

ADVANCE LEVEL- PATIENT SAFETY STANDARD FOR HEALTH CARE ORGANIZATIONS (HCO)

Association of Healthcare Providers (India)

... Educating & Advocating for Well Being of Common Man ...

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FOREWORD

Patient Safety is a major concern in healthcare. We need to define framework for quality governance of Health Card Organizations (HCO) across the nation, which can enable them to monitor and measure adverse events and take corrective and preventive measures. The framework should also help in measuring hospital acquired infections and clinical outcomes. These simple measures will be able to build culture of safety within a healthcare organisation.

I am happy to note that the Association of Healthcare Providers (India) have come out with two standards on Patient Safety for their member hospitals. As I see, the standards are at two levels, one Basic and other Advance. Both are inclusive and progressive. This will help the HCOs to progress from one level to another. The standards include parameters relating to structure, processes and outcomes. A Self Assessment check list, which is an integral part of standards, will guide HCO to monitor the compliance.

I wish to compliment the AHPI for releasing the standards which I believe will help in improving the Patient Safety in HCOs.

(Keshav Desiraju)

New Delhi,

Dated the 30th August 2013.



Message from WHO SEARO for Launch of Standards on Patient Safety

The fundamental principle of healthcare is that it should do no harm. Hospitals are where people go with trust that they will get better and become free of ailments. And when a patient is harmed in the hospital it is a great erosion of that trust. An essential aspect of quality care, Patient Safety is about preventing medical error that may lead to adverse events and harm.

The safety of the patient has to be kept in forefront during all modalities of prevention, diagnosis, treatment and follow up and in all levels of care: Primary, secondary and tertiary. Due to complexity of healthcare and growing needs for healthcare in the population the risk and potential for harm is increased. In developed countries as many as one in ten patients is harmed while receiving healthcare. In developing countries there is even greater risk of harm - estimated to be as much as 20 times higher - due to limitations in infrastructure, technologies and human resources.

Taking cognizance of the fact that patient safety is a growing public health problem, in 2002, WHO Member States resolved to pay the closest possible attention to the issue of patient safety and the World Alliance for Patient Safety was formed. Promotion of Patient Safety was further endorsed by the regional committee in 2006 and the Member States of the WHO South East Asia Region resolved to support and enable health care institutions at all levels to implement systems changes and practices conducive to patient safety.

India is moving towards universal health coverage (UHC) with a master plan. While investing on achieving UHC we need to improve quality in healthcare and make it available and affordable. There are few success stories found in India of improving quality and safety of healthcare provided by institutions. These successful proven interventions need to be replicated and promoted across the large number of hospitals in general and in the smaller nursing homes in particular. It is necessary to define quality framework which is based on basic principles of patient safety, which can enable them to maintain surveillance, monitor and measure adverse events and take corrective and preventive measures. The framework should also help in measuring hospital acquired infection and other clinical outcomes. These simple measures will be able to build safety culture within a healthcare organization.

WHO has developed numerous guidelines on patient safety to minimize healthcare acquired infections, antimicrobial resistance and medical mismanagement. We are happy to note that ASSOCIATION OF HEALTHCARE PROVIDERS (INDIA) have come out with two standards on Patient Safety for their member hospitals, which are based on well-known model i.e. STRUCTURE-PROCESSES-OUTCOMES. The standards are in two levels; one BASIC and other ADVANCE, both are inclusive and progressive. This will help the HCO to progress from one level to another. Other good feature is that it has provided SELF ASSESSMENT check list for all three sections as integral part of standard, which will help HCO as guidance to monitor the compliance.

WHO wish to compliment the AHPI for releasing the standards which will help in improving the Patient safety in the large number of HCOs.

A handwritten signature in black ink, appearing to read 'Sunil Senanayake'.

Dr Sunil Senanayake

Regional Adviser

Health Systems Management and Patient Safety Regional Office for South-East Asia

World Health Organization

06 September 2013

PREFACE

Quality in healthcare is generally driven by the regulatory framework. This has not been the case in India. Paying/Empanelling agencies can play very effective role in driving of quality. Here also we have limitation as over 80% of people pay for healthcare services out of pocket. In third scenario, empowered society, which is capable of taking informed decision, can drive the quality. This again is not the case as healthcare has limited availability/ accessibility and even limited awareness among vast majority of society.

Advent of NABH in year 2006 provided the optimum framework for Quality for the first time in the country, meeting global benchmarks as prescribed by International Society for Quality in Healthcare. During past seven years, about two hundred hospitals have taken NABH accreditation. There are some state driven empanelment/insurance schemes, having their own quality criteria. These schemes at best may cover few thousands hospitals. Considering that there are more than 50,000 hospitals/nursing homes in the country, we have long way to go in ensuring that these hospitals/nursing homes and clinics are complying with appropriate level of patient safety standard/criteria.

