective Element

- Potable water and electricity are available round the clock
- Alternate sources are provided for in case of failure and tested regularly

FMS.5 THE ORGANIZATION HAS PLANS FOR FIRE AND NON-FIRE EMERGENCIES WITHIN THE FACILITIES.

Objective Element

- The organization has plans and provisions for early detection, abatement and containment of fire and non-fire emergencies.
- The organization has a documented safe exit plan in case of fire and non-fire emergencies.
- Staff is trained for their role in case of such emergencies

CHAPTER 8

HUMAN RESOURCE MANAGEMENT (HRM)

HRM.1 THE ORGANIZATION HAS A DOCUMENTED SYSTEM OF HUMAN RESOURCE PLANNING.

Objective Element

- The organization maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.
- The required job specifications and job description are well defined for each category of staff
- The organization verifies the antecedents of the potential employee with regards to criminal/negligence background.

HRM.2 THE STAFF JOINING THE ORGANIZATION IS ORIENTED TO THE HOSPITAL ENVIRONMENT.

Objective Element

- Each staff member is appropriately oriented to the organization's mission and goals.
- Each staff member is made aware of hospital wide policies and procedures.
- All employees are educated with regard to patients' rights and responsibilities.
- All employees are oriented to the service standards of the organization.
- Training is provided when job responsibilities change / new equipment is introduced

HRM.3 THERE IS A PROCESS FOR AUTHORISING ALL MEDICAL PROFESSIONALS

Objective Element

- Medical professionals permitted by law, regulation and the hospital to provide patient care without supervision are appointed
- The education, registration, training and experience of the identified medical professionals is documented and updated periodically.
- The services provided by the medical professionals are in consonance with their qualification, training and registration.

HRM.4 THERE IS A PROCESS FOR AUTHORISING ALL NURSING STAFF AND TECHNICIANS

Objective Element

- The clinical work assigned to nursing staff and technicians is in consonance with their qualification, training and registration.
- All such information pertaining to the nursing staff and technicians is appropriately verified when possible.

CHAPTER 9

INFORMATION MANAGEMENT SYSTEM (IMS)

IMS.1. POLICIES AND PROCEDURES EXIST TO MEET THE INFORMATION NEEDS OF THE ORGANIZATION.

Objective Element

- The information needs of the organization are identified and addressed.
- The organization contributes to external databases in accordance with the law and regulations.
- The organisation carries out regular medical records audit

IMS.2. THE ORGANIZATION HAS A COMPLETE AND ACCURATE MEDICAL RECORD FOR EVERY PATIENT.

Objective Element

- Every medical record has a unique identifier.
- Organization policy identifies those authorized to make entries in medical record.
- Every medical record entry is dated and timed.
- The author of the entry can be identified.
- The contents of medical record are identified and documented.
- The record provides an up-to-date and chronological account of patient care.
- The medical record contains information regarding reasons for admission, diagnosis and plan of care.
- Operative and other procedures performed are incorporated in the medical record.

- When patient is transferred to another hospital, the medical record contains the date of transfer, the reason for the transfer and the name of the receiving hospital.
- The medical record contains a copy of the discharge note duly signed by appropriate and qualified personnel.
- In case of death, the medical record contains a copy of the death certificate indicating the cause, date and time of death.
- Care providers have access to current and past medical record.

IMS.3. POLICIES AND PROCEDURES ARE IN PLACE FOR MAINTAINING CONFIDENTIALITY, INTEGRITY AND SECURITY OF INFORMATION.

Objective Element

- Procedures exist for maintaining confidentiality, security and integrity of information
- Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorization.

CHAPTER 10

CONTINUOUS QUALITY IMPROVEMENT (CQI)

CQI 1. THERE IS A STRUCTURED QUALITY ASSURANCE AND CONTINUOUS MONITORING PROGRAMME IN THE ORGANIZATION.

Objective Element

- The quality assurance programme is developed, implemented and maintained by a multi-disciplinary committee.
- The quality assurance programme is documented.
- There is a designated individual for coordinating and implementing the quality assurance programme
- The quality assurance programme is comprehensive and covers all the major elements related to quality assurance and risk management.

CQI 2. THE QUALITY IMPROVEMENT PROGRAMME IS SUPPORTED BY THE MANAGEMENT.

Objective Element

- Hospital Management makes available adequate resources required for quality improvement programme.
- Appropriate statistical and management tools are applied whenever required.

CQI 3. SENTINEL EVENTS ARE INTENSIVELY ANALYZED.

Objective Element

- The organisation has defined sentinel events.

- Sentinel events are intensively analysed when they occur.
- Actions are taken upon findings of such analysis.

Standards for Medical
Testing Laboratories and
Imaging Centres for
empanelment under
WBHS 2008

Introduction

Medical Testing Laboratories and Imaging Centres play a vital role in supporting the clinical specialists in offering evidence based management of cases.

The standards try to ensure that along with important structures, processes and outcomes are given adequate attention so that all testing shall be correct and reproducible, reducing operator and machine bias to the bare minimum.

Essential Requirements

Essential requirements

1. Laboratory services

- a. Large Laboratory as defined by the CE Rules 2003
- b. **Diagnostic Laboratories** should have at least 4 full time technicians and 1 full time laboratory in charge. At least one consultant/ part time specialist, having MCI recognised qualification, should be available at all times. Signing of reports is to be done by the consultants for their respective disciplines only, (i.e. the discipline for which they hold PG qualifications only).

