ACCREDITATION STANDARDS GUIDEBOOK FOR HOSPITALS

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS (NABH)

Guide Book to Accreditation Standards for Hospitals *(4th edition)*

December 2015

National Accreditation Board for Hospitals
and Healthcare Providers (NABH)

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Chapter 1
Access Assessment and Continuity of Care (AAC)

Intent of the chapter:

Patients are well informed of the services that an organisation provides. This will facilitate in appropriately matching patients with the organisation's resources. Only those patients who can be cared for by the organisation are admitted to the organisation. Emergency patients receive life-stabilising treatment and are then either admitted (if resources are available) or transferred appropriately to an organisation that has the resources to take care of such patients. Out-patients who do not match the organisation's resources are similarly referred to organisations that have the matching resources.

Patients that match the organisations resources are admitted using a defined process. Patients cared for by the organisation undergo an established initial assessment and periodic and regular reassessments.

Assessments include planning for utilisation of laboratory and imaging services. The laboratory and imaging services are provided by competent staff in a safe environment for both patients and staff.

These assessments result in formulation of a definite Care plan.

Patient care is multidisciplinary in nature and encourages continuity of care through well-defined transfer and discharge protocols. These protocols include transfer of adequate information with the patient.

Summary of Standards

AAC.1.	The organisation defines and displays the healthcare services that it provides.
AAC.2.	The organisation has a well-defined registration and admission process.
AAC.3.	There is an appropriate mechanism for transfer (in and out) or referral of patients.
AAC.4.	Patients cared for by the organisation undergo an established initial assessment.
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AAC.6.	Laboratory services are provided as per the scope of services of the organisation.
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AAC.13.	The organisation has a documented discharge process.
AAC.14.	Organisation defines the content of the discharge summary.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

AAC.1.	**The organisation defines and displays the healthcare services that it provides.**

Objective Elements

a. The healthcare services being provided are clearly defined and are in consonance with the needs of the community.

Interpretation: The services provided are clearly defined by senior management and also are in consonance with the requirements of the community. The needs of the community should be considered especially when planning a new organisation or adding new services. The same could be captured through various feedback mechanisms.

b. Each defined service should have appropriate diagnostics and treatment facilities with suitably qualified personnel who provide out-patient, in-patient and emergency cover.

Interpretation: The organisation shall ensure that before starting a service, suitably qualified medical and nursing staff are available to take care of patient's clinical needs. The said service shall have outpatient facility and inpatient facility and the consultant shall provide emergency cover. Appropriate infrastructure for diagnostics and treatment facilities should be available for regular functioning.

c. The defined healthcare services are prominently displayed.

Interpretation: The services so defined should be displayed prominently in an area visible to all patients entering the organisation. The display could be in the form of boards, citizen's charter, etc. They should be of permanent nature. Care should be taken to ensure that these are displayed in the language(s) the patient understands. Healthcare services routinely associated with standard of care within the defined scope of healthcare services, but not offered in the organisation should be clearly displayed as not available. Display in the form of

brochures only is NOT acceptable. Display should be at least bi-lingual (English and the state language/language spoken by the majority of people in that area).

d. The staff are oriented to these services.

Interpretation: All the staff in the hospital mainly in the reception/registration, OPD, IPD are oriented to these facts through regular training programme or through manuals. Records of all such training shall be available.

Standard

AAC.2.	**The organisation has a well-defined registration and admission process.**

Objective Elements

a. Documented policies and procedures are used for registering and admitting patients. *

Interpretation: Organisation shall prepare document(s) detailing the policies and procedures for registration and admission of patients which should also include unidentified patients. All patients who are assessed in the hospital shall be registered. All admissions must be authorised by a doctor. Additional documentation as required shall be included for foreign nationals.

b. The documented procedures address out-patients, in-patients and emergency patients. *

Interpretation: It is preferable if each one of these is separately addressed.

c. A unique identification number is generated at the end of registration.

Interpretation: The organisation shall ensure that every patient gets a unique number which is generated at the end of registration of the first interaction that the patient has with the organisation. This number shall be used for identification of the patient across the hospital and to ensure continuity of care across the hospital. All hospital records of the patient shall have this number.

“Unique” implies that this is a one-time affair.

Please note that a particular patient can have only one unique number. However, in case of multiple visits (OP/IP) a different number could be generated in addition to the above-mentioned unique number. To ensure continuity of care these numbers shall be linked to the unique number.

d. Patients are accepted only if the organisation can provide the required service.

Interpretation: The staff handling admission and registration needs to be aware of the services that the organisation can provide. It is also advisable to have a system wherein the staff is aware as to whom to contact if they need any clarification on the services provided. In case of emergency, life-saving treatment shall be initiated before any decision is taken regarding acceptance.

e. The documented policies and procedures also address managing patients during non-availability of beds. *

Interpretation: The organisation is aware of the availability of alternate organisations where the patients may be directed in case of non-availability of beds. In case the organisation admits these patients in a temporary holding area it shall ensure that there is adequate infrastructure to take care of these patients. Further, the organisation shall define as to how long patients are kept on temporary beds before a decision to transfer out is taken.

The documented procedure also addresses managing patients when bed space is not available in the desired bed category or unit and the financial implications explained to the patient of the same.

f. Access to the healthcare services in the organisation is prioritised according to the clinical needs of the patient.

Interpretation: Patients with clinical problem which warrant an earlier response are identified and prioritised in all care settings. For eg. A patient waiting in the OPD who complains of giddiness, is seen as soon as possible.

g. The staff are aware of these processes.

Interpretation: All the staff handling these activities should be oriented to the applicable policies and procedures.

Standard

AAC.3.	**There is an appropriate mechanism for transfer (in and out) or referral of patients.**

Objective Elements

a. Documented policies and procedures guide the transfer-in of patients to the organisation. *

Interpretation: This shall address both planned and unplanned transfers. For unplanned transfers and in case of suspected unstable patients, the organisation could send a suitably trained person with the ambulance. However, this shall be guided by the information received by the organisation.

b. Documented policies and procedures guide the transfer-out/referral of unstable patients to another facility in an appropriate manner. *

Interpretation: Patients needing transfer include those who have come to the emergency but need to be transferred to another organisation or those already admitted but who now require care in another organisation. It also includes patients being shifted for diagnostic tests. The organisation shall define who is an unstable patient. This shall be defined based on physiological criteria. The documented procedure should address the methodology for safe transfer of the patient in a life-threatening situation (like those who are on ventilator) to another organisation. There should be availability of an appropriate ambulance fitted with-life support facilities and accompanied by trained personnel.

c. Documented policies and procedures guide the transfer- out/referral of stable patients to another facility in an appropriate manner. *

Interpretation: Patients needing transfer include those who have come to the emergency but need to be transferred to another organisation or those already admitted but who now require care in another organisation. It also includes patients being shifted for diagnostic tests. Patients not in a life threatening situation (stable) should also be transported in a safe manner.

d. The documented procedures identify staff responsible during transfer/referral. *

Interpretation: The staff accompanying shall at least be a trained trauma/ emergency technician/nurse. He/she shall have undergone training in Basic or advanced cardiopulmonary resuscitation as may be appropriate. Further, the staff identified should be aware of the transfer procedure. A doctor should accompany an unstable patient.

e. The organisation gives a summary of patient's condition and the treatment given.

Interpretation: The organisation gives a transfer summary mentioning the significant findings and treatment given to all patients who are being transferred from emergency ward / other settings. This shall also include patients being transferred for diagnostic and therapeutic purposes. In case of a patient being discharged from the organisation, a discharge summary is given to all patients including those patients going against medical advice. A copy of the same shall be retained by the organisation.

Standard

AAC.4.	**Patients cared for by the organisation undergo an established initial assessment.**

Objective Elements

a. The organisation defines and documents the content of the initial assessment for the out–patients, in-patients and emergency patients. *

Interpretation: The organisation shall have a format using which a standardised initial assessment of patients is done in the OPD, emergency and in-patients. The initial assessment could be standardised across the hospital or it could be modified depending on the need of the department. However, it shall be the same in that particular area, e.g. in paediatric OPD the weight and height may be a must, whereas it may not be so for orthopaedics OPD. In emergency department, this shall include recording the vital parameters. The format shall be designed to ensure that the laid-down parameters are captured. Every initial assessment shall contain the presenting complaints, vital signs and salient examination findings (especially of the system concerned). This shall incorporate initial assessment by doctors and nursing staff in case of in-patients. Abridged documentation may be used for day care as appropriate.

b. The organisation determines who can perform the initial assessment. *

Interpretation: The assessment could be done by various categories of staff. The organisation determines who can do what assessment and it should be the same across the organisation. Assessments are performed by each discipline within its scope of practice, registration and applicable laws and regulations. Only doctors/nurses shall conduct the assessments.

c. The organisation defines the time frame within which the initial assessment is completed based on patient's needs. *

Interpretation: The organisation has defined and documented the time frame within which the initial assessment is to be completed with respect to OPD/

emergency/ indoor patients. The time frame shall be from the time that the patient has registered or it is the arrival time to the emergency department till the time that the initial assessment is documented by the medical and nursing team. Patients may be assessed earlier depending upon the clinical need.

d. The initial assessment for in-patients is documented within 24 hours or earlier as per the patient's condition, as defined in the organisation's policy. *

Interpretation: This should cover history, examination including vital signs and documentation of any drug allergies. It should mention the provisional diagnosis. For an admitted patient, if a detailed assessment has been done earlier (either in OPD or emergency on the same day), it need not be written in detail again. However, there shall be a comment linking the assessment to the earlier assessment and the findings of all such assessments shall be reviewed and/or verified. Note that the maximum time allowed for documentation is 24 hours. However, the organisation shall define and document the appropriate time depending on the patient's condition and the scope of its services.

e. Initial assessment of in-patients includes nursing assessment which is done at the time of admission and documented. *

Interpretation: This shall identify the nursing needs and also help identify any special needs of the patient. It shall be completed within a defined time frame. This assessment shall help in identifying the nursing needs of the patient. A checklist or template could be used for the same.

f. Initial assessment includes screening for nutritional needs.

Interpretation: The protocol for patient's initial assessment should cover his/her nutritional needs. This is only a screening for nutritional needs and not a complete assessment. This could be done by the treating doctor/ attending nurse or a dietician if available. Nutritional screening shall be done for all patients including OP and IP for relevant parameters.

Nutritional screening could result in a need for a detailed nutritional assessment which shall be done wherever necessary.

g. The initial assessment results in a documented care plan. *

Interpretation: This shall be documented by the treating doctor or by a member of his team in the patient record. Care plan is prepared and documented based on initial assessment and result of diagnostic tests if available. It should include a provisional diagnosis / differential diagnosis, relevant diagnostic investigations when required, initial treatment suggested and specific instructions if any. The care plan shall be subject to modifications or changes at reassessments.

h. The care plan reflects desired results of the treatment, care or service.

Interpretation: The components of the Care plan are directed to achieve desired outcomes which are apparent to the treating team members and the patient / family.

i. The care plan is countersigned by the clinician in-charge of the patient within 24 hours.

Interpretation: The treatment of the patient could be initiated by a junior doctor but the same should be countersigned and authorised by the treating doctor within 24 hours. The clinician in charge implies the treating doctor.

Standard

AAC.5.	**Patients cared for by the organisation undergo a regular reassessment.**

Objective Elements

a. Patients are reassessed at appropriate intervals.

Interpretation: After the initial assessment, the patient is reassessed periodically and this is documented in the case sheet. The frequency may be different for different areas based on the setting and the patient's condition, e.g. patients in ICU need to be reassessed more frequently compared to a patient in the ward.

Reassessments shall also be done in response to significant changes in patient's condition. Every patient shall be reassessed at least once every day by the treating doctor. Reassessments shall also be done for day-care patients (before discharging) or patients awaiting admission / bed.

b. Out-patients are informed of their next follow-up, where appropriate.

Interpretation: This could be either in terms of a specific date or after a certain periods (weeks / months) and shall be documented in the medical record. This may not be applicable in cases where patient has come for just an opinion or the patient's condition does not warrant repeat visits.

c. For in-patients during reassessment the care plan is monitored and modified, where found necessary.

Interpretation: The care plan shall be dynamic and modified where necessary by the treating doctor according to the patient's condition. The changing care plan is documented in the medical record. This could be evidenced in different sections such as progress notes, doctor's orders or medication charts.

d. Staff involved in direct clinical care document reassessments. *

Interpretation: Actions taken under reassessment are documented. The staff could be the treating doctor or any member of the team as per their domain of responsibility of care. At a minimum, the documentation shall include vitals, systemic examination findings and medication orders. The nursing staff can document patient's vitals. Only phrases like "patient well"; "condition better" would not be acceptable.

e. Patients are reassessed to determine their response to treatment and to plan further treatment or discharge.

Interpretation: Self-explanatory.

f. The organisation lays down guidelines and implements processes to identify early warning signs of change or deterioration in clinical conditions for initiating prompt intervention.

Interpretation: The organisation trains the staff to use defined physiological parameters to identify clinical deterioration. These may include assessment of vital parameters, airway, circulation, neurological status, and any other concerns felt by the staff or patient /patient family. The organisation has a mechanism whereby this information is made available to appropriate medical personnel to initiate prompt and appropriate actions.

Standard

AAC.6.	**Laboratory services are provided as per the scope of services of the organisation.**

Objective Elements

a. Scope of the laboratory services commensurate to the services provided by the organisation.

Interpretation: The organisation should ensure availability of laboratory services commensurate with the healthcare services offered by it. The organisation shall ensure that these services are available round the clock and patient care does not suffer. Test results required for emergency management (RBS, ABG etc.) must be available within its premises. For example, a cardiac care organisation must necessarily have facilities for cardiac enzyme.

b. The infrastructure (physical and equipment) is adequate to provide the defined scope of services.

Interpretation: Laboratory shall have adequate space and equipment to meet its defined scope of services which shall include

- Physical space
- Mechanical electrical and plumbing requirements (MEP).

- Equipment required to conduct these tests including suitable backup plan (internal or external).
- Appropriate workflow

Reports should not get delayed due to lack of adequate equipment.

c. The manpower is adequate to provide the defined scope of services.

Interpretation: The number of laboratory personnel should be commensurate with the work load with sufficient staff for each shift and emergencies. Reports should not get delayed due to lack of adequate manpower (including personnel authorised to report results).

d. Qualified and trained personnel perform, supervise and interpret the investigations.

Interpretation: The staff employed in the lab should be suitably qualified (appropriate degree) and trained to carry out the tests. Pathologist, microbiologist and biochemist supervise the staff.

e. Documented procedures guide ordering of tests, collection, identification, handling, safe transportation, processing and disposal of specimens. *

Interpretation: The organisation has documented procedures for ordering, collection, identification, handling, safe transportation, processing, and disposal of specimens, to ensure safety of the specimen till the tests and retests (if required) are completed (observing standard and special precautions). The organisation shall ensure that the unique identification number is used for identification of the patient. In addition, it could use another number (for example, lab number) to identify the sample. The disposal of waste shall be as per the statutory requirements (Bio-medical waste management and handling rules.)

f. Laboratory results are available within a defined time frame. *

Interpretation: The organisation shall define the turnaround time for all tests. The organisation should ensure availability of adequate staff, materials and

equipment to make the laboratory results available within the defined time frame. The turnaround time could be different for different tests and could be decided based on the nature of test, criticality of test and urgency of test result (as desired by the treating doctor).

g. Critical results are intimated immediately to the personnel concerned. *

Interpretation: The laboratory shall establish its biological reference intervals for different tests. The laboratory shall establish and document critical limits for tests which require immediate attention for patient management and the same shall be documented. The critical test results shall be communicated to the personnel concerned and this shall be documented. This shall include critical results of outsourced investigations. If it is not practical to establish the biological reference interval for a particular analysis the laboratory should carefully evaluate the published data for its own reference intervals. Relevant staff are made aware and trained on the critical values and its reporting process through suitable mechanism.

h. Results are reported in a standardised manner.

Interpretation: At a minimum, the report shall include the name of the organisation (or in case of outsourced laboratory, the name of the same), the patient's name, the unique identification number, reference range of the test (where applicable) and the name and signature of the person reporting the test result. All reports from the outsourced laboratory shall incorporate these features and the organisation shall not alter/modify anything in the report.

In case of outsourced test results, the same shall be either on the outsourced laboratory's letter head or on the organisation's letter head. If it is done on organisation's letter head it should include atleast the name of the outsourced laboratory, date and reference number of the report given by the outsourced laboratory.

i. There is a mechanism to address recall / amendment of reports whenever applicable.

Interpretation: These could include recall for errors due to pre analytical, analytical and post analytical factors. Whenever there is a recall of a particular report, withdrawal from clinical areas, medical records, LIS and HIS. If already issued to the patient, the amended report is made available to the patient with the caution to ignore the earlier one. The same shall be documented. Placement of corrected report in all these areas is also evidenced. Corrective and preventive action is implemented as appropriate based on detailed analysis.

j. Laboratory tests not available in the organisation are outsourced to organisation(s) based on their quality assurance system. *

Interpretation: The organisation has documented procedure for outsourcing tests for which it has no facilities. This should include:

i. A list of tests for outsourcing.
ii. Identity of personnel in the outsourced facilities to ensure safe and timely transportation of specimens and completing of tests as per requirements of the patient concerned and receipt of results at organisation.
iii. Manner of packaging of the specimens and their labelling for identification and this package should contain the test requisition with all details as required for testing.
iv. A methodology to check the performance of service rendered by the outsourced laboratory, as per the requirements of the organisation.

The organisation shall have MoU / agreement for the same, which incorporates quality assurance and requirements of this standard.

Standard

AAC.7.	**There is an established laboratory quality assurance programme.**

Objective Elements

a. The laboratory quality assurance programme is documented. *

Interpretation: The organisation has a documented quality assurance programme. Quality assurance includes internal quality control, external quality assurance, pre-analytic phase, test standardisation, post-analytic phase, management and organisation. The laboratory shall participate in external quality assurance programme when available. When such programmes are not available, the laboratory could exchange samples with another laboratory for purposes of peer comparison. There is a mechanism to obtain feedbacks from various stakeholders to evaluate the laboratory services.

b. The programme addresses verification and / or validation of test methods. *

Interpretation: Verification of an analytical procedure is the demonstration that a laboratory is capable of replicating with an acceptable level of performance a standard method. Verification of Standard method performance can be defined for two situations:

I. For verifying method performance for existing tests in the laboratory - each new batch / lot of reagents must be compared with the results of a defined number of tests done with an earlier lot / batch.

II. The first use of a standard method within the laboratory. Verification under conditions of use is demonstrated by meeting the specifications established for that method as well as a demonstration of accuracy and precision or other method parameters for that method. Eg – If the Laboratory introduces a new methodology of testing Blood Glucose levels, in addition to meeting the specifications established by that particular method (recommended by the manufacturer in case of a commercial kit), it should also demonstrate accuracy and precision by alternate established methods either within the laboratory or from outside laboratory.

Validation of method: Non-standard and laboratory-developed methods need method validation.

Methods requiring validation include:

- ✓ Modified official methods
- ✓ In-house developed methods
- ✓ Methods extended to a component, analysis or matrix not previously tested or included in validation
- ✓ Changes involving new technology or automation

Verification usually includes accuracy, precision and linearity. Validation in addition includes sensitivity and specificity. This also holds true for any laboratory-developed methods.

c. The programme addresses surveillance of test results. *

Interpretation: Surveillance of laboratory results like controls, external and internal quality assurance results, non-conformances etc shall be periodically assessed by the designated individual(s). This shall be done in a structured manner.

d. The programme includes periodic calibration and maintenance of all equipment. *

Interpretation: Traceability certificate(s) of all calibration done shall also be documented and maintained. This shall also include point of care equipment wherever feasible.

e. The programme includes the documentation of corrective and preventive actions.*

Interpretation: Self-explanatory.

Standard

AAC.8.	**There is an established laboratory safety programme.**

Objective Elements

a. The laboratory safety programme is documented. *

Interpretation: A well-documented laboratory safety manual is available in the lab. This takes care of the safety of the workforce as well as the equipment available in the laboratory. It shall be in consonance with the risks and hazards identified. This could be as per Occupational Health and Safety Management System.

b. This programme is aligned with the organisation's safety programme.

Interpretation: Laboratory safety programme is aligned with the safety programme of the organisation. The broad principles shall be the same as that of the organisation's safety programme.

c. Written procedures guide the handling and disposal of infectious and hazardous materials. *

Interpretation: The lab staff should follow standard precautions. The disposal of waste is according to Biomedical Waste management and handling rules.

Material safety and data sheets (MSDS-where applicable) shall be available and staff well versed in the same.

d. Laboratory personnel are appropriately trained in safe practices.

Interpretation: All the laboratory staff undergo training regarding safe practices in the laboratory. The training need identification has to be done commensurate with the job description of the staff.

e. Laboratory personnel are provided with appropriate safety equipment / devices.

Interpretation: Adequate safety devices are available in the lab, e.g. PPE, eye wash facilities, dressing materials, disinfectants, fire extinguishers etc. It should

address safety issues at all levels. All laboratory personnel shall adhere to standard precautions at all times. All lab staff shall be appropriately immunised.

Standard

AAC.9.	**Imaging services are provided as per the scope of services of the organisation.**

Objective Elements

a. Imaging services comply with legal and other requirements.

Interpretation: The organisation is aware of the legal and other requirements of imaging services and the same are documented for information and compliance by all concerned in the organisation. The organisation maintains and updates its compliance status of legal and other requirements in a regular manner. All the statutory requirements are met with such as AERB clearance, dosimeters, lead shields, lead aprons, signage, display as per PC-PNDT act, reports to competent authority, etc. The organisation shall have a Radiation Safety Officer (of appropriate level).

b. Scope of the imaging services is commensurate to the services provided by the organisation.

Interpretation: Self-explanatory.

c. The infrastructure (physical and equipment) and manpower is adequate to provide for its defined scope of services.

Interpretation:

Imaging services shall have adequate space and equipment to meet its defined scope of services which shall include

- Physical space
- Mechanical electrical and plumbing requirements (MEP).
- Equipment required to conduct these tests including suitable backup (internal or external).

- Appropriate workflow

Reports should not get delayed due to lack of adequate equipment or manpower (including personnel authorised to report results).

d. Adequately qualified and trained personnel perform, supervise and interpret the investigations.

Interpretation: AERB guidelines could be used as a reference document for radiation based imaging.

e. Documented policies and procedures exist to ensure correct identification and safe and timely transportation of patients to and from the imaging services. *

Interpretation: The aim is to ensure patient identification at all times so that correct procedure is carried out for a patient and correct report is handed over.

Procedure addresses the safe and timely transportation to and from the imaging services. This should also address transfer of unstable patients.

f. Imaging results are available within a defined timeframe. *

Interpretation: The organisation shall document turnaround time of imaging results for all modalities. The organisation shall monitor the waiting times, time taken to perform the tests and time taken to prepare the reports of the tests for all modalities; for in-patient, outpatient and emergency. The defined timeframes could be different for different type of tests and could be decided on the basis of the nature of the test, modality, and criticality of the test and the urgency of the test result (as required by the treating doctor).

g. Critical results are intimated immediately to the personnel concerned. *

Interpretation: The organisation shall define and document the critical results which require immediate attention of clinician, e.g. ectopic pregnancy. The critical test results shall be communicated to the personnel concerned and this shall be documented. This shall include critical results of outsourced investigations.

Relevant staff are made aware and trained on the critical values and its reporting process through suitable mechanism.

h. Results are reported in a standardised manner.

Interpretation: At a minimum, the report shall include the name of the hospital (or in case of outsourced imaging centre, the name of the same), the patient's name, the unique identification number, and the name and signature of the person reporting the test result. In case of tele-radiology, there shall be the name of the reporting doctor and a remark to that effect. It should also include the name of the reporting organisation if outsourced to an organisation. All reports from the outsourced imaging centre shall incorporate these features and the hospital shall not alter/modify anything in the report.

The report should be in prevailing context taking into account the clinical details and results of any previous imaging.

i. There is a mechanism to address recall / amendment of reports whenever applicable.

Interpretation: These could include recall for errors at all levels. Whenever there is a recall of a particular report, withdrawal from clinical areas, medical records, RIS and HIS should be ensured. If already issued to the patient, the amended report is made available to the patient with the caution to ignore the earlier one. The same shall be documented. Placement of corrected report in all these areas is also evidenced. Corrective and preventive action is implemented as appropriate based on detailed analysis.

j. Imaging tests not available in the organisation are outsourced to organisation(s) based on their quality assurance system. *

Interpretation: The organisation has documented procedure for outsourcing tests for which it has no facilities. This should include:

i. list of tests for outsourcing,

ii. identity of personnel in the outsourced facilities to ensure safe transportation of patients and completing of imaging results,

iii. manner of identification of patients and the test requisition with all details as required for testing and

iv. a methodology to check the selection and performance of service rendered by the outsourced imaging facility as per the requirements of the organisation.

The organisation shall have an MOU / agreement for the same, which incorporates quality assurance and requirements of this standard.

Standard

AAC.10.	**There is an established quality assurance programme for imaging services.**

Objective Elements

a. The quality assurance programme for imaging services is documented. *

Interpretation: The QA programme for imaging should involve all stakeholders. It should be a comprehensive programme addressing equipment QA, Protocols, safety, education and surveillance. In addition, AERB requirement will have to be met.

Some examples for QA of radiation equipment include congruence of optical and radiation field, focal spot size, output consistency, leakage rate, etc.

b. The programme addresses periodic internal / external peer review of imaging protocols and results using appropriate sampling.

Interpretation: A peer review system will be in place to review the reports and outcomes of interventional procedures performed. This shall be done in a structured manner, and the sample size, periodicity for each modality shall be defined. The results of such reviews shall be discussed with all stake holders in "discrepancy meetings" and the same shall be documented. The peer review can be performed by the head of department or by a group of peers, with or without blinding of the original reports. Discrepancies in the reports will be graded on the

severity and impact on changes on patient management strategy, and the corrective and preventive actions taken to minimize these will be documented. The purpose is to prevent errors in future, and continuous quality improvement rather than computation or error rates of the individuals.

c. The programme addresses surveillance of imaging results in collaboration with referring clinicians for follow up wherever applicable *

Interpretation: Structured peer review of the imaging protocols and procedures shall be periodically performed and they should be modified in accordance of the current best practices. Surveillance of the quality of images, and completeness of the imaging procedures should be performed to ensure that they are appropriate for the indications for which the imaging has been performed. For example: CT for acute renal colic requires only a low dose non-contrast CT and a multiphase CT urography would expose the patient to unnecessary radiation and contrast media injection; while for Obstructive uropathy with urosepsis will require it to be tailored for identifying abscesses, and hence would be multiphase CT.

d. A system is in place to ensure the appropriateness of the investigations and procedures for the clinical indication.

Interpretation: The investigation orders are screened prior to performing of the imaging or interventional procedure to ensure that they are appropriate investigation (as per current best practice guidelines and patient safety) based on for the clinical indication, otherwise alternate investigations are offered in consultation with the treating doctor. For example: Mammography for a lactating 25 yrs old lady with fever and a lump is inappropriate, and will never reveal the breast abscess; Ultrasound scan of the breast will be the best investigation.

e. The programme includes periodic calibration and maintenance of all equipment. *

Interpretation: Quality Assurance including calibration and maintenance of all equipment will be performed as per AERB guidelines, as well as the manufacturer's recommendations and records of the same shall be maintained.

All such activities will be performed by persons who are appropriately trained and certified by the regulatory authorities for this purpose. Traceability certificates of all Calibrations done by calibrated equipment shall be maintained.

f. The programme includes the documentation of corrective and preventive actions.*

Interpretation: In case of any deviations noted from the laid down quality assurance programme, the organisation shall institute corrective and preventive actions as may be appropriate.

Standard

AAC.11.	**There is an established safety programme in the imaging services.**

Objective Elements

a. The radiation-safety programme is documented. *

Interpretation: Refer to AERB guidelines. The programme also include implementation of "As Low As Reasonably Achievable" (ALARA) principle in investigations involving Radiation and Screening of those patients who are at a high risk for radiation. Eg : Routine daily Chest Radiograph for all ICU patients cannot be justified, more so in Paediatric or Neonatal ICUs. ; CT scan protocols are modified to use the exposure parameters to the lowest possible for each individual, to maintain the image quality appropriate for the clinical indication - CT for ureteric calculi can be done with low dose; renal tumour will require higher dose; The CT stetting for a 50 Kg and a 100 Kg patient cannot be the same.

b. This programme is aligned with the organisation's safety programme.

Interpretation: Imaging safety programme is aligned with the safety programme of the organisation. The broad principles shall be the same as that of the organisation's safety programme.

c. Patients are appropriately screened for safety / risk prior to undergoing an imaging on a particular modality.

Interpretation: Patients in the child bearing age group who need to be exposed to radiations should be screened for pregnancy (via questionnaire/interview). Patients undergoing MRI should be screened (through questionnaire/interview) for any magnetic substance. This shall also apply to attendants accompanying the patient/child into the imaging area.

Informed consent should be taken for contrast injection, moderate-deep sedation, interventional procedures and whenever higher risk of imaging is found on risk screening.

d. Handling, usage and disposal of radio-active and hazardous materials are as per statutory requirements.

Interpretation: Document on safe use of radioactive isotopes for imaging services shall be available and implemented. Radioactive and hazardous materials shall be disposed of as per guidelines laid down by competent bodies. Material safety and data sheets (MSDS-where applicable) shall be available and staff well versed in the same.

e. Imaging personnel and patients are provided with appropriate radiation safety and monitoring devices where applicable.

Interpretation: Shielding of body parts of staff and patients, attendants shall be adhered to using appropriate aprons and shields. The number of such devices shall be adequate to ensure that all workers have proper protection. Each staff in the radiation area is provided with TLD badges/dosimeters as applicable.

f. Radiation-safety and monitoring devices are periodically tested and results are documented. *

Interpretation: Protective devices, e.g. lead aprons, should be exposed to X-ray or fluoroscopy or CT scout view for verification of cracks and damages. This is done periodically.

It is preferable that the image of the same be stored (either physical or electronic).This shall be done at least once a year.

Where appropriate corrective and/or preventive action shall be taken and documented.

g. Imaging and ancillary personnel are trained in imaging safety practices and radiation-safety measures.

Interpretation: Imaging safety practices include training of imaging and ancillary personnel on MRI safety, kinking of tubes, fall prevention and handling patients in the imaging areas. Radiation safety measures refer to the steps taken to protect the patient and staff from unwanted radiation.

The ancillary staff refers to those staff who are posted in the imaging service who support the radiologist, radiographers, MRI / CT technicians in the activities in the imaging service. These staff may include Nurses, Helper staff, stretcher bearers, housekeeping, security, etc.

h. Imaging signage are prominently displayed in all appropriate locations.

Interpretation: This includes safety signage and display of signage as required by regulatory authorities.

Standard

AAC.12.	**Patient care is continuous and multidisciplinary in nature.**

Objective Elements

a. During all phases of care, there is a qualified individual identified as responsible for the patient's care.

Interpretation: The organisation shall ensure that the care of patients is always given by appropriately qualified medical personnel (resident doctor, consultant and/or nurse). Although care may be provided by a team, the hospital record shall identify a doctor as being responsible for patient care.

b. Care of patients is coordinated in all care settings within the organisation.