In view of above AHPI has come out with two levels of Patient Safety Standards i.e. BASIC and ADVANCE. The two standards will provide with the opportunity for vast majority of healthcare providers to establish and self-assess the compliance to patient safety norms as provided in the respective standards. The two levels are designed as inclusive and progressive, in the sense that BASIC LEVEL standard is sub-set of ADVANCE level standard.. Where needed, the AHPI CERTIFICATION CENTER will provide independent certification for compliance of these standards.

The BASIC LEVEL-PATIENT SAFETY STANDARD, as the name suggests, is intended to be used by vast majority of healthcare providers to establish, a basic level patient safety framework by way of structure, process and outcomes, to provide basic healthcare services to the community. It can be adopted by variety of healthcare providers i.e. hospitals/nursing homes for general disease/ general medicine/ general surgery/ obstetrics & gynaecology/ paediatrics etc. It can also be adopted by clinics/polyclinics and other similar providers howsoever named. The standard however is not meant for hospitals providing super specialty services for which AHPI's ADVANCE LEVEL- Patient Safety Standard is applicable

Standard can also be adopted by the central as well as the state governments for their primary and community health centres (PHCs/CHCs).The standard can be used by the central/state governments for empanelment of small hospitals located in semi-urban/rural areas, under government insurance schemes including RSBY. It can be adopted by various insurance companies and other empanelling agencies, which will bring uniform and objective way of assessment across the country.



(Dr Girdhar J. Gyani)
Director General

ADVANCE LEVEL- PATIENT SAFETY STANDARD FOR HEALTH CARE ORGANIZATIONS (HCO)

Scope:

The ADVANCE LEVEL-PATIENT SAFETY STANDARD is intended to be used by vast majority of Health Care Organizations (HCO) to establish, a robust patient safety framework by way of structure, process and outcomes, to provide appropriate healthcare services to the society. It can be adopted by Hospitals engaged in delivery of specialty/super-specialty healthcare services. It can be adopted by hospitals/nursing homes delivering variety of services i.e. general disease/ general medicine/ general surgery/ obstetrics & gynecology/ pediatrics etc. The standard can also be used as up-grade standard by those who are practicing AHPI's BASIC LEVEL- Patient Safety Standard.

Introduction:

The Patient Safety and Quality of Care are synonymous. Quality of Care as such is directly aimed at saving of precious human lives. Reports from various parts of the globe have shown that hundreds of thousands of preventable deaths occur due to want of safe healthcare practices. Unfortunately there has not been any conscious effort in monitoring/measuring of sentinel/adverse events in most of the developing nations, which would have given the necessary thrust to initiate quality practices in the health sector.

Quality in healthcare is to be driven through combination of regulation and by way of community demand. Empanelment of healthcare organization under Government scheme or by insurance/ paying agencies can play important role in driving quality. The criteria for such empanelment should be based on the patient safety protocols and should be assessed using independent agencies on behalf of the empanelling authorities.

This standard can very much be used for these purposes, where payer/ empanelling agencies want to ensure that healthcare providers indeed have systems which are based on sound principles of quality management and provide assurance that they follow patient safety protocols.

Basic Quality Management System (QMS) Requirements:

The HCO shall develop, implement and maintain an on-going Quality Management System (QMS) for managing quality and patient safety. The HCO shall implement quality assessment and performance improvement programs to monitor quality of care and patient safety. The HCO shall ensure that adequate resources are allocated to implement Quality Management System (QMS) for assessing and improving the HCO's performance by way of identified managerial and clinical

indicators, with a view to reduce risk to patients. This quality management system shall ensure that corrective and preventive actions taken by the HCO are implemented and reviewed for their effectiveness.

Some of the key steps needed for the Quality Management System (QMS) are as follows;

1. Assign or designate a person from TOP MANAGEMENT as Quality Manager responsible for all Quality processes, who has authority to ensure the implementation of Quality management systems. He /She should have basic training in quality and accreditation.
2. Standardize all the clinical and managerial process by preparing appropriate written documents, which will mainly include – Quality Manual, Safety & Security Manual, Infection Control Manual, Laboratory and Radiology's Quality and Safety Manual, Departmental Standard Operating Procedures (SOPs) and various Standardize Forms, Formats and Signage's.
3. Establishing of various Multi-Disciplinary Operational Committees i.e. Hospital Quality Committee, Hospital Safety Committee, Pharmaceutical& Therapeutics Committee
4. Infection Control Committee, Medical Audit Committee etc.
5. Conduct regular internal audit with the help of trained internal auditors and Management Review Meetings to review the audit finding to close the gaps and ensure implementation and maintenance of Quality Management System (QMS) based on the requirements listed in the standard.
6. Prepare annual training and retraining plan covering organization wide and departmental training i.e. safety protocols, nursing practices ,infection control, Medication safety, Fire safety, Emergency Codes etc.

