

ACCREDITATION STANDARDS GUIDEBOOK FOR AYURVEDA HOSPITALS

NATIONAL ACCREDITATION BOARD FOR HOSPITALS AND HEALTHCARE PROVIDERS (NABH)

Guidebook to
Accreditation Standards
for Ayurveda Hospitals *(2nd edition)*

April 2016



National Accreditation Board for Hospitals
and Healthcare Providers (NABH)





N A B H

QUALITY : SAFETY : WELLNESS



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NABH PLEDGES

Taking Quality to the Last Man in the Line

HAPPY INDEPENDENCE DAY
15th August 2020



PREFACE TO THE RE-PRINT

National Accreditation Board for Hospitals and Healthcare Providers (NABH), a constituent board of Quality Council of India, established in 2005, is in its 15th year of creating an ecosystem of quality in healthcare in India. NABH standards focus on patient safety and quality of the delivery of services by the hospitals in the changing healthcare environment. Without being prescriptive, the objective elements remain informative and guide the organisation in conducting its operations with a focus on patient safety.

All NABH standards have been developed in consultation with various stakeholders in the healthcare industry and if implemented help the healthcare organizations in stepwise progression to mature quality systems covering the entire spectrum of patient safety and healthcare delivery.

The NABH organization & the hospital accreditation standards are internationally recognized and benchmarked. NABH is an Institutional as well as a Board member of the International Society for Quality in Health Care (ISQua) and Asian Society for Quality in Health Care (ASQua) and a member of the Accreditation Council of International Society for Quality in Health Care (ISQua).

Over the years, successive NABH standards have brought about not only paradigm shifts in the hospitals' approach towards delivering the healthcare services to the patients but have equally sensitised the healthcare workers and patients towards their rights and responsibilities.

In celebration of our 74th Independence Day, on 15th of August, 2020, we are pleased to announce, that starting today, in an enhanced effort to connect with people, all NABH standards, across programmes, will be available free of charge as downloadable documents in PDF format on the NABH website www.nabh.co. (The Printed copies of Standards and Guidebooks will continue to remain available for purchase at a nominal price).

NABH also announces the enriched continuation of its **"NABH Quality Connect-Learning with NABH"** initiative, connecting free monthly training classes, webinars and seminars. The various topics that will be taken up will cover all aspects of patient safety, including: Key Performance Indicators, Hospital Infection Control, Management of Medication, Document Control etc.

Recently introduced communication initiatives like **Dynamic Website Resource Center** and **NABH Newsletter Quality Connect** (focusing on sharing the best quality practices, news and views) will also be bettered.

It is sincerely hoped that all stakeholders will certainly benefit from the collective efforts of the Board and practical suggestions of thousands of Quality Champions from India and abroad

NABH remains committed to ensuring healthy lives and promote wellbeing for all at all ages (SDG-3-Target 2030), creating a culture of quality in healthcare and taking Quality, Safety and Wellness to the Last Man in the Line.

Jai Hind

(Dr. Atul Mohan Kochhar)
CEO-NABH

15th August 2020

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 organization can and cannot provide. This will facilitate in appropriately matching patients with the organization's resources. Only those patients who can be cared for by the organization are admitted to the organization. Out-patients who do not match the organization's resources are similarly referred to organizations that have the matching resources.

Patients that match the organizations resources are admitted using a defined process that includes patient and family education.

Patients cared for by the organization undergo an established initial assessment and periodic and regular reassessments.

Assessments may include 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 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 or referral of patients who do not match the organizational resources.
AAC.4.	Patients cared for by the organisation undergo an established initial assessment.
AAC.5.	All patients cared for by the organisation undergo a regular reassessment.
AAC.6.	Laboratory services, if applicable are provided as per the scope of services of the organisation.
AAC.7.	There is an established laboratory quality assurance programme.
AAC.8.	There is an established laboratory-safety programme.
AAC.9.	Imaging services, if applicable are provided as per the scope of services of the organization.
AAC.10.	There is an established quality assurance programme for imaging services.
AAC.11.	There is an established radiation safety programme.
AAC.12.	Patient care is continuous and multidisciplinary in nature.
AAC.13.	The organization has a documented discharge process.
AAC.14.	Organization defines the content of the discharge summary.

Standards and Objective Elements

Standard

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

Objective Elements

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

Interpretation: The organisation shall define this keeping in mind the scope of services applied for. The needs of the community should be considered especially when planning a new organisation or adding new services. The same could be captured through the feedback mechanism.

- b. The defined 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. Claims of services and expertise being available should actually be 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).

- c. The staff is oriented to these services.

Interpretation: All the staff in the hospital mainly in the reception/registration, OPD, IPD are oriented to these services 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.

- b. The Documented policies and 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 each time. 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.

- 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. Also refer to AAC 3.

- f. **The staff is aware of these processes.**

Interpretation: All the staff handling these activities should be oriented to these policies and procedures. Orientation can be provided by documentation/ training.

- g. **Maintenance of separate daily record of bed occupancy with monthly conclusion of occupancy.**

Interpretation: There is a record/register in which the patients admitted/ discharged on a particular day are entered. It should be able to reflect the number of beds occupied at any given point of time and the statistics of a particular time frame i.e., monthly, etc.

Standard

AAC.3.	There is an appropriate mechanism for transfer or referral of patients who do not match the organizational resources.
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Objective Elements

- a. **Documented policies and procedures guide the transfer of patients to another facility in an appropriate manner.**

Interpretation: The documented procedure should address the methodology of safe transfer of the patient in a life-threatening situation to another organisation. There should be availability of an appropriate ambulance fitted with-life support facilities and accompanied by trained personnel. These patients 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. Also refer to COP 3.

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

Interpretation: Patients not in a life threatening situation (stable) should also be transported in a safe manner. Also refer to COP 3.

- c. Procedures identify staff responsible during transfer/referral.

Interpretation: The staff accompanying shall at least be a trained staff. He/she shall have undergone training in BLS. Further, the procedure shall identify the responsible staff for various steps of the procedure. A doctor should accompany an unstable patient.

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

Interpretation: The organisation gives a case summary mentioning the significant findings and treatment given in case of patients who are being transferred from emergency. A copy of the same shall be retained by the organisation. For admitted patients a discharge summary has to be given (refer AAC 13 & 14). The same shall also be given to patients leaving against medical advice. This shall include patients being transferred both for diagnostic and/or therapeutic purposes.

Standard

AAC.4.	Patients cared for by the organisation undergo an established initial assessment.
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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 IPD. 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 Kaumarabhritya OPD the weight and height may be a must, whereas it may not be so for Shalakyia OPD. In emergency department, this shall include recording of vital parameters. The format shall be designed to ensure that the laid-down parameters are captured. Every initial assessment shall contain rogi

and roga pariksha. This shall incorporate initial assessment by Doctors and Paricharaka in case of in-patients.

- 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. Doctors/Paricharakas shall conduct the assessments. Also refer to HRM 10 a&d, HRM 11 a&d, HRM 12 c.

- c. **The organisation defines the time frame within which the initial assessment is completed based on patient 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/ in-patients. The time frame shall be from the time that the patient has registered (or in case of emergency: come to the emergency) till the time that the initial assessment is documented by the treating consultant. The time frame shall be reasonable and match with the organisational resources and patient load. In case of out-patients there could be a separate timeframe for patients coming with appointment and for “walk-in” patients. Patient’s needs mean the condition of the patient.

- d. **The initial assessment for in-patients is documented within 24 hours or earlier as per the patient’s condition or hospital policy. Initial assessment includes identification of medication that the in-patient is using of the relevant AYUSH system, of any other AYUSH system and of modern medicine.**

Interpretation: This should cover rogi and roga pariksha. It should mention the provisional diagnosis and a list of medicines that the in-patient is already using. For an admitted patient, if a detailed assessment has been done earlier (either in OPD within the past seven days or emergency), 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. Please 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 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. A detailed nutritional assessment shall be done wherever necessary. This could be done by the treating doctor. Questionnaires could be used for the same. Where appropriate the organisation could consider providing a nutritional assessment for out-patients also.

- f. Care plan has to be documented and is monitored after the initial assessment.

Interpretation: This shall be documented by the treating doctor or by a member of his team in the patient record. For definition of "care plan" refer to glossary. This is applicable only for day-care and in-patients. Also refer PRE 3 d & e.

- g. The care plan also includes preventive aspects of the care where appropriate.

Interpretation: The documented care plan should cover preventive actions as necessary in the case and could include diet, drugs etc. In conditions where it is not possible to incorporate this at the time of assessment (e.g. diagnosis not made/unclear) the same shall be done as soon as a definite diagnosis is arrived at. This could also be done through booklets/patient information leaflets etc. e.g. Madhumeha, Kushtaroga etc.

- h. The care plan is countersigned by the doctor 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.

- i. The care plan includes desired results of the treatment, care or service.

Interpretation: The indicative results are curative, preventive and rehabilitative.

Standard

AAC.5.	All patients cared for by the organisation undergo a regular reassessment.
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Objective Elements

- a. All Patients are reassessed at appropriate intervals.

Interpretation: After the initial assessment, the patient is reassessed periodically and this is documented in the medical record. The frequency may be different for different areas based on the setting and the patient's condition, e.g. patients undergoing Shodhana Chikitsa to be reassessed more frequently compared to a patient undergoing Shamana Chikitsa. 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 completion of treatment /discharging) or patients awaiting admission/bed.

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

Interpretation: The reassessment notes shall reflect the patient's response to treatment and at a minimum capture the symptoms (change or fresh) and vital signs. This would 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.

- 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 pareeksha as per Ayurveda such as Ashta sthana pareeksha, Dashavidha rogi pareeksha etc, vitals, systemic examination findings. (and medication orders). The doctor/paricharika 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.

Standard

AAC.6.	Laboratory services, if applicable are provided as per the scope of services of the organisation.
---------------	--

Objective Elements

- a. Scope of the laboratory services are commensurate to the services provided by the organization.

Interpretation: The organisation should ensure availability of laboratory services commensurate to the healthcare services offered by it either by providing the same in house or by outsourcing.

- b. Adequately qualified and trained personnel perform and/or supervise the investigations.

Interpretation: The staff employed in the lab should be suitably qualified (appropriate degree) and trained to carry out the tests. Pathologist/Microbiologist/Biochemist shall supervise the staff. For adequacy of qualification refer to NABL 112.

- c. Documented policies and procedures guide collection, identification, handling, safe transportation, processing and disposal of specimens.

Interpretation: The organisation has documented procedures for 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. 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. This should be in line with standard precautions. The disposal of waste shall be as per the statutory requirements (Bio-medical waste management and handling rules, 1998.)

- d. 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).

e. **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. 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.

f. **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 on that lab's letterhead.

g. **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 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 an 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.
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Objective Elements

- a. **The laboratory quality assurance programme is documented.**

Interpretation: The organisation has a documented quality assurance programme (preferably as per ISO 15189 Medical laboratories – Particular requirements for quality and competence). 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.

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

Interpretation: This holds true for any laboratory-developed methods. Standard methods need verification to ensure that the laboratory is capable of performing the analysis. Verification usually includes accuracy, precision and linearity. Validation in addition includes sensitivity and specificity.

- c. **The programme addresses surveillance of test results.**

Interpretation: The head of laboratory/department shall periodically assess the test results. This shall be done in a structured manner. The organisation shall specify the frequency and the sample size that it shall use for the surveillance.

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

Interpretation: Refer to ISO 15189. Traceability certificate(s) of all calibration done shall also be documented and maintained.

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

Interpretation: Self-explanatory.

Standard

AAC.8.	There is an established laboratory-safety programme.
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Objective Elements

- a. The laboratory-safety programme is documented.

Interpretation: A well-documented lab safety manual is available in the lab. This takes care of the safety of the workforce as well as the equipment available in the lab. It shall be in consonance with the risks and hazards identified. This could be as per Occupational Health and Safety Management System -OHSAS 18001:1999.

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

Interpretation: Lab-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, 1998. Material safety and data sheets (where applicable) shall be available and staff well versed in the same.

- d. Laboratory personnel are appropriately trained in safe practices.

Interpretation: All the lab staff undergo training regarding safe practices in the lab.

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

Interpretation: Adequate safety devices are available in the lab, e.g. fire extinguishers, dressing materials, disinfectants etc. This should be sufficient to address the safety issue. At a minimum, standard precautions are adhered to.

Standard

AAC.9.	Imaging services, if applicable are provided as per the scope of services of the organization.
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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 BARC clearance, dosimeters, lead sheets, lead aprons, signage, display as per PNDDT act, reports to competent authority, etc. The organisation shall have an RSO (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 manpower) is adequate to provide for its defined scope of services.**

Interpretation: The equipment available and manpower should be able to effectively deliver its imaging services. Reports should not get delayed due to lack of adequate equipment or manpower (including people authorised to report results).