Interpretation: Care of patients is co-ordinated among various care-providers in a given setting *viz* OPD, emergency, IP, ICU, etc. The organisation shall ensure that there is effective communication of patient requirements amongst the care-providers in all settings.

c. Information about the patient's care and response to treatment is shared among medical, nursing and other care-providers.

Interpretation: The organisation ensures periodic discussions about each patient (covering parameters such as patient care, response to treatment, unusual developments if any, etc.) amongst medical, nursing and other care-providers. This could be done on the basis of entries either on case sheet or on electronic patient records (EPR).

d. Information is exchanged and documented during each staffing shift, between shifts, and during transfers between units/departments.

Interpretation: For example

1) Structured Clinical handover by doctors and nurses has to be done and documented
2) Transfer summary.

e. Transfers between departments/units are done in a safe manner.

Interpretation: The organisation shall ensure that intra-organisation transfers are done adhering to safe practices. The patients shall be transported in a safe manner and a proper handover and takeover shall be documented.

f. The patient's record(s) is available to the authorised care-providers to facilitate the exchange of information.

Interpretation: The record could be kept in the nursing station for that area.

g. Documented procedures guide the referral of patients to other departments/ specialities. *

Interpretation: The organisation has clearly defined and documented the procedures to be adopted to guide the personnel dealing with referral of patients to other departments or specialties. The organisation shall ensure that where appropriate a multi-disciplinary team shall provide care. Established criteria or policies should be used to determine the appropriateness of transfers within the organisation. Referral could be for opinion, co-management and takeover. It could be graded into immediate, urgent, priority or routine category. All referrals shall be based on clinical significance and for better outcome. All referrals shall be seen in a defined time frame. This could be different based on the urgency of referral.

h. The organisation ensures continuity of care while adhering to defined timelines and informs the caregiver and/or the patient/family whenever there is a change in schedule.

Interpretation: The organisation has defined timelines (eg: Laboratry, Radio Logy, OPD waiting time) to ensure continuity of care. Patients are informed of the same. Whenever there is a deviation from the defined timelines the patient/family are informed of the change in schedule. The organisation shall also inform the caregiver so as to ensure that the continuity of care is not compromised

i. The organisation has a mechanism in place to monitor whether adequate clinical intervention has taken place in response to a critical value alert.

Interpretation: The attending clinician shall respond immediately to a critical value alert. The organisation has a mechanism to periodically review the intervention to assess for timeliness and appropriateness of response. In case of outpatient, efforts will be taken to alert the patient or family about the critical values.

Standard

AAC.13.	**The organisation has a documented discharge process.**

Objective Elements

a. The patient's discharge process is planned in consultation with the patient and/or family.

Interpretation: The patient's treating doctor determines the readiness for discharge during regular reassessments. The same is discussed with the patient and family.

b. Documented procedures exist for coordination of various departments and agencies involved in the discharge process (including medico-legal and absconded cases). *

Interpretation: The discharge procedures are documented to ensure coordination amongst various departments including accounts so that the discharge papers are complete well within time. For medico-legal cases (MLC) the organisation shall ensure that the police are informed.

c. Documented policies and procedures are in place for patients leaving against medical advice and patients being discharged on request. *

Interpretation: The organisation has a documented policy for such cases. The treating doctor should explain the consequences of this action to the patient/attendant. This policy could address the reasons of LAMA for any possible corrective and/or preventive action by the organisation.

d. A discharge summary is given to all the patients leaving the organisation (including patients leaving against medical advice and on request).

Interpretation: The organisation hands over the discharge summary and reports to the patient/attendant in all cases and a copy is retained in the medical record. In LAMA cases,. The patient's right to refuse treatment and his/her request to leave the organisation is respected, the declaration of the patient/attendant is to

be recorded on a proper format and a discharge summary and all reports are handed over as usual. Terminology used to refer to such patients may differ, but the intent of issuing the discharge summary with reports remains the same.

e. The organisation defines the time taken for discharge and monitors the same.

***Interpretation*:** The hospital defines discharge time and monitors delay if any. The organisation shall make an effort to ensure that all steps involved in the discharge process are completed in timely manner and delays are avoided.

Standard

AAC.14.	**Organisation defines the content of the discharge summary.**

Objective Elements

a. Discharge summary is provided to the patients at the time of discharge.

Interpretation: The discharge summary shall be signed by the treating doctor or a member of his/her team. Patient/ family acknowledges the receipt of the same.

b. Discharge summary contains the patient's name, unique identification number, date of admission and date of discharge.

Interpretation: Self-explanatory.

c. Discharge summary contains the reasons for admission, significant findings and diagnosis and the patient's condition at the time of discharge.

Interpretation: Self-explanatory.

d. Discharge summary contains information regarding investigation results, any procedure performed, medication administered and other treatment given.

Interpretation: In addition it could also have the name of the primary physician and other consultants involved in the treatment.

e. Discharge summary contains follow-up advice, medication and other instructions in an understandable manner.

Interpretation: This shall also incorporate preventive aspects, where appropriate. The organisation ensures that the follow-up advice, medication and other instructions are explained to the patient and or relatives in a language and manner that they understand. Medical terms eg BD, TDS, QID should not be used.

f. Discharge summary incorporates instructions about when and how to obtain urgent care.

Interpretation: The organisation should outline conditions regarding 'when' to obtain urgent care. For example, a post-op patient should report when having fever, bleeding/discharge from site. This could be in the form of what medicines to take, when to consult a doctor or how to seek medical help and contact number of the hospital/doctor. The organisation ensures that instructions about when and how to obtain urgent care are explained to the patient and or relatives in a language and manner that they understand.

g. In case of death, the summary of the case also includes the cause of death.

Interpretation: In case the cause of death is not clear and a post mortem is being performed (Eg MLC), the same shall be documented.

Chapter 2
Care of Patients (COP)

Intent of the chapter:

The organisation provides uniform care to all patients in different settings. The different settings include care provided in outpatient units, various categories of wards, intensive care units, procedure rooms and operation theatre. When similar care is provided in these different settings, care delivery is uniform. Policies, procedures, applicable laws and regulations guide emergency and ambulance services, cardio-pulmonary resuscitation, use of blood and blood components, care of patients in the intensive care and high dependency units.

Policies, procedures, applicable laws and regulations also guide care of vulnerable patients (elderly, physically and/or mentally-challenged and children), high-risk obstetrical patients, paediatric patients, patients undergoing moderate sedation, administration of anaesthesia, patients undergoing surgical procedures, patients under restraints, research activities and end of life care.

Pain management, nutritional therapy and rehabilitative services are also addressed with a view to providing comprehensive health care.

The standards aim to guide and encourage patient safety as the overall principle for providing care to patients.

Summary of Standards

COP 1:	Uniform care to patients is provided in all settings of the organisation and is guided by the applicable laws, regulations and guidelines.
COP 2:	Emergency services are guided by documented policies, procedures applicable laws and regulations.
COP 3:	The ambulance services are commensurate with the scope of the services provided by the organisation.
COP 4.	The organisation plans for handling community emergencies, epidemics and other disasters**.**
COP 5:	Documented policies and procedures guide the care of patients requiring cardio-pulmonary resuscitation.
COP 6:	Documented policies and procedures guide nursing care.
COP 7:	Documented procedures guide the performance of various procedures.
COP 8:	Documented policies and procedures define rational use of blood and blood components.
COP 9:	Documented policies and procedures guide the care of patients in the intensive care and high dependency units.
COP 10:	Documented policies and procedures guide the care of vulnerable patients.
COP 11:	Documented policies and procedures guide obstetric care.

COP 12:	Documented policies and procedures guide paediatric services.
COP 13:	Documented policies and procedures guide the care of patients undergoing moderate sedation.
COP 14:	Documented policies and procedures guide the administration of anaesthesia.
COP 15:	Documented policies and procedures guide the care of patients undergoing surgical procedures.
COP.16	Documented policies and procedures guide organ transplant programme in the organisation.
COP 17:	Documented policies and procedures guide the care of patients under restraints (physical and/or chemical).
COP 18:	Documented policies and procedures guide appropriate pain management.
COP 19:	Documented policies and procedures guide appropriate rehabilitative services.
COP 20:	Documented policies and procedures guide all research activities.
COP 21:	Documented policies and procedures guide nutritional therapy.
COP 22:	Documented policies and procedures guide the end of life care.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

COP.1.	**Uniform care to patients is provided in all settings of the organisation and is guided by the applicable laws, regulations and guidelines.**

Objective Elements

a. Care delivery is uniform for a given health problem when similar care is provided in more than one setting. *

***Interpretation*:** The organisation shall ensure that patients with the same health problems and care needs receive the same quality of health care throughout the organisation, irrespective of the category of the ward. Further, in case the organisation has separate OPDs for a different category of patients the methodology for care delivery shall be uniform in all OPDs.

b. Uniform care is guided by documented policies and procedures**.**

***Interpretation*:** Self-explanatory.

c. These reflect applicable laws, regulations and guidelines.

***Interpretation*:** Where applicable, the organisation shall adhere to the norms laid down by the government through relevant legislations like the Clinical Establishment, PCPNDT, HOTA. MTP Act or any such similar legislation**.** For example, consent before surgery, providing first aid to emergency patients and police intimation in cases of medico-legal cases.

d. The organisation adapts evidence-based medicine and clinical practice guidelines to guide uniform patient care.

***Interpretation*:** For definitions of “evidence-based medicine” and “clinical practice guidelines”, refer to the glossary.

Standard

COP.2.	**Emergency services are guided by documented policies, procedures, applicable laws and regulations.**

Objective Elements

a. There shall be an identified area in the organisation which is easily accessible to receive and manage emergency patients.

***Interpretation*:** The identified area to treat emergency patients should be easily accessible for initiation of care.

b. Policies and procedures for emergency care are documented and are in consonance with statutory requirements. *

Interpretation: These could include SOPs/protocols to provide either general emergency care or management of specific conditions, e.g. poisoning. It shall address both adult and paediatric patients. The procedure shall incorporate at a minimum identification, assessment and provision of care. The organisation shall also define the minimum number of beds based on its scope of services. Emergency services should have adequate manpower. All patients coming to the hospital shall be provided with first aid before transferring them to another centre.

c. This also addresses the handling of medico-legal cases. *

Interpretation: The policy shall be in line with statutory requirements w.r.t. documentation and intimation to police. The organisation shall also define as to what constitutes an MLC (in accordance with statutory guidelines).

d. The patients receive care in consonance with the policies**.**

Interpretation: Poisoning cases, road-traffic accidents, patients with coronary disease, etc. shall be dealt as per hospital policies and procedures.

e. Documented policies and procedures guide the triage of patients for initiation of appropriate care. *

Interpretation: Triage shall be done only by qualified/trained individuals. This should be based on good clinical practices. The triage should be part of routine day-to-day functioning of the emergency department and not only from a disaster point of view. The criteria could be separate for trauma & non-trauma patients and for adults and children. For “triage” refer to the glossary.

f. Staff are familiar with the policies and trained on the procedures for care of emergency patients.

***Interpretation*:** All the staff working in the area should be oriented to the policies and practices through training/documents. Staff should be trained in basic cardiopulmonary resuscitation, and preferably be trained / well versed in advanced cardiopulmonary resuscitation (adult, paediatric, neonatal).

g. Admission or discharge to home or transfer to another organisation is also documented.

Interpretation: Self-explanatory.

h. In case of discharge to home or transfer to another organisation, a discharge note shall be given to the patient.

Interpretation: The discharge note shall incorporate salient features of investigations that were done and treatment given.

i. Quality assurance programmes are documented and implemented. *

Interpretation: The quality and safety programme should be documented and involve all aspects of the functioning in the Emergency department. Processes should be in place to ensure the patient safety. The Emergency department should collect data on key performance indicators as part of its quality improvement programme. The collected data should be collated, analyzed and

used for further improvements. The improvements should be monitored for sustenance.

j. The documented policies and procedures guide management of patients found dead on arrival to the hospital. *

Interpretation: There are clear policies and guidelines for managing situations where a patient is either found dead on arrival to the Emergency department or dies on arrival to the Emergency department.

The policies and procedure in case of patient **found dead on arrival** to the Emergency department address:

a) Maintaining a log book of patients found dead on arrival
b) Medico-legal formalities and police information of the same,
c) Decision on whether to perform post-mortem,
d) Temporary storage of the body in appropriate conditions,
e) What to do in case of unclaimed/unaccompanied bodies.

Due diligence to be exercised by the organisation to ensure that the policies laid down are in accordance with the local laws.

In case of **death on arrival** the policies and procedure shall address:

a) Process of registration of such patients and recording the entire resuscitation events,
b) Guidelines for breaking of bad news
c) Medico-legal formalities, police information and post-mortem when appropriate,
d) Storage of the body till further procedures,
e) Death certificate and handing over of the body.

Standard

COP.3.	**The ambulance services are commensurate with the scope of the services provided by the organisation.**

Objective Elements

a. There is adequate access and space for the ambulance(s).

***Interpretation*:** The organisation shall demarcate a proper space for the ambulance(s).This shall be demarcated keeping in mind easy accessibility for receiving patients and to enable the ambulance(s) to exit quickly.

b. The ambulance adheres to statutory requirements.

***Interpretation*:** This is in the context of Motor Vehicle Act. e.g. Licence of Driver , Fitness Certificate, Pollution Control certificate and Insurance & registration of vehicle.

c. The ambulance(s) is appropriately equipped.

Interpretation: This shall be done based on the organisation's scope. It is expected that any ambulance shall be equipped with at least basic life support. Equipment for both adult and paediatric patients shall be present.

d. The ambulance(s) is manned by trained personnel.

***Interpretation*:** The ambulance should be manned by a trained driver, technician/nurse and/or doctor depending on the situation. Personnel shall be trained in basic cardiopulmonary resuscitation.

e. The ambulance(s) is checked on a daily basis.

***Interpretation*:** The check shall also clearly indicate the functioning status of the ambulance like lights, siren, beacon lights, etc. In addition, the ambulance shall undergo servicing as per the set schedule.

f. Equipments are checked on a daily basis using a checklist. *

***Interpretation*:** The check shall clearly indicate the functioning status of the equipment.

g. Emergency medications are checked daily and prior to dispatch using a checklist.

***Interpretation*:** This also includes checking the expiry date of drugs. In case a rapid turnaround of the ambulance is required (where checking may not be possible prior to dispatch), only the medications used could be topped up or the organisation could keep an additional set of drugs as standby.

h. The ambulance(s) has a proper communication system.

***Interpretation*:** The ambulance shall be connected with the organisation/control room by wireless/mobile phones. The communication system should encompass the whole process of patient transport. There should be laid down policy by the organisation as to how a call for patient transport is received, who are the people expected to respond and organise the transport. The communication ensures that ambulance leaves the hospital within predefined timeframe based upon the patient's needs.

i The emergency department identifies opportunities to initiate treatment at the earliest when the patient is in transit to the organisation.

Interpretation: From the time of first communication with the patient / patient's attendant, attempts are made to gather important clinical information (patient's age, weight, provisional diagnosis and ongoing treatment at the referral hospital is noted down while discussing on the phone.) This information is used by the ambulance personnel of the receiving hospital to be better prepared to assess, initiate interventions during transit and transport the patient safely.

During the transit, when required, there is an exchange of information between the ambulance personnel and the medical professional at the receiving hospital. This will help the doctor at the receiving hospital guide the ambulance personnel

to facilitate the management during the transit. When the patient is being shifted by an external agency, where possible, an attempt is made by the doctor of the receiving hospital to communicate with the ambulance personnel of the external agency to ascertain the clinical situation and make appropriate suggestions. However, the medical professional in the ambulance would be responsible for decision making regarding the interventions during the transit.

Standard

COP.4	**The organisation plans for handling community emergencies, epidemics and other disasters.**

Objective Elements

a. The organisation identifies potential emergencies. *

Interpretation: The organisation has a documented plan and procedure for handling the situations like sudden rush of victims of

i. earthquake,
ii. flood,
iii. train accident,
iv. civil unrest outside the organisation's premises,
v. major fire, and
vi. invasion by the enemy, etc.

These plans and procedures cover ensuring adequacy of medical supplies, equipment, materials, identified-trained personnel, transportation aids, communication aids and mock-drill methodology.

b. The organisation has a documented disaster management plan. *

Interpretation: The disaster plan must incorporate essential elements of alert code, information and communication, action cards for each of the staff, availability and earmarking of resources, establishment of command nucleus, training and mock drills, managing clinical activities during the event. Refer to

National Disaster Management Authority (NDMA) guidelines. Emergency room could follow triage policy according to NDMA guidelines.

c. Provision is made for availability of medical supplies, equipment and materials during such emergencies.

Interpretation: Resource availability should be according to threat perception. The quantity of resources, i.e. medical stores, etc. to be cross-checked with expected workload.

d. Staff are trained in the hospital's disaster management plan.

Interpretation: The training shall include the various elements of the disaster plan.

e. The plan is tested at least twice a year.

Interpretation: This shall test all the components of the plan and not just awareness. Simulated patients (not real) shall be used. This is only the minimum frequency and this may be increased. At the conclusion of every mock drill, the variations are identified, reason for the same is analysed, debriefing of the drill conducted and where appropriate the necessary corrective and/or preventive actions are taken.

Standard

COP.5.	**Documented policies and procedures guide the care of patients requiring cardio-pulmonary resuscitation.**

Objective Elements

a. Documented policies and procedures guide the uniform use of resuscitation throughout the organisation. *

***Interpretation*:** The organisation shall document the procedure for same. This shall be in consonance with accepted practices. Where appropriate, it shall address adult, paediatric and neonatal patients. The organisation shall ensure

that adequate and appropriate resources (both men and material) are provided. Basic life support should be initiated as soon as a condition requiring CPR is identified. This is implemented in all areas of the hospital. The protocols could be displayed prominently in all critical areas such as emergency, ICU, OT, etc.

b. Staff providing direct patient care are trained and periodically updated in cardio-pulmonary resuscitation.

***Interpretation*:** These aspects shall be covered by hands-on training which could be done by trainers from within or outside the organisation using established evidence-based protocols. If the organisation has a CPR team (e.g. code blue team) it shall ensure that it is trained in advanced cardiopulmonary resuscitation (adult, paediatric and neonatal) and is present in all shifts.

All doctors, rehabilitation staff and nursing staff must at least be trained to provide basic life support. All doctors and nurses working in intensive care/high dependency units should undergo appropriate training.

c. The events during a cardiopulmonary resuscitation are recorded.

***Interpretation*:** In the actual event of a CPR or a mock drill of the same, all the activities along with the personnel attended should be recorded. At the minimum, it will include timeliness of response, availability of manpower, equipment, drugs, and barriers if any. This could be done using the pre-defined procedural checklist and by monitoring whether the prescribed activity has been performed properly and in the right sequence.

d. A post-event analysis of all cardiopulmonary resuscitations is done by a multidisciplinary committee.

Interpretation: The analysis shall focus on the initiation of CPR, time of arrival of the team, availability of suitable resources, recording of the sequence of events during CPR (including technique) and the overall coordination. The organisation shall also monitor the outcomes. The multidisciplinary committee shall be

independent and include at least one physician/cardiologist, anaesthesiologist, one member from the code blue team and nurse. The analysis should be completed within a defined time frame.

e. Corrective and preventive measures are taken based on the post-event analysis.

Interpretation: Corrective and preventive measures should be completed within a defined time frame. During subsequent resuscitations, it is preferable that implementation of these actions is noted and training be modified, if necessary.

Standard

COP.6.	**Documented policies and procedures guide nursing care.**

Objective Elements

a. There are documented policies and procedures for all activities of the nursing services. *

Interpretation: This could be in the form of a nursing manual incorporating all nursing procedures.

b. These reflect current standards of nursing services and practice, relevant regulations and purposes of the services.

***Interpretation*:** Nursing practice is in accordance with nationally accepted standards and shall include:

i. Documented individualised patient-focused nursing care plan for each patient to achieve appropriate outcomes;
ii. Monitoring of the patient to assess the outcome of the care;
iii. Modifying the care when necessary;
iv. Completing the care;
v. Planning and follow-up, to include discharge planning that reflects the continuity of care.

c. Assignment of patient care is done as per current good practice guidelines.

Interpretation: Assignment shall be based on the patient's clinical requirements and shall incorporate the guidelines laid down by regulatory and professional bodies.

d. Nursing care is aligned and integrated with overall patient care.

***Interpretation*:** This shall be provided as per the nursing Care plan. The nursing Care plan shall be aligned with the Care plan of the patient. Uniformity and continuity of care should be practised.

e. Care provided by nurses is documented in the patient record. ***

***Interpretation*:** This includes all nursing-related care and not just monitoring of vitals and documentation of medication administration.

f. Nurses are provided with adequate equipment for providing safe and efficient nursing services.

***Interpretation*:** There shall be an adequate number of sphygmomanometers, thermometers, weighing scale(s), etc.

g. Nurses are empowered to take nursing-related decisions to ensure the timely care of patients.

Interpretation: Self-explanatory.

Standard

COP.7.	**Documented procedures guide the performance of various procedures.**

Objective Elements

a. Documented procedures are used to guide the performance of various clinical procedures. *

***Interpretation*:** This is a broad guideline which is common to all the procedures. It shall incorporate as to who will do the procedure, the pre-procedure instructions, the conduct of the procedure and post-procedure instructions.

b. Only qualified personnel order, plan, perform and assist in performing procedures.

***Interpretation*:** The organisation could conduct a clinical audit of various procedures especially with respect to indications.

c. Documented procedures exist to prevent adverse events like a wrong site, wrong patient and wrong procedure. *

***Interpretation*:** At least two identifiers should be used to identify the patient out of which one method should the unique hospital ID. In addition, the organisation should have a procedure to identify the site of the procedure, where appropriate. The organisation identifies those procedures within its scope where a pre-procedure checklist could be used to mitigate the risk of wrong site/side, wrong patient and wrong procedure.

d. Informed consent is taken by the personnel performing the procedure, where applicable.

***Interpretation*:** The consent shall be taken by the person performing the procedure or a member of his/her team. In case the procedure is being done by a person in training, it shall specify the same. All such procedures shall be supervised by the treating doctor.

e. Adherence to standard precautions and asepsis is adhered to during the conduct of the procedure.

***Interpretation*:** This shall include standard precautions, appropriate use of PPE, preparation and disinfection of body parts, high-level chemical disinfection and sterilisation of reusable equipment and instruments.

f. Patients are appropriately monitored during and after the procedure.

***Interpretation*:** At a minimum this shall include pulse, blood pressure and respiratory rate which shall be monitored for at least two hours after the procedure or as clinically required.

g. Procedures are documented accurately in the patient record. *

***Interpretation**:* The documentation shall mention the name of the procedure, the person who performed the procedure, salient steps of the procedure, key findings and the post-procedure care. All documentation shall have name, date, time and signature.

Standard

COP.8.	**Documented policies and procedures define rational use of blood and blood components.**

Objective Elements

a. Documented policies and procedures are used to guide the rational use of blood and blood components. *

***Interpretation*:** This shall address the conditions where blood and blood components can be used. It shall also address inventory and ordering schedules (planned and unplanned).

b. Documented procedures govern transfusion of blood and blood components *

***Interpretation*:** This shall at a minimum include how the orders are written including pre-medications if any (rate needs to be mentioned for paediatric

patients), transport of blood, how the blood/blood product is verified prior to transfusion, how the patient is identified and how the patient is monitored.

This shall include procedures for availability and transfusion of blood/blood components for emergency use/in an emergency.

A good reference guide is the NABH standards for blood banks.
In case the organisation does not have a blood bank, it shall have a MoU with a blood bank/organisation having a blood bank and ensure that patient care does not suffer. Verification, transportation, cold chain and delivery at the right source should be taken care of. Blood shall be transported from the external blood bank in a safe and proper manner.

c. The transfusion services are governed by the applicable laws and regulations.
Interpretation: Refer to Drugs and Cosmetics Act.

d. Informed consent is obtained for donation and transfusion of blood and blood components.
***Interpretation*:** Consent should be taken for transfusion of blood or blood components when there is a requirement for transfusion. The same consent may be valid for multiple transfusions of blood/ blood components in a given admission (in-patient) which has a defined validity period.

In case of patients who are transfusion dependent (e.g. haemophilia, thalassemia etc.) the consent can be taken at the first instance and once in six months. Such consent shall have a defined validity period but not more than 6 months. The patient/competent relative or guardian endorses the consent at each repeat transfusion.

The consent should include risks, benefits and possible complications of multiple transfusions.

e. Informed consent also includes patient and family education about the donation.

***Interpretation*:** This could be in the form of a booklet/leaflet. This has to be given along with the consent form.

f. The organisation defines the process for availability and transfusion of blood/blood components for use in emergency situations. *

***Interpretation*:** The organisation shall define as to what constitutes "use in an emergency situation" and accordingly develop procedures.

This is applicable even if the organisation doesn't have the blood bank facility in-house. It is preferable that the organisation also define the time frame within which blood must be available for use in an emergency situation. Use in emergency includes both for emergency stand-by and use in an emergency.

g. Post-transfusion form is collected, reactions if any identified and are analysed for preventive and corrective actions.

***Interpretation*:** The organisation shall ensure that any transfusion reaction is reported. It is preferable that the organisation capture feedback regarding every transfusion (including the ones without reaction) as this would enable it to capture all transfusion reactions. These are then analysed (by individual/ committee as decided by the organisation) and appropriate corrective/ preventive action is taken. The organisation shall maintain a record of transfusion reactions. For "transfusion reactions" refer to the glossary. .

h. Staff are trained to implement the policies.

***Interpretation*:** This shall include doctors and can be done either by training and/or by providing written instructions. Records of the same should be available.

Standard

COP.9.	**Documented policies and procedures guide the care of patients in the intensive care and high dependency units.**

Objective Elements

a. Documented policies and procedures are used to guide the care of patients in the intensive care and high dependency units. *

***Interpretation*:** At a minimum this should include as to how care is organised, how patients are monitored and the nurse-patient ratio.

b. The organisation has documented admission and discharge criteria for its intensive care and high dependency units**. ***

Interpretation: The organisation should develop criteria based on physiologic parameters and adhere to it. A good starting point could be various national and international critical care society guidelines.

c. Staff are trained to apply these criteria.

Interpretation: This shall be done by training and/or by displaying the criteria.

d. Adequate staff and equipment are available.

Interpretation: The ICU should be equipped with all necessary life-saving and monitoring equipment as well as suitably manned by trained staff. The exact requirements shall be decided by the organisation based on the scope and complexity of its services. However, the organisation is expected to follow best clinical practices.

A good reference guide for nursing manpower is the Indian Nursing Council recommendations.

e. Defined procedures for the situation of bed shortages are followed. *

Interpretation: As and when there are no vacant beds in the ICU and there is a requirement of such bed, a detailed policy and procedure should be in place to address the situation.

f. Infection control practices are documented and followed. *

Interpretation: These could be developed individually or it could be a part of the infection control manual. The organisation shall ensure that the practices are in consonance with good clinical practices.

g. A quality assurance programme is documented and implemented. *

Interpretation: These could be developed individually or it could be a part of the organisation's quality-assurance programme. The organisation shall ensure that the programme is in consonance with good clinical practices. Good clinical practices include monitoring infection rates, re-admission rates, re-intubation rates, etc.

Further, a good starting point could be various national and international critical care society guidelines on quality assurance in ICUs.

h. Patients and families are counselled by the treating medical professional at periodic intervals and when there is a significant change in the condition of the patient, and same is documented. *

Interpretation: Patients and families need to be counselled at periodic intervals (at-least once a day) by any doctor of the treating team to inform them and answer queries related to the changing condition of the patient. The periodicity should be at least once a day or more often, based on the clinical condition of the patient and same needs to be documented.

Standard

COP.10.	**Documented policies and procedures guide the care of vulnerable patients.**

Objective Elements

a. Policies and procedures are documented and are in accordance with the prevailing laws and the national and international guidelines. *

Interpretation: The organisation shall identify the vulnerable patients. It could include (but not limited to) elderly, children, physically and/or mentally challenged, comatose, patients under sedation and anaesthesia etc. The procedure shall also include who is responsible for identifying these patients, risk management in these patients and monitoring of these patients (at least twice a day). All these patients shall be assessed for risk of falls and the same documented.

b. Care is organised and delivered in accordance with the policies and procedures.

Interpretation: Organisation develops standard operating procedures (SOPs) for delivery of care.

c. The organisation provides for a safe and secure environment for the vulnerable group.

Interpretation: The organisation shall provide proper environment taking into account the requirement of the vulnerable group. For example, playroom for children, fall preventive measures for elderly, ramps with railings for disabled, etc.

d. A documented procedure exists for obtaining informed consent from the appropriate legal representative. *

Interpretation: The informed consent for this group of people should be obtained from their family or legal representative.

e. Staff are trained to care for the vulnerable group.

Interpretation: All staff involved in the care of this group shall be adequately trained in identifying and meeting their needs. Records of the same should be available.

Standards

COP.11.	**Documented policies and procedures guide obstetric care.**

Objective Elements

a. There is a documented policy and procedure for obstetric services. *

Interpretation: At a minimum, this shall include assessment of these patients including nutrition, immunisations and education. It could include prenatal safety guidelines such as monitoring standards, labour augmentation bundle, etc.

b. The organisation defines and displays whether high-risk obstetric cases can be cared for or not.

***Interpretation*:** The organisation shall define as to what constitutes high-risk obstetric case in consonance with best clinical practices. The display should be in a prominent location (either near the entrance or registration counter or near the OPD). This is applicable only if it cares for such patients. The organisation caring for high-risk obstetric cases has the facilities to take care of such mothers.

c. Persons caring for high-risk obstetric cases are competent.

***Interpretation*:** These shall not just be doctors but shall include nursing staff also. The competency shall be based on qualification, experience and training. It is preferable that persons caring for high-risk obstetric cases either have adequate experience or additional training for taking care of such patients.

d. Documented procedures guide the provision of ante-natal services. *

Interpretation: This shall at a minimum include assessment, immunisation, diet counselling and frequency of visits. There shall be an ante-natal card (or equivalent) for every such patient.

e. Obstetric patient's assessment also includes maternal nutrition.

Interpretation: It is preferable that this is done by a dietician.

f. Appropriate pre-natal, peri-natal and post-natal monitoring is performed and documented. *

Interpretation: This is in context of maternal and foetal monitoring.

g. The organisation caring for high-risk obstetric cases has the facilities to take care of neonates of such cases.

Interpretation: The organisation shall have an NICU (level I, II or III) with appropriate equipment and staff

Standard

COP.12.	**Documented policies and procedures guide paediatric services.**

Objective Elements

a. There is a documented policy and procedure for paediatric services. *

***Interpretation*:** At a minimum this shall include assessment of these patients, organisation of care and addressing special needs.

b. The organisation defines and displays the scope of its paediatric services.

Interpretation: The scope shall include various paediatric sub specialities and special clinics. for eg. Well baby clinics, different levels of NICUs, PICU etc. The display should be in a prominent location (either near the entrance or registration counter or near the OPD).

c. The policy for care of neonatal patients is in consonance with the national/ international guidelines. *

Interpretation: There are national and international guidelines available for the case of neonates by WHO, etc. The hospital should take them into account. The hospital shall actively promote breastfeeding practice.

d. Those who care for children have age-specific competency.

Interpretation: These shall not just be for doctors but shall include nursing staff also. The competency shall be based on qualification, experience and training.

e. Provisions are made for special care of children.

Interpretation: Adequate amenities for the care of infants and children to be available in the hospital. The environment should be child friendly. For example, playroom, breast-feeding room etc.

f. Patient assessment includes detailed nutritional, growth, developmental and immunisation assessment.