STRUCTURAL REQUIREMENT (SR)

SR-1 : Building and Utility services

SR1.1 PHYSICAL FACILITY

1. Physical facilities and the overall hospital environment shall be developed and maintained to ensure safety and well-being of patients, visitors, and staff.
2. Facility shall be clean and well managed and flooring shall be non slippery.
3. HCO shall have adequate space for ambulance and patient movement
4. HCO shall have adequate measures in the facility including wheel chairs, trolleys etc. for easy access and movement of vulnerable patients.
5. HCO shall have adequate lighting, cooling and heating facilities.
6. HCO shall have adequate waiting area, bathrooms, canteen facility within the premises. One toilet and a bathroom for every 6 beds / Separate for male and female shall be provided.
7. HCO shall ensure that adequate privacy is ensured in Out Patient Department (OPD) and In-Patient Department (IPD).

SR1.2 WATER AND ELECTRICITY

1. Potable water and electricity shall be made available for 24hrs
2. In case of non-availability of water and electricity, alternate sources shall be arranged with adequate storage
3. Water including from alternate sources shall be tested on periodical basis including for bacterial sterility.

SR1.3 MEDICAL GASES , VACUUM AND COMPRESSED AIR

1. Medical gases, vacuum and compressed air shall be made available all the time. HCO shall maintain 'operating instructions' for their safe handling, storage, maintenance and distribution.
2. Alternate sources shall be provided and tested on periodical basis.

SR-2 SIGNAGE'S

1. Adequate internal and external Signage's shall be displayed in English and in the language understood by patient / family and community.
2. All Signage's and those required by law (i.e. Fire exit, Pre Conception and Pre Natal Diagnostic Techniques (PC & PNDT Act) shall be displayed at all strategic location.

SR-3 LABORATORY SERVICES AND BLOOD BANK

1. Diagnostic services shall be available as per the scope of services. In case diagnostic services are outsourced, critical biochemistry and hematology shall be available for immediate diagnosis aiding urgent treatment. A small sample collection room shall also be provided.
2. Blood bank Services if available shall be as per the statutory/regulatory norms. If Blood Bank is not available, adequate supply/ storage shall be ensured.

SR-4 IMAGING SERVICES

1. The services and facilities should adhere to the practices specified under the Atomic Energy Regulatory Board (AERB) including guidelines from BARC regarding radiation safety measures and the PC & PNDT Act.
2. HCO shall adhere to the radiation safety precautions including adequate shielding for relatives, visitors and the staff (use of TLD badges). HCO shall ensure appropriate storage, usage and disposal of radioactive materials.

SR-5 INTENSIVE CARE

1. Intensive Care unit (ICU) services shall be available as per the scope of services
2. Appropriate infrastructure and manpower shall be made available
3. HCO shall ensure that emergency drugs and equipment required for critical care management i.e. medicine crash cart or trays with all the life- saving medicines/injections and defibrillator are available, and maintained.
4. HCO shall ensure that adequate facility for hand washing is available in adequate numbers with dryers or tissue papers.

SR-6

OPERATION THEATER

1. OT complex needs to be divided into sterile and non-sterile zones i.e. waiting area, clean area and disposal area.
2. Adequate light and air conditioning needs to be provided in the OT
3. Indoor Quality shall be tested periodically by at least dish plate system and appropriate action is taken to maintain the quality all the time.
4. HCO shall ensure that appropriate temperature and relative humidity is monitored and maintained inside the OT.
5. HCO shall ensure that positive pressure is maintained inside the OT by Air Handling Unit or any other appropriate technology.

SR-7

INFECTION CONTROL AND WASTE DISPOSAL

1. HCO shall ensure that adequate hand wash facility and Alcohol hand rubs are available
2. HCO shall ensure that appropriate infection control practices are followed in the ICU
3. HCO shall ensure that appropriate prophylactic antibiotic and rational antibiotics are followed
4. HCO shall ensure waste management practices as per the statutory norms (BMW Rules 1998).
5. Adequate personal protective equipment (gloves, mask, apron etc.) shall be available in OT/ ICU/Laboratory and in the critical areas
6. HCO shall ensure provisions for sterilization of the facility, equipment, linen etc. as appropriate.

SR-8

MEDICAL STAFF

1. The HCO shall ensure that all medical staff is adequately credentialed.
2. HCO shall ensure that healthcare professionals (doctors, nurses and paramedical staff) are provided as per the statutory norms viz. MCI (Medical Council of India) and INC (Indian Nursing Council).
3. Contact information in respect of key medical staff by way of telephone/mobile number/ residence address shall be available in the emergency department.

4. At least one medical officer and a nurse shall be available all the time for emergency cases.
5. HCO shall have system in place to call specialists, whenever required for appropriate patient care.

SR-9 MEDICAL EQUIPMENT

1. Adequate Bio Medical equipment shall be available as per the scope of services.
2. Regular/Preventive maintenance including their periodic calibration shall be carried out.