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

Interpretation: As per AERB guidelines.

- e. **Documented policies and procedures guide identification and safe transportation of patients to imaging services.**

Interpretation: The organisation has documented policies and procedures for informing the patients about the imaging activities, their identification and safe transportation to the imaging services. This should also address transfer of unstable patients to imaging services. The patients shall also be transported back

in a safe manner.

- f. **Imaging results are available within a defined time frame.**

Interpretation: The organisation shall document turnaround time of imaging results for all modalities. The defined time frame could be different for different type of 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: Critical results shall be intimated to the treating clinician at the earliest on phone, followed by a written report. The same shall be documented. The organization shall define and document the critical results which require immediate attention of clinician e.g. Asthi Bhagna.

- h. **Results are reported in a standardized 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. All reports from the outsourced imaging centre shall incorporate these features and the hospital shall not alter/modify anything in the report.

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

Interpretation: The organization 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 specimens 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 organization.

The organization 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.
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Objective Elements

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

Interpretation: Refer to AERB guidelines. Some examples include congruence of optical and radiation field, focal spot size, output consistency, leakage rate, etc.

- b. The programme addresses verification and/or validation of imaging methods.

Interpretation: This holds true for any in-house developed methods.

- c. The programme addresses surveillance of imaging results.

Interpretation: The head of the department shall periodically assess the imaging results. This shall be done in a structured manner. The organisation shall specify the frequency and the sample size that it shall use for the surveillance.

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

Interpretation: Calibration and maintenance of all equipment shall be carried out by competent persons. Traceability certificate(s) of all calibration done by calibrated equipment shall be documented and maintained.

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

Interpretation: Self-explanatory.

Standard

AAC.11.	There is an established radiation safety programme.
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Objective Elements

- a. The radiation-safety programme is documented.

Interpretation: Refer to AERB guidelines. RSO shall devise, implement and monitor the process.

- b. This programme is integrated with the organization's safety programme.

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

- c. 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 (where applicable) shall be available and staff well versed in the same.

- d. Imaging personnel are provided with appropriate radiation safety devices.

Interpretation: This includes lead aprons, shields and dosimeters to name a few. The number of such devices shall be adequate to ensure that all staff have proper protection.

- e. Radiation-safety devices are periodically tested and results documented.

Interpretation: Protective devices, e.g. lead aprons, should be exposed to X-ray for verification of cracks and damages. It is preferable that the film 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.

- f. Imaging personnel are trained in radiation-safety measures.

Interpretation: Self-explanatory.

- g. 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.
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Objective Elements

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

Interpretation: The organization shall ensure that the care of patients is always given by appropriately-qualified medical personnel (resident doctor, consultant and/or Paricharaka). 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 organization.

Interpretation: Care of patients is co-ordinated among various care-providers in a given setting viz., OPD, IPD, Panchakarma, OT, etc. The organization 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 organization 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 in medical record or on electronic medical records (EMR).

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

Interpretation: For example, Paricharakas handing-taking over notes, Transfer summary, etc.

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

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

- f. Documented policies and procedures guide the referral of patients to other departments/ specialties.

Interpretation: The organization 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 organization 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 organization. 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.

Standard

AAC.13.	The organization has a documented discharge process.
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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 policies and 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 MLC the organization shall ensure that the police are informed. In case of discharges not happening on a particular day, the discharges are planned keeping this in mind.

- c. Documented policies and procedures are in place for patients leaving against medical advice (LAMA) and patients being discharged on request.

Interpretation: The organization 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 organization.

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

Interpretation: The organization hands over the discharge papers to the patient/attendant in all cases and a copy is retained. In LAMA cases, the declaration of the patient/attendant is to be recorded on a proper format.

Standard

AAC.14.	Organization defines the content of the discharge summary.
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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.

- 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: Self-explanatory.

- 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 instructions shall be in a manner that the patient can easily understand and avoid use of medical terms, e.g. BID, TID, etc.

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

Interpretation: The organization should outline conditions regarding 'when' to obtain urgent care. For example, increase in pain, fever, or any specific symptom related to treatment/procedure. 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.

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

Interpretation: In case of MLC, this shall not be applicable.

Chapter 2

Care of Patients (COP)

Intent of the standards

The organization provides uniform care of patients in different settings. The different settings include care provided in outpatient units, various categories of wards, 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.

Policies, procedures, applicable laws and regulations also guide care of vulnerable patients (elderly, physically and/or mentally challenged and children), obstetrical patients, pediatric patients, patients undergoing parasurgical procedures, patients undergoing Panchakarma Therapy, patients under restraints and research activities. Pain management, Poshna karma and rehabilitative services are also addressed with a view to provide 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 of patients is provided in all settings of the organization and is guided by the applicable laws, regulations and guidelines.
COP.2.	Emergency services are guided by policies, procedures and applicable laws and regulations.
COP.3.	The ambulance services are commensurate with the scope of the services provided by the organization.
COP.4.	Documented policies and procedures guide the care of vulnerable patients (elderly, physically and/or mentally challenged and children).
COP.5.	Documented policies and procedures guide obstetric (Ante Natal & Post Natal) care.
COP.6.	Documented policies and procedures guide obstetric (Normal Labour and Caesarean Section) care
COP.7.	Documented policies and procedures guide Neonatal care.
COP.8.	Documented policies and procedures guide the care of Pediatric patients.
COP.9.	Documented policies and procedures guide the care of patients undergoing surgical, parasurgical, panchakarma and other treatment procedures
COP.10.	Documented policies and procedures guide the care of patients undergoing moderate sedation.
COP.11.	Documented policies and procedures guide the administration of anaesthesia.
COP.12.	Documented policies and procedures define rational use of blood and blood products.
COP.13.	Documented policies and procedures guide the care of patients in the intensive care and high dependency units.
COP.14.	Documented policies and procedures guide the care of patients under restraints.

COP.15.	Documented policies and procedures guide appropriate pain management.
COP.16.	Documented policies and procedures guide appropriate rehabilitative services.
COP.17.	Documented policies and procedures guide all research activities.
COP.18.	Documented policies and procedures guide Therapeutic diet.

Standards and Objective Elements

Standard

COP.1.	Uniform care of patients is provided in all settings of the organization and is guided by the applicable laws, regulations and guidelines.
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Objective Elements

- a. Care delivery is uniform when similar care is provided in more than one setting.

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

- b. Uniform care reflects applicable laws, regulations and guidelines.

Interpretation: Where applicable, the organization shall adhere to the norms laid down by government by relevant legislations like clinical establishment 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.

- c. Standard guidelines are adopted to guide uniform patient care whenever possible.

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

Standard

COP.2.	Emergency services are guided by policies, procedures and applicable laws and regulations.
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Objective Elements

- a. Policies and procedure for emergency care are documented

Interpretation: These could include SoPs/protocols to provide general emergency care happening within the hospital e.g. management of dehydration due to atiyoga of Vamana and Virechana.

- b. Policies also address 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 rules).

- c. The patients receive care in consonance with the policies.

Interpretation: This shall be dealt as per hospital Documented policies and procedures e.g. Road traffic accidents

- d. 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. For “triage” refer to glossary.

- e. Staff is 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 BLS.

- f. Admission or discharge to home or transfer to another organization is also documented.

Interpretation: Self-explanatory.

- g. In case of discharge to home or transfer to another organization a discharge note shall be given to the patient.

Interpretation: Also refer to AAC 13 and 14. The discharge note shall incorporate salient features of investigations done and the treatment given.

Standard

COP.3.

The ambulance services inhouse or outsourced are commensurate with the scope of the services provided by the organization.

Objective Elements

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

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

- b. **The ambulance adheres to statutory requirements.**

Interpretation: This is in the context of Motor Vehicle Act. Eg. Insurance & registration of vehicle

- c. **Ambulance(s) is appropriately equipped.**

Interpretation: This shall be done based on the organisation's scope. This shall be in consonance with BLS guidelines. 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. **Ambulance(s) is manned by trained personnel.**

Interpretation: The ambulance should be manned by a licensed and trained driver, technician/Paricharaka and/or doctor depending on the situation. Personnel shall be trained in BLS.

- e. **Ambulance is checked on a daily basis.**

Interpretation: The check shall 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. **Equipment are checked on a daily basis.**

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

- g. **Emergency medications are checked daily and prior to dispatch.**

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 stand by.

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

Interpretation: The ambulance shall be connected with the organization/control room by wireless/mobile phones.

Standard

COP.4.	Documented policies and procedures guide the care of vulnerable patients (elderly, physically and/or mentally challenged and children).
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Objective Elements

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

Interpretation: At a minimum, it shall incorporate as to who the vulnerable patients are, 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. Refer to disability act, mental act.

- b. **Care is organized and delivered in accordance with the policies and procedures.**

Interpretation: Organisation develops SoPs for delivery of care.

- c. **The organisation provides for a safe and secure environment for this vulnerable group.**

Interpretation: The organisation shall provide proper environment taking into account the requirement of the vulnerable group. For example, playroom for children, anti-skid floor, ramps with railings for disabled, grab bars, toilets for physically challenged 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 representative. Refer to PRE 4e.

- e. Staff is trained to care for this 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.

Standard

COP.5.	Documented policies and procedures guide obstetric (Antenatal and Post Natal) Care.
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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 and education. It could include Ante-natal & Post-natal care.

- b. The organization defines and displays whether Obstetric cases can be cared or not.

Interpretation: The organization shall define the type of obstetric care provided. 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.

- c. Documented procedures guide provision of Ante-natal services.

Interpretation: This shall at a minimum include assessment, diet counseling and frequency of visits. There shall be an ante-natal card for every such patient.

- d. Obstetric patient's assessment also includes maternal nutrition.

Interpretation: Self-explanatory.

- e. Appropriate Ante-natal and Post-natal monitoring is performed and documented.

Interpretation: This is in the context of maternal and fetal monitoring.

Standard

COP.6.	Documented policies and procedures guide obstetric (Normal Labour and Caesarean Section) care.
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Objective Elements

- a. There is a documented policy and procedure for obstetric (Normal Labour and Caesarean Section) services.

Interpretation: This shall include assessment of these patients including nutrition, immunisations and education, Normal and High risk patients. It could include prenatal safety guidelines such as monitoring standards, labour augmentation bundle, etc.

- b. 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.

- c. Appropriate peri-natal monitoring is performed and documented.

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

- d. 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 with appropriate equipment and staff.

Standard

COP.7.	Documented policies and procedures guide Neonatal care.
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Objective Elements

- a. There is a documented policy and procedure for Neonatal services.

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

- b. 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 breast feeding practice.

- c. 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.

- d. Provisions as permitted by state law are made for special care of neonates.

Interpretation: Adequate amenities for the care of neonates to be available in the hospital. For example, breast-feeding room.

- e. Patient assessment includes detailed nutritional, growth, and immunization assessment.

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

- f. Documented policies and procedures prevent neonate abduction and abuse.

Interpretation: The organisation shall ensure that there is an adequate security/surveillance to prevent such happenings. Examples could include identification tag.

- g. The children's family members are educated about nutrition, immunization and safe parenting and this is documented in the medical record.

Interpretation: For example, 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.8.	Documented policies and procedures guide the care of Pediatric patients.
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Objective Elements

- a. There is a documented policy and procedure for Paediatric services.

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

- b. The organization defines and displays the scope of its pediatric services.

Interpretation: The display should be in a prominent location (either near the entrance or registration counter or near the OPD). Refer to AAC 1b also.

- c. Provisions are made for special care of children.

Interpretation: Adequate amenities for the care of infants and children to be available in the hospital. E.g. playroom and breast-feeding room.

- d. Patient assessment includes detailed nutritional, growth and psychosocial assessment.

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

- e. Documented policies and procedures prevent child abduction and abuse.

Interpretation: The organization shall ensure that there is an adequate security/surveillance to prevent such happenings. Examples could include identification tag.

- f. The family members of the child are educated about nutrition, immunization and safe parenting and this is documented in the medical record.

Interpretation: For example, growth charts, immunization 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.9.	Policies and procedures guide the care of patients undergoing Surgical, parasurgical, panchakarma and other treatment procedures
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Objective Elements

- a. The policies and procedures are documented.

Interpretation: This shall include the list of and parasurgical procedures, panchakarma therapies and treatment procedure as well as competency level for performing these procedures. Examples for Parasurgical procedures include ksarasutra, raktamokshana, agnikarma, kshara karma, etc. Examples for Treatment procedures include Abhyanga, Pinda sweda etc.; Shalaky procedures like Kriya kalpas, Prasooti & Stree roga procedures like Uttara basti, Pichu, Prakshalana, etc.