Interpretation: The same needs to be documented. This could be done using a standard format like a checklist or questionnaire.

g. Documented policies and procedures prevent child/neonate abduction and abuse. *

***Interpretation*:** The organisation shall have child abduction prevention protocols and shall ensure that there is an adequate security/surveillance to prevent such happenings. Example: Installation of CCTV cameras. There is a defined process for rapid response in case of an eventuality. This shall be tested at pre-defined intervals. Staff are trained in prevention and rapid response.

h. The children's family members are educated about nutrition, immunisation and safe parenting and this is documented. *

***Interpretation*:** This could include growth chart, immunisation chart, etc. This (original/copy) should be a part of the medical record. The education should preferably be in the language that the family understands.

Standard

COP.13.	**Documented policies and procedures guide the care of patients undergoing moderate sedation.**

Objective Elements

a. Documented procedures guide the administration of moderate sedation. *

***Interpretation*:** At a minimum, this shall include identification of procedures where this is required, the mechanism for writing orders, the pre-procedure assessment, monitoring during and after the procedure and the discharge/transfer out criteria after the procedure.

b. Informed consent for administration of moderate sedation is obtained.

Interpretation: This shall be taken by the person performing the procedure/administering sedation or a member of the team doing the procedure. The patient / family need to give consent for moderate sedation apart from the procedure. However, both can be obtained in the same consent form.

c. Competent and trained persons perform sedation.

Interpretation: Whenever parenteral route is used this may be administered by a doctor or a nurse under supervision of a doctor. Technician shall not administer sedation.

d. The person administering and monitoring sedation is different from the person performing the procedure.

***Interpretation*:** Self-explanatory.

e. Intra-procedure monitoring includes at a minimum the heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation, and level of sedation.

Interpretation: The same should be documented. In addition, certain other parameters may be monitored on a case-to-case basis. The cardiac rhythm may be monitored on a monitor during the procedure and the same need not be documented. However, in case of rhythm abnormalities the same shall be documented.

f. Patients are monitored after sedation and the same documented. *

***Interpretation*:** The patient's vitals shall be monitored at regular intervals (as decided by the organisation) till he/she recovers completely from the sedation.

At a minimum, the heart rate, respiratory rate, blood pressure, oxygen saturation and level of sedation are monitored. The level of sedation can be monitored by using a checklist which incorporates the various components of levels of sedation (mild, moderate and deep).

g. Criteria are used to determine appropriateness of discharge from the observation/recovery area. *

Interpretation: These shall be developed and documented by the organisation in consonance with physiologic parameters and good clinical practices. The criteria shall be applied by a qualified individual and the same is documented.

h. Equipment and manpower are available to manage patients who have gone into a deeper level of sedation than initially intended.

***Interpretation*:** The equipment shall include emergency resuscitation equipment. A person trained in airway management/anaesthesiologist shall be available in the area.

Standard

COP.14.	**Documented policies and procedures guide the administration of anaesthesia.**

Objective Elements

a. There is a documented policy and procedure for the administration of anaesthesia. *

***Interpretation*:** Organisation shall document regarding the indications, the type of anaesthesia and procedure for the same. For definition of the "anaesthesia" refer to the glossary. The standard is not applicable for local anaesthesia.

b. Patients for anaesthesia have a pre-anaesthesia assessment by a qualified anaesthesiologist.

***Interpretation*:** This shall be done before the patient is wheeled into the OT complex. It shall be applicable for both routine and emergency cases. It is preferable to do the assessment in a standardised format. The pre-anaesthesia assessment may even be carried out prior to admission in case of elective surgeries.

c. The pre-anaesthesia assessment results in formulation of an anaesthesia plan which is documented.

Interpretation: The plan should mention the pre-medications, type of anaesthesia, special requirements and anticipated post-anaesthesia care where appropriate. The anaesthesiologist would review the medication the patient is currently taking.

d. An immediate preoperative re-evaluation is performed and documented.

Interpretation: This is essentially a pre-induction assessment and shall be done by an anesthesiologist just before the patient is wheeled into the respective OT. Any planned changes to the anaesthesia plan shall be documented.

When anaesthesia needs to be provided on an urgent basis, the pre-anaesthesia assessment and pre-induction assessment may be performed immediately following one another, or simultaneously, but should be documented separately.

e. Informed consent for administration of anaesthesia is obtained by the anesthesiologist.

***Interpretation*:** Patient and/or, family are educated on the risks, benefits, and alternatives of anaesthesia by the anaesthesiologist. This shall be separate from the surgery consent.

f. During anaesthesia monitoring includes regular recording of temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and end tidal carbon dioxide.

***Interpretation*:** The same should be documented.

In case of regional anaesthesia instead of end-tidal carbon dioxide the adequacy of ventilation shall be evaluated by continual observation of qualitative clinical signs.

Anaesthesiologist shall be present throughout the procedure. In addition, certain other parameters may be monitored on a case-to-case basis.

The cardiac rhythm may be monitored on a monitor during the procedure and the same need not be documented. However, in case of rhythm abnormalities the same shall be documented.

g. Patient's post-anaesthesia status is monitored and documented.

Interpretation: This shall be done in the recovery area/OT and at least include monitoring of vitals till the patient recovers completely from anaesthesia and shall be done by an anaesthesiologist. If the patient's condition is unstable and he/she requires ICU care the same shall be monitored there.

h. The anaesthesiologist applies defined criteria to transfer the patient from the recovery area. *

***Interpretation*:** The organisation documents these criteria which should be based on physiologic parameters and in consonance with good clinical practices.

i. The type of anaesthesia and anaesthetic medications used are documented in the patient record. *

***Interpretation*:** It shall have the name of the anaesthesiologist who performed the procedure and also the names of individuals (with their designation) who helped in the procedure. The documentation shall have name, date, time and signature.

j. Procedures shall comply with infection control guidelines to prevent cross-infection between patients.

Interpretation: The guidelines shall be documented either separately or as a part of the infection control manual. This could include management of circuits, infection control measures during administration etc.

k. Adverse anaesthesia events are recorded and monitored.

***Interpretation*:** All such events are documented and monitored for the purpose of taking corrective and preventive action.

At the outset, the organisation shall define the various adverse anaesthesia events. These essentially are adverse events following the administration of anaesthesia. The hospital should have a mechanism to ensure that all adverse events are captured. It could do the same by incorporating in the anaesthesia record a heading for the same.

Standard

COP.15.	**Documented policies and procedures guide the care of patients undergoing surgical procedures.**

Objective Elements

a. The policies and procedures are documented. *

Interpretation: This shall include the list of surgical procedures as well as competency level for performing these procedures.

b. Surgical patients have a preoperative assessment and a provisional diagnosis documented prior to surgery.

Interpretation: All patients undergoing surgery are assessed pre-operatively and a provisional diagnosis is made which is documented. This shall be applicable for both routine and emergency cases. This shall be done by the operating surgeon.

c. An informed consent is obtained by a surgeon prior to the procedure.

Interpretation: The consent shall be taken by the operating surgeon or a member of his team. In case if there is a change in clinical status/expected outcomes after consent, but prior to the surgery, the same is explained to the patient/family and is documented. In case, the procedure is changed intra-op (and was not planned or an explicit consent taken for the same) a fresh consent needs to be taken.

d. Documented policies and procedures exist to prevent adverse events like wrong site, wrong patient and wrong surgery. *

Interpretation: Procedure should be available for preventing adverse events like wrong patients, wrong site by a suitable mechanism. The organisation should be able to demonstrate methods to prevent these events, e.g. identification tags, badges, cross-checks, time-outs etc. Refer to WHO “Safe surgery saves lives” initiative.

e. Persons qualified by law are permitted to perform the procedures that they are entitled to perform.

***Interpretation*:** The organisation identifies the individuals who have the required qualification(s), training and experience to perform procedures in consonance with the law.

f. A brief operative note is documented prior to transfer out of patient from recovery.

Interpretation: This note provides information about the procedure performed, postoperative diagnosis and the status of the patient before shifting and shall be documented by the surgeon/member of the surgical team.

At a minimum, it shall include the surgery performed, name of the surgeon (s), name of anaesthesiologist, salient steps of the procedure and the key findings intra-op. If it is documented by a person other than the chief operating surgeon the same shall be countersigned by the chief surgeon.

g. The operating surgeon documents the postoperative care plan.

***Interpretation*:** The plan shall include advice on IV fluids, medication, care of wound, nursing care, observing for any complications, etc. This plan could be written in collaboration with the anaesthesiologist.

h. Patient, personnel and material flow conform to infection control practices.

Interpretation: The layout of the theatre should be such that the mix of sterile and unsterile patients does not happen or if it is not possible the mix is reduced to the bare minimum.

i. Appropriate facilities and equipment/appliances/instrumentation are available in the operating theatre.

Interpretation: The organisation shall ensure that the operating theatre has facilities for pre-op holding, separate changing rooms for males and females, hand-washing area, operating rooms, waiting area for relatives, storage area,

collection area for waste and linen and recovery room. In addition to the equipment required for anaesthesia and surgery, there shall be equipment for resuscitation, radiation protection (where applicable) etc.

j. A quality assurance programme is followed for the surgical services. *

Interpretation: This shall be an integral part of the organisation's overall quality assurance programme. It shall focus on post-operative complications, e.g. bleeding, rational use of antibiotics, etc.

k. The quality assurance programme includes surveillance of the operation theatre environment. *

Interpretation: Surveillance activities include the daily monitoring of humidity and temperature; at least monthly monitoring of pressure differential, and at least six monthly monitoring of the integrity of filter. In addition, the efficacy of OT cleaning and disinfection processes shall be monitored. For air-conditioning of OT, refer to the guidelines issued by NABH.

Standard

COP.16.	**Documented policies and procedures guide organ transplant programme in the organisation.**

a. The organ transplant program shall be in consonance with the legal requirements and shall be conducted in an ethical manner.

***Interpretation*:** The organisation shall ensure that the required regulatory licences are in place and enrols with the organ donation programs at the central level eg. National organ and tissue transplant organisation (NOTTO) or state level as applicable. Specific permissions are also taken prior to these transplants under the provisions of the applicable Act (HOTA). The organisation also ensures that the relevant medical professionals have been permitted by the appropriate authorities to participate in the organ transplant program. The organisation shall

ensure that the requisite reports are submitted to the appropriate authorities in a timely manner.

b. Documented policies and procedures guide the organ transplant program. *

Interpretation; The organisation shall prepare broad guidelines for the organ transplant programme in consonance with current and established good practices. The guideline includes the process to be followed, responsibilities and monitoring mechanisms. Each department(s) where the organ donation programme is implemented has its own organ specific guidelines which include indication for transplant, recipient fitness, donor fitness, education and consent process. It is preferable that the organisation encourages departments to develop care paths which help guide these patients.

c. The organisation ensures education and counselling of recipient and donor through trained / qualified counsellors before organ transplantation.

Interpretation; The organisation ensures that qualified / trained councillors are available to counsel the recipient and donor about the proposed organ donation. Doctors and counsellors educate and counsel the recipient and donor on the benefits and possible risks to make informed decisions. The recipients are also educated about immunosuppression (benefits and risks) and the required monitoring and follow up. Counselling and education can also be done during the interview by the Local Authorisation Committee of the organisation. Evidence of counselling is recorded and maintained in the requisite statutory formats apart from the organisation's individual needs.

d. The organisation shall take measures to create awareness regarding organ donation.

Interpretation; This would be applicable for all organisations irrespective of whether organ transplantation is carried out or not. This could be in the form of standees, hand-outs, etc. The myths of the public regarding organ donation should be addressed. Whenever a patient is declared brain dead, the family are

also counselled on organ transplant where appropriate. They should be educated in a very sensitive and courteous manner.

Standard

COP 17	**Documented policies and procedures guide the care of patients under restraints (physical and/or chemical).**

Objective Elements

a. Documented policies and procedures guide the care of patients under restraints. *

***Interpretation**:* This shall clearly state the conditions/circumstances under which restraints shall be used. It shall also specify as to who can authorise the use of restraints, the frequency of monitoring these patients and the validity of restraint orders.

b. The policies and procedures include both physical and chemical restraint measures.

Interpretation: Physical restraints include boxer's bandage, use of cuffs, etc. Chemical restraints include sedatives.

c. The reasons for restraints are documented.

***Interpretation*:** The reasons for restraint will be documented after informing the patient's attendants about the same.

d. Patients on restraints are more frequently monitored.

***Interpretation*:** The organisation shall specify the parameters and frequency of monitoring and accordingly implement the same.

e. Staff receives training and periodic updating in control and restraint techniques.

***Interpretation*:** It is applicable to all personnel involved in the care of patients. The staff shall be updated at least once a year. Records of the same should be maintained.

Standard

COP.18.	**Documented policies and procedures guide appropriate pain management.**

Objective Elements

a. Documented policies and procedures guide the management of pain. *

***Interpretation*:** It shall include as to how patients are screened for pain, the mechanism to ensure that a detailed pain assessment is done (when necessary), pain mitigation techniques and monitoring.

b. All patients are screened for pain.

Interpretation: Every patient entering the hospital shall be screened for pain. Pain shall be considered the fifth vital sign. This could be done by incorporating a sub-heading in the initial assessment for pain.

c. Patients with pain undergo detailed assessment and periodic reassessment.

Interpretation: A detailed pain assessment is done when the pain is the predominant (or one of the main) symptom(s). It shall be done for all post-operative patients. The pain assessment shall include intensity of pain (can be done using a pain rating scale), pain character, frequency, location, duration and referral and/or radiation. The assessment should be done in an objective manner so that it facilitates regular reassessment. For example, cancer pain, neuralgia and arthralgia. This does not include chest pain due to angina or where the aetiology of pain is physiological like labour pain.

d. Pain alleviation measures or medications are initiated and titrated according to patient's need and response.

Interpretation: Based on the assessment of pain and the underlying conditions, pain alleviation methods or medication are initiated for the patient. Subsequently the patient is monitored for response to pain alleviation methods. Based on the response, measures and medication are duly titrated.

e. The organisation respects and supports management of pain for such patients.

***Interpretation*:** The organisation provides primary measures for immediate pain relief. In case the hospital does not have facilities for further pain management it could refer such patients to centres specialising in pain management. Pain management includes medical, surgical and anaesthetic techniques.

f. Patient and family are educated on various pain management techniques, where appropriate.

***Interpretation*:** This could be done only for patients who are likely to have long-term pain in view of the underlying condition not being treatable.

Standard

COP.19.	**Documented policies and procedures guide appropriate rehabilitative services.**

Objective Elements

a. Documented policies and procedures guide the provision of rehabilitative services. *

***Interpretation*:** This includes physiotherapy, occupational therapy and speech therapy, etc.

b. These services are commensurate with the organisational requirements.

Interpretation: The scope of the departments is in consonance with the scope of the hospital. For example, provision of ante-natal and post-natal exercises could form a part of the obstetric rehabilitation programme.

c. Care is guided by functional assessment and periodic re-assessment which is done and documented by qualified individual(s).

Interpretation: This can be done using relevant functional assessment scales.

d. Care is provided adhering to infection control and safe practices.

***Interpretation*:** Eg: Safe practices include ensuring that when using hot wax there are no burns to the patient.

e. Rehabilitative services are provided by a multidisciplinary team.

***Interpretation*:** The team shall have a treating doctor, a rehabilitation therapist, rehabilitation nurses and other professional experts.

f. There is adequate space and equipment to perform these activities.

Interpretation: The equipment shall be as per the scope of rehabilitation services provided. However, equipment for resuscitation shall be available in these areas.

Standard

COP.20.	**Documented policies and procedures guide all research activities.**

Objective Elements

a. Documented policies and procedures guide all research activities in compliance with regulatory, national and international guidelines. *

***Interpretation*:** Any research undertaken in the hospital falls under its ambit. This includes both funded and non-funded and also student studies. For example, International Conference on Harmonisation (ICH) of Good Clinical Practice (GCP) and Declaration of Helsinki Somerset (1996) and Ethical Guidelines for Biomedical Research on Human Subjects (ICMR-2000).

b. The organisation has an ethics committee to oversee all research activities.

Interpretation: An ethics committee should be framed in the hospital to monitor activities undertaken by various providers. The committee has the powers to discontinue a research trial when risks outweigh the potential benefits. The committee is registered with appropriate authority as per current requirements. Refer to Schedule Y of Drugs and Cosmetics Act and to ICMR guidelines.

c. The committee has the powers to discontinue a research trial when risks outweigh the potential benefits.

***Interpretation*:** Self-explanatory.

d. Patient's informed consent is obtained before entering them in research protocols.

Interpretation: This shall be done in a language that the patient understands.

e. Patients are informed of their right to withdraw from the research at any stage and also of the consequences (if any) of such withdrawal.

Interpretation: This shall be done in a language that the patient understands.

f. Patients are assured that their refusal to participate or withdrawal from participation will not compromise their access to the organisation's services.

***Interpretation*:** Self-explanatory.

Standard

COP.21.	**Documented policies and procedures guide nutritional therapy.**

Objective Elements

a. Documented policies and procedures guide nutritional therapy including assessment and reassessment. *

***Interpretation*:** This shall at a minimum incorporate as to in whom nutritional assessment will be done, how the type of diet is planned ,prepared and delivered to the patient. The process ensures that the patient receives food as per the diet order. Nutritional assessment shall be done by a dietician for all patients found at risk during nutritional screening.

b. Nutritional therapy is planned and provided in a collaborative manner.

Interpretation: The dietician shall ensure that this is planned in consultation with the treating doctor and the patient/patient's relative after taking into regard the patient's food habits (veg/non-veg) and likes and dislikes.

c. There is a written order for the diet.

Interpretation: The dietician shall prepare this in the form of a diet sheet and patient shall receive food accordingly. This shall be written in a uniform location in the medical record.

d. Patients receive food according to their clinical needs.

Interpretation: A dietician shall do the assessment of the patient in consultation with the clinician and advice regarding food. For example, diabetic diet, high protein diet, total parenteral nutrition, etc.

e. Food is prepared, handled, stored and distributed in a safe manner.

Interpretation: The dietary services to be designed in a manner that there is no criss-cross of traffic. All the activities fall in a sequence. The organisation shall ensure that hygienic conditions are followed all throughout.

Other indicative points are:

i. dedicated food storage/refrigeration areas exist to ensure food preservation;
ii. food storage areas/refrigerators are maintained appropriately;
iii. all food products are stored off the floor;
iv. cleaning supplies stored in a separate location way from food;
v. separate dedicated food preparation areas exist;
vi. measures are in place to ensure that flies and insects do not come in contact with prepared/stored food;
vii. food distribution to patients occurs where possible in temperature appropriate food service trolleys (hot food kept hot and cold food kept cold).

f. When families provide food, they are educated about the patient's diet limitations.

***Interpretation*:** The dietician/nurse shall ensure this during planning.

Standard

COP.22.	**Documented policies and procedures guide the end of life care.**

Objective Elements

a. Documented policies and procedures guide the end of life care. *

***Interpreta*tion:** The organisation develops its own policy and procedure for End of Life Care based on good practices (National and International) and in accordance with the law of the land.

This shall include:

i. providing appropriate pain and palliative care according to the wishes of the family and patient;
ii. sensitively addressing such issues as autopsy and organ donation;
iii. respecting the patient's values, religion, and cultural preferences;
iv. involving the patient and family in all aspects of care; and
v. responding to the psychological, emotional, spiritual, and cultural concerns of the patient and family (where possible).

The procedure should also incorporate requirements of objective element "c" and shall be prepared keeping in mind objective element "b".

Refer to the glossary for definition of "end of life".

b. These policies and procedures are in consonance with the legal requirements.

***Interpretation*:** Decisions like "Do not resuscitate/Do not intubate/Allow natural death etc." shall be only as per the statutory laws and within the guidelines framed by the legal system.

c. These also address the identification of the unique needs of such patient and family.

***Interpretation*:** The religious and socio-cultural beliefs of patients/ family shall be addressed and respected.

d. Symptomatic treatment is provided and where appropriate measures are taken for the alleviation of pain.

***Interpretation*:** The emphasis shall be on providing symptomatic treatment of such patients and to prevent complications to the possible extent. The patient and/or family shall be involved while taking all such decisions. To the extent possible (and as per the law), the patient and/or family's choices shall be respected.

e. Staff are educated and trained in end of life care.

***Interpretation*:** This shall be done to the staff dealing with such patients.
Records of the same shall be available.

Chapter 3
Management of Medication (MOM)

Intent of the chapter:

The organisation has a safe and organised medication process. The process includes policies and procedures that guide the availability, safe storage, prescription, dispensing and administration of medications.

The standards encourage integration of the pharmacy into everyday functioning of hospitals and patient care. The pharmacy should guide and audit medication processes. The pharmacy should have oversight of all medications stocked out of the pharmacy. The pharmacy should ensure correct storage (as regards to temperature, light, look-alike, sound-alike etc.), expiry dates and maintenance of documentation.

The availability of emergency medication is stressed upon. The organisation should have a mechanism to ensure that the emergency medications are standardised throughout the organisation, readily available and replenished in a timely manner. There should be a monitoring mechanism to ensure that the required medications are always stocked and well within expiry dates.

Every high-risk medication order should be verified by an appropriate person so as to ensure accuracy of the dose, frequency and route of administration. The “appropriate person” could be another doctor, registered nurse or, a clinical pharmacist. Safe use of high-risk medication like narcotics, chemotherapeutic agents and radioactive isotopes are guided by policies and procedures.

The process also includes monitoring of patients after administration and procedures for reporting and analysing medication errors.

Patients and family members are educated about safe medication and food-drug interactions.

Medications also include blood, implants and devices..

Summary of Standards

MOM 1:	Documented policies and procedures guide the organisation of pharmacy services and usage of medication.
MOM 2:	There is a hospital formulary.
MOM 3:	Documented policies and procedures guide the storage of medication.
MOM 4:	Documented policies and procedures guide the safe and rational prescription of medications.
MOM 5:	Documented policies and procedures guide the safe dispensing of medications.
MOM 6:	There are documented policies and procedures for medication administration.
MOM 7:	Patients are monitored after medication administration.
MOM 8:	Near misses, medication errors and adverse drug events are reported and analysed.
MOM 9:	Documented procedures guide the use of narcotic drugs and psychotropic substances.
MOM 10:	Documented policies and procedures guide the usage of chemotherapeutic agents.
MOM 11:	Documented policies and procedures govern usage of radioactive drugs.
MOM 12:	Documented policies and procedures guide the use of implantable prosthesis and medical devices.
MOM 13:	Documented policies and procedures guide the use of medical supplies and consumables.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

MOM.1.	**Documented policies and procedures guide the organisation of pharmacy services and usage of medication.**

Objective Elements

a. There is a documented policy and procedure for pharmacy services and medication usage. *

Interpretation: The policies and procedures shall address the issues related to procurement, storage, formulary, prescription, dispensing, administration, monitoring and use of medications. All the required procedures under this chapter can be clubbed together and documented.

b. Policies and procedures comply with the applicable laws and regulations. *

Interpretation: Relevant legislations include Drugs and Cosmetics Act, Pharmacy Act, Narcotic Drugs and Psychotropic Substances Act, Drugs and Magical Remedies (Objectionable Advertisement) Act, etc.

c. A multidisciplinary committee guides the formulation and implementation of these policies and procedures. *

Interpretation: The committee shall be representative of major clinical departments, administration and shall include a pharmacist/clinical pharmacologist. The objectives of this committee, its composition, frequency of meetings, quorum required and the minutes of the meeting shall be documented. At a minimum, the committee shall meet once in three months.

eg. pharmaco-therapeutic committee.

d. There is a procedure to obtain medication when the pharmacy is closed. *

Interpretation: When the pharmacy is closed, there should be a standard operating procedure to procure the drugs. It is preferable that the organisation has a 24-hour pharmacy.

Standard

MOM.2.	**There is a hospital formulary.**

Objective Elements

a. A list of medications appropriate for the patients and as per the scope of the organisation's clinical services is developed collaboratively by the multidisciplinary committee.

Interpretation: The organisation's formulary shall be prepared by multidisciplinary committee. The formulary could be prepared keeping in mind the "National List of Essential Medicines" and "WHO Model List of Essential Medicines". Please note that implants also come under drugs. The organisation could look at the possibility of having system wise / speciality wise formulary.

b. The list is reviewed and updated collaboratively by the multidisciplinary committee at least annually.

Interpretation: The review may be done speciality wise. Non formulary drugs which were procured in the previous year on a regular basis may be included in the reviewed list.

c. The formulary is available for clinicians to refer and adhere to.

Interpretation: The formulary shall be made available to all treating doctors of the organisation. The organisation shall ensure that the prescriptions are as per the formulary. It shall monitor the frequency of prescriptions being rejected because it contained non-formulary drugs. The formulary could be made available in either physical or electronic form. The formulary is made accessible to the treating team (including doctors, nurses and pharmacists).

d. There is a defined process for acquisition of these medications. *

Interpretation: The process should address the issues of vendor selection, vendor evaluation, reorder levels, indenting process, generation of purchase order, and receipt of goods. The process also addresses managing stock outs due to various reasons.

e. There is a process to obtain medications not listed in the formulary. *

Interpretation: For example, local purchase/hot line which takes care of the immediate requirement. Whenever there is local purchase of medication that is not listed in a formulary, the organisation has a process of evaluation, authorization and ratification and to decide on its subsequent inclusion in formulary if necessary.

Standards

MOM.3.	**Documented policies and procedures guide the storage of medication.**

Objective Elements

a. Documented policies and procedures exist for storage of medication. *

Interpretation: These should address issues pertaining to temperature (refrigeration), light, ventilation, preventing entry of pests/rodents and vermin.

b. Medications are stored in a clean, safe and secure environment; and incorporating manufacturer's recommendation(s).

Interpretation: The organisation shall also ensure that the storage requirements of the drug as specified by the manufacturer are adhered to. This shall be applicable to all areas where medications are stored including wards.

Medications shall be protected from loss or theft. The overall cleanliness of the storage area shall be maintained.

Vaccines could preferably be kept in vaccine refrigerators (Ice Lined Refrigerator). Where appropriate, temperature monitoring of the room, the cold

storage area / refrigerator shall be done at least once a day. In case of areas which are not open all days, it shall be done on all working days.

To check for loss or theft the organisation could conduct audits at regular intervals (as defined by the organisation) to verify the stock and detect instances of loss or theft.

c. Sound inventory control practices guide storage of the medications in all areas throughout the organisation.

Interpretation: Organisation shall follow or demonstrate ABC, VED, FSN, FIFO-lead time analysis, etc. The medicines can be stored in alphabetical order of generic or brand name. The organisation also has a mechanism for handling medications / consumables which are not part of the regular inventory. Eg physician's sample medications.

d. Look-alike and Sound-alike medications are identified and stored physically apart from each other. *

Interpretation: Many drugs in ampoules, vials or tablets may look-alike or sound-alike. These are identified periodically and the LASA list shall be made available in all units where drugs are stored. The list shall be developed from the hospital formulary. The list will have to be identified at regular intervals depending on the changes in the formulary and changes in packaging (in case of look-alike). One look alike is stored apart from its other look alike(s). The same is applicable for sound-alike(s). This is in addition to regular storage practices.

e. The list of emergency medications is defined and is stored in a uniform manner. *

Interpretation: This list shall be prepared in consonance with good clinical practices and documented. List of drugs shall be uniform across the organisation, however the quantity can differ.

A crash cart would help the organisation to store these medications in a standardised manner, i.e. the rows and drawers have defined medicines.

No other drugs shall be kept stored with emergency medications.

f. Emergency medications are available all the time.

Interpretation: Adequate quantity of emergency medicines should be stocked at all times.

g. Emergency medications are replenished in a timely manner when used.

Interpretation: An inventory check shall be done at least daily to ensure this. In case the organisation follows a system of sealing the emergency cart then the check shall be carried out after each use of the cart.

Standard

MOM.4.	**Documented policies and procedures guide the safe and rational prescription of medications.**

Objective Elements

a. Documented policies and procedures exist for prescription of medications. *

Interpretation: Self Explanatory

b. These incorporate inclusion of good practices/guidelines for rational prescription of medications.

Interpretation: The organisation shall ensure that the clinicians are trained / sensitised on the rational prescription of medications.

WHO states: “Rational use of medicines requires that patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community."

c. The organisation determines the minimum requirements of a prescription. *

Interpretation: Prescriptions generated within the organisation (IPD, OPD and emergency) shall adhere to national/international guidelines and regulatory bodies.

At a minimum, the prescription shall have the name of the patient; unique hospital number; name of the drug, dose, route and frequency of administration of the medicine; name, signature and registration number of the prescribing doctor. All hand written prescriptions shall be written in capital letters.

Prescription errors or illegible prescriptions will be initialled after single strike through and rewritten.

A good reference is the Drugs and Cosmetics Act and Code of Medical Ethics.

d. Known drug allergies are ascertained before prescribing.

Interpretation: It is a good practice to document drug allergies in a prominent manner in the medical record, both in OP and IP.

e. The organisation determines who can write orders. *

Interpretation: This shall be done by a doctor who at a minimum holds a MBBS qualification.

The medication order card in the IP shall be have the orders written by a doctor, even if it is the case of transcribing orders of the treating consultant from an OP record or an admission note.

In facilities which use Hospital information system (EMR), the doctor shall directly enter the prescription in the Hospital Information System (HIS) using his or her unique login. In case the HIS entry is made by an assistant, the same shall be verified and authorized by the doctor in some manner.

f. Orders are written in a uniform location in the medical records which also reflects patient's name and unique identification number.

Interpretation: All the orders for medicines are recorded on a uniform location of the case sheet. Electronic orders when typed shall again follow the same principles.

It is preferable that the prescription and the administration record is on the same sheet. This would help minimise medication errors. A drug 'kardex' could be used for this purpose.

The treatment orders are written daily or authorized daily in a 'kardex' like format. Phrases like "CST" / "continue same treatment" / "repeat all" / "repeat 1,4,5,8" should not be accepted.

Whenever there is a modification in the medication order in the existing order for a particular drug, a fresh order will have to be written for that drug. Eg: Tab. PCM 500 mg QID changed to Tab.PCM 500 mg BD – this shall warrant the first order to be discontinued and a fresh medication order to be written.

g. Medication orders are clear, legible, dated, timed**,** named and signed.

Interpretation: All hand written prescriptions shall be written in Capital letters.

In case abbreviations are used, a standardised list of approved abbreviations for medication orders shall be used throughout the organisation. Dangerous abbreviations shall not be used. A good reference is the Institution for Safe Medication Practices guidelines.

h. Medication orders contain the name of the medicine, route of administration, dose to be administered and frequency/time of administration.

Interpretation: In case of a medicine having two or more drugs (tablet/capsule/injection) the dose of all the individual drugs shall be written. This may not be applicable for preparations having a combination of vitamins and/or minerals.

Medication orders are recorded separately if the dose differs for each time of administration.

i. Documented policy and procedure on verbal orders is implemented. *

Interpretation: The organisation shall ensure that it has a policy to address this issue and it shall mention who can give verbal orders and how these orders will be validated. Organisation should have approved list of drugs which can be ordered verbally.

It shall ensure that the procedure incorporate good practices like "read back".