SR-10 SAFETY (FIRE AND NON-FIRE EMERGENCY) AND SECURITY

1. Appropriate fire detection and fire- fighting equipment shall be installed
2. Hospital staff should be trained to handle all such equipment and in containment of fire.
3. Fire exit, escape/ evacuation routes shall be displayed at all appropriate locations.
4. DO'S AND DON'T'S during fire shall be displayed.
5. Emergency contact numbers to handle all emergencies shall be displayed.
6. NO SMOKING SIGNAGES shall be displayed
7. Relevant safety information for patient and staff shall be displayed at all strategic locations.
8. Nurse Call facility shall be available to address patient emergency.
9. Organization shall have security procedure in place to address issues related to abduction, elopement, visitors, workplace violence, and property losses.
10. Organization shall have arrangement in place for management and/ or evacuation of patients, relatives and staff, in case of natural disaster like earthquake, flood etc

SR-11 HAZARDOUS MATERIAL

1. Hazardous material for each department shall be identified.
2. Staff shall be trained to manage spills of hazardous materials.
3. Required tools and equipment shall be available to manage the spill, in the form of a kit identified as Hazardous Material (HAZMAT) KIT.

SR-12

SUPPORT SERVICES

1. HCO shall ensure that services i.e. (Laundry, Housekeeping, Dietary, security, Ambulance, Mortuary, Central Sterile Supply Department (CSSD) etc. are available (in-house or outsourced).
2. In case of services being outsourced, a periodic Monitoring / inspection of outsourced services should be ensured.

PROCESS REQUIREMENTS (PR)

PR-1 ENQUIRY

1. Adequate number of enquiry and admission counters, duly manned by staff shall be provided.
2. HCO shall display the list of services which are being offered in accordance to the scope of service. List of doctors shall also be displayed in bilingual language.
3. Staff shall be aware of list of services provided by the HCO and all related information of the hospital.

PR-2 REGISTRATION

1. All the patients who visit to the organization shall be registered and unique Identification number shall be generated.
2. Patient shall be registered only if the required services are available.

PR-3 ADMISSION

1. HCO shall admit a patient only after examination and written order of a doctor.
2. Admission shall be done after checking the availability of required beds and shall have the laid down procedure for emergency admissions.
3. Documented policies and procedures shall be established on dealing with the situation like; non-availability of beds. Staff needs to be adequately trained to deal with such situations.
4. General Consent and Informed Consent (Bilingual) shall be taken during the admission and before doing any procedures / surgery.

PR-4 TRANSFER OUT AND REFERRAL

1. Patient shall be referred to another facility along with the documented clinical information, in case of non-availability of services and/or beds.
2. In case of critical / serious patients, competent staff with appropriate ambulance should be arranged for transfer of patient to another facility.
3. Care needs to be taken to stabilize the patient before sending to other facility

PR-5 BILLING

1. Information regarding total cost shall be explained and provided to the patients at the time of registration and admission to ward. In case of any Change in medical and surgical plan, the cost difference shall be brought to the notice of patient/associate.

PR-6 EMERGENCY CARE

1. In case of an emergency, the treatment to the patient shall be provided on immediate basis. In case of non-availability of services and/or beds, the patient shall be transferred to another hospital after stabilizing. Staff shall be trained to handle emergencies with adequate skills.
2. Organization shall follow all statutory requirements in medico legal cases.

PR-7 OUTPATIENT DEPARTMENT (OPD)

1. The equipment required to measure height, weight, Blood Pressure (BP) and to conduct general examination, shall be available in the OPD.
2. Privacy to be ensured in OPD during consultation and examination as per the principles of medical ethics.

PR-8 CLINICAL ASSESSMENTS AND REASSESSMENTS

1. Initial assessment shall be conducted for all the patients by qualified and licensed healthcare professionals. The patient information should be coordinated and made available to all the relevant care providers.
2. Additional care (nutritional, rehabilitation etc.) and reassessment requirement shall be adhered to and documented including in the patient medical records for continuity of care.
3. The reassessment shall be done atleast once a day by concerned medical / surgical team.

PR-9 DIAGNOSTIC SERVICES (LABORATORY AND IMAGING SERVICES)

1. Diagnostic services shall carry out appropriate internal Quality Assurance (QA) checks and shall undertake appropriate corrective and preventive measures.

2. The organization shall follow Radiation Safety norms.
3. In case services are outsourced, the organization shall ensure all quality norms are followed by the outsourced organization by visiting the outsourced organization. Records for such assessment shall be maintained.

PR-10 | **MEDICATION MANAGEMENT**

1. HCO shall ensure that all medications and associated instructions are written in the prescription.
2. Prescription shall be legible, clear and explained in the language understood by the patients.
3. Medication administration shall follow- 7 R's of Medication Administration i.e. Right Patient, Right Medication, Right Route, Right Time, Right DOSE, Right Frequency, and Right Documentation.
4. Look Alike and Sound Alike Medicines need to be identified and stored separately to avoid any dispensing and administration errors.
5. Documented policies and procedures shall guide identification, safe dispensing and administration of all high risk medicines.
6. Medicine storage shall be in a clean, well lit, and in safe environment in accordance with applicable laws and regulations, as applicable for Drugs Procurement, Storage, Dispensing, Narcotics Drugs and psychotropic substances.
7. HCO shall ensure that all medication errors, adverse drug reactions are captured and corrective and preventive measures are taken.