- b. An informed consent is obtained by a Physician/Surgeon prior to the procedure.

Interpretation: The consent shall be taken by the operating surgeon or a member of his team. In case, the procedure is changed intra-op (and was not planned or an explicit consent not taken for the same) a fresh consent needs to be taken. In case of change in careplan, a fresh consent needs to be taken. Also refer to PRE 4f.

- c. Patients shall have a preoperative (parasurgical), preprocedure (panchakarma) assessment and a provisional diagnosis documented prior to surgery/procedures

Interpretation: All patients undergoing Parasurgical Procedure are assessed pre-operatively which is documented by a surgeon/physician. Similarly all panchakarma procedures are assessed before the procedure by the physician and should include yogya-ayogya for the particular therapy, and a provisional diagnosis is made which is documented. This shall be applicable for both routine and emergency cases.

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

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 etc. Refer to WHO "Safe surgery save 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, Parasurgical/panchakarma procedures in consonance with the law. Also refer to HRM 10 f, 11 & 12.

- f. A brief operative note / note regarding the procedure is documented prior to transfer of patient from recovery area.

Interpretation: This note provides information about the procedure performed and the status of the patient before shifting and shall be documented by the surgeon or Physician/member of the surgical team. At a minimum, it shall include the Parasurgical procedure performed, name of the surgeon(s)/physician, salient steps of the procedure and the key findings. It includes monitoring of samyak and asamyak lakshanas of the procedure. If it is documented by a person other than the physician, the same shall be countersigned by the Physician.

- g. The operating surgeon/physician document the post-operative/post-procedure care plan.

Interpretation: Post-operative plan shall include advice on IV fluids, medication, care of wound, nursing care, observing for any complications, etc. For post-procedures, the plan shall include advice on Samsarjana Krama for vamana/virechana, pathya-apathya for other procedures, nursing care, observing for any vyapaths, etc.

- h. Adequate area, appropriate facilities and equipment/instruments are available in the OT / Panchakarma therapy and Treatment procedure room

Interpretation: For Surgical/parasurgical procedures, the organisation shall ensure that the OT has facilities for pre-op holding, hand-washing area, operating rooms, storage area, recovery room, collection area for waste and linen etc. Panchakarma therapy and treatment procedure room may be combined or

separate. If separate attached toilet and bathroom with hot water facility should be available. The rooms shall have sufficient light and ventilation.

- i. **Patient, personnel and material flow conforms to infection control practices.**

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

- j. **Guidelines for various Parasurgical procedures / Panchakarma therapy and other Treatment procedures are prepared separately and adhered.**

Interpretation: For Parasurgical procedures e.g. the methodology of Ksharasutra, agnikarma etc. followed in the HCO shall be documented. For Parasurgical procedures the methodology may be based on classical texts like Susrutasamhita, Astangahridaya etc. e.g. "Parasurgical procedure protocol".

For Panchakarma therapy and other Treatment procedures like Vamana karma protocol, Abhyanga protocol, Netra tarpana protocol, pichu protocol, etc followed in the HCO shall be documented. For Panchakarma therapy and other Treatment procedures, SOP for the documented procedures are prepared based on classical texts like Charaka Samhita, Susruta samhita, Astangahridaya, etc.

- k. **Standard precautions and asepsis is adhered to during the conduct of therapies.**

Interpretation: In case the organization has a policy of re-using devices it shall ensure that they are properly sterilized where appropriate. Further, the integrity of the devices shall be checked.

- l. **A quality assurance program is followed for the Parasurgical / panchakarma therapy and other treatment 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, non healing wound etc. For panchakarma therapy & other treatment procedures, it shall focus on yogya-ayogya lakshanas, samyak-asamyak lakshanas, vyapaths, etc.

- m. **The quality assurance program includes surveillance of the OT / panchakarma or treatment procedure room.**

Interpretation: Surveillance activities include the monitoring of efficacy of OT / panchakarma, treatment procedure room cleaning, disinfection processes etc.

Standard

COP.10.	Documented policies and procedures guide the care of patients undergoing moderate sedation.
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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. Also refer to PRE 4d.

- c. Competent and trained persons perform 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.

- 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 (minimal, moderate and deep).

- g. Criteria are used to determine appropriateness of discharge from the recovery area.

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

- h. Equipment and manpower are available to rescue patients from a deeper level of sedation than that intended.

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

Standard

COP.11.	Documented policies and procedures guide the administration of anaesthesia.
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Objective Elements

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

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

- b. All 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 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, the drug(s) to be used for induction and the drug to be used for maintenance. It should also mention about other concomitant medications and IV fluids, special monitoring requirements where appropriate and anticipated post-anaesthesia care. This could be captured using a template.

- d. **An immediate pre-operative re-evaluation is performed and documented.**

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

Interpretation: The 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. Also refer to PRE 4d.

- 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. All 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.12.	Documented policies and procedures define rational use of blood and blood products.
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Objective Elements

- a. Documented policies and procedures are used to guide rational use of blood and blood products.

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

- b. Documented procedures govern transfusion of blood and blood products.

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 procedure for availability and transfusion of blood/blood components for emergency use/in 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 an 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 products.

Interpretation: Consent should be taken for every transfusion. However, with the same consent you can give multiple transfusions in the same sitting. For example, two pints of blood may be transfused serially using the same consent. However, if the same is given over two days or hours apart, then a separate consent is required. Also refer to PRE4 d. In case of patients who are transfusion dependent

(e.g. haemophilia, thalassemia etc.) the consent can be taken once in six months. However, before every transfusion a verbal approval shall be taken.

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

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

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

Interpretation: The organisation shall define as to what constitutes use in emergency 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 emergency. Use in emergency includes both for emergency use (stand-by) and in 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 glossary.

- h. **Staff is 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.13.	Documented policies and procedures guide the care of patients in the intensive care and high dependency units.
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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 Paricharaka-patient ratio. This could also incorporate objective elements b, f, g.

- 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 is 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 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.

Standard

COP.14.	Documented policies and procedures guide the care of patients under restraints.
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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 authorize the use of restraints, the frequency of monitoring these patients and the validity of restraint orders.

- b. These include physical restraint measures.

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

- c. These include documentation of reasons for restraints.

Interpretation: Self-explanatory.

- d. These patients are more frequently monitored.

Interpretation: The organization 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 care of patients. The staff shall be updated at least once a year. Records of the same should be maintained.

Standard

COP.15.	Documented policies and procedures guide appropriate pain management.
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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. Patients with pain undergo detailed assessment and periodic re-assessment.

Interpretation: A detailed pain assessment is done when 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 neuralgia and arthralgia. This does not include chest pain due to angina or where the aetiology of pain is physiological like labour pain.

- c. The organization respects and supports the management of pain for all patients.

Interpretation: In case the hospital does not have facilities for pain management it could refer such patients to centers specializing in pain management.

- d. 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 or in view of the underlying condition not being treatable.

Standard

COP.16.	Documented policies and procedures guide appropriate rehabilitative services.
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Objective Elements

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

Interpretation: This includes Vyayama, Yoga, Physiotherapy etc.

- b. The scope of rehabilitative services are commensurate with the organization's requirements.

Interpretation: E.g. in the management of *Pakshaghata*.

- 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 objective parameters.

- d. Rehabilitative services are provided by a multidisciplinary team.

Interpretation: The team shall have a treating doctor and other professional experts.

- e. 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 as appropriate

Standard

COP.17.	Documented policies and procedures guide all research activities.
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Objective Elements

- a. Documented policies and procedures guide all research activities in compliance with 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 organization 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. 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 organization's services.

Interpretation: Self-explanatory.

Standard

COP.18.	Documented policies and procedures guide Therapeutic diet (Poshana Karma).
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Objective Elements

- a. Documented policies and procedures guide implementation of therapeutic diet (poshana karma) after assessment and reassessment of patient needs.

Interpretation: This shall at a minimum, incorporate as to whom assessment will be done, how it will be done, how the food is prepared and ensured that the patient

receives food as per the diet order. Assessment shall be done by doctor for all patients found at risk during screening.

- b. **Patients receive food according to their clinical needs.**

Interpretation: A doctor shall do the assessment of the patient and advice regarding food. E.g. pathya and apathya ahara etc.

- c. **There is a written order for the pathyahara.**

Interpretation: The doctor 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. **When families provide food, they are educated about the patient's pathya and apathya.**

Interpretation: The doctor shall ensure this during planning.

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

Interpretation: The dietary services to be designed in a manner that 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 away from food;
- v. Separate dedicated food preparation areas exist;
- vi. Measures are in place to ensure that flies 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 boxes (hot food kept hot and cold food kept cold).

Chapter 3

Management of Medication (MOM)

Intent of the standards

The organization has a safe and organized medication process. The process includes documented 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 have oversight of all medications stocked out of the pharmacy. The pharmacy should ensure correct storage (as regards to temperature, look-alike, sound-alike etc), expiry dates and maintenance of documentation.

Every high alert medication order should be verified by an appropriate person so as to ensure accuracy of the dose, frequency and route of administration.

The process also includes monitoring of patients after administration and procedures for reporting and analyzing medication errors & adverse drug events.

Policies and procedures guiding the use of formulations containing toxic/narcotic drugs.

Safe use of high alert medication is guided by documented policies and procedures. Patients and family members are educated about safe medication. Policies and procedures guide the use of medical supplies and consumables.

Summary of Standards

MOM.1.	Documented policies and procedures guide the organization of pharmacy services and usage of medication.
MOM.2.	There is a hospital formulary.
MOM.3.	Documented policies and procedures exist for storage of medication.
MOM.4.	Documented policies and procedures exist for prescription of medications.
MOM.5.	Documented policies and procedures guide the safe dispensing of medications.
MOM.6.	There are defined procedures for medication management.
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 policies and procedures guide the use of medical supplies and consumables.
MOM.10.	Documented policies and procedures guide the use of formulations containing toxic/narcotic drugs.

Standards and Objective Elements

Standard

MOM.1.	Documented policies and procedures guide the organization of pharmacy services and usage of medication.
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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 in a “Pharmacy/Medication Usage Manual”.

- b. These comply with the applicable laws and regulations.

Interpretation: Relevant legislations include Drugs and Cosmetics Act

- c. A multidisciplinary committee guides the formation and implementation of these policies and procedures.

Interpretation: This shall be representative of major clinical departments, administration and shall include a paricharika trained in pharmacy. 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. For example, pharmaco-therapeutic committee.

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

Interpretation: When pharmacy is closed, there should be a SoP to procure the medicines. It is preferable that the organization has a 24-hour pharmacy.

Standard

MOM.2.	There exists a hospital formulary.
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Objective Elements

- a. A list of medication appropriate for the patients and organization's resources is developed.

Interpretation: The organization's formulary shall be prepared and be preferably updated at regular intervals. The formulary could be prepared keeping in mind Department of AYUSH "Essential Drug List" (EDL).

- b. The list is developed collaboratively by the multidisciplinary committee.

Interpretation: Refer to MOM 1c.

- 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 organization. The organization 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.

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

Interpretation: The process should address the issues of vendor selection, vendor evaluation, indenting process, generation of purchase order and receipt of goods.

- e. There is a defined process for preparation of these medications.

Interpretation: SOP will be developed for preparation of medications required for Out-Patients, In-Patients, Panchakarma therapies, other treatment procedures, etc. The medicine preparation of Panchakarma therapies and other treatment procedures may be included in the "Guideline for Panchakarma therapies and other treatment procedures" "Panchakarma protocol". e.g. preparation of Kashaya basti yoga, Putapaka for netra rogas, Yoni pichu etc. Ref. COP 9I.

- f. There is a process to obtain medications not listed in the formulary.

Interpretation: For example, local purchase (for immediate requirement).

Standard

MOM.3.	Documented policies and procedures exist for storage of medication.
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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, vermin etc.

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

Interpretation: The organization 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. To check for loss or theft the organization could conduct audits at regular intervals (as defined by the organization).

- c. Sound inventory control practices guide storage of the medications.

Interpretation: Organisation shall follow or demonstrate ABC, VED, FSN, FIFO-led time analysis, etc. The medicines shall be stored in alphabetical or company's name.

- d. Sound alike and look alike medications are identified and stored separately.

Interpretation: Many drugs may look-alike or sound-alike. They should be documented, segregated and stored separately at all locations. The organization can follow a method of storing drugs in an alphabetical order to address this issue. 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).

Standard

MOM.4.	Documented policies and procedures exist for prescription of medications.
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Objective Elements

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

Interpretation: Refer to MOM 1a. It could also incorporate objective elements “b”, “f” and “h” of MOM 4.

- b. The organisation determines the minimum requirements of a prescription.