Verbal orders shall be counter-signed by the doctor who ordered it within 24 hours of ordering. This is not applicable if a doctor of the treating team consulted the treating doctor and writes down the orders.

j. The organisation defines a list of high-risk medication(s). *

Interpretation: High risk /high alert medications carry a heightened risk for adverse outcomes and catastrophic harm whenever there is an error. High-risk medications/ high alert medications include low therapeutic window, controlled substances, psychotherapeutic medications, and look-alike and sound-alike medications, concentrated electrolytes.

k. Audit of medication orders/prescription is carried out to check for safe and rational prescription of medications.

Interpretation: The scope of the audit shall include:

i. Legibility, use of capitals in written orders.
ii. The appropriateness of the drug, dose, frequency, and route of administration;
iii. The presence of therapeutic duplication;
iv. The possibility of drug interaction and measures taken to avoid the same;
v. The possibility of food-drug interaction and measures taken to avoid the same.
vi. The requirements of this standard(MOM 4c, f-h).

This shall be done at least once a month using a representative sample size.

It could preferably be done by a clinical pharmacist. In case there is no clinical pharmacist it shall be done by the multidisciplinary committee.

l. Reconciliation of medications occur at transition points of patient care.

Interpretation: The purpose of the medication reconciliation is to ensure that the list of medication that a patient is to receive is complete and up to date in relation to past clinical conditions and present Care plan. The prescribed medications

shall be checked for accuracy at the transition points, such as the time of admission, transfer of the patient from one ward setting / department to another, or at the time of discharge. There is a system for effective communication during handover regarding reconciliation of medications.

m. Corrective and/or preventive action(s) is taken based on the analysis, where appropriate.

Interpretation: Self-explanatory.

Standard

MOM.5.	**Documented policies and procedures guide the safe dispensing of medications.**

Objective Elements

a. Documented policies and procedures guide the safe dispensing of medications. *

Interpretation: Clear policies to be laid down for dispensing of medication, e.g. route of administration, dosage, rate of administration, expiry date, etc. This shall include both bulk and retail pharmacy.

Physicians' samples shall not be sold.

b. The procedure addresses medication recall. *

Interpretation: Recall may be based on letters from regulatory authorities or internal feedback (e.g. visible contaminant in IV fluid bottle). Recall procedure in response to internal feedback also includes providing information to appropriate regulatory authority.

c. Expiry dates are checked prior to dispensing.

Interpretation: This shall be done at all levels, e.g. pharmacy, ward, etc. This shall also be applicable for physicians' samples.

d. There is a procedure for near expiry medications. *

Interpretation: This procedure shall ensure that near expiry drugs are withdrawn and that no beyond expiry date medication is available.

The organisation could define as to what constitutes “near expiry”. For example, three months prior to the expiry date.

e. Labelling requirements are documented and implemented by the organisation. *

Interpretation: At a minimum, labels must include the drug name, strength, frequency of administration (in a language the patient understands) and expiry dates.

This is applicable to all dispensing areas wherein medicines are dispensed either as cut strips or from bulk containers. It shall also be applicable where drugs are diluted eg. Chemotherapy. This shall be applicable for both IPD and OPD.

f. High-risk medication orders are verified prior to dispensing.

Interpretation: These medications shall be given only after written orders and it should be verified by the staff before dispensing.

This shall adhere to statutory requirements where applicable.

Standard

MOM.6.	**There are documented policies and procedures for medication administration.**

Objective Elements

a. Medications are administered by those who are permitted by law to do so.

Interpretation: Self-explanatory.

b. Prepared medication is labelled prior to preparation of a second drug.

Interpretation: This is applicable when drugs are prepared and loaded but administered after an interval. This is commonly encountered for anaesthetic drug preparation in OTs.

c. Patient is identified prior to administration.

Interpretation: Identification shall be done by unique identification number (e.g. hospital number/IP number, etc.) and/or name.

d. Medication is verified from the order and physically inspected prior to administration.

Interpretation: Staff administering medications should verify the order and ensure that medications are administered appropriately. It is required to check the general appearance of the medication (e.g. melting, clumping etc.) and the expiry dates before administration. If any of the parameters with respect to an order namely name, dose, route or frequency/time are missing / incomplete the medication administration shall be deferred pending early verification by the treating team.

In case of high risk medication(s), the verification shall be done by at least two staff (nurse-nurse or nurse-doctor) independently and documented. The nurses are knowledgeable regarding high risk medications and are empowered to highlight prescription errors noted while verifying the orders.

e. Dosage is verified from the order prior to administration.

Interpretation: Self-explanatory.

f. Route is verified from the order prior to administration.

Interpretation: Where applicable the site of administration shall also be verified.

g. Timing is verified from the order prior to administration.

Interpretation: The organisation needs to define the timing of administration of medications.

h. Medication administration is documented.

Interpretation: The organisation shall ensure that this is done in a uniform location and it shall include the name of the medication, dosage, route of

administration, timing and the name and signature of the person who has administered the medication. Medicines administered are documented separately each time for each dose of the same medication.

In case of infusions, it shall capture the start time, the rate of infusion and end time.

The records shall reflect the actual administration. For example, if brand Y was given in place of brand X (same generically) the documentation shall be of brand Y. Similarly, if the order was for a tablet of 250mg but the administration was ½ a tablet of 500mg the latter shall be documented.

i. Documented policies and procedures govern patient's self-administration of medications. *

Interpretation: At the outset the organisation could define if it would permit self-administration of medications. In case the organisation permits then the policy shall include the medications which the patient can self-administer. It is preferable that the organisation also incorporates a method to ensure that the patient is reminded to take the medication (before every dose) and document the same. Eg : self- administration of insulin.

j. Documented policies and procedures govern patient's own medications brought from outside the organisation. *

Interpretation: These shall address as to what are the prerequisites for such a medication (e.g. clear label with mention of the name, dose, expiry date, batch number etc).

Standard

MOM.7.	**Patients are monitored after medication administration.**

Objective Elements

a. Documented policies and procedures guide the monitoring of patients after medication administration. *

Interpretation: The purpose of monitoring is to verify that the medicine is having its intended effect. In addition this would help identify near misses, medication errors and adverse drug events.

b. The organisation defines those situations where close monitoring is required. *

Interpretation: For example, administration of high-risk medicines, concentrated electrolytes, chemotherapeutic drugs.

c. Monitoring is done in a collaborative manner.

Interpretation: This shall be done by the clinician and nurse. A clinical pharmacist may also be involved.

d. Medications are changed where appropriate based on the monitoring.

Interpretation: For eg: Medication changes are based on clinical response and adverse drug reactions.

Standard

MOM.8.	**Near misses, medication errors and adverse drug events are reported and analysed.**

Objective Elements

a. Documented procedure exists to capture near miss, medication error and adverse drug event. *

Interpretation: This shall outline the process for identifying, documenting, reporting, analysing and taking action.

b. Near miss, medication error and adverse drug event are defined. *

Interpretation: The organisation shall define as to what constitutes these. This shall be in consonance with best practices.

Refer to glossary for “near miss”, “medication error” and “adverse drug event”.

c. These are reported within a specified time frame. *

Interpretation: The organisation shall define the timeframe for reporting once any of this has occurred.

d. They are collected and analysed.

Interpretation: All these incidents are analysed regularly by the multi-disciplinary committee. The analysis shall be completed in a defined time frame.

e. Corrective and/or preventive action(s) are taken based on the analysis where appropriate.

Interpretation: Self-explanatory.

Standard

MOM.9.	**Documented procedures guide the use of narcotic drugs and psychotropic substances.**

Objective Elements

a. Documented procedures guide the use of narcotic drugs and psychotropic substances which are in consonance with local and national regulations. *

Interpretation: This is in the context of Narcotic Drugs and Psychotropic Substances Act.

b. These drugs are stored in a secure manner.

Interpretation: They shall be stored under lock and key with a designated person being responsible for the same.

c. A proper record is kept of the usage, administration and disposal of these drugs.

Interpretation: These shall be kept in accordance with statutory requirements.

A very strict inventory control shall be kept for these drugs. The empty vials shall be disposed as per local regulatory requirements.

d. These drugs are handled by appropriate personnel in accordance with the documented procedure.

Interpretation: Self-explanatory.

Standard

MOM.10.	**Documented policies and procedures guide the usage of chemotherapeutic agents.**

Objective Elements

a. Documented policies and procedures guide the usage of chemotherapeutic agents. *

Interpretation: This could incorporate all the objective elements of this standard.

b. Chemotherapy is prescribed by those who have the knowledge to monitor and treat the adverse effect of chemotherapy.

Interpretation: This shall preferably be a medical oncologist or a doctor who has been trained and has achieved competency in the same.

c. Chemotherapy is prepared in a proper and safe manner and administered by qualified personnel.

Interpretation: It is required that qualified personnel has received special training in preparation and administration of chemo therapeutic drugs. Staff are also trained

A bio-safety cabinet of class II (preferably IIA) with appropriate PPE shall be used for preparing/mixing chemotherapeutic drugs.

d. Chemotherapy drugs are disposed in accordance with legal requirements.

Interpretation: These shall be disposed according to current Biomedical waste management and handling rules or the manufacturer's recommendation.

e. Patient and family are educated regarding benefits/risks of chemotherapy, precautions to be taken and possible adverse reactions.

Interpretation: *Self Explanatory*

Standard

MOM.11.	**Documented policies and procedures govern usage of radioactive drugs.**

Objective Elements

a. Documented policies and procedures govern usage of radioactive drugs. *

Interpretation: The documentation shall incorporate all the objective element of this standard.

b. These policies and procedures are in consonance with laws and regulations.

Interpretation Refer to AERB guidelines.

c. The policies and procedures include the safe storage, preparation, handling, distribution and disposal of radioactive drugs.

Interpretation: This shall be in accordance with AERB guidelines.

d. Staff, patients and visitors are educated on safety precautions.

Interpretation: This refers to the layout/location of radiation waste pipes, delay tanks, etc.

Standard

MOM.12.	**Documented policies and procedures guide the use of implantable prosthesis and medical devices.**

Objective Elements

a. Usage of implantable prosthesis and medical devices is guided by scientific criteria for each individual item and national/international recognised guidelines/ approvals for such specific item(s).

Interpretation: The organisation shall ensure that relevant and sufficient scientific data are available before selection. It shall also look for international

(e.g.US-FDA) or national notification (Drugs and Cosmetics Act notification October 2005) for approval of the particular product.

The multidisciplinary committee shall be responsible for approving the use of a particular implant.

b. Documented policies and procedures govern procurement, storage/stocking, issuance and usage of implantable prosthesis and medical devices incorporating manufacturer's recommendation(s). *

Interpretation: Self-explanatory.

c. Patient and his/her family are counselled for the usage of implantable prosthesis and medical device including precautions, if any.

Interpretation: Precautions could include non-usage of specific drugs and reporting to the hospital if a particular symptom occurs.

d. The batch and serial number of the implantable prosthesis and medical devices are recorded in the patient's medical record, the master logbook and the discharge summary.

Interpretation: In case where implantable prosthesis do not have pre labelled stickers, the organisation shall have suitable mechanisms in place for identifying the implant (manufacturer, type, size, batch number, serial number) and any other important detail.

Standard

MOM.13.	**Documented policies and procedures guide the use of medical supplies and consumables.**

Objective Elements

a. There is a defined process for acquisition of medical supplies and consumables.*

Interpretation: In this context, medication supplies and consumables refer to those items used in patient care excluding medications and implants. The process should address the issues of vendor selection, vendor evaluation, indenting process, generation of purchase order and receipt of goods.

b. Medical supplies and consumables are used in a safe manner, where appropriate.

Interpretation: The items are opened and used using relevant precautions to maintain the sterility and integrity.

c. Medical supplies and consumables are stored in a clean, safe and secure environment; and incorporating manufacturer's recommendation(s).

Interpretation: The organisation shall ensure that the storage requirements specified by the manufacturer are adhered to. This shall be applicable to all areas where these are stored including wards. They shall be protected from loss or theft. Overall cleanliness of the storage area shall be maintained. Hazardous materials are identified and kept in a safe manner.

d. Sound inventory control practices guide storage of medical supplies and consumables.

Interpretation: Organisation shall follow or demonstrate ABC, VED, FSN, FIFO lead time analysis, etc.

e. There is a mechanism in place to verify the condition of medical supplies and consumables.

Interpretation: Medical supplies and consumables shall be in a condition suitable for safe usage. The condition of these materials shall be checked before dispensing and usage Eg: opened package, damp cotton roll, physical damage, unwanted discolouration, etc.

Chapter 4
Patient Rights and Education (PRE)

Intent of the chapter:

The organisation defines the patient and family's rights and responsibilities. The staff is aware of these rights and is trained to protect them . Patients are informed of their rights and educated about their responsibilities at the time of admission. They are informed about the disease, the possible outcomes and are involved in decision making. The costs are explained in a clear manner to patient and/or family. Patients are educated about the mechanisms available for addressing grievances.

A documented process for obtaining patient and/or families consent exists for informed decision making about their care.

Patients and families have a right to seek and get information and education about their healthcare needs in a language and manner that is understood by them.

Summary of Standards

PRE 1:	The organisation protects patient and family rights and informs them about their responsibilities during care.
PRE2:	Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.
PRE3:	The patient and/or family members are educated to make informed decisions and are involved in the care planning and delivery process.
PRE4:	A documented procedure for obtaining patient and/or family's consent exists for informed decision making about their care.
PRE5:	Patient and families have a right to information and education about their healthcare needs.
PRE6:	Patients and families have a right to information on expected costs.
PRE7:	The organisation has a mechanism to capture patient's feedback and redressal of complaints.
PRE8:	The organisation has a system for effective communication with patients and / or families.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

PRE.1.	**The organisation protects patient and family rights and informs them about their responsibilities during care.**

Objective Elements

a. Patient and family rights and responsibilities are documented and displayed. *

Interpretation: Organisation should respect patient's rights and inform them of their responsibilities. The rights and responsibilities of the patients should be displayed (bilingually) in strategic location like the entrance/Lobby of the hospital, registration, billing, outpatient areas etc.. Pamphlets may also be provided regarding the same.

b. Patients and families are informed of their rights and responsibilities in a format and language that they can understand.

Interpretation: Display, information material, communication or counselling should at least be bi-lingual (English and the state language/language spoken by the majority of people in that area/region).

c. The organisation's leaders protect patient and family rights.

Interpretation: The organisation's leaders ensure protection of patient, and family rights and also periodically review and address violations if any.

d. Staff are aware of their responsibility in protecting patient and family rights.

Interpretation: Training and sensitisation programmes shall be conducted to create awareness among the staff.

e. Violation of patient and family rights is recorded, reviewed and corrective/preventive measures taken.

Interpretation: Whenever patients' rights have been infringed upon, management shall document the said violations, investigate and maintain the

record of the incident and its outcomes – correction / corrective / preventive actions. The organisation shall have a mechanism to capture the same. The organisation may develop a list of such instances which could be considered as infringements of patients & families' rights and train the staff accordingly. For example, compromising the privacy and confidentiality, dis-respect to the religious and cultural needs, soliciting money etc. The patient feedback form (by incorporating patient rights worded appropriately) could be used as a tool to capture violation of patient rights.

Standard

PRE.2.	**Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.**

Objective Elements

a. Patients and family rights include respecting any special preferences, spiritual and cultural needs.

Interpretation: This could include dietary preferences and worship requirements. This may also include any specific requirement following death

b. Patient and family rights include respect for personal dignity and privacy during examination, procedures and treatment.

Interpretation: During all stages of patient care, be it in examination or carrying out a procedure, hospital staff shall ensure that patient's privacy and dignity is maintained. The organisation shall develop the necessary guidelines for the same. During procedures the organisation shall ensure that the patient is exposed just before the actual procedure is undertaken. With regards to photographs/recording procedures, the organisation shall ensure that an explicit informed consent is taken and that the patient's identity is not revealed.

c. Patient and family rights include protection from neglect or abuse.

Interpretation: Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations (unwarranted), manhandling, etc. Special precautions shall be taken especially with respect to vulnerable patients, e.g. elderly, neonates, physically and mentally challenged patients, comatose patients, patients under anaesthesia etc.

d. Patient and family rights include treating patient information as confidential.

Interpretation: The organisation and the treating team shall take effective measures to maintain confidentiality of all patient related information. Staff shall avoid having patient-related discussions in public places. Statutory requirements w.r.t. privileged communication shall be followed at all times (refer the glossary for definition of privileged communication). Confidential information including HIV status shall not be revealed without patient's permission. It shall not be explicitly written / pasted on the cover of the medical record nor shall it be displayed in a manner that is easily understandable by the public at large.

e. Patient and family rights include refusal of treatment.

Interpretation: The treating doctor shall discuss all the available options and allow the patient to make an informed choice. In case of refusal, the treating doctor shall explain the consequences of refusal of treatment and document the same.

f. Patient and family have a right to seek an additional opinion regarding clinical care.

***Interpretation*:** There is a mechanism for patient and family to seek a second opinion if they wish, from within or outside the organisation. The organisation shall respect the decision of the patient and family in this regard. The organisation shall allow access to all relevant information or clinical evaluation.

g. Patient and family rights include informed consent before transfusion of blood and blood components, anaesthesia, surgery, initiation of any research protocol and any other invasive / high risk procedures / treatment.

Interpretation: Self explanatory

h. Patient and family rights include right to complain and information on how to voice a complaint

Interpretation: The displayed patient rights should include the right to make a complaint and also mention the methodology to voice the same. Complaint mechanism must be accessible and redressal of complaint must be fair and transparent.

i. Patient and family rights include information on the expected cost of the treatment.

Interpretation: Self-explanatory.

j. Patient and family rights include access to his / her clinical records.

Interpretation: The organisation shall ensure that every patient has access to his/her record. This shall be in consonance with the code of medical ethics and statutory requirements.

k. Patient and family rights include information on Care plan, progress and information on their health care needs.

Interpretation: Self-explanatory.

Standard

PRE.3.	**The patient and/or family members are educated to make informed decisions and are involved in the care planning and delivery process.**

Objective Elements

a. The patient and/or family members are explained about the proposed care including the risks, alternatives and benefits.

Interpretation: The proposed care is discussed by the attending doctor with the patient and/or family members. This should be done in a language the patient/attendant can understand. The above information is to be documented and signed by the doctor concerned.

b. The patient and/or family members are explained about the expected results.

Interpretation: The patients and/or family members are explained in detail by the treating physician or his/her team about the expected outcomes of such treatment at periodic intervals.

c. The patient and/or family members are explained about the possible complications.

Interpretation: Possible complications of the treatment, if any, are clearly communicated to the patient and/or family members.

d. The care plan is prepared and modified in consultation with patient and/or family members.

Interpretation:. During the preparation of the care plan the patient and/or family members are explained about the various treatment options, risks and benefits. The organisation could develop a structured mechanism to implement and capture the same.

e. The care plan respects and where possible incorporates patient and/or family concerns and requests.

Interpretation: The religious, cultural and spiritual views of the patient and/or family shall be considered during the process of care delivery. Incorporating patient and/or family requests shall be limited by the statutory requirements.

f. The patient and/or family members are informed about the results of diagnostic tests and the diagnosis.

Interpretation: Self Explanatory

g. The patient and/or family members are explained about any change in the patient's condition in a timely manner.

Interpretation: This includes improvement, deterioration or occurrence of complications.

Standard

PRE.4.	**A documented procedure for obtaining patient and/or family's consent exists for informed decision making about their care.**

Objective Elements

a. Documented procedure incorporates the list of situations where informed consent is required and the process for taking informed consent. *

Interpretation: The process for taking informed consent shall specify the various steps involved with the responsibility. A list of procedures should be made for which informed consent should be taken. This shall be prepared keeping in mind the requirements of this standard and statutory requirement. For example, some statutory requirements are MTP Act, PC-PNDT Act and Organ Transplantation Act. The policy for HIV testing should follow the national policy on HIV testing (NACO).

b. General consent for treatment is obtained when the patient enters the organisation.

Interpretation: Self-explanatory.

c. Patient and/or his family members are informed of the scope of such general consent.

Interpretation: The organisation shall define as to what is the scope of the general consent and the same shall be communicated to the patient and/or his family members. This cannot include consent for invasive procedures or other procedures for which a specific consent is required as per this standard.

d. Informed consent includes information regarding the procedure, it's risks, benefits, alternatives and as to who will perform the procedure in a language that they can understand.

Interpretation: The consent shall have the name of the doctor performing the procedure. In case if a procedure requires more than one doctor from different specialities, then the same will have to be explained to the patient and consent shall include the name of the principal surgeon from each speciality who is performing the procedure. Each doctor will have to explain his role and address all aspects required for an informed consent. If it is a "doctor under training" the same shall be specified, however the name of the qualified doctor supervising the procedure shall also be mentioned. Consent form shall be in the language that the patient understands.

Eg: If a surgery involves requirement of a neurosurgeon, ENT surgeon and an Ophthalmologist, the consent should reflect the same. It should have the names of the principal surgeons of the three specialities. It is the responsibility of each of the surgeons/team to explain their role and the benefits /risks and alternatives of the procedures they are performing on the patient.

e. The procedure describes who can give consent when patient is incapable of independent decision making. *

Interpretation: The consent shall be taken from the patient in all cases when the patient is capable of giving consent and above the legal age for giving consent. The organisation shall take into consideration the statutory norms when the patient is incapable of independent decision making. This would include next of kin/legal guardian. The order of preference of next of kin/legal guardian is spouse, son/daughter/parents/brothers/sister. For life threatening situations when a patient is incapable and next of kin is not available, in the interest of time the treating doctor and another clinician can take a decision to safeguard the patients' life.

f. Informed consent is taken by the person performing the procedure.

Interpretation: The person performing shall be responsible for the entire consent process including providing explanation and taking the signature. For example, it is not acceptable if the person performing the procedure only explains and the written consent is taken by the nurse. A team member can take consent on behalf of the person performing the procedure.

g. Informed consent process adheres to statutory norms.

Interpretation: This includes (but is not limited to):

i. taking consent before the procedure;

ii. At least one witness signing the consent form.

iii. In case the patient has to undergo a procedure repeatedly for a long time (e.g. dialysis) an informed consent is taken at the first instance. Such consent shall have a defined validity period but not more than 6 months. The patient endorses the consent at each repeat treatment. However if there is a change in the treatment modality or an addition of another modality then fresh consent shall be obtained.

h. Staff are aware of the informed consent procedure.

Interpretation: Staff shall be aware of the conditions which require informed consent and the process for taking informed consent.

Standard

PRE.5.	**Patient and families have a right to information and education about their healthcare needs.**

Objective Elements

a. Patient and/or family are educated about the safe and effective use of medication and the potential side effects of the medication, when appropriate.

Interpretation: The organisation shall make a list of such drugs and accordingly educate, e.g. digoxin. This could also include education regarding the importance of taking a drug at a specific time.,

b. Patient and/or family are educated about food-drug interaction

Interpretation: The organisation shall make a list of such drugs, and accordingly, patient and family should be educated about their diet during medication, e.g. no alcohol when taking metranidazole.

c. Patient and/or family are educated about diet and nutrition.

Interpretation: Self explanatory

d. Patient and/or family are educated about immunisations.

Interpretation:. In adults it could be for influenza, *Streptococcus pneumonia*, typhoid, hepatitis B, *Neisseria meningitides*, etc.

e. Patient and/or family are educated about their specific disease process, complications and prevention strategies.

Interpretation: This could also be done through patient education booklets/videos/leaflets, etc. This shall include information on lifestyle modifications, diet changes and immunisations where appropriate.

f. Patient and/or family are educated about preventing healthcare associated infections.

Interpretation: For example, hand washing and avoiding overcrowding near the patient.

g. The patients and/or family members' special educational needs are identified and addressed.

Interpretation: During the course of the patient's treatment, his/her special educational needs are identified. The patients and/or family members are educated through counselling, use of printed material, audio-visual aids etc.

h. Patient and/or family are educated in a language and format that they can understand.

Interpretation: Self-explanatory.

Standard

PRE.6.	**Patients and families have a right to information on expected costs.**

Objective elements

a. There is a uniform pricing policy in a given setting (out-patient and ward category).

Interpretation: There should be a billing policy which defines the charges to be levied for various activities.

b. The relevant tariff list is available to patients.

Interpretation: The organisation shall ensure that there is an updated tariff list and that the relevant tariff is available for reviewing to patients when required. The organisation shall charge as per the tariff list. Any additional charge should also be enumerated in the tariff and the same communicated to the patients. The tariff rates should be uniform (in a given setting) and transparent.

c. The patient and/or family members are explained about the expected costs.

Interpretation: Patients should be given an estimate of the expenses on account of the treatment preferably in a written form. This estimate shall be prepared on the basis of the treatment plan. It could be prepared by the OPD/ Registration/Admission staff in consultation with the treating doctor. The limitations of the estimate if any (eg; emergency admissions) could also be discussed with the patient.

d. Patient and/or family are informed about the financial implications when there is a change in the patient condition or treatment setting.

Interpretation: When patients are shifted from one setting to another, typically to and from ICUs, the financial implications must be clearly conveyed to them.

Standard

PRE.7.	**The organisation has a mechanism to capture patient's feedback and redressal of complaints.**

Objective elements

a. The organisation has a mechanism to capture feedbacks from patients which includes patient satisfaction and patient experience.

Interpretation: Patient experience goes beyond patient satisfaction and making patient happy. In addition to collecting patient feedback the organisation shall also capture patient experience which may include communication with doctors and nurses, pain management, hospital environment (cleanliness and quietness),

responsiveness of hospital staff, discharge information, communication about medications and overall rating of the hospitals. Eg: There may be a negative outcome but still have a positive patient experience.

b. The organisation has a documented complaint redressal procedure. *

Interpretation: This shall incorporate the mechanism for lodging complaints (including verbal or telephonic complaints), method of compiling them, analysing complaints including the time frame, the person(s) responsible and documenting the action taken. It is for the organisation to decide if it wants to give credence to anonymous complaints.

c. Patient and/or family members are made aware of the procedure for giving feedback and /or lodging complaints.

Interpretation: This shall be either by display or providing written information.

It is important that the organisation creates an environment of trust wherein the patient would be comfortable to air his/her views.

d. All feedback and complaints are reviewed and/or analysed within a defined time frame.

Interpretation: The entire process shall be documented. Where appropriate the patient and/or family could be involved in the discussions and also informed regarding the outcome.

e. Corrective and/or preventive action(s) are taken based on the analysis where appropriate.

Interpretation: Self-explanatory.

Standard

PRE.8.	**The organisation has a system for effective communication with patients and /or families.**

Objective elements

a. Documented policies and procedures guide the effective communication with the patients and/or families. *

Interpretation: The organisation details the components of effective communication for all categories of staff.

b. The organisation shall identify special situations where enhanced communication would be required. *

Interpretation: This could include communication during challenging situations like breaking bad news, handling adverse events, handling an aggressive patient/family, talking to a family of a patient who has expired, counseling for a complicated intervention etc.

c. The organisation lays down an approach for effective communication in these identified situations.

Interpretation: For each identified special situation the organisation shall detail the nature of the enhanced communication that may be required. The organisation identifies potential communication barriers and the preparation required to handle it. The hospital shall have a process to identify the communication barriers of a patient for e.g. Language (organisation could be prepared by having interpreters or staff working in the organisation can act as interpreters).

d. The organisation also defines what constitutes an unacceptable communication and sensitizes the staff about the same. *

Interpretation: The organisation shall identify what constitutes unacceptable behavior and sensitizes it's staff. Eg; Abusing patients, hurting the religious or cultural sentiments, communicating with disrespect, etc.

e. The organisation has a system to monitor and review the implementation of effective communication

Interpretation: This could be done through feedbacks from patients and other stakeholders .

f . The staff are trained in healthcare communication techniques periodically.

Interpretation: Communication plays a major role in both patient satisfaction and patient safety. The staff shall be trained to handle challenging situations as well as in good practices in health care communication. The training needs for communication skills can also be identified by analyzing patient complaints, incident reports, appraisals and employee feedback.

Chapter 5
Hospital Infection Control (HIC)

Intent of the chapter:

The standards guide the provision of an effective healthcare-associated infection prevention and control programme in the organisation. The programme is documented and aims at reducing/eliminating infection risks to patients, visitors and providers of care.

The organisation measures and takes action to prevent or reduce the risk of Healthcare Associated Infection (HAI) in patients and employees.

The organisation provides proper facilities and adequate resources to support the Infection Control Programme.

The organisation has effective antimicrobial management program through regularly updated antibiotic policy based on local data and monitors its implementation. Program also includes monitoring of antimicrobials usage in the organisation.

The programme includes an action plan to control outbreaks of infection, disinfection/ sterilization activities, biomedical waste (BMW) management, training of staff and employee health.

Summary of Standards

HIC 1:	The organisation has a well-designed, comprehensive and coordinated Hospital Infection Prevention and Control (HIC) programme aimed at reducing/eliminating risks to patients, visitors and providers of care.
HIC 2:	The organisation implements the policies and procedures laid down in the Infection Control Manual in all areas of the hospital.
HIC 3:	The organisation performs surveillance activities to capture and monitor infection prevention and control data.
HIC 4:	The organisation takes actions to prevent and control Healthcare Associated Infections (HAI) in patients.
HIC 5:	The organisation provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).
HIC 6:	The organisation identifies and takes appropriate action to control outbreaks of infections.
HIC 7:	There are documented policies and procedures for sterilization activities in the organisation.
HIC 8:	Biomedical waste (BMW) is handled in an appropriate and safe manner.
HIC 9:	The infection control programme is supported by the management and includes training of staff.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

HIC.1.	**The organisation has a well-designed, comprehensive and coordinated Hospital Infection Prevention and Control (HIC) programme aimed at reducing/eliminating risks to patients, visitors and providers of care.**

Objective Elements

a. The hospital infection prevention and control programme is documented which aims at preventing and reducing risk of healthcare associated infections in all areas of the hospital. *

Interpretation: The policies and procedures shall be directed at prevention and control of infection in all areas of the hospital and include its monitoring.

The organisation shall have hospital associated infection prevention and control manual (HIC manual) that shall incorporate the structure of the program, all processes, activities and surveillance procedures related to the program.

This shall be based on current scientific knowledge, guidelines from international/national and professional bodies and statutory requirements, wherever applicable.

Reference documents could include WHO guidelines, CDC Guidelines and Manual for Control of Hospital Associated Infections, Standard Operative Procedures by NACO, Ministry of Health and Family Welfare, Govt. of India.

b. The infection prevention and control programme is a continuous process and updated at least once in a year.

Interpretation: The update shall be done based on newer literature on infection prevention and outbreak prevention mechanisms, infection trends and outcomes of the audit processes. Risk-reduction goals and measurable objectives are established by the committee at least annually and reviewed on a monthly basis by the infection control team.

c. The hospital has a multi-disciplinary infection control committee, which co-ordinates all infection prevention and control activities. *

Interpretation: This shall preferably have Hospital Administrator, Microbiologist, Physician/Infection control specialist, Surgeon, Nursing Manager (Nursing Supervisor), staffs from CSSD and other support services and the hospital infection control nurse. It could also include invitees from various departments as deemed necessary. The committee shall lay down the policies and procedures to guide the implementation. The composition, frequency of meetings, the minimum quorum required and the minutes of the meeting shall be documented.

d. The hospital has an infection control team, which coordinates implementation of all infection prevention and control activities. *

Interpretation: The team is responsible for day-to-day functioning of infection prevention and control programme. It shall support surveillance process and detect outbreaks. It shall also participate in audit activity and in infection prevention and control on a day-to-day basis. The team shall at least comprise of ICO, ICN(s) Infection control team staffed according to hospital size, the level of risk, and the program's complexity and scope. The committee and the team shall not be the same. However, the team shall be part of the committee.

e. The hospital has designated infection control officer as part of the infection control team. *

Interpretation: This shall be a doctor, who is knowledgeable in infection control practices. It is preferable that he/she is a clinical microbiologist. In the absence of microbiologist a surgeon / physician can be designated as infection control officer. The responsibilities of the Infection control officer (ICO) are defined in the privileging document.

f. The hospital has designated infection control nurse(s) as part of the infection control team. *

Interpretation: The criteria for designating shall be either by qualification (Registered Nurse) and based on training. The responsibilities of the ICN(s) are defined in the privileging document. It is preferable for them to have undergone a short-term training programme on infection prevention and control nursing.