PR-11 | **PROCEDURE / SURGERY**

1. Written Informed Consent shall be obtained for Surgical and Invasive Procedures, from the patients/relatives (as prescribed by Law). It shall mention all the details including Risk, Benefits and about alternative procedures/surgery. All informed consents should be bilingual including local Language.
2. In case patient is incapable of giving consent, a surrogate consent procedure shall be established.
3. Pre –operative assessment shall be done and documented by appropriately qualified staff.

4. Documented procedure should exist providing with, verification of patient, just before start of operation, by the person coordinating the check list or another person in the team by asking everyone in the operation room to verbally confirm the name of patient, the surgery to be performed, and site of surgery and where appropriate the position of patient (Time Out).
5. Patients shall be monitored Intra-Operatively and all vitals shall be recorded in a standardized format.
6. Patients shall be monitored in the post procedure care area before sending to another unit.
7. Universal standard criteria shall be established and monitored e.g. Aldrete Scorecard and PACU (Post-Anesthesia Care Unit) monitoring criteria.
8. Operative notes and post op care plan shall be written before the patients are transferred from the OT.
9. All infection control practices shall be followed.
10. Pre washing of instrument in the OT shall be done in the non-sterile Zone.

PR-12

ANESTHESIA / SEDATION

1. Written Informed Consent shall be obtained signed by patient and care provider. All risks, benefits and alternatives shall be discussed and mentioned as part of the consent.
2. Pre- Anesthesia assessments, type of Anesthesia and Post Anesthesia status shall be documented.
3. Immediate Pre-Op Anesthesia assessment shall be done.
4. Monitoring of required parameters shall be done during and post Anesthesia status.
5. All infection control practices shall be followed.

PR-13

INTENSIVE CARE

1. Admission and discharge Criteria shall be documented and followed during transfer of patients. Staff shall be trained to comply with the criteria.
2. All infection control measures shall conform to documented guidelines based on the established practices.

3. HCO shall ensure that all relevant bio- medical equipment required in ICU is available. Medications shall be stored appropriately in refrigerators and temperature of refrigerator is monitored.
4. Appropriate Isolation facility should be established for Infectious patient.
5. Intensive Care Unit shall be manned by the competent staff round the clock.

PR-14 INFECTION CONTROL

1. All high risk areas (OT, ICU, and CSSD) shall comply with the documented 'Good Infection Control Practices'.
2. Staff shall be trained for all infection control practices, hand hygiene guideline, occupational risk and its prevention.
3. Organization shall perform regular surveillance activity for infection control practices.

PR-15 CARDIO PULMONARY RESUSCITATION (CPR)

1. Staff involved in direct patient care shall be trained in Cardio Pulmonary Resuscitation (CPR), Basic Life Support (BLS), and Advance Cardiac Life Support (ACLS). The training shall be periodically updated.
2. Neonatal advanced life support (NALS), Pediatric advanced life support (PALS) training shall also be done as per the scope of the services. .
3. There shall be code blue protocol in the organization.
4. Cardio Pulmonary Resuscitation (CPR) Algorithm should be displayed in all critical care areas. Cardio Pulmonary Resuscitation events are recorded and corrective and preventive measures are taken

PR-16 PAIN , BEDSORE AND FALL MANAGEMENT

1. All the patients should be screened for pain.
2. Pain management protocols shall be followed for patient in pain
3. Patient and family members shall be educated about pain management.
4. Patients shall be assessed and monitored for Bed sores and appropriate interventions are made. Staff shall be trained for pain, bed sore and fall management.

PR-17 PATIENT AND FAMILY EDUCATION / COMMUNICATION

1. Patient and / or family shall be educated for their disease, progress, complication, cost and treatment
2. Patients shall be educated for usage and effect of medication, diet and nutrition, immunizations, preventing infections as deemed appropriate.
3. All matters related to patient education shall be documented and entered in the medical records.

PR-18 PATIENT RIGHTS AND RESPONSIBILITY

1. Patients and families shall be made aware of their rights and responsibilities at the time of admissions. Educating patients should also be pursued through leaflets/posters at Out Patient Department (OPD) and other prominent waiting areas.
2. Staff shall be trained in protecting patient rights.

PR-19 DISCHARGE/ DEATH SUMMARY

1. Discharges shall be planned and discharge summary shall contain diagnosis, history, physical examination, investigation details, treatment provided and instructions thereof.
2. When, where and how to obtain urgent care, should be mentioned in the discharge summary in easy to understand manner.

PR-20 HUMAN RESOURCE MANAGEMENT

1. Organization shall plan human resource with adequate number and with adequate mix of staff
2. Staff shall be recruited after proper antecedent verification.
3. Job responsibility shall be defined for all level of the staff.
4. Annual Training Plan shall be prepared for all staff covering all training needs. Staff shall be trained for all safety related procedures (occupational hazards, fire and non-fire emergency etc.)
5. Organization shall have a procedure to evaluate and monitor performance of the staff.