Interpretation: This shall adhere to national/international guidelines where appropriate. At a minimum, the prescription shall have the date, name of the patient, unique hospital number, name of the drug, dose, route and frequency of administration of the medicine, name, signature of the prescribing doctor.

- c. The organization determines who can write orders.

Interpretation: This shall be done by a doctor who at a minimum holds a recognized qualification in Ayurveda as per Schedule 2 of IMCC Act 1970.

- d. Orders are written in a uniform location in the medical records.

Interpretation: All the orders for medicines are recorded on a uniform location in the medical record. Electronic orders when typed shall again follow the same principles. It is preferable that prescription and administration record is on the same sheet. This would help minimize medication errors.

- e. Medication orders are clear, legible, dated, timed, named and signed.

Interpretation: Only approved abbreviations by the organization shall be used. The organization can explore the possibility of writing orders in block letters so that the issue of legibility is addressed.

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

Interpretation: Medication orders include for those medications required for Panchkarma therapies and other procedures. In case of a medication having two

or more drugs (tablet/capsule/churna) the dose of all the individual drugs shall be written. For example, in a combination of medicines a, b & c the individual dose of a, b & c and the dose of the such mixture to be administered is clearly written. In case abbreviations are used, a standardized list of approved abbreviations for medications shall be used throughout the organization.

g. **Policy on verbal orders is documented and implemented.**

Interpretation: The organization 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. 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.

h. **The organization defines a list of high alert medication.**

Interpretation: High-Alert medications are medications involved in a high percentage of medication errors or sentinel events and medications that carry a high risk for abuse, error, or other adverse outcomes. Examples include look-alike and sound-alike medications, medications containing Visha and Upa-visha dravya, Kupa pakwa rasayanas, etc.

i. **High Alert medication orders are verified prior to dispensing.**

Interpretation: Self-explanatory.

Standard

MOM.5.	Documented policies and procedures guide the safe dispensing of medications.
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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. Physician samples shall not be sold.

- b. The policies include a procedure for medication recall.

Interpretation: Recall may result based on letters from regulatory authorities or internal feedback (e.g. visible contaminant in Arista/Kashaya bottle).

- c. Expiry dates are checked prior to dispensing, wherever applicable.

Interpretation: This shall be done at all levels e.g. pharmacy, ward etc.

- d. Labeling requirements are documented and implemented by the organization.

Interpretation: At a minimum, labels must include the drug name, quantity, 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.

Standard

MOM.6.	There are documented policies and procedures for medication management.
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Objective Elements

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

Interpretation: Refer to statutory requirements. In addition to doctors, Nursing staff, Panchkarma therapist, Paricharakas may also administer. This does not apply to topical administration.

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

Interpretation: E.g. while preparing basti dravya, the first yoga is prepared & labeled and then the subsequent yogas should be prepared & labeled.

- 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 prior to administration.

Interpretation: Staff administering medications should go through the treatment orders before administration of the medication and then only administer them. It is

preferable that they also check the general appearance of the medication (e.g. broken tablet, clumped choorna etc.) before dispensing.

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. However, to ensure that patient care does not suffer a verbal order may be got from the treating doctor followed by ratification of the same (refer to MOM 4e).

In case of high alert medication(s), the verification shall be done by at least two staff (Paricharaka-Paricharaka, Paricharaka-doctor or Paricharaka-doctor) independently and documented.

- 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. e.g. o.d, b.i.d, t.i.d, q.i.d, h.s., stat, sos.

- 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.

- i. Policies and procedures govern patient's self administration of medications.

Interpretation: 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 documentation of self-administration.

- j. Documented policies and procedures govern patient's medications brought from outside the organization.

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

Standard

MOM.7.	Patients are monitored after medication administration.
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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: E.g. observation after administration of Vamana / Virechana yoga

- c. Monitoring is done in a collaborative manner.

Interpretation: This shall be done by the clinician/Paricharaka/Panchkarma therapist.

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

Interpretation: This also includes dose adjustment.

Standard

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

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

Interpretation: This shall outline the process for identifying, capturing, 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 time frame 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 (refer to MOM 1c). 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 policies and procedures guide the use of medical supplies and consumables.
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Objective Elements

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

Interpretation: The process should address the issues of vendor selection, vendor evaluation, indenting process, generation of purchase order and receipt of goods. Ref. MOM 1a.

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

Interpretation: Hazardous materials are identified and kept separately.

- 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 are as specified by the manufacturer as 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.

- 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.

Standard

MOM.10.	Documented policies and procedures guide the use of formulations containing toxic/narcotic drugs.
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Objective Elements

- a. **Documented procedures guide the use of narcotic drugs.**

Interpretation: Self-explanatory. Refer to MOM 1a.

- b. These procedures are in consonance with local and national regulations.

Interpretation: Self-explanatory.

- c. 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.

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

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

Remark(s): A very strict inventory control shall be kept for these drugs.

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

Interpretation: Self-explanatory.

Chapter 4

Patient Rights and Education (PRE)

Intent of the standards

The organization defines the patient and family rights and responsibilities. The staff is aware of these and is trained to protect patient rights. Patients are informed of their rights and educated about their responsibilities at the time of admission. The patients are educated about the mechanisms available for addressing grievances.

Patients and family members are educated about pathya & apathya ahara.

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

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

Summary of Standards

PRE.1.	The organization protects patient and family rights and informs them about their responsibilities during care.
PRE.2.	Patient and family rights support individual beliefs, values and involve the patient and family in decision making processes.
PRE.3.	The patient and/or family members are educated to make informed decisions and are involved in the care planning and delivery process.
PRE.4.	A documented process for obtaining patient and/or family's consent exists for informed decision making about their care.
PRE.5.	Patient and families have a right to information and education about their healthcare needs.
PRE.6.	Patient and families have a right to information on expected costs.
PRE.7.	Organisation has a complaint redressal procedure.

Standards and Objective Elements

Standard

PRE.1.	The organization protects patient and family rights informs them about their responsibilities during care
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Objective Elements

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

Interpretation: Organization should respect patient's rights and inform them of their responsibilities. All the rights of the patients should be displayed in the form of a Citizens' Charter. Display should be at least bi-lingual (English and the state language/ language spoken by the majority of people in that area). The documented patient rights shall include all the points mentioned in PRE 2. e.g. of "patient responsibility" refer to glossary.

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

Interpretation: This could be done in the form of permanent displays at strategic locations within the organisation. Pamphlets could be provided regarding the same.

- c. The organization's leaders protect patient's and family rights.

Interpretation: Protection also includes addressing patient's grievances w.r.t rights.

- d. Staff is aware of their responsibility in protecting patients 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: Where patients' rights have been infringed upon, management must keep records of such violations, as also a record of the consequences e.g. corrective actions to prevent recurrences. The organisation shall have a mechanism to capture the same.

The organisation could develop an indicative list of such items and train the staff accordingly. e.g. repeated examinations, no examination, soliciting money. 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.
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Objective Elements

- a. Patient and family rights address any special preferences, spiritual and cultural needs.

Interpretation: This could include dietary preferences and worship requirements.

- 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 consent is taken and that the patient's identity is not revealed.

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

Interpretation: Special precautions shall be taken especially w.r.t vulnerable patients, e.g. elderly, neonates, etc. Examples of this include falling from the bed/trolley due to negligence, assault, repeated internal examinations, manhandling, etc.

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

Interpretation: Staff shall avoid having patient-related discussions in public places. Statutory requirements w.r.t. privileged communication shall be followed at all times. Confidential information including HIV status shall not be revealed without patient's permission. It shall not be written/pasted on the cover of the medical record. Examples of privileged communications include patients of

tuberculosis or any other infectious disease.

- e. **Patient and family rights include refusal of treatment.**

Interpretation: During management, the patients should be given the choice of treatment. The treating doctor shall discuss all the available options and allow the patient to make an informed choice including the option of refusal. In case of refusal, the treating doctor shall explain the consequences of refusal of treatment and document the same.

- f. **Patient and family rights include informed consent before panchakarma therapy, prasuti tantra and streeroga procedures, shalaky procedures, anesthesia, parasurgical procedure, and surgery, initiation of any research protocol and any invasive/high risk procedures/treatment.**

Interpretation: Informed consent of the patient is mandatory for doing HIV test.

- g. **Patient and family rights include information on how to voice a complaint.**

Interpretation: Grievance redressal mechanism must be accessible and transparent. Displayed information must be clearly available on how to voice a complaint.

- h. **Patient and family rights include information on the expected cost of the treatment.**

Interpretation: Refer PRE 6

- i. **Patient and family have a right to have an access to his/her clinical records.**

Interpretation: The organization 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.

- j. **Patient and family rights include information on care plan, progress and information on their health care needs.**

Interpretation: The care plan as decided by the doctor on duty or the patient management team (as the case may be) is to be discussed 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. Refer AAC 4 f,g, 5c and PRE 3 & 5.

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
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Objective Elements

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

Interpretation: The care plan as decided by the doctor on duty or the patient management team (as the case may be) is to be discussed 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. Refer to AAC 4 f, g & AAC 5c.

- 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 physicians or his/her team about the outcomes of such treatment.

- 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 capture this. The feedback for this could be got at the time of admission and during the re-assessments.

- 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: Confidential information like HIV test result shall only be revealed to the patient.

- g. The patient and/or family members are explained about any change in the patient's condition.

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.
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Objective Elements

- a. General consent for treatment is obtained when the patient enters the organisation.

Interpretation: Self-explanatory.

- b. Patient and/or his family members are informed of the scope of such general consent.

Interpretation: The organization shall define as to what is the scope of this 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.

- c. 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. e.g. some statutory requirements are PNDT Act, Research activities etc. The policy for HIV testing should follow the national policy on HIV testing (NACO).

- d. **Informed consent includes information regarding the procedure, risks, benefits, alternatives and as to who will perform the requisite procedure in a language that they can understand.**

Interpretation: The consent shall have the name of the doctor performing the procedure. 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.

- e. **The procedure describes who can give consent when patient is incapable of independent decision making.**

Interpretation: The organisation shall take into consideration the statutory norms. This would include next of kin/legal guardian. The order of preference is spouse, son, daughter/ brother/ sister/ parents. However, in case of unconscious/ unaccompanied patients the treating doctor can take a decision in life-saving circumstances. 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.

- 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 then the written consent is taken by the Paricharaka. 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/s (either on the day / the previous day);
- ii. At least one independent witness signing the consent form;
- iii. Taking consent every time (especially for procedures which the patient has to undergo lifelong;
- iv. Taking a fresh consent (for the new procedure) in case the procedure has to be changed mid-way.

- h. Staff are aware of the informed consent procedure.

Interpretation: They 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.
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Objective Elements

- a. When appropriate, patient and/or family are educated about the safe and effective use of medication and the potential side effects of the medication.

Interpretation: The organisation shall make a list of such medicine and accordingly educate e.g. Bhallataka Kalpas. This could also include education regarding the importance of taking a medicine at a specific time e.g. Accha snehapana

- b. Patient and/or family are educated about food-medicine interactions.

Interpretation: Patient and family should be counseled about their diet during medication e.g. restriction of milk soon after taking arishtam.

- c. Patient and/or family are educated about pathyahara and poshana

Interpretation: This includes pathya and apathya ahara.

- d. 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 swasthya samrakshana, pathya apathya where appropriate. This is more relevant for chronic conditions.

- e. Patient and/or family are educated about preventing infections.

Interpretation: For example, hand washing and avoiding overcrowding near the patient.

- f. Patient and/or family are educated in a language and format that they can understand.

Interpretation: Self-explanatory.

Standard

PRE.6.	Patient and families have a right to information on expected costs.
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Objective elements

- a. There is uniform pricing policy in a given setting (out-patient and inpatient category).

Interpretation: There should be a billing policy which defines the charges to be levied for various activities.

- b. The tariff list is available to patients.

Interpretation: The organization shall ensure that there is an updated tariff list and that this list is available to patients when required. The organization 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 and transparent.

- c. Patients and family are educated about the estimated costs of treatment.

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.

- d. Patients and family are informed about the financial implications when there is a change in the patient condition or treatment setting.

Interpretation: When treatment plan changes from shamana to shodhana chikitsa, the financial implications must be clearly conveyed to them.

Standard

PRE. 7.	Organisation has a complaint redressal procedure.
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Objective elements

- a. 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.

- b. Patient and/or family members are made aware of the procedure for 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.

- c. All complaints are analysed.

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.

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

Interpretation: Self-explanatory.

Chapter 5

Hospital Infection Control (HIC)

Intent of the standards

The standards guide the provision of an effective infection control program in the organization. The program is documented and aims at reducing/eliminating infection risks to patients, visitors and providers of care.

The organization measures and takes action to prevent or reduce the risk of Hospital Associated Infection (HAI) in patients and employees.

The organization provides proper facilities and adequate resources to support the Infection Control Program.