Standard

HIC.2.	**The organisation implements the policies and procedures laid down in the Infection Control Manual in all areas of the hospital.**

Objective Elements

a. The organisation identifies the various high-risk areas and procedures and implements policies and/or procedures to prevent infection in these areas. *

Interpretation: Infection control program shall include all areas of the hospital and the manual should clearly identify the high-risk areas of the hospital, e.g. ICU, HDU, OT, post-operative ward, Blood bank, CSSD, mortuary and post mortem area etc.

Similarly, all high-risk procedures should be identified from infection control point of view, for example, cardiac catheterization, endoscopies, surgery lasting more than two hours, BMT, etc. The policies and procedures shall be directed at prevention of infection in these areas and include monitoring.

At a minimum, the manual shall incorporate all the requirements of this chapter.

b. The organisation adheres to standard precautions at all times. *

Interpretation: Refer to the glossary for “standard precautions”.

c. The organisation adheres to hand-hygiene guidelines. *

Interpretation: The organisation shall adhere to international/national guidelines on hand hygiene. A good reference is the WHO guidelines of 2009.

The organisation could display the necessary instructions near every hand-washing area.

d. The organisation adheres to transmission-based precautions at all times. *

Interpretation: This shall cover airborne, droplet and contact modes of transmission. Personal protective equipment (PPE) to be used in various situations of patient care are identified and used appropriately. This shall be applicable across the organisation.

Refer to international guidelines like that of CDC.

e. The organisation adheres to safe injection and infusion practices. *

Interpretation: This shall include “One needle, One syringe, Only one time” as recommended by CDC. A good reference guide is “WHO best practices for injections and related procedures toolkit”.

f. The organisation adheres to cleaning, disinfection and sterilization practices. *

Interpretation: It shall be addressed at all levels of the organisation, e.g. ward, OT and CSSD. It is preferable that the organisation follows a uniform policy across different departments within the organisation.

A good reference is “CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008”.

This includes environment, fixtures, fomites, furniture, furnishings, equipment, etc., as applicable. Organisation shall identify various different disinfectants being used in patient care units. The disinfectants’ use is identified and monitored. The common disinfectants used are identified, dilution protocols are established, and its usage in the appropriate situation is complied with. Risks and hazards due to usage of disinfectants are identified and staff is aware of these risks and hazards (This can be done through display of material safety data sheets (MSDS) of such disinfectants and staff are educated through MSDS).

g. An appropriate antibiotic policy is established and documented *

Interpretation: The organisation shall develop a system of monitoring antimicrobial susceptibility (based on culture sensitivity) and accordingly develop its antibiotic policy, which shall be reviewed at periodic intervals (may be once in three months (but at least every year) for its continuing applicability. The organisation can also refer to international guidelines while framing the policy. Use of WHO reference document global strategy for containment of antimicrobial resistance, 2001 [WHO/CDS/CSR/DRS/2001.2] can be a good starting point.

h. The organisation implements the antibiotic policy and monitors rational use of antimicrobial agents. *

Interpretation: The organisation shall identify clinical conditions in which antimicrobial agents (antibiotics and anti-fungal agents) shall be used in terms of type of the antimicrobial agent, monotherapy Vs combination therapy, escalation and de-escalation of therapy, dose and duration of antimicrobial therapy. Deviations are brought to the notice of concerned clinicians and corrective and preventive actions are taken and documented.

i. The organisation adheres to laundry and linen management processes. *

Interpretation: The laundry can be in-house or outsourced. The organisation shall have a policy for change of linen. There shall be separate washing protocols for different categories of linen including blankets (where applicable). Organisation shall have a defined process of handling linen in patient care units, during transport and inside the laundry. If outsourced, the organisation shall ensure that it establishes adequate controls to ensure infection prevention and control.

j. The organisation adheres to kitchen sanitation and food-handling issues. *

Interpretation: This shall be applicable even if this activity is outsourced. The organisation shall adhere to all statutory requirements. It is preferable that they also adhere to national and international guidelines while addressing this issue.

Kitchen sanitation measures are implemented to prevent the risk of cross-contamination. This includes the periodic screening of kitchen workers and food handlers for carriage of parasites and Salmonella Typhi every six months or if the staff rejoins after leave of 15 days or more.

k. The organisation has appropriate engineering controls to prevent infections. *

Interpretation: This shall include the design of patient care areas (optimum spacing between beds is one-two metres), operating rooms, air quality and water supply. Issues such as air-conditioning plant and equipment maintenance, cleaning of AC ducts/filters, AHUs, cleaning / replacement of filters, seepage leading to fungal colonization, replacement/repair of plumbing, sewer lines (in shafts) should be included. Water-supply sources and system of supply, testing for water quality must be included. Any renovation work in hospital patient-care areas should be planned with infection control team with regard to architectural segregation, traffic flow, use of materials, etc. Refer to NABH guidelines on OT air-conditioning.

l. The organisation adheres to housekeeping procedures. *

Interpretation: This shall include categorization of areas/surfaces, general-cleaning procedures for surfaces, furniture/fixtures, and items used in patient care. It shall also include procedures for terminal cleaning, blood and body fluid cleanup, isolation rooms and all high-risk (critical) areas. The common disinfectants used, dilution factors and methodology should be specified. Brooming and a dry dusting of any sorts inside the clinical areas should be avoided.

Standard

HIC.3.	**The organisation performs surveillance activities to capture and monitor infection prevention and control data.**

Objective Elements

a. Surveillance activities are appropriately directed towards the identified high-risk areas and procedures.

Interpretation: The organisation must be able to provide evidence of conducting periodic surveillance activities in its identified high-risk areas and procedures. It shall define the frequency and mode of surveillance. The surveillance system shall be appropriate and adhering to national/ international guidelines. Surveillance activities include areas where demolition, construction or repairs are undertaken, especially in high-risk areas. The organisation shall use a judicious mix of active and passive surveillance. The organisation could lay down the parameters that need to be captured and the process for reporting.

b. A Collection of surveillance data is an on-going process.

Interpretation: The organisation shall ensure that it has a process in place to collect surveillance data and also to ensure that it is able to capture all such data.

c. Verification of data is done on a regular basis by the infection control team.

Interpretation: The data collected shall be authenticated by the infection control team by going through every data or by using random sampling so that the process can be validated. The team shall preferably verify every serious infection (as defined by the organisation) report.

d. The scope of surveillance activities incorporates tracking and analyzing of infection risks, rates and trends.

Interpretation: This shall be done at regular intervals (maybe monthly and consolidated into an annual report) and the organisation shall take suitable steps

based on the analysis. A simple calculation of infected patients (numerator) provides only limited information which would be difficult to interpret. Risk factor analysis would require information for both infected and non-infected patients, in order to calculate infection and risk-adjusted rates.

e. Surveillance activities include monitoring the compliance with hand-hygiene guidelines.

Interpretation: This shall be done at a minimum once every month. An appropriate sample size shall be chosen and all categories of staff (involved in direct patient care) shall be monitored. The compliance levels shall be shared with the relevant staff. A good tool is the WHO's "Observation Form".

f. Surveillance activities include mechanisms to capture the occurrence of epidemiological significant diseases, multi-drug-resistant organisms and highly virulent infections.

Interpretation: The organisation shall closely monitor the occurrence of multi-drug resistant organisms (MDROs) e.g. methicillin resistant *Staphylococcus aureus* (MRSA), multi-drug resistant gram-negative bacteria and monitors any suspected emergence and spread of infection with such microorganisms.

g. Surveillance activities include monitoring the effectiveness of housekeeping services.

Interpretation: This shall be done on a regular basis. The organisation shall define the periodicity. This is applicable even if the housekeeping services are outsourced. It could be done using a checklist. This need not mean routine environmental sampling.

h. Appropriate feedback regarding Healthcare Associated Infection (HAI) rates is provided on a regular basis to appropriate personnel.

Interpretation: The feedback shall include the rates, trends and opportunities for improvement including data from other surveillance activities. It could also

provide specific inputs to reduce the HAI rate. This could be in the form of a bulletin/newsletter.

i. In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.

Interpretation: The organisation shall identify all notifiable diseases after taking into consideration the local/state/national laws, rules, regulations and notifications thereof. The organisation shall ensure that this is sent at the specified frequency and in the format as required by statutory authorities. Refer to the glossary for notifiable diseases..

Standard

HIC.4.	**The organisation takes actions to prevent and control Healthcare Associated Infections (HAI) in patients.**

Objective Elements

a. The organisation takes action to prevent catheter-associated urinary tract Infections.

Interpretation: A good reference is the CDC/WHO/SHEA guidelines.

b. The organisation takes action to prevent Ventilator Associated Pneumonia.

Interpretation*:* This is especially so for Ventilator Associated Pneumonia. A good reference is the CDC/WHO/SHEA guidelines.

c. The organisation takes action to prevent catheter linked blood stream infections.

Interpretation*:* A good reference is the CDC/WHO/SHEA guidelines.

d. The organisation takes action to prevent surgical site infections.

Interpretation: A good reference is the CDC/WHO/SHEA guidelines.

Standard

HIC.5.	**The organisation provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).**

Objective Elements

a. Adequate and appropriate personal protective equipment, soaps, and disinfectants are available and used correctly.

Interpretation: They should be available at the point of use and the organisation shall ensure that it maintains an adequate inventory.

Personal protective equipment includes:

i. Gloves
ii. Protective eye wear (goggles)
iii. Mask
iv. Apron
v. Gown
vi. Boots/shoe covers and
vii. Cap/hair cover

The staff uses PPE appropriate to the risks involved. The PPE are removed as soon as the purpose is served.

b. Adequate and appropriate facilities for hand hygiene in all patient-care areas are accessible to healthcare providers.

Interpretation: The organisation shall ensure that it provides the necessary infrastructure to carry out the same. Optimal hand-hygiene requirements include large washbasins, hands-free control, soap and facility for drying hands without contamination.

c. Isolation/barrier nursing facilities are available.

Interpretation: The organisation shall define the conditions where isolation is required and the conditions wherein barrier nursing or both are required. The

same shall be carried out. The organisation shall ensure that it provides the necessary resources to carry out the activity (e.g. clothing, masks, gloves, etc.). Refer to the glossary for “isolation/barrier nursing”.

Ideally patients requiring isolation (contact, droplet and airborne) should be placed in isolation rooms and airborne cases be kept in negative pressure rooms. The door/s to the aisle or other rooms should be kept closed at all times. Appropriate signage shall be used /displayed.

d. Appropriate pre- and post-exposure prophylaxis is provided to all staff members concerned. *

Interpretation: Infection Control Nurse maintains documentation of all occupational injuries and pre- and post-exposure prophylaxis records.

For example, hepatitis B vaccination and PEP for needle stick injury.

Standard

HIC.6.	**The organisation identifies and takes appropriate action to control outbreaks of infections.**

Objective Elements

a. Organisation has a documented procedure for identifying an outbreak. *

Interpretation: Standard case definitions shall include a unit of time and place along with specific biological and/or clinical criteria. To define as to what constitutes an outbreak, the organisation should have baseline rates.

b. Organisation has a documented procedure for handling such outbreaks. *

Interpretation: Organisation shall investigate outbreaks according to the laid-down procedures. This shall be in accordance with good clinical practices.

c. This procedure is implemented during outbreaks.

Interpretation: The organisation should be able to identify the outbreak, describe the outbreak by developing a case definition, designing a data collection form, collecting data from the affected, constructing an epidemic curve.

d. After the outbreak is over appropriate corrective actions are taken to prevent recurrence.

Interpretation: The organisation should be able to implement basic procedures to prevent recurrence such as source control if source identified, review of all infection control policies, loopholes and compliance gaps, strengthening infection control policies, etc.

Standard

HIC.7.	**There are documented policies and procedures for sterilization activities in the organisation.**

Objective Elements

a. The organisation provides adequate space and appropriate zoning for sterilization activities.

Interpretation: Adequacy of space refers to the CSSD, which should have suitable location, proper layout (unidirectional flow, zoning) and separation of clean and dirty areas.

Sufficient space shall be available to ensure that the activities can be performed properly.

The organisation shall provide for the same in all areas where sterilization activities are carried out. It is preferable to have separate areas for receiving, washing, cleaning, packing, sterilization, sterile storage and issue.

A good reference is Hospital Infection Society India (HISI) and HTM guidelines.

b. Documented procedure guides the cleaning, packing, disinfection and/or sterilization, storing and issue of items. *

Interpretation: The sterilized/disinfected equipment/sets shall be stored in an appropriate manner across the organisation and not just in CSSD.

A good reference is “CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008”. Other references include Hospital Infection Society India (HISI) guidelines.

c. Reprocessing of instruments and equipment are covered**. ***

Interpretation: There is a documented procedure to address cleaning, disinfection or sterilization of various accessories, instruments and equipment between patients.

d. The organisation shall have a documented policy and procedure for reprocessing of devices whenever applicable. *

Interpretation: The organisation identifies those devices which are meant for re-use. The number of reuses and the process of re-use of these items are defined and monitored. The patient is informed about the same. The documented policies and procedures shall be in consonance with the available good practices.

e. Regular validation tests for sterilization are carried out and documented. *

Interpretation: This shall be done by accepted methods, e.g. bacteriologic, strips, etc. Engineering validations like Bowie-Dick tape test and leak rate test needs to be carried out.

WHO recommends each load to have a number, content description, temperature, pressure and time-record chart, physical/chemical tests daily, weekly biological tests, steam processing, and ETO processing. A good reference is “CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008”.

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

Interpretation: The organisation shall ensure that the sterilization procedure is regularly monitored and in the eventuality of a breakdown it has a procedure for withdrawal of such items. The organisation could have a batch-processing system with date and machine number for effective recall.

Standard

HIC.8.	**Biomedical waste (BMW) is handled in an appropriate and safe manner.**

Objective Elements

a. The organisation adheres to statutory provisions with regard to biomedical waste.

Interpretation: The organisation shall be authorized by the prescribed authority for management and handling of biomedical waste. The occupier shall apply in the prescribed form and get approval from the prescribed authority, e.g. pollution control board/committee. It shall adhere to the various requirements specified in the bio-medical waste management rules.

b. Proper segregation and collection of biomedical waste from all patient-care areas of the hospital is implemented and monitored.

Interpretation: Wastes to be segregated and collected in different colour coded bags and containers as per statutory provisions. Monitoring shall be done by members of the infection control committee/team. Biomedical waste shall be handled in the proper manner.

c. The organisation ensures that biomedical waste is stored and transported to the site of treatment and disposal in properly covered vehicles within stipulated time limits in a secure manner.

Interpretation: The waste is transported to the pre-defined site at definite time intervals as per biomedical waste management rules through proper transport vehicles in a safe manner. If this activity is outsourced, the organisation shall

ensure that it is done through an authorized agency. Monitoring of this activity should be done by an infection control team.

d. The biomedical waste treatment facility is managed as per statutory provisions (if in- house) or outsourced to authorized contractor(s).

Interpretation: If the hospital has the waste treatment facility within its premises then it has to be in accordance with statutory provisions or it can outsource it to a central facility. The outsourced facility shall be visited by the organisation at least once in six months to ensure waste disposal according to the BWM rules.

e. Appropriate personal protective measures are used by all categories of staff handling biomedical waste.

Interpretation: Staff handling bio-medical waste shall be provided with personal protective equipment (PPE), for example, gloves and masks, protective glasses, gowns, etc. The staff shall use PPE while handling the waste.

Standard

HIC.9.	**The infection control programme is supported by the management and includes training of staff.**

Objective Elements

a. The management makes available resources required for the infection control programme.

Interpretation: The organisation shall ensure that the resources required by the personnel should be available in a sustained manner. This includes both men and materials.

b. The organisation earmarks adequate funds from its annual budget in this regard.

Interpretation: There shall be a separate budget demarcated for HIC activity. This shall be prepared taking into consideration the scope of the activity and previous years' experience.

c. The organisation conducts induction training for all staff.

Interpretation: There must be a documented evidence of induction training for all categories of staff including doctors before joining department(s) concerned. It should include the policies, procedures and practices of the infection control programme.

d. The organisation conducts appropriate “in-service” training sessions for all staff at least once in a year.

Interpretation: Self-explanatory.

Chapter 6
Continual Quality Improvement (CQI)

Intent of the chapter:

The standards encourage an environment of continual quality improvement. The quality and safety programme should be documented and involve all areas of the organisation and all staff members. The organisation should collect data on structures, processes and outcomes, especially in areas of high-risk situations. The collected data should be collated, analysed and used for further improvements. The improvements should be sustained. The quality programme of the diagnostic services should be integrated into the organisation's quality plan. Infection-control and patient-safety plans should also be integrated into the organisation's quality plan.

The organisation should define its sentinel events and intensively investigate when such events occur.

The quality programme should be supported by the management.

Summary of Standards

CQI 1:	There is a structured quality improvement and continuous monitoring programme in the organisation.
CQI 2:	There is a structured patient-safety programme in the organisation.
CQI 3:	The organisation identifies key indicators to monitor the clinical structures, processes and outcomes, which are used as tools for continual improvement**.**
CQI 4:	The organisation identifies key indicators to monitor the managerial structures, processes and outcomes, which are used as tools for continual improvement**.**
CQI 5:	There is a mechanism for validation and analysis of quality indicators to facilitate quality improvement.
CQI 6:	The quality improvement programme is supported by the management.
CQI 7:	There is an established system for clinical audit.
CQI 8:	Incidents are collected and analysed to ensure continual quality improvement.
CQI 9:	Sentinel events are intensively analysed.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

CQI.1.	**There is a structured quality improvement and continuous monitoring programme in the organisation.**

Objective Elements

a. The quality improvement programme is developed, implemented and maintained by a multi-disciplinary committee.

Interpretation: This committee shall have representation from management, various clinical and support departments of the organisation. This committee shall receive inputs on significant deliberations from other committees in the organisation. The committee may be called as the core committee, quality improvement committee, etc. This programme shall be developed, implemented and maintained in a structured manner***.***

b. The quality improvement programme is documented which is comprehensive and covers all the major elements related to quality assurance.

Interpretation: The document shall incorporate the mission, vision, quality policy, quality objectives, service standards, data collection, important indicators as identified, frequency of mock drills, audit schedules, committees and their terms of reference, review policy and implementation of corrective and preventive action. The quality assurance program for specific areas like Laboratory, Imaging, Operation theatre environment and the ICU services is also summarised.

c. There is a designated individual for coordinating and implementing the quality improvement programme.

Interpretation: This should preferably be a person having a good knowledge of accreditation standards, statutory requirements, hospital quality improvement principles and evaluation methodologies, hospital functioning and operations. For

example, accreditation co-ordinator, quality management representative, quality manager.

d. The quality improvement programme promotes and demonstrates use of innovations to improve process efficiency and effectiveness.

Interpretation: The quality improvement program encourages the use of novel strategies to improve both clinical and managerial processes. The impact of the managerial process innovations may be at the level of the departmental or hospital wide. Innovations may be targeted to improve patient safety, care delivery, reducing costs, introduce environmental friendly measures etc. The management of the organisation promotes these innovations.

e. The designated programme is communicated and coordinated amongst all the staff of the organisation through appropriate training mechanism.

Interpretation: Staff are made aware of the structure of the quality assurance program in the hospital. The staff are also aware of their individual roles in contributing to the quality assurance program as a part of their job description. This could be done through a regular training programme or printed materials.

f. The quality improvement programme identifies opportunities for improvement based on review at pre-defined intervals.

Interpretation: The quality improvement programme is a dynamic process. There is an outline of the periodic review mechanisms at different levels such as department / senior administration / management reviews, etc. The Quality improvement programme needs to be reviewed by the quality improvement committee at regular pre-defined intervals as defined by the organisation in the quality improvement manual but at least once in three months. The review shall include focussed audits, organisational performance, analysis of key indicators as identified and determined by the organisation including the mandatory indicators as laid down in CQI 3 and 4. The minutes of the review meetings should be recorded and maintained.

g. The quality improvement programme is a continuous process and updated at least once in a year.

Interpretation: The inputs for the updates could be based on audits, feedback mechanisms, the review carried out by the quality improvement committee, etc.

h. Audits are conducted at regular intervals as a means of continuous monitoring.

Interpretation: Choice and frequency of audits shall be defined for priority areas in the organisation and for areas of concern as identified by trends in indicators, identified risk, etc. However all the areas of the organisation shall be covered by a hospital wide internal audit at least once in 6 months as per a scheduled plan. This internal audit shall be done by a identified staff or a multi-disciplinary team (preferably trained in NABH standards). The internal audit of a particular area shall include all the applicable standards and objective elements. At the end of the audit, there shall be a formal meeting to summarise the findings and corrective and preventive measures shall be taken and documented. Implementation of changes is verified and recorded. The assessors shall be either trained internally or externally in NABH standards. They shall assess areas independent of their area of work.

i. There is an established process in the organisation to monitor and improve quality of nursing care.

Interpretation: This could be done through clinical audits. This could also be in the form of a competency evaluation by written questionnaire or witnessed demonstration for key nursing procedures such as medication administration, peripheral, iv cannula placement, tracheostomy care etc. The organisation shall identify key performance indicators that reflect excellence in nursing care.

CQI.2.	There is a structured patient-safety programme in the organisation.

Objective Elements

a. The patient-safety programme is developed, implemented and maintained by a multi-disciplinary committee.

Interpretation: This committee shall have representation from management, various clinical and support departments of the organisation. This programme shall be developed, implemented and maintained in a structured manner with the purpose to protect the patient from harm either from the environment or for lack of appropriate care or safety measures. This committee could be called Patient safety Committee, Clinical risk management committee, etc. This committee could have a mix of administrators, engineers, doctors and nurses.

Refer to glossary for definition of "safety programme".

b. The patient-safety programme is documented. *

Interpretation: This should be documented as a manual. The manual shall incorporate all the requirements of this standard. This should be documented keeping in mind requirements of other objective elements in the standard.

c. The patient-safety programme is comprehensive and covers all the major elements related to patient safety and risk management.

Interpretation: Risk management shall include risk identification and risk mitigation. It shall be done in a structured manner.

d. The scope of the programme is defined to include adverse events ranging from “no harm” to “sentinel events”.

Interpretation: The organisation shall clearly define as to what constitutes no harm and sentinel events with regards to the patient. Refer to glossary for definition of "adverse events", “no harm” and "sentinel events".

e. There is a designated individual for coordinating and implementing the patient-safety programme.

Interpretation: This should preferably be a person having a good knowledge of both patient and general safety. For example: Safety officer.

f. The designated programme is communicated and coordinated amongst all the staff of the organisation through appropriate training mechanism.

Interpretation: This could be done through regular training programme or printed materials.

g. The patient-safety programme identifies opportunities for improvement based on review at pre-defined intervals.

Interpretation: As patient safety is paramount, it needs to be reviewed at regular pre-defined intervals (as defined by the organisation in the safety manual but at least once in four months). The review at a minimum shall include review of facility inspection rounds and analysis of key-safety indicators. The minutes of the review meetings should be recorded and maintained.

h. The patient-safety programme is a continuous process and updated at least once in a year.

Interpretation: The updates could be based on findings of audits, the review carried out by the safety committee, etc.

i. The organisation adapts and implements national/international patient-safety goals/solutions.

Interpretation: At a minimum, the organisation shall adhere to the current national patient-safety goals or WHO patient-safety solutions. It is preferable that the organisation also participates by contributing to such databases.

Standard

CQI.3.	**The organisation identifies key indicators to monitor the clinical structures, processes and outcomes, which are used as tools for continual improvement.**

Objective Elements

a. Monitoring includes appropriate patient assessment.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Time for initial assessment of indoor and emergency patients.

ii. Percentage of cases (in-patients) wherein care plan with desired outcomes is documented and counter-signed by the clinician.

iii. Percentage of cases (in-patients) wherein screening for nutritional needs has been done.

iv. Percentage of cases (in-patients) wherein the nursing care plan is documented.

b. Monitoring includes safety and quality-control programmes of all the diagnostic services.

Interpretation: The organisation shall develop appropriate key performance indicators suitable for all diagnostic services. The following is, however, mandatory:

i. Number of reporting errors/1000 investigations.

ii. Percentage of re-dos.

iii. Percentage of reports co-relating with clinical diagnosis.

iv. Percentage of adherence to safety precautions by employees working in diagnostics.

Reporting errors need to be captured. It is better if the organisation captures these errors as errors picked up before dispatching the reports and errors picked after the dispatch of reports. This includes transcription errors also.

Re-dos include tests which needed to be repeated in view of poor sample or improper positioning and in case of radiology also includes films wastage.

The organisation could decide as to which tests will be monitored for clinical correlation. For example: This could include sampling of critical results, expensive tests, clinicians queries on reports, etc. However, in case of laboratory, it shall be captured for all histo-pathological tests and in case of radiology it shall be captured for CT and MRI. To capture co-relation it becomes mandatory that all investigation forms have a provisional diagnosis/relevant clinical details written on them. The form can have the differential diagnosis also written in them.

To capture adherence to safety precautions the organisation needs to do a random check of all employees per month (working in these areas and including all categories of staff) and capture data.

c. Monitoring includes medication management.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Incidence of medication errors.
ii. Percentage of admissions with adverse drug reaction(s).
iii. Percentage of medication charts with error prone abbreviations.
iv. Percentage of patients receiving high-risk medications developing adverse drug event.

The organisation shall document a list of approved abbreviations for medication charts. This shall be based on best national and international practices. For example, “ISMP List of Error-Prone Abbreviations, Symbols, and Dose Designations”.

d. Monitoring includes use of anaesthesia.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of modification of anaesthesia plan.

ii. Percentage of unplanned ventilation following anaesthesia.

iii. Percentage of adverse anaesthesia events.

iv. Anaesthesia-related mortality rate.

Anaesthesia plan is prepared at the time of pre-anaesthesia assessment. The same shall be reviewed during the immediate pre-operative re-evaluation. Modifications done in the plan based on this assessment shall be captured.

Adverse anaesthesia events include events, which happen during the procedure like hypoxia, arrhythmias, cardiac arrest, etc.

e. Monitoring includes surgical services.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of unplanned return to OT.

ii. Percentage of re-scheduling of surgeries

iii. Percentage of cases where the organisation's procedure to prevent adverse events like wrong site, wrong patient and wrong surgery have been adhered to.

iv. Percentage of cases who received appropriate prophylactic antibiotics within the specified time frame.

Unplanned return to OT shall be captured only during the same admission.

Re-scheduling of patients includes cancellation and postponement (beyond four hours) of the surgery because of poor communication, inadequate preparation or inefficiency within the system.

Intraoperative change(s) in the surgical plan are captured.

Prophylactic antibiotics should be administered ideally within 30-60 minutes but certainly within two hours of the time of incision.

f. Monitoring includes use of blood and blood components.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of transfusion reactions.
ii. Percentage of wastage of blood and blood components.
iii. Percentage of blood component usage.
iv. Turnaround time for issue of blood and blood components.

Wastage includes blood components found unfit for use.

g. Monitoring includes infection control activities.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Catheter Associated Urinary Tract Infection rate.
ii. Ventilator Associated Pneumonia rate.
iii. Central line associated bloodstream infection rate.
iv. Surgical site infection rate.

In addition to capturing Ventilator Associated Pneumonia (VAP), hospital should make efforts to monitor Ventilator Associated Events (VAE). For definition of VAE, refer to glossary/CDC guidelines.

h. Monitoring includes review of mortality and morbidity indicators.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Mortality rate.
ii. Return to ICU within 48 hours.
iii. Return to the emergency department within 72 hours with similar presenting complaints.
iv. Re-intubation rate.

i. Monitoring includes clinical research.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of research activities approved by ethics committee.
ii. Percentage of patients withdrawing from the study.
iii. Percentage of protocol violations/deviations reported.
iv. Percentage of serious adverse events (which have occurred in the organisation) reported to the ethics committee within the defined time frame.

The organisation shall keep a track of number of research protocols submitted to the ethics committee and the number of protocols approved (including protocols approved after clarifications).

Refer to ICMR guidelines and GCP for reporting time of serious adverse events.

This includes consent forms and patient information sheet.

j. Monitoring includes patient safety goals.

Interpretation: The organisation shall monitor the following patient safety indicators.

i. Incidence of Communication errors including handovers
ii. Incidence of Patient identification errors
iii. Compliance to Hand hygiene practice
iv. Compliance rate to medication prescription in capitals

Other patient safety indicators based on the international / national patient safety goals may also be identified and monitored based on an internal prioritization in the organisation.

k. The organisation identifies and monitors priority aspects of patient care.

Interpretation: The organisation may choose to monitor other clinical indicators in relation to key steps in the evaluation of common disorders, treatment protocols and outcomes. A minimum of four such indicators shall be monitored. These indicators are based on available literature or created in accordance to

good practice. Eg Compliance in ordering antiplatelet agent to MI patients at discharge, door to first dose of antibiotic in patient admitted with septic shock, Timely Cessation of antibiotics for surgical patients, Caesarean section rate, pain relief following intervention, etc.

Standard

CQI.4.	**The organisation identifies key indicators to monitor the managerial structures, processes and outcomes, which are used as tools for continual improvement.**

Objective Elements

a. Monitoring includes procurement of medication essential to meet patient needs.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of drugs and consumables procured by local purchase.

ii. Percentage of stock outs including emergency drugs.

iii. Percentage of drugs and consumables rejected before preparation of goods receipt note.

iv. Percentage of variations from the procurement process.

Local purchase implies drugs and consumables purchased outside the formulary/inventory.

b. Monitoring includes risk management.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Number of variations observed in mock drills.

ii. Incidence of falls.

iii. Incidence of hospital associated pressure ulcer after admission.

iv. Percentage of staff provided pre-exposure prophylaxis.

Mock drills include fire, non-fire and disaster management. Refer to glossary for definition of "risk management".

c. Monitoring includes utilisation of space, manpower and equipment.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Bed occupancy rate and average length of stay.
ii. OT and ICU utilisation rate.
iii. Critical equipment down time.
iv. Nurse-patient ratio for ICUs and wards.

Any equipment the failure of which could impede patient care shall be considered critical. Some examples are ventilators, cardiac monitors and pulse-oximeter. However, every organisation shall identify its list of critical equipment and accordingly capture the indicator. The downtime has to be captured irrespective of whether it has a backup or not.

d. Monitoring includes patient satisfaction which also incorporates waiting time for services.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Out-patient satisfaction index.
ii. In-patient satisfaction index.
iii. Waiting time for services including diagnostics and out-patient consultation.
iv. Time taken for discharge

Waiting time implies the time taken from the time that the patient registers to the time taken for assessment to be done by the doctor/ diagnostic procedure to be performed.