6. Credentials of all clinical staff should be verified and documented in the files of the staff. Even telephone verification should be documented.
7. Sexual harassment and grievance handling procedure shall be available and staff shall be trained for the same.

PR-21 FACILITY MAINTENANCE

1. Facility shall be inspected for all safety related issues at regular intervals
2. Organization shall develop plan for maintenance, testing, and inspection processes for critical utilities (Medical gases /Heating, Ventilation and Air Condition (HVAC) / water / electricity etc.)
3. There shall be a documented preventive and breakdown maintenance plan for all facilities.

PR-22 MEDICAL EQUIPMENT MANAGEMENT

1. Organization shall develop plan for regular testing, and inspection of all bio-medical equipment.
2. Medical equipment shall be calibrated on a periodic basis.
3. HCO shall ensure that preventive and breakdown maintenance plan for Bio-Medical equipment is followed.

PR-23 MEDICAL RECORD MANAGEMENT

1. Medical records shall be retained as per the policies of HCO based on national and local law. It shall be stored in safe and secure place. Confidentiality of medical records shall be ensured.
2. The medical records reviews are done regularly by the concerned stake holders and based on which appropriate corrective and preventive measures are taken.

PR-24 SUPPORT SERVICE MANAGEMENT

1. Documented policies and procedures shall be available for all support services including Laundry, Housekeeping, Security, Ambulance etc. The procedures shall take into considerations, all the appropriate provisions covered in this standard for their procurement, provisioning and maintenance.
2. In case any of these services are outsourced, same procedures shall be applied on the outsourced organization(s).

OUTCOME REQUIREMENT (OR)

OR-1 PATIENT OUTCOME

1. Monthly Out Patient Department (OPD) and In-Patient Department (IPD) admissions rates
2. Mortality and Length of stay
3. Infection Rates
 - a. Surgical Site
 - b. Urinary tract
 - c. Blood Stream
 - d. Ventilator Associated Pneumonia (VAP) / Hospital acquired Pneumonia
4. Transfusion reaction

OR-2 SERVICE OUTCOME

1. Bed occupancy
2. Percentage of patient satisfaction
3. Percentage of Employee satisfaction
4. Waiting time – Out Patient Department (OPD) and discharges
5. Medical record documentation per the laid down policy

OR-3 RISK MANAGEMENT

1. Reporting of sentinel events
2. Reporting of Adverse events
3. Reporting of Falls , Percentage of Bedsores
4. Reporting of Thefts / Security related incidents
5. Reporting of Needle stick Injuries
6. Reporting of Medication and adverse drug reactions

All the indicator monitoring shall result into improvement plans which help the organization in improving patient safety, outcome and quality of care.