The program includes an action plan to control outbreaks of infection, disinfection/sterilization activities, Bio-medical Waste (BMW) management, training of staff and employee health.

Summary of Standards

HIC.1.	The organization has a well-designed, comprehensive and coordinated infection control programme aimed at reducing/ eliminating risks to patients, visitors and providers of care.
HIC.2.	The organization implements the policies and procedures laid down in the Infection Control Manual.
HIC.3.	The organization performs surveillance activities to capture and monitor infection prevention and control data.
HIC.4.	The organization takes actions to prevent or reduce the risk of Hospital Associated Infections (HAI) in patients and employees.
HIC.5.	The organization provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).
HIC.6.	Biomedical waste (BMW) is handled in an appropriate and safe manner.
HIC.7.	The infection control programme is supported by the organization's management and includes training of staff.
HIC.8.	There are documented policies and procedures for sterilization activities in the organization.

Standards and Objective Elements

Standard

HIC. 1.	The organization has a well-designed, comprehensive and coordinated infection control programme aimed at reducing/eliminating risks to patients, visitors and providers of care
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Objective Elements

- a. The hospital infection control programme is documented which aims at preventing and reducing risk of healthcare associated infections.

Interpretation: 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 updation shall be done based on newer literature on infection prevention and outbreak prevention mechanisms, infection trends and outcomes of the audit processes.

- c. The hospital has a multi-disciplinary infection control committee which coordinates all infection prevention and control activities

Interpretation: This shall preferably have Infection control officer, Hospital Administrator, Physician, Surgeon, head/senior Paricharaka and other support services. It could also include invitees from various departments as deemed necessary. The committee shall lay down the documented policies and procedures to guide the implementation. The composition, frequency of meetings, 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 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 committee and the team shall not be the same. However, the team shall be represented in the committee. This shall preferably have Infection control Officer, Hospital Physician, head/senior Paricharaka and one support services staff.

- e. The hospital has designated infection control officer as part of the infection control team.

Interpretation: This shall be a doctor. It is preferable that he/she is trained / experience in infection control activities

Standard

HIC. 2.	The organization implements the policies and procedures laid down in the Infection Control Manual.
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Objective Elements

- a. The organization identifies the various high-risk areas and procedures and implements policies and/or procedures to prevent infection in these areas.

Interpretation: The manual should clearly identify the high-risk areas of the hospital, e.g **Procedure room, Panchkarma theatre, OT, Recovery room**, etc. Similarly, all high- risk procedures should be identified from infection control point of view, for example, **Surgical, Parasurgical procedures, Striroga procedures, Basti**, etc. The Documented 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 organization adheres to standard precautions at all times.

Interpretation: Refer to glossary for “standard precautions”.

- c. The organization adheres to hand-hygiene guidelines.

Interpretation: The organisation shall adhere to international/national guidelines on hand hygiene. A good reference is the latest WHO guidelines. The organization could display the necessary instructions near every hand-washing area.

- d. **The organization adheres to cleaning, disinfection and sterilization practices.**

Interpretation: It shall be addressed at all levels of the organization, e.g. ward, OT, treatment procedure rooms, panchkarma theatre, OT etc. It is preferable that the organization follows a uniform policy across different departments within the organization. Sterilization of equipments required for various procedures will be done appropriately and logs maintained. This includes equipment, environment fixtures, fomites, furniture, furnishings, etc. as applicable.

- e. **An appropriate antibiotic policy for organisations providing integrated services with allopathy is established and implemented.**

Interpretation: Based on the scope of services, the organisation shall develop a system of monitoring drug susceptibility (based on culture sensitivity) and accordingly develop its antibiotic policy. This shall be reviewed at periodic intervals (at least every year) for its continuing applicability. The organisation could 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.

- f. **Laundry and linen management processes are also included**

Interpretation: The laundry can be in-house or outsourced. The organization shall have a policy for change of linen. There shall be separate washing protocols for different categories of linen including blankets (where applicable). If outsourced, the organization shall ensure that it establishes adequate controls to ensure infection prevention and control.

- g. **Kitchen sanitation and food handling issues are included in the manual.**

Interpretation: This shall be applicable even if this activity is outsourced. The organization shall adhere to all statutory requirements. It is preferable that they also adhere to national and international (ISO 22000:2005) guidelines while addressing this issue.

- h. **Engineering controls to prevent infections are included.**

Interpretation: This shall include design of patient care areas, operating theatres, Panchakarma theatre, air quality and water supply. Issues such as air-conditioning plant and equipment maintenance, cleaning of AC ducts, AHUs, replacement of filters, seepage leading to fungal colonisation, 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.

- i. **The organisation adheres to housekeeping procedures.**

Interpretation: This should include categorisation of areas/surfaces, general-cleaning procedures for surfaces, furniture/fixtures, and items used in patient care. It should also include procedures for terminal cleaning, blood and body fluid cleanup and all high-risk (critical) areas. The common disinfectants used, dilution factors and methodology should be specified.

- j. **Mortuary practices and procedures are included as appropriate to the organization.**

Interpretation : Self-explanatory.

Standard

HIC. 3.	The organization performs surveillance activities to capture and monitor infection prevention and control data.
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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 should 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 organization should use a judicious mix of active and passive surveillance. The organization could lay down the parameters that need to be captured and the process for reporting.

- b. **Collection of surveillance data is an ongoing process.**

Interpretation: The organization 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 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 organization) report.

- d. **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 organization 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 effectiveness of housekeeping services.**

Interpretation: This shall be done on a regular basis. The organization 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.

- f. **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. A good tool is the WHO's "Observation Form".

- g. **Appropriate feedback regarding HAI rates are provided on a regular basis to appropriate personnel.**

Interpretation: The feedback shall include the rates, trends and opportunities for improvement. It could also provide specific inputs to reduce the HAI rate. This could be in the form of a bulletin/newsletter.

- h. In cases of notifiable diseases, information (in relevant format) is sent to appropriate authorities.

Interpretation: The organization shall identify all notifiable diseases after taking into consideration the local/state/national laws, rules, regulations and notifications thereof. The organization shall ensure that this is sent at the specified frequency and in the format as required by statutory authorities. Refer to glossary for notifiable diseases.

Standard

HIC. 4.	The organization takes actions to prevent or reduce the risk of Hospital Associated Infections (HAI) in patients and employees.
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Objective Elements

- a. The organization takes action to prevent urinary tract infections.

Interpretation: Self-explanatory.

- b. The organization takes action to prevent respiratory tract infections.

Interpretation: Self-explanatory.

- c. The organization takes action to prevent Parasurgical site infections and other HAI.

Interpretation: Self-explanatory.

- d. The organization takes action to prevent skin infections.

Interpretation: Self-explanatory.

- e. The organization takes action to prevent surgical site infections and other HAI.

Interpretation: Self-explanatory.

- f. Appropriate pre- and post-exposure prophylaxis is provided to all staff members concerned.

Interpretation: Pre and post prophylaxis should be considered for staff involved in surgical procedures and deliveries. Infection Control Officer 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.5.	The organization provides adequate and appropriate resources for prevention and control of Healthcare Associated Infections (HAI).
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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 organization 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

Refer glossary for personal protective equipment.

- b. Adequate and appropriate facilities for hand hygiene in all patient-care areas are accessible to healthcare providers.

Interpretation: The organization shall ensure that it provides 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.

Standard

HIC.6.	Biomedical waste (BMW) is handled in an appropriate and safe manner.
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Objective Elements

- a. The organization adheres to statutory provisions with regard to biomedical waste.

Interpretation: The organization 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 organization ensures that biomedical waste is stored and transported to the site of treatment and disposal in proper covered vehicles within stipulated time limits in a secure manner.

Interpretation: The waste is transported to the pre-defined site at definite time intervals (maximum within 48 hours) through proper transport vehicles in a safe manner. If this activity is outsourced, the organization shall ensure that it is done through an authorized contractor. Monitoring of this activity should be done by an infection control team.

- d. Biomedical waste treatment facility is managed as per statutory provisions (if in-house) or outsourced to authorized contractor(s).

Interpretation: If the hospital has 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. Outsourced facility shall be visited by the organization at least once in six months to ensure waste disposal according to the BMW rules.

- e. Appropriate personal protective measures are used by all categories of staff handling biomedical waste.

Interpretation: E.g. gloves and masks, protective glasses, gowns, etc.

Standard

HIC. 7.	The infection control programme is supported by the organization's management and includes training of staff.
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Objective Elements

- a. Hospital management makes available resources required for the infection control programme.

Interpretation: The organization shall ensure that the resources required by the personnel should be available in a sustained manner. This includes both men and materials.

- b. The hospital 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 before joining department(s) concerned. It should include the policies, procedures and practices of the infection control programme. Doctors also need to be trained.

- d. The organisation conducts appropriate "in-service" training sessions for all staff at least once in a year.

Interpretation: Self-explanatory.

Standard

HIC. 8.	There are documented policies and procedures for sterilization activities in the organization.
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Objective Elements

- a. **There is adequate space available for sterilization activities**

Interpretation: Adequate space which should have suitable location, proper layout and separation of clean and dirty areas. The organisation shall provide for the same in all areas where sterilisation activities are carried out. It is preferable to have separate areas for receiving, washing, cleaning, packing, sterilisation, sterile storage and issue. A good reference is Hospital Infection Society India and HTM 2010 guidelines.

- b. **Documented procedure guides the cleaning, packing, disinfection and/or sterilisation, storing and issue of items.**

Interpretation: The sterilised/disinfected equipment/sets shall be stored in an appropriate manner across the organization. A good reference is “CDC Guideline for Disinfection and Sterilisation in Healthcare Facilities, 2008”. Other references include ISO 17665, Health Technical Memorandum (HTM) 2010 on Sterilisation and Hospital Infection Society India guidelines.

- c. **Regular validation tests for sterilisation are carried out and documented.**

Interpretation: This shall be done by accepted methods e.g. bacteriological strips, etc. Engineering validations like Bowie Dick tape test and leak rate test need to be carried out. WHO recommends each load to have a number, content description, temp, pressure and time-record chart, physical/chemical tests daily, weekly biological tests, steam processing, and ETO processing.

- d. **There is an established recall procedure when breakdown in the sterilisation system is identified.**

Interpretation: The organisation shall ensure that the sterilisation 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.

Chapter 6

Continuous Quality Improvement (CQI)

Intent of the standards

The standards encourage an environment of continuous quality improvement. The quality program should be documented and involve all areas of the organization and all staff members. The organization should collect data on structures, processes and outcomes, especially in areas of high risk situations. The collected data should be collated, analyzed and used for further improvements. The improvements should be sustained. Infection control and patient safety plans should also be integrated into the organization's quality plan.

The organization 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 organization.
CQI.2.	There is a structured patient-safety programme in the organisation.
CQI.3.	The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement.
CQI.4.	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tools for continual improvement.
CQI.5.	The quality improvement programme is supported by the management.
CQI.6.	There is an established system for clinical audit.
CQI.7.	Incidents, complaints and feedback are collected and analysed to ensure continual quality improvement.
CQI.8.	Sentinel events are intensively analyzed.

Standards and Objective Elements

Standard

CQI. 1.	There is a structured quality improvement and continuous monitoring programme in the organization.
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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 organization. This programme shall be developed, implemented and maintained in a structured manner. E.g. core committee, quality improvement committee, etc.

- b. The quality improvement programme is documented.

Interpretation: This should be documented as a manual. The manual shall incorporate the mission, vision, quality policy, quality objectives, service standards, important indicators as identified, etc. The manual could be stand-alone but shall have cross linkages with other manuals. Refer to AAC 7, AAC 10 also. This should be documented keeping in mind requirements of objective elements d, f, and g. It should also incorporate the various indicators as required by CQI 3 and 4.

- 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. E.g. accreditation co-ordinator, quality management representative, quality manager.

- d. The quality improvement programme is comprehensive and covers all the major elements related to quality improvement and risk management.

Interpretation: This shall cover all aspects including documentation of the programme, monitoring it, data collection, review of policy and corrective action. Also refer to CQI 1b. Refer to glossary for definition of "quality improvement".

- e. The designated programme is communicated and coordinated amongst all the employees of the organization through proper training mechanism.

Interpretation: This could be done through a regular training programme or printed materials.

- f. The quality improvement programme is reviewed at predefined intervals and opportunities for improvement are identified.

Interpretation: As quality improvement is a dynamic process, it needs to be reviewed at regular pre-defined intervals (as defined by the organization in the quality improvement manual but at least once in six months). The review shall include internal audits, organizational performance improvement targets (analysis of key indicators as identified and determined by the organization including the indicators as laid down in CQI 3 and 4. The minutes of the review meetings should be recorded and maintained. This also applies to other quality-assurance programmes like Lab, Imaging, Panchakarma, Shalakya, Prasooti tantra and Stree roga, Surgical, Parasurgical services etc.