Time taken for discharge implies the time from which the doctor writes for discharge to the time for final clearance.

e. Monitoring includes employee satisfaction.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Employee satisfaction index.
ii. Employee attrition rate.
iii. Employee absenteeism rate.
iv. Percentage of employees who are aware of employee rights, responsibilities and welfare schemes.

f. Monitoring includes adverse events and near misses.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of sentinel events reported, collected and analysed within the defined time frame.
ii. Percentage of near misses.
iii. Incidence of blood body fluid exposures.
iv. Incidence of needle stick injuries.

g. Monitoring includes availability and content of medical records.

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

i. Percentage of medical records not having discharge summary.
ii. Percentage of medical records not having codification as per International Classification of Diseases (ICD).
iii. Percentage of medical records having incomplete and/or improper consent.
iv. Percentage of missing records.

Missing records include records within the retention time only.

h. The organisation identifies and monitors priority managerial activities in the organisation.

Interpretation: The organisation may choose to monitor other indicators in relation to common or important activities. A minimum of four indicators shall be monitored. These indicators are based on available literature or created in

accordance to good practice. Turnaround time (TAT) for dispensing medication, non-availability of consultants when on call, timely refilling of fire extinguishers, etc.

Standard

CQI.5.	**There is a mechanism for validation and analysis of quality indicators to facilitate quality improvement.**

Objective Elements

a. There is a mechanism for validation of data.

Interpretation: The data which is collected is validated from time to time and in response to queries or when an unexplained trend occurs, etc.

b. There is a mechanism for analysis of data which results in identifying opportunities for improvement.

Interpretation: Self-explanatory.

c. The opportunities for improvement are implemented and evaluated.

Interpretation: All improvement activities carried out by the organisation shall have an evaluable outcome. The same shall be captured.

d. The organisation uses appropriate quality improvement, statistical and management tools in its quality improvement programme.

Interpretation: Wherever possible the appropriate principles and methodology are used. For e.g. Root Cause Analysis, FMEA, Project Evaluation and Review Technique (PERT), Critical Path Method (CPM), Control Charts, Seven tools of quality etc.

e. Feedback about care and service is communicated to staff.

Interpretation: At a minimum, patient satisfaction levels shall be communicated on a monthly basis. This could be done using internal communication.

It is equally important that positive feedback about care and service is communicated to staff.

Standard

CQI.6.	**The quality improvement programme is supported by the management.**

Objective Elements

a. The leaders at all levels in the organisation are aware of the intent of the quality improvement program and the approach to its implementation.

The organisation and departmental leaders are aware of the quality improvement program, its intent and applicability to the respective areas and how it contributes to the organisation as a whole.

b. The management makes available adequate resources required for quality improvement programme.

Interpretation: This shall include the men, material, machine, money and method. These should be in steady supply so as to ensure that the programme functions smoothly.

c. Organisation earmarks adequate funds from its annual budget in this regard.

Interpretation: Appropriate fund allocation is done by the organisation for the smooth functioning of the programme. The budget could be earmarked based on previous year's spending. The next year's budget is discussed and noted in the quality core committee and by the top management. If no data is available the organisation could make a beginning by earmarking a budget but reviewing it at the end of six months to make any necessary modifications.

d. The management identifies organisational performance improvement targets.

Interpretation: The management shall identify organisation and department level quality objectives, set targets, monitor them (at least once in three months)

and modify the target (at least annually).The targets should be shared with the faculty and staff and regular feedback taken.

Standard

CQI.7.	**There is an established system for clinical audit.**

Objective Elements

a. Medical and nursing staff participates in this system.

Interpretation: The organisation shall identify such personnel. It could be a mix of clinicians, administrators and nurses. These could be members of the core committee/quality assurance committee, etc.

b. The parameters to be audited are defined by the organisation.

Interpretation: The organisation shall identify and work on at least four clinical audits in identified priority patient care aspects. As these audits are retrospective/concurrent in nature, it is imperative that this be done using predefined parameters so that there is no bias. The parameters could be disease based, cost based, community based or based on morbidity (length of stay). It shall lay down the objectives, the parameters that are going to be captured, develop a checklist where required, sampling and data collection guidelines and preparation of report.

The audit shall encompass all aspects of clinical and nursing care. .

c. Patient and staff anonymity is maintained.

Interpretation: This means that the names of the patients and the hospital staff who may figure in the audit documents must not be disclosed nor any reference be made to them in public discussions/conferences. This is at the stage of report preparation and dissemination. The staff participating in the audit shall maintain patient and staff anonymity and not reveal names.

d. All audits are documented.

Interpretation: The organisation could use a checklist with the predefined parameters and the audit findings could be recorded on this sheet.

e. Remedial measures are implemented.

Interpretation: All remedial measures as ascertained should be documented and implemented and improvements thereof recorded to complete the audit cycle. This should preferably be done based on root-cause analysis.

Standard

CQI.8.	**Incidents are collected and analysed to ensure continual quality improvement.**

Objective Elements

a. The organisation has an incident reporting system. *

Interpretation: The incident reporting system includes:

i. identification
ii. reporting
iii. review
iv. action on incidents

While capturing the organisation shall capture all incidents without going into the severity or whether harm was caused.

b. The organisation has established processes for analysis of incidents.

Interpretation: The quality improvement committee (refer to CQI 1a) shall be responsible for this activity. This could preferably be done by identifying the root cause. Where possible, it is preferable that patients and other stakeholders be included in analysing the feedback and complaint.

c. Corrective and preventive actions are taken based on the findings of such analysis.

Interpretation: The objective of this is to continually improve the quality of patient-care services. All such action shall be documented.

d. The organisation shall have a process for informing various stakeholders in case of a near miss / adverse event.

Interpretation: After due analysis an incident could be termed as a near miss or adverse event. Based on the nature of the near miss or adverse event the organisation shall inform the stakeholders regarding the relevant concerns in addition to initiating the corrective and preventive action.

Standard

CQI.9.	**Sentinel events are intensively analysed.**

Objective Elements

a. The organisation has defined sentinel events. *

Interpretation: The sentinel events relating to system or process deficiencies that are relevant and important to the organisation must be clearly defined.

The list of the identified and relevant sentinel events shall be documented.

Refer to glossary for definition of "sentinel events".

b. The organisation has established processes for intense analysis of such events.

Interpretation: The established processes should include reporting the occurrence of such events on standardised incident report forms.

c. Sentinel events are intensively analysed when they occur.

Interpretation: Root-cause analysis of all such events should be carried out by a multi-disciplinary committee taking inputs from the units/ discipline/departments concerned. All sentinel events shall be analysed within 24-working hours of occurrence.

d. Corrective and preventive actions are taken based on the findings of such analysis.

Interpretation: The findings and recommendations arrived at after the analysis should be communicated to all personnel concerned to correct the systems and processes to prevent recurrences. Any change in the policy or procedure is reflected as an amendment in the organisation's documentation.

Chapter 7
Responsibilities of Management (ROM)

Intent of the chapter:

The standards encourage the governance of the organisation in a professional and ethical manner. The responsibilities of the management are defined. The organisation complies with all applicable regulations. The organisation is led by a suitably qualified and experienced individual .The responsibilities of the leaders at all levels are defined. The services provided by each department are documented.

Leaders ensure that patient-safety and risk-management issues are an integral part of patient care and hospital management.

Summary of Standards

ROM 1:	The responsibilities of those responsible for governance are defined.
ROM 2:	The organisation is responsible for and complies with the laid-down and applicable legislations, regulations and notifications.
ROM 3:	The services provided by each department are documented.
ROM 4:	The organisation is managed by the leaders in an ethical manner.
ROM 5:	The organisation displays professionalism in management of affairs.
ROM 6:	Management ensures that patient-safety aspects and risk-management issues are an integral part of patient care and hospital management.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

ROM.1.	**The responsibilities of those responsible for governance are defined.**

Objective Elements

a. Those responsible for governance lay down the organisation's vision, mission and values. *

Interpretation: The organisation shall enunciate its vision, mission and values through an authorized document. It is not only the head of the organisation but the members of the board of governors (where applicable) who need to define it. For definition of "mission", "vision" and "values" refer to glossary.

b. Those responsible for governance approve the strategic and operational plans and organisation's annual budget

Interpretation: Self-explanatory. Refer to glossary for "strategic and operational plans".

c. Those responsible for governance monitor and measure the performance of the organisation against the stated mission.

Interpretation: The governing board and the head of the organisation shall develop quarterly (at least) performance reports based on the strategic and operational plans. Performance shall be discussed in management review meeting and action items are regularly followed up.

d. Those responsible for governance establish the organisation's organogram. *

Interpretation: The organisation shall have a well-defined organisation structure/chart and this shall clearly document the hierarchy, line of control, along with the functions at various levels. Organogram is transparent and is

disseminated to all stakeholders. The organogram shall also incorporate various committees

e. Those responsible for governance appoint the senior leaders in the organisation.

Interpretation: Senior leaders include the first two rungs of the organogram.

f. Those responsible for governance support safety initiatives and quality-improvement plans.

Interpretation: All risk assessment and risk reduction is known and measures to reduce are discussed for corrective actions. Reports of the safety and quality improvement committee's discussions are shared and funds and resources allocated for corrective and preventive action.

g. Those responsible for governance support research activities.

Interpretation: Support in research shall include providing resource, budget, following ethical and legal norms.

h. Those responsible for governance address the organisation's social responsibility.

Interpretation: The governing board and head of the organisation shall willfully develop social responsibility policy and accordingly address it. For example, free camps, outreach programmes, adoption of villages, PHCs, etc. The organisation should be aware of the national public health programs and supports the same based on its scope of services and statutory obligations.

i. Those responsible for governance inform the public of the quality and performance of services.

Interpretation: This could be done in the form of displays or brochures or on the website. This could include results of surveys done by independent third parties and results of benchmarking done by professional bodies.

Standards

ROM.2.	**The organisation is responsible for and complies with the laid-down and applicable legislations, regulations and notifications.**

Objective Elements

a. The management is conversant with the applicable laws and regulations and undertakes the responsibility to adhere to the same.

Interpretation: The management of the hospital is conversant with the different statutory requirements as per the scope of services and ensures to adhere to the same. The hospital conducts its functioning as a duly permitted legal entity in accordance with the relevant registering authority(s). The Head of the hospital gives an undertaking in a standardised format that he/she is conversant with the applicable laws and regulations and has adhered to the same.

b. The management ensures that the policies and procedures pertaining to patient care are in compliance with the prevailing laws, regulations and notifications.

Interpretation: These include implementation and adherence to the requirements related to Biomedical waste management rules, AERB requirements, PCPNDT Act , MTP Act, Drug And Cosmetic Act and Narcotics Drugs and Psychotropic Substances Act, Blood bank requirements and Transplantation of Human Organs and Tissues Rules, Code of Medical Ethics, etc.

Examples of notifications: guidelines and protocols for medico legal care of victims/survivors of Sexual Violence. (MoHFW)

c. The management has a mechanism which ensures implementation of these requirements.

Interpretation: A designated management functionary could be given the responsibility to enlist the laws and regulation as applicable to the organisation. This functionary in turn could identify the appropriate personnel in the

organisation who are supposed to implement the respective laws and regulations.

d. Management has a mechanism which regularly updates any amendments in the prevailing laws of the land.

Interpretation: Self-explanatory.

e. There is a mechanism to regularly update licenses/registrations/certifications.

Interpretation: For example, license for Pharmacy, Narcotics, Clinical establishment act (where applicable), etc.

The organisation could develop a tracker sheet for this purpose. Applications to update these statutory documents must be made in accordance with the timelines set out in the relevant laws/registration authority requirements so as to ensure continuity of statutory compliances..

Standards

ROM.3.	**The services provided by each department are documented.**

Objective Elements

a. Scope of services of each department is defined. *

Interpretation: Each department's activity is to be predefined. This could be documented either at individual department level or the organisation could have a brochure detailing the scope of each department. This includes clinical and non-clinical departments. For example, nephrology department could do all activities like biopsy, shunts, fistulas, dialysis (hemodialysis and CAPD), etc.

b. Administrative policies and procedures for each department are maintained. *

Interpretation: This shall include all administrative procedures like attendance, leave, conduct, replacement, etc. This shall be documented. It could be common for the entire organisation.

c. Each organisational programme, service, site or department has effective leadership.

Interpretation: There needs to be a minimum essential qualification and/or relevant experience of the leader. The leader should have domain knowledge of that particular department.

d. Departmental leaders are involved in quality improvement.

Interpretation: To effectively implement this, each department could have its department objectives/key performance indicators and the responsibility of achieving them could be that of the leader / designated person.

Standards

ROM.4.	**The organisation is managed by the leaders in an ethical manner.**

Objective Elements

a. The leaders make public the vision, mission and values of the organisation.

Interpretation: This shall be done by displaying the same prominently. For definition of "mission", “vision” and “values” refer to glossary. Only a display on its website would not be appropriate. It is preferable that the same be translated and displayed in the local language also.

b. The leaders establish the organisation’s ethical management. *

Interpretation: The organisation shall function in an ethical manner.

Transparency in its actions shall be one of its guiding principles. Handling of complaints, grievances, clinical care delivery and research shall be some of the areas to address. A good reference guide is "Code of medical ethics-2002" published by MCI. The organisation’s established ethical management shall be documented.

c. The organisation discloses its ownership.

Interpretation: The ownership of the hospital, e.g. trust, private, public has to be disclosed. The disclosure could be in the registration certificate/quality manual, etc.

d. The organisation honestly portrays the services which it can and cannot provide.

Interpretation: Documentation with respect of service non-availability and its communication to patients is maintained. The word 'portrays' implies that the organisation conveys to the patients clearly what it can and cannot provide. The services that it cannot provide could also be conveyed verbally.

e. The organisation honestly portrays its affiliations and accreditations.

Interpretation: Here implies that the organisation convey is affiliations, accreditations for specific departments or whole hospital wherever applicable.

f. The organisation accurately bills for its services based upon a standard billing tariff.

Interpretation: This essentially means that the organisation does not charge differentially from different patients in the same bed category for the same surgery or procedure.

Standard

ROM.5.	**The organisation displays professionalism in management of affairs.**

Objective elements

a. The person heading the organisation has requisite and appropriate administrative qualifications.

Interpretation: This implies to the individual looking after the day-to-day operations and not to the chairman of the Board of Governors. Appropriate implies qualification in hospital management/administration.

b. The person heading the organisation has requisite and appropriate administrative experience.

Interpretation: Self-explanatory. Appropriate implies administrative experience in a hospital.

c. The organisation prepares the strategic and operational plans including long-term and short-term goals commensurate to the organisation's vision, mission and values in consultation with the various stakeholders.

Interpretation: The leader(s) shall define and develop the process for strategic and operation plans so as to achieve the organisational vision and mission statement and adhere to the values. It shall be discussed with all stakeholders. Some of the inputs that should be considered while finalising these plans shall be the findings of the risk management plan, patient safety goals and results of facility rounds. This shall at least be done on an annual basis. Refer to glossary for "strategic and operational plans". Stakeholders include the community the organisation serves.

d. The organisation coordinates the functioning with departments and external agencies, and monitors the progress in achieving the defined goals and objectives.

Interpretation: The reasons for not achieving any particular goal shall be analysed and appropriate action shall be taken. This could be done through management review meetings.

e. The organisation plans and budgets for its activities annually.

Interpretation: Adequate budget shall also be allocated for infection control and quality-improvement activities. This could be either done on a calendar year basis or financial year (April-March) basis.

f. The performance of the senior leaders is reviewed for their effectiveness.

Interpretation: Key result areas of each leader can be established or it can be done through performance appraisal. This shall be done by those responsible for governance.

g. The functioning of committees is reviewed for their effectiveness.

Interpretation: This shall be done by the management. The review of the functioning shall include if the purpose of having the committee is being met, if the committee is meeting at the prescribed frequency and if the committee is suggesting remedial measures and if there is adequate monitoring of the corrective and preventive action suggested by the committee by way of risk mitigation within the scope of the particular committee. For an effective review, it is preferable that the organisation documents the scope of every committee, the roles and responsibilities assigned to various members and the frequency of meetings. Agenda shall be prepared for all meetings and documentation of each committee meeting is kept.

h. The organisation documents employee rights and responsibilities. *

Interpretation: The organisation shall define the same in consonance with statutory requirements.

i. The organisation documents the service standards. *

Interpretation: The organisation shall develop benchmarks for different services being provided. This could be based on the organisation's mission, vision and values. This could also include soft skills, behaviour, attitude, communication skills, etc.

j. The organisation has a formal documented agreement for all outsourced services.

Interpretation: The agreement shall specify the service parameters. Even if a sister concern is providing services, there shall be an agreement with that unit.

k. The organisation monitors the quality of the outsourced services.

Interpretation: The frequency of monitoring shall be determined by the organisation but shall not be less than once year. This shall be done keeping in mind the criticality of that service towards providing patient care. It is preferable that the monitoring be done as per the service standards laid down by the organisation.

Standard

ROM.6.	**Management ensures that patient-safety aspects and risk-management issues are an integral part of patient care and hospital management.**

Objective elements

a. Management ensures proactive risk management across the organisation.

Interpretation: This shall include clinical and non-clinical (strategic, financial, operational and hazard) risks. It shall include risk identification, prioritisation and risk alleviation. This shall be documented as a “risk management plan”. It shall include the various risks identified, the action taken for risk alleviation of each of these risks and the mechanism for informing staff regarding the same.

Further, the risk management plan shall be monitored and reviewed for continued effectiveness at least annually. The results of the review shall be communicated to the relevant stakeholders in the organisation. This could be done using a matrix.

Clinical-risk assessment could include:

i. Medication management, covering issues such as patient/service-user allergies and antibiotic resistance,

ii. Equipment risks, e.g. fire/injury risks from use of laser, and

iii. Risks resulting from long-term conditions.

b. Management provides resources for proactive risk assessment and risk-reduction activities.

Interpretation: There shall be sufficient resources kept as contingency to address the risk reduction activities as and when the leaders proactively suggest. The end-result of these shall result in preventive actions. Refer to glossary for definition of “risk assessment” and “risk reduction”.

c. Management ensures implementation of systems for internal and external reporting of system and process failures. *

Interpretation: The organisation has a system in place for internal and external reporting of system and process failures. Contingency plan shall be in place to deal with the situation of system and process failure anticipated within the organisation. For example, MRI machine of the organisation breaks down. In this case internal reporting is to be done to head of the organisation and external reporting to be done to the patients. E.g., in case of a radiation source, external agency reporting is to AERB. In case of fire incidents, strong internal and external reporting systems are required. The system for reporting shall be documented.

d. Management ensures that appropriate corrective and preventive actions are taken to address safety-related incidents.

Interpretation: This shall be taken after an analysis. The analysis could be done by the safety committee and preferably a root-cause must be identified.

Chapter 8
Facility Management and Safety (FMS)

Intent of the chapter:

The standards guide the provision of a safe and secure environment for patients, their families, staff and visitors. The organisation shall take steps to ensure this, including proactive risk mitigations.

To ensure this, the organisation conducts regular facility inspection rounds and takes the appropriate action to ensure safety.

The organisation provides for safe water, electricity, medical gases and vacuum systems.

The organisation has a programme for medical and utility equipment management.

The organisation plans for emergencies within the facilities.

The organisation is a no-smoking area and manages hazardous materials in a safe manner.

The organisation works towards measures on being energy efficient.

Summary of Standards

FMS 1:	The organisation has a system in place to provide a safe and secure environment.
FMS 2:	The organisation's environment and facilities operate in a planned manner to ensure safety of patients, their families, staff and visitors and promotes environment friendly measures.
FMS 3:	The organisation has a programme for engineering support services and utility system.
FMS 4:	The organisation has a programme for bio-medical equipment management.
FMS 5:	The organisation has a programme for medical gases, vacuum and compressed air.
FMS 6:	The organisation has plans for fire and non-fire emergencies within the facilities.
FMS 7:	The organisation has a plan for management of hazardous materials.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

FMS.1.	**The organisation has a system in place to provide a safe and secure environment.**

Objective Elements

a. Safety committee coordinates development, implementation and monitoring of the safety plan and policies.

Interpretation: The organisation ensures that the above committee functions on a regular basis to coordinate development, implementation and monitoring of the safety plans and policies so as to provide a safe and secure facility and environment. The plans are fully implemented and there is a process for periodic review of plans. The safety committee must include representatives from facility management, clinicians, administrator, nursing and paramedical staff. These individuals function as patient safety and/ or facility safety officers respectively. It is preferable that the organisation conducts an exercise of Hazard Identification and Risk Analysis (HIRA) in both clinical & non clinical area and accordingly takes all necessary steps to eliminate or reduce such hazards and associated risks.

b. Patient-safety devices & infrastructure are installed across the organisation and inspected periodically.

Interpretation: For example, grab bars, bed rails, sign posting, safety belts on stretchers and wheel chairs, alarms both visual and auditory where applicable, warning signs like radiation or biohazard, call bells, fire-safety devices, etc. Provisions are made available for physically challenged/vulnerable person as per regulatory requirement example special toilet for physically challenged.

c. The organisation is a non-smoking area.

Interpretation: The organisation shall adhere to statutory requirements.

d. There is a procedure which addresses the identification and disposal of material(s) not in use in the organisation. *

Interpretation: Organisation shall condemn and dispose in a systematic manner the material which is not in usage such as non-functioning items, excess unwanted material, general waste, scrap material etc.

e. Facility inspection rounds to ensure safety are conducted at least twice in a year in patient-care areas and at least once in a year in non-patient-care areas.

Interpretation: Rounds to be carried out by members of safety committee. The organisation plans and budgets for upgrading or replacing key systems, buildings, or components based on the facility inspection, in keeping with laws and regulations. During these rounds potential safety risks are identified. This could be carried out using a checklist incorporating some of the more common safety hazards. The potential security risk areas and restricted areas are identified & methodology is worked out to monitor and secure identified areas.

f. Inspection reports are documented and corrective and preventive measures are undertaken.

Interpretation: The inspection report tracker to be maintained & reviewed periodically. Evidences of pre and post corrective actions are maintained at least for one accreditation cycle.

g. There is a safety education programme for staff.

Interpretation: This is to be included as part of employee induction & refresher training programme. This should include training on fire safety, occupational safety, radiation safety, laboratory safety and others as applicable as per the scope of services of the organisation.

Standard

FMS.2.	**The organisation's environment and facilities operate in a planned manner to ensure safety of patients, their families, staff and visitors and promotes environment friendly measures.**

Objective Elements

a. Facilities are appropriate to the scope of services of the organisation.

Interpretation: The basis of appropriateness will be the best practices/ national /international guidelines.

b. Up-to-date drawings are maintained which detail the site layout, floor plans and fire-escape routes.

Interpretation: A designated person maintains the drawings. In addition to fire-evacuation plans, it is preferable that separate civil, electrical, plumbing, HVAC and piped medical gas drawings are maintained.

c. There is internal and external sign postings in the organisation in a language understood by the patient, families and community.

Interpretation: Fire signage should follow the norms laid down by National Building Code and/or respective statutory body (for example, fire service). These signage shall guide patients and visitors. It is preferable that signage are bi-lingual. Statutory requirements shall be met.

d. The provision of space shall be in accordance with the available literature on good practices (Indian or international standards) and directives from government agencies.

Interpretation: For example, IPHS standards and various international standards, directive of government agencies like AERB guidelines for Radiation equipment, etc.

e. Operational planning describes access to different areas in the hospital by staff, patients, visitors and vendors.

Interpretation: There is a process and means to identify staff, visitors, vendors in the hospital. Access to different areas in the hospital by staff, visitors and vendors is controlled as per the organisation's policy.

f. Potable water and electricity are available round the clock.

Interpretation: The organisation shall make arrangements for supply of adequate potable water and electricity. The potable water quality is monitored quarterly or more frequently and documented. For water quality, refer to IS 10500.

g. Alternate sources for electricity and water are provided as backup for any failure/shortage.

Interpretation; At the outset, the organisation shall ensure that there is sufficient water supply to meet the requirements. Further, the electric load applied for shall be appropriate to the requirements of the organisation and adhere to the regulatory requirements. In case of a shortfall in water or electricity, alternate sources shall be arranged. A good reference for estimating the water requirement is the National Building Code. Alternate electric supply could be from DG sets, solar energy, UPS and any other suitable source. The organisation could consider having multiple alternate sources depending on the criticality of the activity. The organisation identifies & mitigates the risk of critical areas/services during electrical supply failure or when water is contaminated or interrupted. In case of electrical supply through alternate sources (Diesel generator or uninterrupted power supply), the capacity & longevity of power availability based on usage is considered.

h. The organisation regularly tests these alternate sources.

Interpretation: The results of these tests shall be documented. In case of water, the testing includes bio-chemical and microbiological analysis.

i. There are designated individuals (with appropriate equipment) responsible for the maintenance of all the facilities.

Interpretation: A person in the organisation is designated to be in-charge of maintenance of facilities. The organisation has the required number of supervisors and tradesmen to manage the facilities. The necessary infrastructure and tools are available like ladder, voltmeter, spanner and relevant PPE norms like safety boots, gloves by DG operator are properly followed. The person could be qualified by experience or training.

j. Maintenance staff is contactable round the clock for emergency repairs.

Interpretation: The maintenance escalation matrix (if emergency repair is not possible by staff on duty, more qualified/experienced staff should be available) is available in nursing station and other departments.

k. There is a maintenance plan for facility and furniture. *

Interpretation: This shall include civil work like wall, floor and roof etc, fixed furniture like nurse station, shoe racks etc loose furniture like emergency cart, chairs and trolleys. This shall adhere to manufacturer's recommendations, good infection-control practice requirement, etc. This includes regular inspections, timely repair of civil structure like walls, servicing of furniture etc.

l. Response times are monitored from reporting to inspection and implementation of corrective actions.

Interpretation: A complaint attendance register is to be maintained (physical or electronic) to indicate the date and time of receipt of complaint, allotment of job and completion of job. Completion of the job should always be ratified by the user department.

m. The organisation takes initiatives towards an energy efficient and environmental friendly hospital. *

Interpretation: This includes using the concepts of reduce, recycle and reuse in promoting the basic concepts of green hospital. eg: energy efficient lighting in a phased manner, rain water harvesting, increase usage of solar power, recycling where possible.

Standard

FMS.3.	**The organisation has a programme for engineering support services and utility system.**

Objective Elements

a. The organisation plans for equipment in accordance with its services and strategic plan.

Interpretation: This shall also take into consideration future requirements like DG set, Chiller plant. The plans should be fully implemented and there should be a process for periodic review of plans.

b. Equipment are selected, rented, updated or upgraded by a collaborative process.

Interpretation: Collaborative process implies that during equipment selection there is involvement of end-user, management, finance and engineering departments.

c. Equipment are inventoried and proper logs are maintained as required.

Interpretation: A unique identification is provided to each equipment. Where applicable, the relevant quality conformance certificates/marks along with manufacturer factory test certificate need to be retained as part of documentation.

d. Qualified and trained personnel operate, inspect, test and maintain equipment and utility systems.

Interpretation: The necessary inventories like bulbs, paints are held by engineering team. The person could be qualified by experience or training.

e. Utility equipment are periodically inspected and calibrated (wherever applicable) for their proper functioning.

Interpretation: For example, pressure gauges of steam steriliser, temperature gauges of medication refrigerators. The organisation either calibrates the utility equipment in-house or outsources, maintaining traceability to national or international or manufacturer's guidelines/standards.

f. There is a documented operational and maintenance (preventive and breakdown) plan. *

Interpretation: The operator is trained in handling the equipment. The operational plan must assist the operator in operating the equipment on a daily basis. The original equipment manual is a good source for this. In case this is not available the organisation shall develop the operational plan for the concerned equipment. The maintenance plan should consider manufacture's recommendations, risk level & past maintenance history. There shall be a planned preventive maintenance tracker.

This shall include utility equipment like steam steriliser, DG set.

g. There is a maintenance plan for water management. *

Interpretation: This shall also include cleaning of water storage tanks at regular intervals and treating of water, where appropriate. It shall also include an RO unit and STP in case it is available in the organisation. In case of an RO plant of dialysis unit, the water shall be tested for endotoxin levels every month to ensure that levels should conform to national and/or international guidelines. The regular checking of pH, TDS, hardness etc. are included in this plan.

h. There is a maintenance plan for electrical systems. *

Interpretation: This shall incorporate statutory requirements where applicable. Transformers, LT and/or HT panel maintenance shall also be included. All lifts shall be included in this maintenance plan.

i. There is a maintenance plan for heating, ventilation and air-conditioning. *

Interpretation: This shall include chiller unit, AHU, FCU and various air-conditioners. This shall adhere to manufacturer's recommendations and good infection-control practice requirement. This includes timely cleaning and/or replacement of filters.

j. There is a maintenance plan for Information technology & communication network *

Interpretation: This shall include Data Server units, telephone exchange units, computers, telephone lines, nurse call system etc. This shall adhere to manufacturer's recommendations, regular inspections etc. This includes timely repair of telephone, printer unit.

k. There is a documented procedure for equipment replacement and disposal. *

Interpretation: The organisation shall plan for this keeping in mind the strategic plans, upgrade/update path and the equipment log. Organisation shall dispose (condemn) unusable equipment and other engineering waste material in a systematic manner. All records pertaining to condemnation of equipment shall be maintained.

Standard

FMS.4.	**The organisation has a programme for bio-medical equipment management.**

Objective Elements

a. The organisation plans for equipment in accordance with its services and strategic plan.

Interpretation: This shall also take into consideration future requirements.

The equipment shall be appropriate to its scope of services. A good reference for minimum equipment is the IPHS guideline.

b. Equipment are selected, rented, updated or upgraded by a collaborative process.

Interpretation: Collaborative process implies that during equipment selection there is involvement of end-user, management, finance, engineering and bio-medical departments. The organisation could define differential financial clearance in accordance with the policy. For example, purchase of BP apparatus can be done by the departmental head.

c. Equipment are inventoried and proper logs are maintained as required.

Interpretation: A unique identifier is provided for each equipment.

This includes equipment on a rental basis and equipment kept for demonstration purpose. The relevant quality conformance certificates/marks along with manufacturer factory test certificate needs to be retained as part of documentation for all equipment.

d. Qualified and trained personnel operate and maintain the medical equipment.

Interpretation: The operator of the medical equipment is trained to use medical equipment in safe and effective manner. Eg: Nurse trained to use Blood gas analyser, ECG machine and syringe pump etc.

Maintenance of bio-medical equipment shall be done by a bio-medical engineer/technician or instrumentation engineer/technician with relevant training and experience.

e. Equipment are periodically inspected and calibrated for their proper functioning.

Interpretation: The organisation has weekly/monthly/annual schedules of inspection and calibration of equipment, which involve measurement, in an appropriate manner. The organisation either calibrates the equipment in-house or outsources, maintaining traceability to national or international or manufacturer's guidelines/standards. The organisation shall ensure that calibration and conformance testing of the equipment has been done prior to commissioning.

f. There is a documented operational and maintenance (preventive and breakdown) plan for equipment. *

Interpretation: The operator is trained in handling the equipment. The operational plan must assist the operator in operating the equipment on a daily basis. The original equipment manual is a good source for this. In case this is not available the organisation shall develop the operational plan for the concerned equipment. The operational plan of medical equipment includes evaluation of safe usage of equipment like validation with respect to instruction manual, user training on equipment, operational check of equipment and verification of set parameter .The maintenance plan includes periodic checks, execution of timely preventive maintenance, and response to any breakdown issues including at night & weekends. There shall be a planned preventive maintenance tracker.

g. There is a documented procedure for equipment replacement and disposal. *

Interpretation: The organisation shall plan for this keeping in mind the strategic plans, upgrade/update path and the equipment log. Organisation shall condemn (dispose) equipment in a systematic manner.

h. The procedure addresses medical equipment recalls. *

Interpretation: Recalls are on based on letters/hazard notice issued from manufacturer and or from regulatory authorities. This may not be a routine occurrence but whenever hospital authorities receive or become aware of such recalls, it should be immediately acted upon and the said medical equipment should not be put into further clinical use till the issue is resolved.

i. Response times are monitored from reporting to inspection and implementation of corrective actions.