ASSESSMENT TOOL-KIT

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
SR-1 : BUILDING AND UTILITY SERVICES			
SR1.1 : PHYSICAL FACILITY			
Physical facilities and the overall hospital environment shall be developed and maintained to ensure safety and well-being of patients, visitors, and staff.			
Facility shall be clean and well managed and flooring shall be non slippery.			
HCO shall have adequate space for ambulance and patient movement			
HCO shall have adequate measures in the facility including wheel chairs, trolleys etc. for easy access and movement of vulnerable patients.			
HCO shall have adequate lighting, cooling and heating facilities.			
HCO shall have adequate waiting area, bathrooms, canteen facility within the premises. One toilet and a bathroom for every 6 beds / Separate for male and female shall be provided.			
HCO shall ensure that adequate privacy is ensured in Out Patient Department (OPD) and In-Patient Department (IPD).			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
SR1.2 : WATER AND ELECTRICITY			
Potable water and electricity shall be made available for 24hrs			
In case of non-availability of water and electricity, alternate sources shall be arranged with adequate storage			
Water including from alternate sources shall be tested on periodical basis including for bacterial sterility.			
SR1.3 : MEDICAL GASES, VACUUM AND COMPRESSED AIR			
Medical gases, vacuum and compressed air shall be made available all the time. HCO shall maintain 'operating instructions' for their safe handling, storage, maintenance and distribution.			
Alternate sources shall be provided and tested on periodical basis.			
SR-2 : SIGNAGE'S			
Adequate internal and external Signage's shall be displayed in English and in the language understood by patient / family and community.			
All Signage's and those required by law (i.e. Fire exit, Pre Conception and Pre Natal Diagnostic Techniques (PC & PNDT Act) shall be displayed at all strategic location.			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
SR-3 : LABORATORY SERVICES AND BLOOD BANK			
Diagnostic services shall be available as per the scope of services. In case diagnostic services are outsourced, critical biochemistry and hematology shall be available for immediate diagnosis aiding urgent treatment. A small sample collection room shall also be provided.			
Blood bank Services if available shall be as per the statutory/regulatory norms. If Blood Bank is not available, adequate supply/ storage shall be ensured.			
SR-4 : IMAGING SERVICES			
The services and facilities should adhere to the practices specified under the Atomic Energy Regulatory Board (AERB) including guidelines from BARC regarding radiation safety measures and the PC & PNDT Act.			
HCO shall adhere to the radiation safety precautions including adequate shielding for relatives, visitors and the staff (use of TLD badges). HCO shall ensure appropriate storage, usage and disposal of radioactive materials.			
SR-5 : INTENSIVE CARE			
Intensive Care unit (ICU) services shall be available as per the scope of services			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Appropriate infrastructure and manpower shall be made available			
HCO shall ensure that emergency drugs and equipment required for critical care management i.e. medicine crash cart or trays with all the life- saving medicines/ injections and defibrillator are available, and maintained.			
HCO shall ensure that adequate facility for hand washing is available in adequate numbers with dryers or tissue papers.			
SR-6 : OPERATION THEATER			
OT complex needs to be divided into sterile and non-sterile zones i.e. waiting area, clean area and disposal area.			
Adequate light and air conditioning needs to be provided in the OT			
Indoor Quality shall be tested periodically by at least dish plate system and appropriate action is taken to maintain the quality all the time.			
HCO shall ensure that appropriate temperature and relative humidity is monitored and maintained inside the OT.			
HCO shall ensure that positive pressure is maintained inside the OT by Air Handling Unit or any other appropriate technology.			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
SR -7 : INFECTION CONTROL AND WASTE DISPOSAL			
HCO shall ensure that adequate hand wash facility and Alcohol hand rubs are available			
HCO shall ensure that appropriate infection control practices are followed in the ICU			
HCO shall ensure that appropriate prophylactic antibiotic and rational antibiotics are followed			
HCO shall ensure waste management practices as per the statutory norms (BMW Rules 1998).			
Adequate personal protective equipment (gloves, mask, apron etc.) shall be available in OT/ICU/Laboratory and in the critical areas			
HCO shall ensure provisions for sterilization of the facility, equipment, linen etc. as appropriate.			
SR-8 : MEDICAL STAFF			
The HCO shall ensure that all medical staff is adequately credentialed.			
HCO shall ensure that healthcare professionals (doctors, nurses and paramedical staff) are provided as per the statutory norms viz.MCI(Medical Council of India) and INC (Indian Nursing Council).			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Contact information in respect of key medical staff by way of telephone/mobile number/residence address shall be available in the emergency department.			
At least one medical officer and a nurse shall be available all the time for emergency cases.			
HCO shall have system in place to call specialists, whenever required for appropriate patient care.			
SR-9 : MEDICAL EQUIPMENT			
Adequate Bio Medical equipment shall be available as per the scope of services.			
Regular/Preventive maintenance including their periodic calibration shall be carried out.			
SR-10 : SAFETY (FIRE AND NON-FIRE EMERGENCY) AND SECURITY			
Appropriate fire detection and fire-fighting equipment shall be installed			
Hospital staff should be trained to handle all such equipment and in containment of fire.			
Fire exit, escape/ evacuation routes shall be displayed at all appropriate locations.			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
DO'S AND DON'T'S during fire shall be displayed.			
Emergency contact numbers to handle all emergencies shall be displayed.			
NO SMOKING SIGNAGES shall be displayed			
Relevant safety information for patient and staff shall be displayed at all strategic locations.			
Nurse Call facility shall be available to address patient emergency.			
Organization shall have security procedure in place to address issues related to abduction, elopement, visitors, workplace violence, and property losses.			
Organization shall have arrangement in place for management and/ or evacuation of patients, relatives and staff, in case of natural disaster like earthquake, flood etc			
SR-11 : HAZARDOUS MATERIAL			
Hazardous material for each department shall be identified.			
Staff shall be trained to manage spills of hazardous materials.			

STRUCTURAL REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Required tools and equipment shall be available to manage the spill, in the form of a kit identified as Hazardous Material (HAZMAT) KIT.			
SR-12 : SUPPORT SERVICES			
HCO shall ensure that services i.e. (Laundry, Housekeeping, Dietary, security, Ambulance, Mortuary, Central Sterile Supply Department (CSSD) etc. are available (in-house or outsourced).			
In case of services being outsourced, a periodic Monitoring / inspection of outsourced services should be ensured.			