- g. The quality improvement programme is a continuous process and updated at least once in a year.

Interpretation: The inputs for updation could be based on the review carried out by the quality improvement committee.

- h. Audits are conducted at regular intervals as a means of continuous monitoring.

Interpretation: This audit shall be done by a multi-disciplinary team (preferably trained in NABH standards) including all the applicable standards and objective elements. All the areas of the organization shall be covered. At the end of the audit, there shall be a formal meeting to summarize the findings and corrective and preventive measures shall be taken and documented. The assessors shall be either trained internally or externally in NABH standards. They shall assess areas independent of their area of work. All audits shall be documented.

Standard

CQI.2.	There is a structured patient-safety programme in the organisation.
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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 organization. This programme shall be developed, implemented and maintained in a structured manner. This committee could be called safety committee. This committee could have a mix of administrators, engineers, doctors and Paricharakas. Refer to glossary for definition of "safety programme". Also refer FMS 1.

- 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 objective elements "c", "d", "g", "h" and "l".

- 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. Refer to glossary for definition of "risk management". Also refer to ROM 6a.

- d. The scope of the programme is defined to include adverse events ranging from "no harm" to "sentinel events".

Interpretation: The organization shall clearly define as to what constitutes no harm and sentinel events. 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. E.g. safety officer.

- f. The designated programme is communicated and coordinated amongst all the staff of the organization 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 organization in the safety manual but at least once in four months). The review at a minimum shall include review of facility inspection rounds (refer to FMS 1e) and analysis of key-safety indicators (which could be taken from CQI 3 and 4). 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 inputs for updation could be based on the review carried out by the safety committee.

- i. The organization adopts 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.

- j. The organization uses at least two identifiers to identify patients across the organization.

Interpretation: This shall be used for identifying patient for all care-related events like medication administration, conducting procedures, etc. One of the identifiers shall be the unique hospital ID generated at the time of registration/admission.

Standard

CQI. 3.	The organization identifies key indicators to monitor the clinical structures, processes and outcomes which are used as tools for continual improvement.
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Objective Elements

- a. **Monitoring includes appropriate patient assessment.**

Interpretation: The organization shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

- i. Time for initial assessment of in-patients and out-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 the treatment outcomes is documented. e.g. Samyak, atiyoga, vyapath etc. of Panchakarma therapies.

- b. **Monitoring includes safety and quality control programmes of the diagnostics services.**

Interpretation: The organization shall develop appropriate key performance indicators suitable for all diagnostic services (if In house). 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 organization 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.

To capture co-relation it becomes mandatory that all investigation forms have a provisional diagnosis/relevant clinical details written on them. The organisation could decide as to which tests will be monitored.

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 organization 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-alert medications developing adverse drug event.

The organization shall document a list of approved abbreviations for medication charts.

d. **Monitoring includes availability and content of medical records.**

Interpretation: Self-explanatory.

e. **Monitoring includes infection control activities.**

Interpretation: The organization shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

- i. Urinary tract infection rate.
- ii. Bacteri infection rate
- iii. Parasurgical site infection rate.

f. **Monitoring includes Parasurgical services.**

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

- i. Percentage of re-scheduling of the procedure.
- ii. Percentage of cases where the organisation's procedure to prevent adverse events like wrong site, wrong patient, wrong procedures and wrong surgery have been adhered to.

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.

g. **Monitoring includes Panchakarma therapies and Treatment procedures**

Interpretation: The organisation shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

- i. Percentage of re-scheduling of the procedure.
- ii. Percentage of cases where the organisation's procedure to prevent adverse events like wrong site, wrong patient and wrong procedure have been adhered to.

Re-scheduling of patients includes cancellation and postponement (beyond four hours) of the Panchakarma/procedure because of poor communication, inadequate preparation or inefficiency within the system.

h. **Monitoring includes clinical research.**

Interpretation: The organization 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 organization 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.

i. **Monitoring includes data collection to support further improvements.**

Interpretation: The data could be collected at pre-defined intervals e.g. monthly/quarterly. This data is analyzed for improvement opportunities and the same are carried out. Also refer to CQI 1f. For example, data can be collected to study the reasons (root cause analysis) for basti vyapaths. Data could be represented graphically, e.g. bar chart, pie chart, etc. Also refer to CQI 5d.

j. **Monitoring includes data collection to support evaluation of these improvements.**

Interpretation: All improvement activities carried out by the organization shall have an evaluable outcome. The same shall be captured and analyzed. For example, once the reasons for basti vyapaths have been analyzed and preventive and corrective measures undertaken then data can be collected to confirm that reductions have occurred in the incidence of basti vyapath.

k. **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 (COP 19b). The same shall be reviewed during the immediate pre-operative re-evaluation (COP 19d). 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.

l. **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 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.

Prophylactic antibiotics should be administered ideally within 30-60 minutes but certainly within two hours of the time of incision.

m. **Monitoring includes use of blood and blood products.**

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 products.
- iii. Percentage of blood component usage.

Turnaround time for issue of blood and blood components. Wastage includes blood products found unfit for use.

Standard

CQI. 4.	The organization identifies key indicators to monitor the managerial structures, processes and outcomes which are used as tools for continual improvement.
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Objective Elements

- a. **Monitoring includes procurement of medication essential to meet patient needs.**

Interpretation: The organization shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

- i. Percentage of medicines and consumables procured by local purchase.
- ii. Percentage of stock outs including emergency drugs.
- iii. Percentage of medicines and consumables rejected before preparation of goods receipt note.
- iv. Percentage of variations from the procurement process.

Local purchase implies medicines and consumables purchased outside the formulary/inventory.

- b. **Monitoring includes reporting of activities as required by laws and regulations.**

Interpretation: e.g. notifiable diseases, form C for admission of foreign patients etc.

- c. **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 bed sores after admission.
- iv. Incidence of burn injury during treatment procedures.

- v. Percentage of employees provided pre-exposure prophylaxis.
- vi. Incidence of Panchakarma vyapaths, Uttara basti vyapat.

Remark(s): Mock drills include fire, non-fire and disaster management.

Refer to glossary for definition of "risk management".

d. **Monitoring includes utilization of space, manpower and equipment.**

Interpretation: The organization shall develop appropriate key performance indicators suitable to it. The following is, however, mandatory:

- i. Bed occupancy rate and average length of stay.
- ii. Panchakarma Theatre and OT-utilization rate.
- iii. Critical equipment down time.
- iv. Paricharaka-patient ratio for various types of wards.

Any equipment the failure of which could impede patient care shall be considered critical. Some examples are Panchakarma equipments, autoclave, gyser etc. However, every organization 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.

e. **Monitoring includes patient satisfaction which also incorporates waiting time for services.**

Interpretation: The organization 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.

f. **Monitoring includes employee satisfaction.**

Interpretation: The organization 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.

g. **Monitoring includes adverse events and near misses.**

Interpretation: The organization 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. Other issues as per scope of services such as blood body fluid exposure, needles stick injury etc.

h. **Monitoring includes availability and content of medical records.**

Interpretation: The organization 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 Care plan
- 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.

- i. **Monitoring includes data collection to support further improvements.**

Interpretation: The data could be collected at pre-defined intervals e.g. monthly/quarterly. This data is analyzed for improvement opportunities and the same are carried out. Also refer to CQI 1f. E.g. waiting time in OPD. Also refer CQI 5d.

- j. **Monitoring includes data collection to support evaluation of these improvements.**

Interpretation: All improvement activities carried out by the organization shall have an evaluable outcome. The same shall be captured and analyzed. E.g. reduction in the waiting time.

Standard

CQI. 5.	The quality improvement programme is supported by the management.
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Objective Elements

- a. **Hospital 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.

- b. **Hospital 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. 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.

- c. **The management identifies organizational performance improvement targets.**

Interpretation: The management shall identify organization and department level quality objectives, set targets, monitor them (at least once in six months) and modify the target (at least annually). The targets should be shared with the faculty and staff and regular feedback taken.

- d. **Appropriate statistical and management tools are applied whenever required**

Interpretation: E.g. Root Cause Analysis, FMEA etc.

Standard

CQI. 6.	There is an established system for clinical audit.
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Objective Elements

- a. **Medical and nursing staff participates in this system.**

Interpretation: The organization shall identify such personnel. It could be a mix of clinicians, administrators and Paricharakas. These could be members of the core committee/quality assurance committee, etc.

- b. **The parameters to be audited are defined by the organization.**

Interpretation: 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 care including clinical and nursing.

- 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 or 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 organization 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.7.	Incidents, complaints and feedback are collected and analysed to ensure continual quality improvement.
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Objective Elements

- a. The organization 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 organization has a process to collect feedback and receive complaints.

Interpretation: This shall be communicated to the patients using displays or brochures.

- c. The organization has established processes for analysis of incidents, feedbacks and complaints.

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 be included in analyzing the feedback and complaint.

- d. 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.

- 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. 8.	Sentinel events are intensively analyzed.
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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 organization 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 organization has established processes for intense analysis of such events.

Interpretation: The established processes should include reporting the occurrence of such events on standardized incident report forms.

- c. Sentinel events are intensively analyzed 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 analyzed 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.

Chapter 7

Responsibilities of Management (ROM)

Intent of the standards

The standards encourage the governance of the organization in a professional and ethical manner. The organization complies with the laid down and applicable legislations and regulations. 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 the management are defined.
ROM.2.	The organization complies with the laid-down and applicable legislations and regulations.
ROM.3.	The services provided by each department are documented.
ROM.4.	The organization is managed by the leaders in an ethical manner.
ROM.5.	The organisation displays professionalism in management of affairs.
ROM.6.	Management ensure that patient safety aspects and risk management issues are an integral part of patient care and hospital management.

Standards and Objective Elements

Standard

ROM.1.	The responsibilities of the management are defined.
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Objective Elements

- a. Those responsible for governance lay down the organization's vision and mission statement

Interpretation: 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 "vision and mission" refer to glossary.

- b. Those responsible for governance approve the strategic and operational plans and organization's budget.

Interpretation: Refer to glossary for "strategic and operational plans".

- c. Those responsible for governance approve the organization's budget and allocate the resources required to meet the organization's mission.

Interpretation: Self-explanatory.

- d. Those responsible for governance monitor and measure the performance of the organization 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.

- e. Those responsible for governance establish the organization'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 incorporate various committees.

- f. Those responsible for governance appoint the senior leaders in the organization.

Interpretation: Senior leaders include the first two rungs of the organogram. Appointment of senior leaders shall be through selection committee.

- g. 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.

- h. Those responsible for governance support research activities

Interpretation: Support in research shall include providing resource, budget, following ethical and legal norms.

- i. Those responsible for governance address the organization's social responsibility.

Interpretation: The governing board and head of the organisation shall willfully develop social responsibility policy and accordingly address it. E.g. free camps, outreach programmes, adoption of villages, PHCs, etc.

Standard

ROM.2.	The organisation complies with the laid-down and applicable legislations and regulations.
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Objective Elements

- a. The management is conversant with the laws and regulations and knows their applicability to the organisation.

Interpretation: This shall include central legislations (e.g. The Indian Medicine Central Council Act, 1970, State Board Act eg. Travancore-Cochin Medical Practitioners Act 1953, Drugs and Cosmetics Act and MTP Act, PNDT Act, 1996), Bio Medical Waste Act, Air (Prevention and Control of Pollution) Act, 1981, Atomic Energy Regulatory Body Approvals, License under Bio-medical Management and Handling Rules, 1998, respective of state legislations (Karnataka Private Medical Establishments Act 2007, Maharashtra Maintenance of Clinical Records Act, Clinical establishment of West Bengal) and local regulations (e.g. building byelaws).

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.

- b. **The management ensures implementation of these requirements.**

Interpretation: All relevant clauses under the rules and acts are abided by the organisation.

- c. **Management regularly updates any amendments in the prevailing laws of the land.**

Interpretation: Self-explanatory.

- d. **There is a mechanism to regularly update licenses/registrations/certifications.**

Interpretation: E.g. license for lifts, DG sets, etc. The organisation could develop a tracker sheet for this purpose.

Standard

ROM.3.	The services provided by each department are documented.
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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. E.g. Kayachikitsa department can provide medical services for swasa roga, udararoga, yakritroga, sandhi roga, 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 organizational program, service, site or department has effective leadership.**

Interpretation: There needs to be a minimum essential qualification and 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. Also refer CQI 3 & 4.

Standard

ROM.4.	The organization is managed by the leaders in an ethical manner.
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Objective Elements

- a. **The leaders make public the mission statement of the organization.**

Interpretation: This shall be done by displaying the same prominently. For definition of "mission" 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 organization'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.