Interpretation: A complaint attendance register is to be maintained (physical or electronic) to indicate the date and time of receipt of complaint, allotment of job and completion of job. Completion of the job should always be ratified by the user department.

Standard

FMS.5.	**The organisation has a programme for medical gases, vacuum and compressed air.**

Objective Elements

a. Documented procedures govern procurement, handling, storage, distribution, usage and replenishment of medical gases. *

Interpretation: This shall be applicable to all gases used in the organisation. It shall also address the issue of statutory requirements and approvals wherever applicable. It shall follow a uniform colour coding system. A good reference is HTM 02-01 or NFPA's Medical Gas and Vacuum Systems Installation Handbook (NFPA's new NFPA 99C solution). Proper signage is kept for used, full, empty cylinders. The organisation shall adhere to statutory requirements under the provisions of Indian Explosives Act, Gas Cylinder rules and Static and Mobile Pressure Vessel (unfired) rules.

b. Medical gases are handled, stored, distributed and used in a safe manner.

Interpretation: Standardised colour coding of the cylinders and pipelines should be maintained. A good reference for medical gas systems are HTM 02-01, ISO 7396-1:2007 (Medical gas pipeline systems -- Part 1: Pipeline systems for compressed medical gases and vacuum), ISO 7396-2:2007 (Medical gas pipeline systems -- Part 2: Anaesthetic gas scavenging disposal systems), ISO 9170-1:2008 (Terminal units for medical gas pipeline systems -- Part 1: Terminal units for use with compressed medical gases and vacuum), ISO 9170-2:2008 (Terminal units for medical gas pipeline systems -- Part 2: Terminal units for anaesthetic gas scavenging systems), ISO 10083:2006 (Oxygen concentrator supply systems for use with medical gas pipeline systems), ISO 10524- Part 1 to 4 (Pressure regulators for use with medical gases), ISO 11197:2004 (Medical supply units), ISO 15002:2008 (Flow-metering devices for connection to terminal units of medical gas pipeline systems).It is mandatory that compressed air purity be checked (at the level of terminal outlet) once in a year atleast in one terminal from OT and ICU.

c. The procedures for medical gases address the safety issues at all levels.

Interpretation: This shall include from the point of storage/source area, gas supply lines and the end-user area. Appropriate safety measures shall be developed and implemented for all levels. This shall include alarm units and valve boxes installation at various locations and 24X7 monitoring of plant alarm unit for gas pressure going beyond the set limit, pin-indexed medical gas outlets, auto-change over from one source to alternate source.

d. Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.

Interpretation: In case of air compressor and vacuum pump, it could be the stand by air compressor and vacuum pump unit. For medical gases it could be stand by gas manifold/bulk cylinders.

e. The organisation regularly tests these alternate sources.

Interpretation: The results of these tests shall be documented.

f. There is an operational, inspection, testing and maintenance plan for, piped medical gas, compressed air and vacuum installation. *

Interpretation: This shall adhere to manufacturer's recommendations.

Standard

FMS.6.	**The organisation has plans for fire and non-fire emergencies within the facilities.**

Objective Elements

a. The organisation has plans and provisions for early detection, abatement and containment of fire, and non-fire emergencies. *

Interpretation: The organisation shall:

i. have a fire plan covering fire arising out of burning of inflammable items, explosion, electric short circuiting or acts of negligence or due to incompetence of the staff on duty;

ii. deploy adequate and qualified personnel for this;

iii. acquire adequate fire fighting equipment for this and records are kept up-to-date;

iv. have adequate training plans;

v. have schedules for conduct of mock fire drills;

vi. maintain mock drill records;

vii. display exit plans well;

viii. have a dedicated emergency illumination system, which comes into effect in case of fire.

The organisation shall take care of non-fire emergency situations by identifying them and by deciding appropriate course of action. These may include:

i. terrorist attack,

ii. invasion of swarms of insects and pests,
iii. earthquake,
iv. invasion of stray animals,
v. hysteric fits of patients and/or relatives,
vi. civil disorders effecting the organisation,
vii. anti-social behaviour by patients/relatives,
viii. temperamental disorders of staff causing deterioration in patient care,
ix. Spillage of hazardous (acids, mercury, etc.), infected materials (used gloves, syringes, tubing, sharps, etc.) medical wastes (blood, pus, amniotic fluid, vomits, etc.),
x. building or structural collapse,
xi. fall or slips (from height or on floor) or collision of personnel in passageway,
xii. fall of patient from bed,
xiii. bursting of pipelines,
xiv. sudden flooding of areas like basements due to clogging in pipelines,
xv. sudden failure of supply of electricity, gas, vacuum, etc., and
xvi. bursting of boilers and/or autoclaves.

The organisation shall establish liaison with civil and police authorities and fire brigade as required by law for enlisting their help and support in case of an emergency. The National Building Code is a good reference guide.

b. The organisation has a documented safe-exit plan in case of fire and non-fire emergencies.

Interpretation: Fire-exit plan shall be displayed on each floor particularly close to the lifts. Exit doors should remain open all the time. The signage of fire exits shall be as per the National Building Code and/or respective statutory body (for example, fire service). Safe exit plans for non-fire emergencies are also incorporated.

c. Staff is trained for its role in case of such emergencies.

Interpretation: In case of fire, a designated person is assigned a particular work. The training shall include various classes of fire, information and demonstration on how to use a fire extinguisher and the procedure to be followed in case of fire and non-fire emergencies. Staff training also includes non-fire emergencies.

d. Mock drills are held at least twice a year.

Interpretation: This shall test all the components of the plan and not just awareness/ demonstration of practices. Simulated patients (not real) shall be used for evacuation. Mock drills are conducted atleast twice a year for fire and important non fire emergencies***.*** This is only the minimum frequency and this may be increased. At the conclusion of every mock drill, the variations are identified, reason for the same analysed, debriefing of the drill conducted and, where appropriate, the necessary corrective and/or preventive actions are taken.

e. There is a maintenance plan for fire-related equipment & infrastructure *

Interpretation: The plan should address inspection, testing, preventive & breakdown maintenance**.** This shall adhere to manufacturers and/or statutory recommendations.

Standard

FMS.7.	**The organisation has a plan for management of hazardous materials.**

Objective Elements

a. Hazardous materials are identified within the organisation. *

Interpretation: The organisation shall identify, list and document the hazardous materials and has a documented procedure for their sorting, storage, handling, transpirations, disposal mechanism, and method for managing spillages and adequate training of the personnel for these jobs. The hazardous materials could be identified as per part II of Manufacture, Storage and Import of Hazardous Chemical (Amendment) Rules, 2000.In addition, biological materials like blood,

body fluids and microbiological cultures, mercury, nuclear isotopes, medical gases, LPG gas, steam, ETO, etc., are some of the other common hazardous materials.

b. The organisation implements processes for sorting, labelling, handling, storage, transporting and disposal of hazardous material. *

Interpretation: The organisation shall conduct an exercise of hazard identification and risk analysis (HIRA) associated with handling of hazardous materials and accordingly taken all necessary steps to eliminate or reduce such hazards and associated risks. The organisation has ensured display of Material Safety Data Sheets (MSDS) for all hazardous materials and has accordingly arranged training of personnel who handle such materials. The situational hazards also need to be covered in HIRA so that any emergency situation arising out of process of storing, handling, storage, transportation and disposal of such hazardous materials are met effectively. The organisation has the requisite training need identification for material handling and those trainings are included in the organisation's training calendar.

c. Requisite regulatory requirements are met in respect of radioactive materials.

Interpretation: The appropriate personnel in the organisation are aware about the rules and regulations such as the Atomic Energy Act, the norms issued by Atomic Energy Regulatory Board (AERB) and the directives from the Health Physics Division of Bhaba Atomic Research Centre (BARC).

d. There is a plan for managing spills of hazardous materials. *

Interpretation: The organisation could have a HAZMAT kit(s) as part of PPE for handling spills.

e. Staff are educated and trained for handling such materials.

Interpretation: Self explanatory.

Chapter 9
Human Resource Management (HRM)

Intent of the chapter:

The most important resource of a hospital and healthcare system is the human resource. Human resources are an asset for effective and efficient functioning of a hospital. Without an equally effective human resource management system, all other inputs like technology, infrastructure and finances come to naught. Human resource management is concerned with the "people" dimension in management.

The goal of human resource management is to acquire, provide, retain and maintain competent people in right numbers to meet the needs of the patients and community served by the organisation. This is based on the organisation's mission, objectives, goals and scope of services. Effective human resource management involves the following processes and activities:-

(a) Acquisition of Human Resources which involves human resource planning, recruiting and socialisation of the new employees.
(b) Training and development relates to the performance in the present and future anticipated jobs. The employees are provided with opportunities to advance personally as well as professionally.
(c) Motivation relates to job design, performance appraisal and discipline.
(d) Maintenance relates to safety and health of the employees.

The term "employee" refers to all salaried personnel working in the organisation. The term "staff" refers to all personnel working in the organisation including employees, "fee for service" medical professionals, part-time workers, contractual personnel and volunteers.

Summary of Standards

HRM 1:	The organisation has a documented system of human resource planning.
HRM 2:	The organisation has a documented procedure for recruiting staff and orienting them to the organisation's environment.
HRM 3:	There is an ongoing programme for professional training and development of the staff.
HRM 4:	Staff are adequately trained on various safety-related aspects.
HRM 5:	An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.
HRM 6:	The organisation has documented disciplinary and grievance handling policies and procedures.
HRM 7:	The organisation addresses the health needs of the employees.
HRM 8:	There is documented personal information for each staff member.
HRM 9:	There is a process for credentialing and privileging of medical professionals, permitted to provide patient care without supervision.
HRM 10:	There is a process for credentialing and privileging of nursing professionals, permitted to provide patient care without supervision.

*** This implies that this objective element requires documentation.**

Standards and Objective Elements

Standard

HRM.1.	**The organisation has a documented system of human resource planning.**

Objective Elements

a. Human resource planning supports the organisation's current and future ability to meet the care, treatment and service needs of the patient. *

Interpretation: This shall be done in a structured manner keeping in mind the hospital's mission, volume and mix of patients, services, and medical technology. This is done with involvement of various stake holders It shall use recognised methods for determining levels of staffing.

It shall match the strategic and operational plan of the organisation.

b. The organisation maintains an adequate number and mix of staff to meet the care, treatment and service needs of the patient.

Interpretation: The staff should be commensurate with the workload and the clinical requirement of the patients. Whenever there is a shortfall of staff, contingency plans to meet workforce shortage exists. Nursing numbers shall be as per published guidelines.

c. The required job specification and job description are well defined for each category of staff. *

Interpretation: The content of each job should be well defined and the qualifications, skills and experience required for performing the job should be clearly laid down. The job description should be commensurate with the qualification.

Refer to glossary for definition of "job description" and "job specification". For a job which requires the skills of a doctor or a nurse the minimum qualification shall be an MBBS and GNM degree respectively.

d. The organisation verifies the antecedents of the potential employee with regards to criminal/negligence background.

Interpretation: The organisation can have a suitable methodology to implement the same

Standard

HRM.2.	**The organisation has a documented procedure for recruiting staff and orienting them to the organisation's environment.**

Objective Elements

a. There is a documented procedure for recruitment. *

Interpretation: The recruitment process ensures an adequate number and skill mix of staff to provide the organisation's services. The procedure shall ensure that the staff has the necessary registration, qualifications, skills and experience to perform its work.

Recruitment is undertaken in accordance with statutory requirements, where applicable.

b. Recruitment is based on pre-defined criteria.

Interpretation: The laid-down recruitment procedure shall be adhered to. The entire process shall be documented. This shall ensure that the recruitment is done in a transparent manner.

c. Every staff member entering the organisation is provided induction training.

Interpretation: The organisation shall determine as to when induction training shall be conducted. However, it shall be within 15 days of the staff joining.

Objective elements "d" to "g" shall be covered in this training. Similarly, all other requirements of this standard could be covered.

The contents of this training could be provided to every staff in the form of a booklet.

There can be separate induction training at the organisational level and for the respective departments.

d. The induction training includes orientation to the organisation's vision, mission and values.

Interpretation: The organisation's staff including the outsourced staff should be aware and should correctly interpret the vision, mission and values of the organisation.

e. The induction training includes awareness on employee rights and responsibilities.

Interpretation: Self-explanatory.

f. The induction training includes awareness on patient's rights and responsibilities.

Interpretation: The employees should be able to identify and report violation of patient rights as and when it occurs.

g. The induction training includes orientation to the service standards of the organisation.

Interpretation: The employees should be trained to implement the service standards of the organisation.

h. Every staff member is made aware of organisation's wide policies and procedures as well as relevant department/unit/service/programme's policies and procedures.

Interpretation: The organisation's staff including the outsourced staff should be aware and should correctly interpret the policies and operating procedures of the organisation as well as that of the department/ unit/ service in which he is performing the requisite duties. It also requires continuous on the job training to reinforce the correct interpretation of policies and procedures.

Standard

HRM.3.	**There is an on-going programme for professional training and development of the staff.**

Objective Elements

a. A documented training and development policy exists for the staff. *

Interpretation: A training manual incorporating the procedure for identification of training needs, the training methodology, documentation of training, training assessment, impact of training and the training calendar should be prepared.

The training shall be for all categories of staff including doctors and outsourced staff (wherever applicable).

b. The organisation maintains the training record.

Interpretation: The HR department shall maintain a record of all trainings provided. At a minimum, it shall include the title of the training, the trainer(s), list of trainees (with signatures). Where possible, the contents of the training may also be captured.

c. Training also occurs when job responsibilities change/new equipment is introduced.

Interpretation: The training should focus on the revised job responsibilities as well as on the newly introduced equipment and technology. In case of new equipment, the operating staff should receive training on operational as well as daily-maintenance aspects.

d. Evaluation of training effectiveness is done by the organisation

Interpretation: This shall include pre and post training documented evaluation.

e. Feedback mechanisms are in place for improvement of training and development programme.

Interpretation: This shall include both internal and external training. Feedback includes collecting information on appropriateness of course material, facilities for the training program and capability of the trainer.

HRM.4.	**Staff are adequately trained on various safety-related aspects.**

Objective Elements

a. Staff are trained on the risks within the organisation's environment.

Interpretation: The organisation shall define such risks that shall include patient, visitors and employee-related risks. For example, fire and non-fire emergency, needle stick injury, etc.

b. Staff members can demonstrate and take actions to report, eliminate, or minimise risks.

Interpretation: Staff should be able to practically demonstrate actions like taking care of blood spills, medication errors and other adverse event reporting systems.

c. Staff members are made aware of procedures to follow in the event of an incident.

Interpretation: *T*he staff should be able to intimate the sequence of events that they will undertake in the eventuality of occurrence of any adverse event.

d. Staff are trained on occupational safety aspects.

Interpretation: The organisation shall identify the areas with potential occupational hazards. Staff are made aware of the possible risks involved and the preventive actions to avoid risks. For example: Needle Stick Injury and Blood/Body Fluid Exposure, radiation exposure, chemotherapy exposure, noise in utility areas.

Standard

HRM.5.	**An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.**

Objective Elements

a. A documented performance appraisal system exists in the organisation. *

Interpretation: This shall be done for all categories of employees starting from the person heading the organisation and including doctors who are employees. For definition of "performance appraisal" refer to glossary.

b. The employees are made aware of the system of appraisal at the time of induction.

Interpretation: This could be incorporated in the service booklet and included in the induction training.

c. Performance is evaluated based on the pre-determined criteria.

Interpretation: Self-explanatory.

d. The appraisal system is used as a tool for further development.

Interpretation: This can be done by identifying training requirements and accordingly providing for the same (wherever possible). Key result areas are identified for each staff and training need assessment is also done.

e. Performance appraisal is carried out at pre-defined intervals and is documented.

Interpretation: Self-explanatory. This shall be done at least once a year.

Standard

HRM.6.	**The organisation has documented disciplinary and grievance handling policies and procedures.**

Objective Elements

a. Documented policies and procedures exist. *

Interpretation: The documentation shall be done keeping in mind objective elements “c, d and e”. For definition of "disciplinary procedure" and "grievance handling" refer to glossary.

b. The policies and procedures are known to all categories of staff of the organisation.

Interpretation: All the staff should be aware of the disciplinary procedure and the process to be followed in case they feel aggrieved.

c. The disciplinary policy and procedure is based on the principles of natural justice.

Interpretation: This implies that both parties (employee and employer) are given an opportunity to present their case and decision is taken accordingly.

d. The disciplinary and grievance procedure is in consonance with the prevailing laws.

Interpretation: Refer to relevant labour laws and CCS (CCA) rules. Internal Complaints committee should also be established in the organisation.

e. There is a provision for appeals in all disciplinary cases.

Interpretation: The organisation shall designate an appellate authority to consider appeals in disciplinary cases. Appellate authority should be higher than the disciplinary authority.

f. The redress procedure addresses the grievance.

Interpretation: Self-explanatory.

g. Actions are taken to redress the grievance.

Interpretation: Actions that are taken shall be documented and communicated to the aggrieved staff.

Standard

HRM.7.	**The organisation addresses the health needs of the employees.**

Objective Elements

a. A pre-employment medical examination is conducted on all the staff

Interpretation: This shall be in consonance with the law of the land. For example, performing pre-employment HIV testing without consent is illegal.

b. Health problems of the employees are taken care of in accordance with the organisation's policy.

Interpretation: This shall be in consonance with the law of the land and good clinical practices. For example: employee health and safety policy.

c. Regular health checks of staff dealing with direct patient care are done at least once a year and the findings/results are documented.

Interpretation: The results should be documented in the personal file. The organisation could define the parameters and it could be different for different categories of personnel. The organisation could also identify competent individuals to perform the same. The staff member shall not be charged for this health check.

d. Occupational health hazards are adequately addressed.

Interpretation: Appropriate personal protective equipment are provided to the staff concerned and they are educated on how to use them. For definition of "occupational health hazard" refer to glossary.

Standard

HRM.8.	**There is documented personal information for each staff member.**

Objective Elements

a. Personal files are maintained with respect to all staff.

Interpretation: Each file must be current and updated. The organisation maintains confidentiality and its access are controlled. Documented policies and procedures are needed for maintaining confidentiality and who can have access to the personnel file.

b. The personal files contain personal information regarding the staff's qualification, disciplinary background and health status.

Interpretation: Self-explanatory.

c. All records of in-service training and education are contained in the personal files.

Interpretation: Self-explanatory. In case of internal trainings the organisation could file a summary of all trainings attended by the employee on an annual basis. However, there shall be a supporting document to verify that the employee has actually attended the training. In case if the organisation maintains training records elsewhere, traceability shall be provided in the personal file to ensure that the intent of the objective element is addressed.

d. Personal files contain results of all evaluations.

Interpretation: Evaluations would include performance appraisals, training assessment and outcome of health checks.

Standard

HRM.9.	**There is a process for credentialing and privileging of medical professionals, permitted to provide patient care without supervision.**

Objective Elements

a. Medical professionals permitted by law, regulation and the organisation to provide patient care without supervision are identified.

Interpretation: The organisation identifies the individuals who have the required qualification(s), training and experience to provide patient care in consonance with the law. For definition of "credentialing" refer to glossary.

b. The education, registration, training and experience of the identified medical professionals is documented and updated periodically.

Interpretation: Update is done after acquisition of new skills and/or qualification.

c. All such information pertaining to the medical professionals is appropriately verified when possible.

Interpretation: The organisation shall do the same by verifying the credentials from the organisation which has awarded the qualification/training. A good reference could be MCI's website.

d. Medical professionals are granted privileges to admit and care for patients in consonance with their qualification, training, experience and registration.

Interpretation: The organisation shall identify services which each medical professional is authorised to do.

This shall be done based on qualification, experience and any additional training received.

For example, radiotherapy can only be given by a radiation oncologist.

e. The requisite services to be provided by the medical professionals are known to them as well as the various departments/units of the organisation.

Interpretation: This could be done by internal communication.

f. Medical professionals admit and care for patients as per their privileging.

Interpretation: A standardised format can be used for each faculty and a norm for providing privilege should be practised uniformly. New faculty members can be under proctorship till independent privileges are provided. The organisation could evolve a mechanism to ensure that medical professionals are providing only those services that they have been privileged to offer.

Standard

HRM.10.	**There is a process for credentialing and privileging of nursing professionals, permitted to provide patient care without supervision.**

Objective Elements

a. Nursing staff permitted by law, regulation and the organisation to provide patient care without supervision are identified.

Interpretation: The organisation identifies the individuals who have the required qualification(s), training and experience to provide patient care in consonance with the law. Refer to Indian Nursing Council Act, 1947.

b. The education, registration, training and experience of nursing staff is documented and updated periodically.

Interpretation: Updation is done after acquisition of new skills and/or qualification.

c. All such information pertaining to the nursing staff is appropriately verified when possible.

Interpretation: The organisation shall do the same by verifying the credentials from the organisation which has awarded the qualification/training.

d. Nursing staff are granted privileges in consonance with their qualification, training, experience and registration.

Interpretation: The organisation shall identify as to what each nurse is authorised to do. For example, an Infection Control Nurse should have had requisite in-house/external training and experience and the aptitude and knowledge to perform the tasks required of her.

e. The requisite services to be provided by the nursing staff are known to them as well as the various departments/units of the organisation.

Interpretation: This could be done by internal communication.

f. Nursing professionals care for patients as per their privileging.

Interpretation: New staff members can be under the supervision till independent privilege is being provided for each staff. The organisation could evolve a mechanism to ensure that nursing professionals are providing only those services that they have been privileged to offer.

Chapter 10
Information Management System (IMS)

Intent of chapter:

Information is an important resource for effective and efficient delivery of health care. Provision of health care and its continued improvement is dependent to a large extent on the information generated, stored and utilised appropriately by the organisations. One of the major intent of this chapter is to ensure data and information meet the organisation's needs and support the delivery of quality care and service.

Provision of patient care is a complex activity that is highly dependent on communication of information. This communication is to and from the community, patients and their families, and other health professionals. Failures in communication are one of the most common root causes of patient safety incidents. The goal of Information management in a hospital is to ensure that the right information is made available to the right person. This is provided in an authenticated, secure and accurate manner at the right time and place. This helps achieve the ultimate organisational goal of a satisfied and improved provider and recipient of any health care setting.

An effective Information management system is based on the information needs of the organisation. The system is able to capture, transmit, store, analyse, utilise and retrieve information as and when required for improving clinical outcomes as well as individual and overall organisational performance.

Although a digital-based information system improves efficiency, the basic principles of a good information management system apply equally to a manual/paper-based system. These standards are designed to be equally compatible with non-computerised systems and future technologies.

Summary of Standards

IMS 1:	Documented policies and procedures exist to meet the information needs of the care providers, management of the organisation as well as other agencies that require data and information from the organisation.
IMS 2:	The organisation has processes in place for effective control and management of data.
IMS 3:	The organisation has a complete and accurate medical record for every patient.
IMS 4:	The medical record reflects continuity of care.
IMS 5:	Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information.
IMS 6:	Documented policies and procedures exist for retention time of records, data and information.
IMS 7:	The organisation regularly carries out review of medical records.

*** This implies that this objective element requires documentation.**

Standard

IMS.1.	**Documented policies and procedures exist to meet the information needs of the care providers, management of the organisation as well as other agencies that require data and information from the organisation.**

Objective Elements

a. The information needs of the organisation are identified and are appropriate to the scope of the services being provided by the organisation. *

Interpretation: The organisation has manual and/or electronic hospital information system and/or management information system which provide relevant information to all stakeholders concerned. The identified information needs shall be documented. This shall include the information needs of the care providers, management and external agencies/governmental bodies. For example, daily census report, utilization rates, etc.

There shall be a contingency plan in place to ensure continuity in providing information needs when the electronic hospital information system is experiencing a downtime.

In case the organisation uses electronic medical records, they could refer to EHR/EMR guidelines published by MoHFW.

b. Documented policies and procedures to meet the information needs exist. *

Interpretation: A policy document is available where the HIS/MIS is described.

This shall also specify the frequency of data collection and the person(s) responsible.

c. All information management and technology acquisitions are in accordance with the documented policies and procedures.

Interpretation: The organisation shall define the needs for software and hardware solutions as per the information requirements and future necessities. The organisation shall ensure that it has the necessary license for software.

d. Documented policies and procedures guide the use of Telemedicine facility in a safe and secure manner.

Interpretation: Whenever Telemedicine facility is used, the organisation shall develop a 'policy and procedure' and implement the same. This takes into account the patient's identity, confidentiality, limitations of Telemedicine and other requirements (if any). The organisation shall have mechanism for appropriate data storage and retrieval.

e. The organisation contributes to external databases in accordance with the law and regulations.

Interpretation: The organisation shall define the system of releasing the relevant information to the authority as per statutory norms. For example, sending birth and death statistics, notifiable diseases (refer to glossary) and acute flaccid paralysis reporting. The organisation contributes to databases in accordance national programmes and initiatives for example – hemovigilance(HVPI) and pharmacovigilance(PVPI).

Standard

IMS.2.	**The organisation has processes in place for effective control and management of data.**

Objective Elements

a. The organisation has an effective process for document control. *

Interpretation: The organisation ensures that all documents including forms, formats, policies and procedures are current and updated. They are created, reviewed for adequacy, authorized and released by designated individuals. Only the latest authorized documents are in use. Documents are reviewed for updating them as per a planned schedule. All approved documents are identifiable. Obsolete documents are removed from use and archived as per a planned retention period based on hospital's policy. Filled in forms, formats, etc. are retained as per the organisation's policy and regulatory requirements.

b. Formats for data collection are standardized.

Interpretation: MIS/HIS data are collected in standardized format from all areas/services in the organisation. This is in the context of frequency of capturing data, namely daily, weekly, monthly, quarterly, yearly etc. (e.g. Statistical bulletin).

c. Necessary resources are available for analyzing data.

Interpretation: The organisation shall make available men, material, space and budget.

d. Documented procedures are laid down for timely and accurate dissemination of data. *

Interpretation: A timely feedback is given to relevant stakeholders after data generation and analysis. The organisation could decide on which data needs to be shared with whom and also the modalities (e.g. memos, circulars, etc.) for dissemination of such data.

e. Documented procedures exist for storing and retrieving data. *

Interpretation: The organisation shall define data management policy and ensure adequate safeguards for protection of data, wherever physical or electronic data is stored. Storage could be physical or electronic. Wherever electronic storage is done the organisation shall ensure that there are adequate safeguards for protection of data.

f. Appropriate clinical and managerial staff participates in selecting, integrating and using data.

Interpretation: They are responsible for the appropriate selection of indicators, measurement of trends and initiating action, wherever required. This could be done by a multi-disciplinary committee.

Standard

IMS.3.	**The organisation has a complete and accurate medical record for every patient.**

Objective Elements

a. Every medical record has a unique identifier.

Interpretation: This shall also apply to records on digital media.

Every sheet in the medical record shall have this unique identifier. In case of electronic records, all entries for one unique identifier shall be available in one place. For example, CR number, UHID, hospital number, etc.

b. Organisation policy identifies those authorized to make entries in medical record.

Interpretation: Organisation shall have a written policy authorizing who can make entries and the content of entries. This could be different category of personnel for different entries, but it shall be uniform across the organisation, e.g. progress record by doctor and medication administration chart by nurse.

c. Entry in the medical record is named, signed, dated and timed.

Interpretation: All entries should be documented immediately but no later than one hour of completion of the assessment/procedure. For records on electronic media it is preferable that the date and time is automatically generated by the system.

d. The author of the entry can be identified.

Interpretation: This could be by writing the full name or by mentioning the employee code number, or with the help of stamp, etc. In case of electronic-based records, authorised e-signature provision as per statutory requirements must be kept.

e. The contents of medical record are identified and documented. *

Interpretation: The organisation identifies which documents form part of the medical records, documents and implements the same. For example, admission orders, face sheet, IP sheet, discharge summary, doctor's order sheet, TPR chart, consent form, etc.

f. The organisation has a documented policy for usage of abbreviations and develops a list based on accepted practices.

Interpretation: In case abbreviations are used, a standardized list of approved abbreviations shall be used throughout the organisation. For medications, error-prone abbreviations shall not be used.

g. The record provides a complete, up-to-date and chronological account of patient care.

Interpretation: Every medical record has all the identified sheets filed in the proper order. The organisation shall decide the format for maintaining the continuity in the medical records. It shall ensure that all medico-legal case records have the mandatory information.

In case a particular sheet is missing a note to that effect would be put in the medical record.

h. Provision is made for 24-hour availability of the patient's record to healthcare providers to ensure continuity of care.

Interpretation: In case of physical records, when the MRD is not open, there should be a system in place by which authorised personnel can open the MRD and retrieve the record. For all existing hospital patients coming to the emergency room medical records shall be easily retrieved.

Standard

IMS.4.	**The medical record reflects continuity of care.**

Objective Elements

a. The medical record contains information regarding reasons for admission, diagnosis and care plan.

Interpretation: The final diagnosis (IP) must be documented by the treating doctor in all records. This could preferably be as per ICD. However, in the medical records department all such diagnoses shall be codified as per ICD. For definition of "Care plan" refer to glossary.

b. The medical record contains the results of tests carried out and the care provided.

Interpretation: It is preferable that the medical record also reflects any delay in tests and treatment planned or provided for the patient. This could be taken up for clinical audit.

c. Operative and other procedures performed are incorporated in the medical record.

Interpretation: These include name and details of the operative and other procedures performed.

d. 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.

Interpretation: It is mandatory to mention the clinical condition of the patient before transfer is effected. If the patient has been transferred at his/her request, a note may be added to that effect. In such instances, the name of the receiving hospital could be the name the patient desires to go to. However, if the patient has been transferred by the organisation, it shall document the same.

All available details of the transfer are documented.

e. The medical record contains a copy of the discharge summary duly signed by appropriate and qualified personnel.

Interpretation: Self-explanatory.

f. In case of death, the medical record contains a copy of the cause of death certificate.

Interpretation: This shall mention the cause, date and time of death The organisation provides the death certificate as per the International Form of Medical Certificate of Cause of Death (WHO).

Cardiac and respiratory arrest is an event of death and not the cause of death.

g. Whenever a clinical autopsy is carried out, the medical record contains a copy of the report of the same.

Interpretation: For definition of "clinical autopsy" refer to the glossary. This does not include postmortems done for medical legal cases.

h. Care providers have access to current and past medical record.

Interpretation: The organisation provides access to medical records to designated healthcare providers (those who are involved in the care of that patient). For electronic medical record system, identified care providers shall have a user ID and a password.

Standard

IMS.5.	**Documented policies and procedures are in place for maintaining confidentiality, integrity and security of records, data and information.**

Objective Elements

a. Documented policies and procedures exist for maintaining confidentiality, security and integrity of records, data and information. *

Interpretation: The organisation shall control the accessibility to the MRD and to its Hospital Information System. For physical records, it shall ensure the usage of tracer card for movement of the file in and out of the MRD.