2. Imaging services

CE Act and BARC approved Imaging Centre with AERB clearance having at least

- a. One 300 mA X Ray machine
- b. One USG machine with probes capable of abdominal, gynaecological & obstetric and paediatric screening and recording
- c. At least two full time radiodiagnosis technicians

Organisation Structure (OS)

1. OS 1 The services provided by the organization is clearly known
 - a. The organization shall clearly mention the services it provides
 - b. The organization shall display the important services it provides
 - c. The staff is oriented to these services
2. OS 2 The management structure is transparent
 - a. There is a in charge of the organisation's operations
 - b. There is an organogram for the organization

Facility and Equipment Management (FEM)

1. FEM 1 The infrastructure of the organization is adequate to meet the needs of the services provided
 - a. There is a reception area as required by the CE Rules 2003
 - b. There is a waiting area required by the CE Rules 2003
 - c. There is a comfortable collection room
 - d. Potable water is available for patients and staff
 - e. Separate toilet facilities are available for males and females
 - f. The different sections of the laboratory/ imaging centre are separated according to the services provided
 - g. Adequate space is available for cleaning and sterilization activities
 - h. Stores are kept separately from the main work areas
 - i. Temperature sensitive stores are kept in dedicated refrigerators
 - j. Temperature of all refrigerators are monitored daily
 - k. Adequate back up for electricity and water supply is available
2. FEM 2 The equipment available with the organization is adequate the technical needs of the services provided
 - a. There is an inventory of the equipment which indicates the name, unique ID, serial no, date of procurement, date of manufacture and calibration records
 - b. The equipment should be capable of providing the services as per existing international norms
 - c. Each equipment shall be uniquely labeled along with its calibration status
3. FEM 3 The facilities and equipment are adequately maintained
 - a. There is an identified facility manager
 - b. AMCs for equipment is kept up to date
 - c. There is a equipment maintenance (preventive and breakdown) plan which is adhered to

- d. There is a equipment calibration plan which is in accordance with the manufacturers recommendation and is adhered to
 - e. There are defined procedures for the procurement of kits and consumables and they are checked for quality prior to being put into use
 - f. New investigations are properly validated prior to reporting
4. FEM 4 Bio medical Wastes should be properly disposed
- a. There is licence to operate/ NOC from the PCB
 - b. BMW should be segregated at point of generation
 - c. BMW should be disposed of as per PCB norms
 - d. Liquid wastes should be treated prior to discharge in sewerage system

Personnel Management (PM)

1. PM 1 The technical needs of the organisation are adequately addressed
 - a. There should be technical specialists as per the CE Act norms
 - b. Job descriptions should be available containing the responsibilities and authorities of each technical specialist
 - c. Technical specialists providing professional judgements (opinions, interpretations, predictions and others) should have qualifications, professional experience and training for doing the same
2. PM 2 There should be adequate backing by trained technical support staff (technicians)
 - a. Laboratory/ Imaging technicians employed should adhere to CE Act norms
 - b. Adequate number of technicians should be employed according to the work load
3. PM 3 There are adequate non technical support staff
 - a. A female attendant is always present in the organization during the working hours
 - b. Cleaning and house keeping staff are in adequate numbers
4. PM 4 Training needs of the technical staff are addresses
 - a. Regular training sessions are held for the technical staff
5. PM 5 Staff are encouraged to work in a safe environment
 - a. There is an infection control plan
 - b. Susceptible staff are provided with Inj Tetvac & Hep B immunization
 - c. PEP is available
 - d. Radiation safety equipment is available
 - e. Radiation safety badges (TLD) are available for all radiation exposed staff
 - f. Adequate signage is provided in vulnerable areas

Report Process Management (RPM)

1. RPM 1 There is a pre analytical process management
 - a. There is a sample collection manual having specific instructions for patient preparation, identification, collection procedure, labeling, storage, transport and disposal after use
 - b. There is sufficient infrastructure to store samples prior to analysis
 - c. There should be a system of traceability of patient to samples
 - d. There should be defined criteria for acceptance and rejection of samples
2. RPM 2 There is analytical process management
 - a. The laboratory shall use only standard and validated current methods (as given in standard text books and indexed journal) for testing
 - b. SOPs for all tests should be prepared
3. RPM 3 There is post analytical process management
 - a. All test results shall be approved by a designated person
 - b. There should be a policy regarding duration of retention of samples
 - c. Samples should be stored in a separate refrigerator
 - d. There should defined responsibility regarding signing of reports, only those with qualifications and training shall sign the report of a specialty
 - e. There shall be a policy on signing of emergency testing
 - f. There shall be a system of reporting critical test results without delay

Document Control (DC)

1. DC 1 All medical records should be safely stored
 - a. Each patient shall be uniquely identified
 - b. All patient records shall be kept in a safe place
 - c. Privileged information should be protected

Continuous Quality Improvement (CQI)

1. CQI 1 There is a document quality assurance programme
 - a. There is a designated person for QA activities
 - b. There is budgetary provisions for QA activities
 - c. All sections are under an External Quality Assurance Programme
 - d. There is system of peer comparisons/ EQAS/ Proficiency Testing
 - e. Sentinel events are listed and monitored
 - f. Non conformities are controlled and analysed