- c. **The organisation's established ethical management shall be documented.**

Interpretation: Self-explanatory.

- d. **The organization 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.

- e. **The organization 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. Here 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. Refer to AAC 1

also.

- f. The organization honestly portrays its affiliations and accreditations.

Interpretation: Here implies that the organisation convey its affiliations, accreditations for specific departments or whole hospital wherever applicable.

- g. The organization accurately bills for its services based upon a standard billing tariff.

Interpretation: Also refer to PRE 6. The tariff could be devised by a tariff committee.

Standard

ROM.5.	The organisation displays professionalism in management of affairs.
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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: 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. One of the inputs that should be considered while finalising these plans shall be the findings of the "risk-management plan" (refer to ROM 6a). 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. It is preferable that every department has a budget.

- f. The functioning of committees is reviewed for their effectiveness.

Interpretation: This shall be done by the management. The review at a minimum 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. 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.

- g. The organisation documents employee rights and responsibilities.

Interpretation: The organisation shall define the same in consonance with statutory requirements.

- h. 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.

- i. The organisation monitors the quality of the outsourced services.

Interpretation: The frequency of monitoring shall be determined by the organisation. 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 or as per the requirements of this standard.

Standard

ROM.6.	Management ensure that patient safety aspects and risk management issues are an integral part of patient care and hospital management.
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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 adverse drug reactions and medication errors.
 - ii. Equipment risks e.g. fire/injury risks from use of swedana.
- 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 organization 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 organization. For example, Swedna yantra or autoclave machine breaks down. In this case internal reporting is to be done to head of the department and external reporting to

be done to the patients. 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 standards

The standards guide the provision of a safe and secure environment for patients, their families, staff and visitors. To ensure this, the organization complies with the relevant rules and regulations, laws and byelaws and requisite facility inspection requirements. The organization plans for emergencies within the facilities and the community.

The organization plans for eliminating smoking within the facility and safe management of hazardous materials.

The organization provides for safe water, electricity, medical gases and vacuum systems.

The organization has a program for clinical and support service equipment management.

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 to ensure safety of patients, their families, staff and visitors.
FMS.3.	The organisation has a programme for engineering support services.
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 if applicable.
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.
FMS.8.	The organisation has herbal plantation

Standards and Objective Elements

Standard

FMS.1.	The organisation has a system in place to provide a safe and secure environment.
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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 plans and policies. 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. It is preferable that the organisation conducts an exercise of Hazard Identification and Risk Analysis (HIRA) and accordingly takes all necessary steps to eliminate or reduce such hazards and associated risks.

- b. Patient-safety devices are installed across the organisation and inspected periodically.

Interpretation: E.g. 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.

- c. The organisation is a non-smoking area.

Interpretation: The organisation shall adhere to statutory requirements.

- d. 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 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.

- e. Inspection reports are documented and corrective and preventive measures are undertaken.

Interpretation: Before and after evidence may be maintained.

- f. There is a safety education programme for staff.

Interpretation: Self-explanatory.

Standard

FMS.2.	The organisation's environment and facilities operate to ensure safety of patients, their families, staff and visitors
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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, 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 college attached hospitals, norms of Central Council of Indian Medicine shall be applicable.

- e. Potable water and electricity are available round the clock.

Interpretation: The organisation shall make arrangements for supply of adequate potable water and electricity. 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.

- f. 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, then also alternate sources shall be required. 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.

- g. 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.

- h. There are designated individuals 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 shall be provided by the organisation. The person could be qualified by experience or training.

- i. There is a documented operational and maintenance (preventive and breakdown) plan.

Interpretation: This shall include facility/building/installations. Refer to glossary for definition of "preventive maintenance" and "breakdown maintenance".

- j. Maintenance staff is contactable round the clock for emergency repairs.

Interpretation: Self-explanatory.

- k. 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.3.	The organisation has a programme for engineering support services.
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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 plans should be fully implemented and there should be a process for periodic review of plans.

- b. Equipment are selected, 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: Where applicable, the relevant quality conformance certificates/marks along with manufacturer factory test certificate need to be retained as part of documentation for every equipment.

- d. Qualified and trained personnel operate and maintain equipment and utility systems.

Interpretation: The person could be qualified by experience or training.

- e. **There is a documented operational and maintenance (preventive and breakdown) plan.**

Interpretation: The manufacturer's instruction manual for equipment exists. The operator is trained in handling the equipment. There shall be a planned preventive maintenance tracker. This shall include all-engineering support service equipment like DG set. Refer to glossary for definition of "preventive maintenance" and "breakdown maintenance".

- f. **There is a maintenance plan for water management.**

Interpretation: This shall 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.

- g. **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.

- h. **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.

- i. **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) equipment 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.
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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.

- b. Equipment are selected, 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. All equipment are inventoried and proper logs are maintained as required.

Interpretation: 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: 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.**

Interpretation: The manufacturer's instruction manual for equipment exists. The operator is trained in handling the equipment. 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.

Standard

FMS.5.	The organisation has a programme for medical gases, vacuum and compressed air if applicable.
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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. Proper signage are 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. The documentation shall cover objective element “b” also.

- 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. It is mandatory that compressed air purity be checked (at the level of terminal outlet) once in a year.

- 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.

- d. Alternate sources for medical gases, vacuum and compressed air are provided for, in case of failure.

Interpretation: Self-explanatory.

- e. The organisation regularly tests these alternate sources.

Interpretation: The results of these tests shall be documented.

- f. There is an operational 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
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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;

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. Hysterical fits of patients and/or relatives;
- vi. Civil disorders affecting 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 (e.g. fire service).

- 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.

- 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 on use of fire fighting equipment. Simulated patients (not real) shall be used for evacuation. 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.

Interpretation: This shall adhere to manufacturer's and/or statutory recommendations.

Standard

FMS.7.	The organisation has a plan for management of hazardous materials
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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. Biological materials like blood

and body fluids, mercury, medical gases, LPG gas, steam, 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. **There is a plan for managing spills of hazardous materials.**

Interpretation: The organisation could have a HAZMAT kit(s) for handling spills.

- d. **Staff is educated and trained for handling such materials.**

Interpretation: Self-explanatory.

Standard

FMS.8.	The organisation has herbal plantation
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Objective Elements

- a. **The organisation has herbal plantation within the organisation.**

Interpretation: The organisation should have herbal plantation preferably at the entrance of the organisation. If space is a constraint, then atleast potted plants or hanging plants should be made available. Example of herbal plants include Tulsi, Neem, Aloe Vera, Brahmi, Mint, etc to name a few.

Remark(s): The herbal plants should have a display card with its scientific name, common name & its uses.

Chapter 9

Human Resource Management (HRM)

Intent of the standards

The most important resource of a hospital and health care 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 organization. This is based on the organization’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 socialization 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 “staff/ employee” refers to all salaried personnel working in the organization as well as contractual personnel. It does not refer to “fee for service” medical professionals.

The term “Paricharaka ” refers to Class XII/PUC with training for 6 months or Class X with 3 years’ relevant experience either in nursing, pharmacy or therapy or personnel having educational qualification less than class X provided he/she is certified by the head of the organisation for their competence and skill.

The term “Panchakarma Therapists” refers to person with qualification of Panchakarma Therapist or paricharaka therapist.

Summary of Standards

HRM.1.	The organization 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, students and volunteers are adequately trained on specific job duties or responsibilities related to safety.
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 organization has a well-documented disciplinary procedure.
HRM.7.	A grievance handling mechanism exists in the organization.
HRM.8.	The organization addresses the health needs of the employees.
HRM.9.	There is a documented personal record for each staff member.
HRM.10.	There is a process for credentialing and privileging of medical professionals, permitted to provide patient care without supervision.
HRM.11.	There is a process for credentialing and privileging of nursing professionals, permitted to provide patient care without supervision.
HRM.12.	There is a process for collecting, verifying and evaluating the credentials (education, training and experience) of Panchakarma Therapist, Paricharaka.

Standards and Objective Elements

Standard

HRM.1.	The organization has a documented system of human resource planning.
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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 scope of services, mission and the healthcare needs of the community that it serves. 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. RMO to be present. Minimum of two Panchakarma therapist - per treatment room; one Paricharaka per 15 beds (provide for 50% capacity utilization scenario).

- c. The required job specifications 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 with the minimum qualification shall be BAMS. A Paricharaka with the minimum qualification shall be 12th Standard or 2nd PUC with job training for 6 months in the hospital (if the Paricharaka is already trained then privileging to be done to assess her skills on job).

- d. The organization verifies the antecedents of the potential employee with regards to criminal/negligence background.

Interpretation: Self-explanatory.

Standard

HRM.2.	The organisation has a documented procedure for recruiting staff and orienting them to the organisation's environment.
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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. For patient rights refer to PRE 1.

- 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 Documented policies and procedures as well as relevant department/unit/service/programme's documented 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 documented policies and procedures.

Standard

HRM.3.	There is an ongoing programme for professional training and development of the staff.
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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) and the post-training feedback. Where possible, the contents of the training may also be captured.

- c. Staff should be given appropriate orientation/training to respective system of medicine.

Interpretation: Self-explanatory.

- d. 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.

- e. Feedback mechanisms for assessment of training and development programme exist.

Interpretation: This shall include both internal and external training. For external training, it could be done either by the organisation itself or by the external agency, which imparted the training. Impact of training at user level should also be documented.

Standard

HRM.4.	Staff, students and volunteers are adequately trained on specific job duties or responsibilities related to safety.
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Objective Elements

- a. All staff is trained on the risks within the hospital 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 can demonstrate and take actions to report, eliminate/minimize 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 are made aware of procedures to follow in the event of an incident.

Interpretation: Self-explanatory. The staff should be able to intimate the sequence of events that they will undertake in the eventuality of occurrence of any adverse event.

- d. Reporting procedures for common problems, failures and user errors exist.

Interpretation: Staff should be able to practically demonstrate actions like taking care of oil spills, medication errors and other adverse event reporting systems. Some examples are, Complaint Register, Equipment breakdown register, etc.

- e. Staff is trained on occupational safety aspects.

Interpretation: This shall include making them aware of the possible risks involved and preventive actions to avoid risks. E.g. burns or scalds during treatment procedure.

Standard

HRM.5.	An appraisal system for evaluating the performance of an employee exists as an integral part of the human resource management process.
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Objective Elements

- a. A documented performance appraisal system exists in the organization.

Interpretation: This shall be done for all categories of employees starting from the person heading the organisation and including doctors who are employees.

Remark(s): 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: This shall be done at least once a year.

Standard

HRM. 6.	The organization has a well-documented disciplinary policies and procedure.
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Objective Elements

- a. Documented policies and procedures exist

Interpretation: For definition of "disciplinary procedure" refer to glossary. The documentation shall be done keeping in mind objective elements "b, d and e".

- b. 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.

- c. The policy and procedure is known to all categories of employees of the organization.

Interpretation: Self-explanatory.

- d. The disciplinary procedure is in consonance with the prevailing laws.

Interpretation: Refer to relevant labour laws and CCS (CCA) rules. Anti-sexual harassment 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.

Standard

HRM. 7.	A grievance handling mechanism exists in the organization.
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Objective Elements

- a. Documented policies and procedures exist.

Interpretation: For definition of "grievance handling" refer to glossary. The documentation shall be done keeping in mind objective elements "c, d and e".

- 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 redress procedure addresses the grievance.

Interpretation: Self-explanatory.

- d. Actions are taken to redress the grievance.

Interpretation: This shall be documented and communicated to the aggrieved staff.

Standard

HRM. 8.	The organization addresses the health needs of the employees.
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Objective Elements

- a. A pre-employment medical examination is conducted on all the employees.

Interpretation: This shall, however, be in consonance with the law of the land. E.g. performing pre-employment stool examination for food handlers is mandatory.

- b. Health problems of the employees are taken care of in accordance with the organization'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. 9.	There is a documented personal record for each staff member.
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Objective Elements

- a. Personal files are maintained in respect of all staff.

Interpretation: Self-explanatory.

- b. The personal files contain personal information regarding the staff 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: 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.

- d. Personal files contain results of all evaluations.

Interpretation: Evaluations would include performance appraisals, training assessment and outcome of health checks.

Standard

HRM. 10.	There is a process for credentialing and privileging of medical professionals, permitted to provide patient care without supervision.
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Objective Elements

- a. Medical professionals permitted by law, regulation and the hospital 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: Updation 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.

- 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.

- 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 observation 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 11.	There is a process for credentialing and privileging of nursing professionals, permitted to provide patient care without supervision.
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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.

- 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 Paricharaka is authorised to do.

- 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 proctorship 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.