It shall have a system in place to ensure that only the authorized care providers have access to the patient's record. Similarly for data and information, it shall ensure that records and data are not taken out from the areas where they are stored. In case of electronic systems it shall ensure that these cannot be copied at all locations. The procedure shall also address how entries in the patient record are corrected or overwritten. The documentation shall be done keeping in mind objective element "b". Objective element "c" could also be included in this procedure.

b. Documented policies and procedures are in consonance with the applicable laws.

Interpretation: This is in the context of Indian Evidence Act, Indian Penal Code and Code of Medical Ethics. For example, privileged communication.

c. The policies and procedure(s) incorporate safeguarding of data/record against loss, destruction and tampering.

Interpretation: For physical, records the organisation shall ensure that there are adequate pest and rodent control measures. For electronic data, there should be protection against virus/trojans and also a proper backup procedure.

To prevent tampering of physical records access shall be limited only to the healthcare provider concerned. In electronic format, this could be done by adequate passwords. In electronic systems, the access should be different for different types of personnel and specific for that user.

The organisation should have a system to keep a track of changes made in the medical record or data.

In case of physical records and data, there must be a provision to either store in fire safe cabinets or there must be adequate (and appropriate) fire-fighting equipment. It is preferable that software, when used, shall be validated and duly authenticated.

d. The organisation has an effective process of monitoring compliance of the laid down policy and procedure.

Interpretation: The organisation carries out regular audits/rounds to check compliance with policies.

e. The organisation uses developments in appropriate technology for improving confidentiality, integrity and security.

Interpretation: The organisation shall review and update its technological features so as to improve confidentiality, integrity and security of information. For example, moving from physical to electronic format, remote backup of data, etc.

f. Privileged health information is used for the purposes identified or as required by law and not disclosed without the patient's authorisation.

Interpretation: The organisation shall define the procedure for privileged communication. The authorisation from the patient shall be obtained in writing. Special care should be taken in medico-legal cases and other special situations identified by Government and the organisation.

g. A documented procedure exists on how to respond to patients/physicians and other public agencies requests for access to information in the medical record in accordance with the local and national law. *

Interpretation: In this context, the release of information in accordance with the Code of Medical Ethics 2002 should be kept in mind. Grievances with respect to RTI shall be addressed by government and other applicable bodies, as per the laid-down policies.

Standard

IMS.6.	**Documented policies and procedures exist for retention time of records, data and information.**

Objective Elements

a. Documented policies and procedures are in place on retaining the patient's clinical records, data and information. *

Interpretation: The organisation shall define the retention period for each category of medical records: Out-patient, in-patient and MLC.

It shall also do the same for various data and the formats (e.g. registers and forms) that have been used for capturing this data. Refer rules laid down by MCI and respective state authority.

The documentation shall be done keeping in mind objective element "b".

b. The policies and procedures are in consonance with the local and national laws and regulations.

Interpretation: Some of the related laws in this context are Code of Medical Ethics 2002, Consumer Protection Act 1986 and relevant state legislation, if any.

c. The retention process provides expected confidentiality and security.

Interpretation: This is applicable for both manual and electronic system.

d. The destruction of medical records, data and information is in accordance with the laid-down policy.

Interpretation: Destruction can be done after the retention period is over and after taking approval of the concerned authority (internal/external).

Standard

IMS.7.	**The organisation regularly carries out review of medical records.**

Objective Elements

a. The medical records are reviewed periodically.

Interpretation: The organisation could define the periodicity. A standardised checklist can be used for this purpose.

b. The review uses a representative sample based on statistical principles.

Interpretation: The organisation shall define the principles on which sampling is based. For example, simple random, systemic random sampling, etc.

Review shall be based on total discharges including deaths, total indoor patients, etc.

c. The review is conducted by identified individuals. .

Interpretation: The organisation shall identify and authorise such individuals.

d. The review focuses on the timeliness, legibility and completeness of the medical records.

Interpretation: Self-explanatory.

e. The review process includes records of both active and discharged patients.

Interpretation: An adequate mix of both active and discharged patients should be used.

f. The review points out and documents any deficiencies in records.

Interpretation: For example, missing final diagnosis, absence of OT notes in an operated patient, etc.

g. Appropriate corrective and preventive measures are undertaken within a defined period of time and are documented.

Interpretation: Self explanatory.

Glossary

The commonly-used terminologies in the NABH standards are briefly described and explained herein to remove any ambiguity regarding their comprehension. The definitions narrated have been taken from various authentic sources as stated, wherever possible. Notwithstanding the accuracy of the explanations given, in the event of any discrepancy with a legal requirement enshrined in the law of the land, the provisions of the latter shall apply.

Accreditation	Act of granting recognition by an external evaluation organisation of the achievement of accreditation standards, demonstrated through an independent external peer assessment of that organisation's level of performance in relation to the standards.
Accreditation assessment	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
Advance life support	Emergency medical care for sustaining life, including defibrillation, airway management, and drugs and medications.
Adverse drug event	***Adverse event:*** Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment. ***Adverse Drug Reaction:*** A response to a drug which is noxious and unintended and ***which occurs at doses normally used in man*** for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function. Therefore ADR = Adverse Event with a causal link to a drug. *Adverse drug event:*The FDA recognises the term *adverse drug event to be* a synonym for *adverse event.*

	In the patient-safety literature, the terms *adverse drug event and adverse event* usually denote a causal association between the drug and the event, but there is a wide spectrum of definitions for these terms, including harm caused by a • drug • harm caused by drug use, and • a medication error with or without harm Institute of Medicine: "An injury resulting from medical intervention related to a drug", which has been simplified to "***an injury resulting from the use of a drug***" *Adverse drug events extend beyond adverse drug reactions to include* harm from overdoses and under-doses usually related to medication errors. A minority of adverse drug events is medication errors, and medication errors rarely result in adverse drug events.
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. (WHO Draft Guidelines for Adverse Event Reporting and Learning Systems)
Ambulance	A patient carrying vehicle having facilities to provide unless otherwise indicated at least basic life support during the process of transportation of patient. There are various types of ambulances that provide special services viz. coronary care ambulance, trauma ambulance, air ambulance, etc.

Anaesthesia	Loss of bodily sensation with or without loss of consciousness
Anaesthesia Death	It is defined as death occurring within 24 hours of administration of anaesthesia due to cases related to anaesthesia. However death may occur even afterwards due to the complications.
Assessment	All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.
Autopsy	1. An examination of a cadaver in order to determine the cause of death or to study pathologic changes. 2. A surgical procedure performed after death to examine body tissues and determine the cause of death
Barrier nursing	The nursing of patients with infectious diseases in isolation to prevent the spread of infection. As the name implies, the aim is to erect a barrier to the passage of infectious pathogenic organisms between the contagious patient and other patients and staff in the hospital, and thence to the outside world. The nurses wear gowns, masks, and gloves, and they observe strict rules that minimise the risk of passing on infectious agents.
Basic life support	Basic life support (BLS) is the level of medical care which is used for patients with life-threatening illnesses or injuries until the patient can be given full medical care.
Breakdown maintenance	Activities which are associated with the repair and servicing of site infrastructure, buildings, plant or equipment within the site's agreed building capacity allocation which have become inoperable or unusable because of the failure of component parts.

Bylaws	A rule governing the internal management of an organisation. It can supplement or complement the government law but cannot countermand it, e.g. municipal bylaws for construction of hospitals/nursing homes, for disposal of hazardous and/or infectious waste
Case Fatality Rate	The reported case fatality rate (CFR) is a measure of the severity of a disease and is defined as the proportion of reported cases of a specified disease or condition which are fatal within a specified time.
Clinical audit	A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. (Principles for Best Practice in Clinical Audit 2002, NICE/CHI)
Clinical practice guidelines	Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. (Field and Lohr 1990. page 38).
Competence	Demonstrated ability to apply knowledge and skills (para 3.9.2 of ISO 9000: 2000). Knowledge is the understanding of facts and procedures. Skill is the ability to perform specific action. For example, a competent gynaecologist knows about the patho-physiology of the female genitalia and can conduct both normal as well as abnormal deliveries.
Confidentiality	Restricted access to information to individuals who have a need, a reason and permission for such access. It also includes an individual's right to personal privacy as well as privacy of information related to his/her healthcare records.`

Consent	1. Willingness of a party to undergo examination/procedure/ treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to take an informed decision of his/her health care. 2. In law, it means active acquiescence or silent compliance by a person legally capable of consenting.In India, legal age of consent is 18 years. It may be evidenced by words or acts or by silence when silence implies concurrence. Actual or implied consent is necessarily an element in every contract and every agreement.
Control Charts	Statistical tool used in quality control to (1) analyze and understand process variables, (2) determine process capabilities, and to (3) monitor effects of the variables on the difference between target and actual performance. Control charts indicate upper and lower control limits, and often include a central (average) line, to help detect trend of plotted values. If all data points are within the control limits, variations in the values may be due to a common cause and process is said to be 'in control'. If data points fall outside the control limits, variations may be due to a special cause and the process is said to be out of control.
Credentialing	The process of obtaining, verifying and assessing the qualification of a healthcare provider.
Critical path method (CPM)	The critical path method (CPM) is a step-by-step technique for process planning that defines critical and non-critical tasks with the goal of preventing time-frame problems and process bottlenecks.

	The CPM is ideally suited to projects consisting of numerous activities that interact in a complex manner. In applying the CPM, there are several steps that can be summarized as follows: • Define the required tasks and put them down in an ordered (sequenced) list. • Create a flowchart or other diagram showing each task in relation to the others. • Identify the critical and non-critical relationships (paths) among tasks. • Determine the expected completion or execution time for each task. • Locate or devise alternatives (backups) for the most critical paths.
Data	Facts or information used usually to calculate analyse or plan something.
Discharge summary	A part of a patient record that summarises the reasons for admission, significant clinical findings, procedures performed, treatment rendered, patient's condition on discharge and any specific instructions given to the patient or family (for example follow-up medications).
Disciplinary proceedings	Sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the healthcare organisation.
Drug dispensing	The preparation, packaging, labeling, record keeping, and transfer of a prescription drug to a patient or an intermediary, who is responsible for administration of the drug.*(Reference: Mosby's*

	Medical Dictionary, 9th edition, 2009, Elsevier.)
Drug Administration	The giving of a therapeutic agent to a patient, e.g. by infusion, inhalation, injection, paste, suppository or tablet. It includes aerosol, oral, transtracheal infusion, subcutaneous, intramuscular, intravenous, intrauterine, intraperitoneal, intra-articular, intramammary, intrathecal, subconjunctival, percutaneous, percutaneous intraruminal, gas inhalation. Mass medication is per feed or drinking water or, in the case of captive fish, in the tank water. For feral animals individual dosing by projectile dart is usual, for group therapy administration by bait is possible.
Effective communication	A two way information sharing process which involves the communicator, communicating a message that is easily understood by the recipient. Good medical care depends upon effective communication between patients and providers. Effective communication with persons who have limited language proficiency or understanding of the subject due to lack of familiarity, often requires interpreters, special efforts or other services.
Employees	All members of the healthcare organisation who are employed full time and are paid suitable remuneration for their services as per the laid-down policy.
End of life Care	Helps all those with advanced, progressive, incurable illness to live as well as possible until they die. It enables the supportive and palliative care needs of both patient and family to be identified and met throughout the last phase of life and into bereavement. It includes management of pain and other symptoms and provision of psychological, social, spiritual and practical support.
Ethics	Moral principles that govern a person's or group's behaviour.

Evidence-based medicine	Evidence-based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.
Family	The person(s) with a significant role in the patient's life. It mainly includes spouse, children and parents. It may also include a person not legally related to the patient but can make healthcare decisions for a patient if the patient loses decision-making ability.
Failure Mode and Effect Analysis (FMEA)	A common process used to prospectively identify error risk within a particular process. FMEA begins with a complete process mapping that identifies all the steps that must occur for a given process to occur (e.g., programming an infusion pump or preparing an intravenous medication in the pharmacy). With the process mapped out, the FMEA then continues by identifying the ways in which each step can go wrong (i.e., the failure modes for each step), the probability that each error will be detected (i.e., so that it can be corrected before causing harm), and the consequences or impact of the error not being detected. The estimates of the likelihood of a particular process failure, the chance of detecting such failure, and its impact are combined numerically to produce a criticality index. This criticality index provides a rough quantitative estimate of the magnitude of hazard posed by each step in a high-risk process. Assigning a criticality index to each step allows prioritization of targets for improvement. For instance, an FMEA analysis of the medication-dispensing process on a general hospital ward might break down all steps from receipt of orders in the central pharmacy to filling automated dispensing machines by pharmacy technicians. Each step in this process would be assigned a probability of failure and an impact score, so that all steps could be ranked according to

	the product of these two numbers. Steps ranked at the top (i.e., those with the highest criticality indices) would be prioritized for error proofing.
Formulary	An approved list of drugs. Drugs contained on the formulary are generally those that are determined to be cost effective and medically effective. The list is compiled by professionals and physicians in the field and is updated at regular intervals. Changes may be made depending on availability or market.
Goal	A broad statement describing a desired future condition or achievement without being specific about how much and when. (ASQ) The term “goals” refers to a future condition or performance level that one intends to attain. Goals can be both short- and longer-term. Goals are ends that guide actions. (MBNQA)
Grievance-handling procedures	Sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
Hazardous waste	Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include biologic waste that can transmit disease (for example, blood, tissues) radioactive materials, and toxic chemicals. Other examples are infectious waste such as used needles, used bandages and fluid soaked items.
Healthcare-associated	Healthcare-associated infections (HAIs) are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses

infection	during the course of receiving medical care. (CDC) This was earlier referred to as Nosocomial/hospital-acquired/ hospital-associated infection(s).
Healthcare organisation	Generic term is used to describe the various types of organisation that provide healthcare services. This includes ambulatory care centres, hospitals, laboratories, etc.
High-dependency unit	A high-dependency unit (HDU) is an area for patients who require more intensive observation, treatment and nursing care than are usually provided for in a ward. It is a standard of care between the ward and full intensive care.
High Risk /High Alert Medications	High-risk / high-alert medications can be defined as those drugs that have a heightened risk for adverse events or have heightened risk of catastrophic harm whenever there is an error. These drugs include generally have low therapeutic index
Incident reporting	It is defined as written or verbal reporting of any event in the process of patient care ,that is inconsistent with the deserved patient outcome or routine operationns of the healthcare facility.
In service education/training	Organised education/training usually provided in the workplace for enhancing the skills of staff members or for teaching them new skills relevant to their jobs/tasks.
Indicator	A statistical measure of the performance of functions, systems or processes overtime. For example, hospital acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.
Information	Processed data which lends meaning to the raw data.
Intent	A brief explanation of the rational, meaning and significance of the standards laid down in a particular chapter.

Inventory control	The method of supervising the intake, use and disposal of various goods in hands. It relates to supervision of the supply, storage and accessibility of items in order to ensure adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
Isolation	Separation of an ill person who has a communicable disease (e.g.,measles, chickenpox, mumps, SARS) from those who are healthy. Isolation prevents transmission of infection to others and also allows the focused delivery of specialised health care to ill patients. The period of isolation varies from disease-to-disease. Isolation facilities can also be extended to patients for fulfilling their individual, unique needs.
Job description	1. It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job. 2. A summary of the most important features of a job, including the general nature of the work performed (duties and responsibilities) and level (i.e., skill, effort, responsibility and working conditions) of the work performed. It typically includes **job specifications** that include employee characteristics required for competent performance of the job. A job description should describe and focus on the job itself and not on any specific individual who might fill the job.
Job specification	1. The qualifications/physical requirements, experience and skills required to perform a particular job/task. 2. A statement of the minimum acceptable qualifications that an incumbent must possess to perform a given job successfully.
Laws	Legal document setting forth the rules of governing a particular kind

	of activity, e.g. organ transplantation act, which governs the rules for undertaking organ transplantation.
Maintenance	The combination of all technical and administrative actions, including supervision actions, intended to retain an item in, or restore it to, a state in which it can perform a required function. (British Standard 3811:1993)
Medical equipment	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of patient.
Medication error	A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packing and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Zipperer, et al)
Medication Order	A written order by a physician, dentist, or other designated health professional for a medication to be dispensed by a pharmacy for administration to a patient. *(Reference: Mosby's Medical Dictionary, 9th edition, Elsevier)* Primary difference between *Prescription & Medication Order* is that the medication order is used after Prescription, to get medicines issued/ dispensed from Pharmacy. Medication Order is an active Record, while Prescription is a Document.

Mission	An organisation's purpose. This refers to the overall function of an organisation. The mission answers the question, “What is this organisation attempting to accomplish?” The mission might define patients, stakeholders, or markets served, distinctive or core competencies, or technologies used.
Monitoring	The performance and analysis of routine measurements aimed at identifying and detecting changes in the health status or the environment, e.g. monitoring of growth and nutritional status, air quality in operation theatre. It requires careful planning and use of standardised procedures and methods of data collection.
Multi-disciplinary	A generic term which includes representatives from various disciplines, professions or service areas.
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.
No harm	This is used synonymously with near miss. However, some authors draw a distinction between these two phrases. A near-miss is defined when an error is realised just in the nick of time and abortive action is instituted to cut short its translation. In no harm scenario, the error is not recognised and the deed is done but fortunately for the healthcare professional, the expected adverse event does not occur. The distinction between the two is important and is best exemplified by reactions to administered drugs in allergic patients. A prophylactic injection of cephalosporin may be stopped in time because it suddenly transpires that the patient is known to be allergic to penicillin (near-miss). If this vital piece of information is overlooked and the cephalosporin administered, the patient may

	fortunately not develop an anaphylactic reaction (no harm event).
Notifiable disease	Certain specified diseases, which are required by law to be notified to the public health authorities. Under the international health regulation (WHO's International Health Regulations 2005) the following diseases are notifiable to WHO: (a) Smallpox (b) Poliomyelitis due to wild-type poliovirus (c) Human influenza caused by a new subtype (d) Severe acute respiratory syndrome (SARS). In India, the following is a indicative list of diseases which are also notifiable, but may vary from state to state: (a) Polio (b) Influenza (c) Malaria (d) Rabies (e) HIV/AIDS (f) Louse-bornetyphus (g) Tuberculosis (h) Leprosy (i) Leptospirosis (j) Viral hepatitis (k) Dengue fever The various diseases notifiable under the factories act lead poisoning, byssinosis, anthrax, asbestosis and silicosis.
Objective	A specific statement of a desired short-term condition or achievement includes measurable end-results to be accomplished by

	specific teams or individuals within time limits. (ASQ)
Objective element	It is that component of standard which can be measured objectively on a rating scale. The acceptable compliance with the measureable elements will determine the overall compliance with the standard.
Occupational health hazard	The hazards to which an individual is exposed during the course of performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards.
Operational plan	Operational plan is the part of your strategic plan. It defines how you will operate in practice to implement your action and monitoring plans--what your capacity needs are, how you will engage resources, how you will deal with risks, and how you will ensure sustainability of the organisation's achievements.
Organogram	A graphic representation of reporting relationship in an organisation.
Outsourcing	Hiring of services and facilities from other organisation based upon one's own requirement in areas where such facilities are either not available or else are not cost-effective. For example, outsourcing of house-keeping, security, laboratory/certain special diagnostic facilities with other institutions after drawing a memorandum of understanding that clearly lays down the obligations of both organisations: the one which is outsourcing and the one which is providing the outsourced facility. It also addresses the quality-related aspects.
Patient-care setting	The location where a patient is provided health care as per his needs, e.g. ICU, speciality ward, private ward and general ward.
Patient record/ medical record/ clinical record	A document which contains the chronological sequence of events that a patient undergoes during his stay in the healthcare organisation. It includes demographic data of the patient,

	assessment findings, diagnosis, consultations, procedures undergone, progress notes and discharge summary. (Death certificate, where required)
Patient Satisfaction and Patient Experience	**Patient satisfaction** is a measure of the extent to which a patient is content with the health care which they received from their health care provider. Patient satisfaction is thus a proxy but a very effective indicator to measure the success of Health care providers. **Patient Experience** is the sum of all interactions, shaped by an organisation's culture, that influence patient perceptions across the continuum of care. It is a holistic perception that the patient forms about the healthcare provider based on the overall interactions/ care touch points.
Performance appraisal	It is the process of evaluating the performance of employees during a defined period of time with the aim of ascertaining their suitability for the job, potential for growth as well as determining training needs.
Point of care equipment	Medical Equipments that are used to deliver care / intervene at or near the site of patient care. These are primarily Point-of-care testing (POCT), or bedside testing equipments that helps in reducing turn-around times. POCT Machine examples; Glucometer, ABG Analyzer, Stat Lab at ICU/ ER, portable USG etc.
Policies	They are the guidelines for decision-making,e.g. admission, discharge policies, antibiotic policy,etc.
Preventive maintenance	It is a set of activities that are performed on plant equipment, machinery, and systems before the occurrence of a failure in order to protect them and to prevent or eliminate any degradation in their operating conditions. The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure

	or the degradation of the functioning of an item.
Prescription	A prescription is a document given by a physician or other healthcare practitioner in the form of instructions that govern the care plan for an individual patient. Legally, it is a written directive, for compounding or dispensing and administration of drugs, or for other service to a particular patient. *(Reference: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, Saunders)*
Privileging	It is the process for authorising all medical professionals to admit and treat patients and provide other clinical services commensurate with their qualifications and skills.
Procedure	1. A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2000). 2. A series of activities for carrying out work which when observed by all help to ensure the maximum use of resources and efforts to achieve the desired output.
Process	A set of interrelated or interacting activities which transforms inputs into outputs (Para 3.4.1 of ISO 9000: 2000).
Programme	A sequence of activities designed to implement policies and accomplish objectives.
Project evaluation and Review Technique (PERT)	PERT is a method to analyze the involved tasks in completing a given project, especially the time needed to complete each task, and to identify the minimum time needed to complete the total project. PERT breaks down the project into events and activities, and lays down their proper sequence, relationships, and duration in the form of a network. Lines connecting the events are called paths, and the longest path resulting from connecting all events is called the critical

	path. The length (duration) of the critical path is the duration of the project, and any delay occurring along it delays the whole project. PERT is a scheduling tool, and does not help in finding the best or the shortest way to complete a project.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	1. Degree to which a set of inherent characteristics fulfil requirements (Para 3.1.1 of ISO 9000: 2000). Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000: 2000). Requirements are a need or expectation that is stated, generally implied or obligatory (Para 3.1.2 of ISO 9000:2000). 2. Degree of adherence to pre-established criteria or standards.
Quality assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled (Para 3.2.11 of ISO 9000:2000).
Quality improvement	Ongoing response to quality assessment data about a service in ways that improve the process by which services are provided to consumers/patients.
Radiation Safety	**Radiation safety** refers to safety issues and protection from radiation hazards arising from the handling of radioactive materials or chemicals and exposure to Ionizing & Non-Ionizing Radiation. This is implemented by taking steps to ensure that people will not receive excessive doses of radiation and by monitoring all sources of radiation to which they may be exposed.*(Reference: McGraw-Hill Dictionary of Scientific & Technical Terms)* In a Healthcare setting, this commonly refers to X-ray machines, CT/ PET CT Scans, Electron microscopes, Particle accelerators,

	Cyclotrone etc. Radioactive substances &radioactive waste are also potential Hazards. **Imaging Safety** includes safety measures to be taken while performing an MRI, Radiological interventions, Sedation, Anaesthesia, Transfer of patients, Monitoring patients during imaging procedure etc.
Re-assessment	It implies continuous and ongoing assessment of the patient which is recorded in the medical records as progress notes.
Reconciliation of medications	Medication reconciliation is the process of creating the most accurate list possible of all medications a patient is taking — including drug name, dosage, frequency, and route — and comparing that list against the physician's admission, transfer, and/or discharge orders, with the goal of providing correct medications to the patient at all transition points within the hospital. *(Reference: Institute for Healthcare Improvement)*
Resources	It implies all inputs in terms of men, material, money, machines, minutes (time), methods, metres (space), skills, knowledge and information that are needed for efficient and effective functioning of an organisation.
Restraints	Devices used to ensure safety by restricting and controlling a person's movement. Many facilities are "restraint free" or use alternative methods to help modify behaviour. Restraint may be physical or chemical (by use of sedatives).
Risk assessment	Risk assessment is the determination of quantitative or qualitative value of risk related to a concrete situation and a recognised threat (also called hazard). Risk assessment is a step in a risk management procedure.

Risk management	Clinical and administrative activities to identify evaluate and reduce the risk of injury.
Risk reduction	The conceptual framework of elements considered with the possibilities to minimise vulnerabilities and disaster risks throughout a society to avoid (prevention) or to limit (mitigation and preparedness) the adverse impacts of hazards, within the broad context of sustainable development. It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.
Root Cause Analysis (RCA)	Root Cause Analysis (RCA) is a structured process that uncovers the physical, human, and latent causes of any undesirable event in the workplace. Root cause analysis (RCA) is a method of problem solving that tries to identify the root causes of faults or problems that cause operating events. RCA practice tries to solve problems by attempting to identify and correct the root causes of events, as opposed to simply addressing their symptoms. By focusing correction on root causes, problem recurrence can be prevented. The process involves data collection; cause charting, root cause identification and recommendation generation and implementation.
Safety	The degree to which the risk of an intervention/procedure, in the care environment is reduced for a patient, visitors and healthcare providers.
Safety programme	A programme focused on patient, staff and visitor safety.
Scope of	Range of clinical and supportive activities that are provided by a

services	healthcare organisation.
Security	Protection from loss, destruction, tampering, and unauthorised access or use.
Sedation	The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation: **Minimal sedation** (anxiolysis) - A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are not affected. **Moderate sedation**/analgesia (conscious sedation) - A drug-induced depression of consciousness during which patients respond purposefully to verbal commands either alone or accompanied by light tactile stimulation. No interventions are needed to maintain a patent airway. **Deep sedation**/analgesia-A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully after repeated or painful stimulation. Patients may need help in maintaining a patent airway.
Sentinel events	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.*
Social responsibility	A balanced approach for organisation to address economic, social and environmental issues in a way that aims to benefit people,

	communities and society,e.g. adoption of villages for providing health care, holding of medical camps and proper disposal of hospital wastes.
Special Educational needs of the patient	In addition to routine carried by the healthcare professionals, patients and family have special educational needs depending on the situation. Eg:\; a post surgical patient who has to take care of his wound, NG tube feeding, Patient on tracheostomy getting discharged who has to be taken care by the family etc. The special educational needs are also greatly influenced by the literacy, educational level, language, emotional barriers and physical and cognitive limitations. Hence it is important for the staff to determine the special educational needs and the challenges influencing the effective education.
Staff	All personnel working in the organisation including employees, “fee-for-service” medical professionals, part-time workers, contractual personnel and volunteers.
Standard precautions	1. A method of infection control in which all human blood and other bodily fluids are considered infectious for HIV, HBV and other blood-borne pathogens, regardless of patient history. It encompasses a variety of practices to prevent occupational exposure, such as the use of personal protective equipment (PPE), disposal of sharps and safe housekeeping 2. A set of guidelines protecting first aiders or healthcare professionals from pathogens. The main message is: "Don't touch or use anything that has the victim's body fluid on it without a barrier." It also assumes that all body fluid of a patient is infectious, and must be treated accordingly. **Standard Precautions** apply to blood, all body fluids, secretions, and excretions (except sweat) regardless of whether or not they

	contain visible blood, non-intact skin and mucous membranes
Standards	A statement of expectation that defines the structures and process that must be substantially in place in an organisation to enhance the quality of care.
Sterilisation	It is the process of killing or removing microorganisms including their spores by thermal, chemical or irradiation means.
Strategic plan	Strategic planning is an organisation's process of defining its strategy or direction and making decisions on allocating its resources to pursue this strategy, including its capital and people. Various business analysis techniques can be used in strategic planning, including SWOT analysis (Strengths, Weaknesses, Opportunities and Threats) e.g. Organisation can have a strategic plan to become market leader in provision of cardiothoracic and vascular services. The resource allocation will have to follow the pattern to achieve the target. The process by which an organisation envisions its future and develops strategies, goals, objectives and action plans to achieve that future.
Surveillance	The continuous scrutiny of factors that determines the occurrence and distribution of diseases and other conditions of ill health. It implies watching over with great attention, authority and often with suspicion. It requires professional analysis and sophisticated interpretation of data leading to recommendations for control activities.
Transfusion reaction	A transfusion reaction is a problem that occurs after a patient receives a transfusion of blood.
Triage	Triage is a process of prioritising patients based on the severity of

	their condition so as to treat as many as possible when resources are insufficient for all to be treated immediately.
Turn-around-time for laboratory test	A parameter of a clinical lab's efficiency, defined as the time between ordering a test / submitting a specimen to the lab till the time the results are made available.
Turn-around-time for Blood banking services	Time taken to be calculated from the time the request/ sample is received in the blood bank till the blood is cross matched/ reserved an available for transfusion. Blood Bank shall set upper limits for routine and emergency issues separately.
Turn-around-time for radiology services	A parameter to monitor the efficiency of Radiological services, defined as the time between ordering the test /performing the test till the time results are made available.
Unstable patient	A patient whose vital parameters need external assistance for their maintenance.
Validation	1. Confirmation through the provision of **objective evidence** that the requirements for a specific intended use or application have been fulfilled. **Objective Evidence** – Data supporting the existence or variety of something. 2. The checking of data for correction or for compliance with applicable standards, rules or conventions. These are the tests to determine whether an implemented system fulfills its requirements. It also refers to what extent does a test accurately measure what it purports to measure.
Values	The fundamental beliefs that drive organisational behaviour and decision-making.

	This refers to the guiding principles and behaviours that embody how an organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation.
Ventilator Associated Adverse Events	The new term, ventilator-associated event (VAE), groups all the conditions that result in a significant and sustained deterioration in oxygenation, (*defined as a greater than 20% increase in the daily minimum fraction of inspired oxygen or an increase of at least 3 cm H2O in the daily minimum positive end-expiratory pressure (PEEP) to maintain oxygenation*). It is imperative to understand that both infectious conditions (*such as tracheitis, tracheobronchitis, and pneumonia*) and non-infectious conditions (such as atelectasis, pulmonary embolism, pulmonary edema, ventilator-induced lung injury, and others) may fulfil this VAE definition. The definition is 3 tiered, as follows: ***Tier 1: ventilator-associated condition (VAC)*** —the patient develops hypoxemia (as defined above) for a sustained period of more than 2 days. The etiology of the hypoxemia is not considered. ***Tier 2: infection-related ventilator-associated complication (IVAC)*** —hypoxemia develops in the setting of generalized infection or inflammation, and antibiotics are instituted for a minimum of 4 days. ***Tier 3: probable or possible ventilator-associated pneumonia (VAP)*** —additional laboratory evidence of white blood cells on Gram stain of material from a respiratory secretion specimen of acceptable quality, or (=possible)/and (=probable) presence of respiratory pathogens on quantitative cultures, in patients with IVAC. Additional criteria are also available for use in meeting the possible or *Probable VAP* (PVAP) definitions.
Vision	An overarching statement of the way an organisation wants to be, an

	ideal state of being at a future point. This refers to the desired future state of an organisation. The vision describes where the organisation is headed, what it intends to be, or how it wishes to be perceived in the future.
Vulnerable patient	Those patients who are prone to injury and disease by virtue of their age, sex, physical, mental and immunological status,e.g. infants, elderly, physically- and mentally-challenged, semiconscious/ unconscious, those on immunosuppressive and/or chemotherapeutic agents.

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