Standard

HRM.12.	There is a process for collecting, verifying and evaluating the credentials (education, training and experience) of Panchakarma Therapist & Paricharaka.
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Objective Element

- a. The education, training and experience of Panchakarma Therapist, Paricharaka are documented and updated periodically.

Interpretation: Updation is done after acquisition of new skills and/or qualification.

- b. All such information 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.

- c. **Panchakarma Therapist and Paricharaka are granted privileges in consonance with their qualification, training, experience and registration.**

Interpretation: The organisation shall identify as to what Panchakarma therapist and **Paricharaka** are authorised to do. For example, **Panchakarma Therapist** should have had requisite in-house/external training and experience and the aptitude and knowledge to perform the tasks required of him/her.

- d. **Panchakarma Therapist and Paricharaka care for patients as per their privileging.**

Interpretation: New staff members can be under the observation 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 Standards

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 utilized appropriately by the organizations.

The goal of Information Management in a hospital is to ensure that the required inputs are available to the right personnel. This is provided in an authenticated, secure and accurate manner at the right time and place. This helps to achieve the ultimate organizational goal of a satisfied and improved provider and recipient of health care.

An effective Information Management system is based on the information needs of the organization. The system is able to capture, transmit, store, analyze, utilize and retrieve information as and when required for improving clinical outcomes as well as individual and overall organizational 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.

Summary of Standards

IMS.1.	Documented policies and procedures exist to meet the information needs of the care providers, management of the organization as well as other agencies that require data and information from the organization.
IMS.2.	The organization has processes in place for effective management of data.
IMS.3.	The organization 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 information.
IMS.6.	Documented policies and procedures exist for retention time of records, data and information.
IMS.7.	The organization regularly carries out review of medical records.

Standards and Objective Elements

Standard

IMS. 1.	Documented policies and procedures exist to meet the information needs of the care providers, management of the organization as well as other agencies that require data and information from the organization.
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Objective Elements

- a. The information needs of the organization are identified and are appropriate to the scope of the services being provided by the organization.

Interpretation: The organisation has manual and/or electronic hospital information system and/or management information system which provide relevant data and information to all stakeholders concerned. This shall include the information needs of care providers, management and external agencies/governmental bodies. E.g. daily treatment schedule, daily bed occupancy, incidence of notifiable diseases etc. Also refer to CQI 3 and CQI 4. The identified information needs shall be documented.

- b. Policies and procedures to meet the information needs are documented.

Interpretation: A policy document is available where the HIS/MIS is described. The documented policies and procedures should evidence document control. Refer Glossary for “Document Control”

- c. These policies and procedures are in compliance with the prevailing laws and regulations.

Interpretation: Some of these include: IT Act, 2000 for computer-based records, RTI Act 2005, etc. Relevant state legislation e.g. Maintenance of Clinical Records Act (MOCRA) in Maharashtra.

- d. 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.

- e. The organization 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.

Standard

IMS. 2.	The organization has processes in place for effective management of data.
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Objective Elements

- a. Formats for data collection are standardized.

Interpretation: MIS/HIS data are collected in standardised format from all areas/services in the organisation, the frequency of the data collection and the person(s) responsible is also specified. The frequency of capturing data namely daily, weekly, monthly, quarterly, yearly etc.

- b. Necessary resources are available for analyzing data.

Interpretation: The organisation shall make available men, material, space and budget.

- c. Documented procedures are laid down for timely and accurate dissemination of data.

Interpretation: All 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.

- d. 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.

- e. 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 organization has a complete and accurate medical record for every patient.
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Objective Elements

- a. Every medical record has a unique identifier.

Interpretation: This shall also apply to records on digital media e.g. EMR. 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. E.g. 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 authorising 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 paricharaka.

- c. Every medical record entry is 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, 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. E.g. admission orders, face sheet, IP sheet, discharge summary, doctor's order sheet, TPR chart, consent form, etc.

- f. The record provides an 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.

- g. 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 after OPD hours, medical records shall be easily retrievable.

Standard

IMS. 4.	The medical record reflects continuity of care.
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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. 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: Also refer to COP 8g, 9f.

- 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. Any element of care carried out during the patient transfer is documented, where appropriate.

- e. The medical record contains a copy of the discharge note duly signed by appropriate and qualified personnel.

Interpretation: Also refer to AAC 13.

- f. In case of death, the medical record contains a copy of the death certificate indicating the cause, date and time of death.

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). Also refer to AAC 14 g. Cardiac and respiratory arrest is an event of death and not the cause of death.

- g. 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, every faculty 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 information.
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Objective Elements

- a. Documented policies and procedures exist for maintaining confidentiality, security and integrity of 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 relevant 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. Objective element "c" could also be included in this procedure. The documentation shall be done keeping in mind objective element "b".

- 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 etc. E.g. privileged communication.

- c. The policies and procedures 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 hospital has an effective process of monitoring compliance of the laid down policy.

Interpretation: The organisation carries out regular audits/rounds to check compliance with policies. Refer to IMS 7.

- 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. E.g. 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 authorization.

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 VIPs identified by Gol 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.
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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 respective state authority. The documentation shall be done keeping in mind objective element “b”.

- b. **The Documented 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 1987 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 competent authority.

Standard

IMS. 7.	The organization regularly carries out review of medical records.
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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 care providers.**

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: E.g. missing final diagnosis, absence of post procedure care plan for Panchakarma, usage of non-approved abbreviation etc.

- g. Appropriate corrective and preventive measures undertaken 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	Accreditation is a self-assessment and external peer review process used by health care organizations to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve the health care system.
Accreditation assessment	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
Adverse drug event and adverse drug reaction	<p>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.</p> <p>Adverse Drug Reaction: A response to a drug which is noxious and unintended and <i>which occurs at doses normally used in man</i> for prophylaxis, diagnosis, or therapy of disease or for the modification of physiologic function.</p> <p>Therefore ADR = Adverse Event with a causal link to a drug.</p> <p><u>Adverse drug event:</u> The FDA recognises the term <i>adverse drug event</i> to be a synonym for <i>adverse event</i>.</p> <p>In the patient-safety literature, the terms <i>adverse drug event</i> and <i>adverse event</i> 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</p> <ul style="list-style-type: none"> • drug • harm caused by drug use, and • a medication error with or without harm <p>Institute of Medicine: “An injury resulting from medical intervention</p>

	<p>related to a drug”, which has been simplified to “<i>an injury resulting from the use of a drug</i>”</p> <p><u>Adverse drug events extend beyond adverse drug reactions to include harm from overdoses and under-doses usually related to medication errors.</u></p> <p>A minority of adverse drug events is medication errors, and medication errors rarely result in adverse drug events.</p>
Adverse event	<p>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).</p>
Ambulance	<p>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.</p>
Anaesthesia	<p>Loss of bodily sensation with or without loss of consciousness</p>
Assessment	<p>All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.</p>
Autopsy	<ol style="list-style-type: none"> 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
Basic life support	<p>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.</p>
Breakdown maintenance	<p>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.</p>

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
Care Plan	A plan that identifies patient care needs, lists the strategy to meet those needs, documents treatment goals and objectives, outlines the criteria for ending interventions, and documents the individual's progress in meeting specified goals and objectives. The format of the plan may be guided by specific policies and procedures, protocols, practice guidelines or a combination of these. It includes preventive, promotive, curative and rehabilitative aspects of care.
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.

	<p>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.</p> <p>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.</p>
Control Charts	<p>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.</p>
Credentialing	<p>The process of obtaining, verifying and assessing the qualification of a healthcare provider.</p>
Data	<p>Facts or information used usually to calculate analyse or plan something.</p>
Discharge summary	<p>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).</p>
Disciplinary proceedings	<p>Sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the healthcare organisation.</p>
Document control	<p>Coordination and control of the flow (storage, retrieval, processing, printing, routing and distribution) of electronic and paper documents in a secure and efficient manner, to ensure that they are accessible</p>

	to authorized personnel as and when required.
Effective communication	<p>A two way information sharing process which involves the communicator, communicating a message that is easily understood by the recipient.</p> <p>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.</p>
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

	<p>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.</p> <p>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.</p>
Formulary	<p>An approved list of drugs. Drugs contained on the formulary are generally those that are determined to be cost effective and medically effective.</p> <p>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.</p>
Goal	<p>A broad statement describing a desired future condition or achievement without being specific about how much and when. (ASQ)</p> <p>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)</p>
Grievance-handling procedures	<p>Sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.</p>
Hazardous materials	<p>Substances dangerous to human and other living organisms. They include radioactive or chemical materials.</p>
Hazardous	<p>Waste materials dangerous to living organisms. Such materials require special precautions for disposal. They include biologic waste</p>

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 infection	Healthcare-associated infections (HAIs) are infections caused by a wide variety of common and unusual bacteria, fungi, and viruses 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 Eg. Bhasmas, Medicaments containing Opium or Cannabis.
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.
Job description	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<p>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. (<i>Reference: Mosby's Medical Dictionary, 9th edition, Elsevier</i>)</p> <p>Primary difference between <i>Prescription & Medication Order</i> is that the medication order is used after Prescription, to get medicines issued/ dispensed from Pharmacy.</p> <p>Medication Order is an active Record, while Prescription is a Document.</p>
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	<p>A near-miss is an unplanned event that did not result in injury, illness, or damage—but had the potential to do so.</p> <p>Errors that did not result in patient harm, but could have, can be categorised as near-misses.</p>
No harm	<p>This is used synonymously with near miss. However, some authors draw a distinction between these two phrases.</p> <p>A near-miss is defined when an error is realised just in the nick of</p>

	<p>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).</p>
Notifiable disease	<p>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:</p> <ul style="list-style-type: none"> (a) Smallpox (b) Poliomyelitis due to wild-type poliovirus (c) Human influenza caused by a new subtype (d) Severe acute respiratory syndrome (SARS). <p>In India, the following is a indicative list of diseases which are also notifiable, but may vary from state to state:</p> <ul style="list-style-type: none"> (a) Polio (b) Influenza (c) Malaria (d) Rabies (e) HIV/AIDS (f) Louse-borne typhus (g) Tuberculosis (h) Leprosy (i) Leptospirosis (j) Viral hepatitis (k) Dengue fever <p>The various diseases notifiable under the factories act lead</p>

	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)

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.
Personal protective equipment	Specialised clothing or equipment worn by an employee for protection against infectious materials (OSHA).
Policies	They are the guidelines for decision-making,e.g. admission, discharge policies, antibiotic policy,etc.
Preventive maintenance	<p>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.</p> <p>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.</p>
Prescription	<p>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.</p> <p>Legally, it is a written directive, for compounding or dispensing and administration of drugs, or for other service to a particular patient.</p> <p><i>(Reference: Miller-Keane Encyclopedia and Dictionary of Medicine, Nursing, and Allied Health, Seventh Edition, Saunders)</i></p>
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	<ol style="list-style-type: none"> 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.
Protocol	A plan or a set of steps to be followed in a study, an investigation or an intervention.
Quality	<p>1. Degree to which a set of inherent characteristics fulfil requirements (Para 3.1.1 of ISO 9000: 2000).</p> <p>Characteristics imply a distinguishing feature (Para 3.5.1 of ISO 9000: 2000).</p> <p>Requirements are a need or expectation that is stated, generally implied or obligatory (Para 3.1.2 of ISO 9000:2000).</p> <p>2. Degree of adherence to pre-established criteria or standards.</p>
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	<p>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.</p> <p>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. <i>(Reference: McGraw-Hill Dictionary of Scientific & Technical Terms)</i></p> <p>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.</p> <p>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.</p>
Re-assessment	It implies continuous and ongoing assessment of the patient which is

	recorded in the medical records as progress notes.
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	<p>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.</p> <p>It is the decrease in the risk of a healthcare facility, given activity, and treatment process with respect to patient, staff, visitors and community.</p>
Root Cause Analysis (RCA)	<p>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.</p> <p>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.</p>

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 services	Range of clinical and supportive activities that are provided by a healthcare organisation.
Security	Protection from loss, destruction, tampering, and unauthorised access or use.
Sedation	<p>The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation. There are three levels of sedation:</p> <p>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.</p> <p>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.</p> <p>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.</p>
Sentinel events	<p>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.</p> <p>Major and enduring loss of function <i>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.</i></p>
Social	A balanced approach for organisation to address economic, social

responsibility	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.
Staff	All personnel working in the organisation including employees, “fee-for-service” medical professionals, part-time workers, contractual personnel and volunteers.
Standard precautions	<ol style="list-style-type: none"> 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. <p>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</p>
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.
Unstable patient	A patient whose vital parameters need external assistance for their maintenance.
Validation	<ol style="list-style-type: none"> 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	<p>The fundamental beliefs that drive organisational behaviour and decision-making.</p> <p>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.</p>
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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