PROCESS REQUIREMENTS

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
PR-1 : ENQUIRY			
Adequate number of enquiry and admission counters, duly manned by staff shall be provided.			
HCO shall display the list of services which are being offered in accordance to the scope of service. List of doctors shall also be displayed in bilingual language.			
Staff shall be aware of list of services provided by the HCO and all related information of the hospital.			
PR-2 : REGISTRATION			
All the patients who visit to the organization shall be registered and unique Identification number shall be generated.			
Patient shall be registered only if the required services are available.			
PR-3 : ADMISSION			
HCO shall admit a patient only after examination and written order of a doctor.			
Admission shall be done after checking the availability of required beds and shall have the laid down procedure for emergency admissions.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Documented policies and procedures shall be established on dealing with the situation like; non-availability of beds. Staff needs to be adequately trained to deal with such situations.			
General Consent and Informed Consent (Bilingual) shall be taken during the admission and before doing any procedures / surgery.			
PR-4 : TRANSFER OUT AND REFERRAL			
Patient shall be referred to another facility along with the documented clinical information, in case of non-availability of services and/or beds.			
In case of critical / serious patients, competent staff with appropriate ambulance should be arranged for transfer of patient to another facility.			
Care needs to be taken to stabilize the patient before sending to other facility			
PR-5 : BILLING			
Information regarding total cost shall be explained and provided to the patients at the time of registration and admission to ward. In case of any Change in medical and surgical plan, the cost difference shall be brought to the notice of patient/ associate.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
PR-6 : EMERGENCY CARE			
In case of an emergency, the treatment to the patient shall be provided on immediate basis. In case of non-availability of services and/or beds, the patient shall be transferred to another hospital after stabilizing. Staff shall be trained to handle emergencies with adequate skills.			
Organization shall follow all statutory requirements in medico legal cases.			
PR-7 : OUTPATIENT DEPARTMENT (OPD)			
The equipment required to measure height, weight, Blood Pressure (BP) and to conduct general examination, shall be available in the OPD.			
Privacy to be ensured in OPD during consultation and examination as per the principles of medical ethics.			
PR-8 : CLINICAL ASSESSMENTS AND REASSESSMENTS			
Initial assessment shall be conducted for all the patients by qualified and licensed healthcare professionals. The patient information should be coordinated and made available to all the relevant care providers.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Additional care (nutritional, rehabilitation etc.) and reassessment requirement shall be adhered to and documented including in the patient medical records for continuity of care.			
The reassessment shall be done atleast once a day by concerned medical / surgical team.			
PR-9 : DIAGNOSTIC SERVICES (LABORATORY AND IMAGING SERVICES)			
Diagnostic services shall carry out appropriate internal Quality Assurance (QA) checks and shall undertake appropriate corrective and preventive measures.			
The organization shall follow Radiation Safety norms.			
In case services are outsourced, the organization shall ensure all quality norms are followed by the outsourced organization by visiting the outsourced organization. Records for such assessment shall be maintained.			
PR-10 : MEDICATION MANAGEMENT			
HCO shall ensure that all medications and associated instructions are written in the prescription.			
Prescription shall be legible, clear and explained in the language understood by the patients.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Medication administration shall follow- 7 R's of Medication Administration i.e. Right Patient, Right Medication, Right Route, Right Time, Right DOSE, Right Frequency, and Right Documentation.			
Look Alike and Sound Alike Medicines need to be identified and stored separately to avoid any dispensing and administration errors.			
Documented policies and procedures shall guide identification, safe dispensing and administration of all high risk medicines.			
Medicine storage shall be in a clean, well lit, and in safe environment in accordance with applicable laws and regulations, as applicable for Drugs Procurement, Storage, Dispensing, Narcotics Drugs and psychotropic substances.			
HCO shall ensure that all medication errors, adverse drug reactions are captured and corrective and preventive measures are taken			
PR-11 : PROCEDURE / SURGERY			
Written Informed Consent shall be obtained for Surgical and Invasive Procedures, from the patients/relatives (as prescribed by Law). It shall mention all the details including Risk, Benefits and about alternative procedures/ surgery. All informed consents should be bilingual including local Language.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
In case patient is incapable of giving consent, a surrogate consent procedure shall be established.			
Pre –operative assessment shall be done and documented by appropriately qualified staff.			
Documented procedure should exist providing with, verification of patient, just before start of operation, by the person coordinating the check list or another person in the team by asking everyone in the operation room to verbally confirm the name of patient, the surgery to be performed, and site of surgery and where appropriate the position of patient (Time Out).			
Patients shall be monitored Intra-Operatively and all vitals shall be recorded in a standardized format.			
Patients shall be monitored in the post procedure care area before sending to another unit.			
Universal standard criteria shall be established and monitored e.g. Aldrete Scorecard and PACU (Post-Anesthesia Care Unit) monitoring criteria.			
Operative notes and post op care plan shall be written before the patients are transferred from the OT.			
All infection control practices shall be followed.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Pre washing of instrument in the OT shall be done in the non-sterile Zone.			
PR-12 : ANESTHESIA / SEDATION			
Written Informed Consent shall be obtained signed by patient and care provider. All risks, benefits and alternatives shall be discussed and mentioned as part of the consent.			
Pre- Anesthesia assessments, type of Anesthesia and Post Anesthesia status shall be documented.			
Immediate Pre-Op Anesthesia assessment shall be done.			
Monitoring of required parameters shall be done during and post Anesthesia status.			
All infection control practices shall be followed.			
PR-13 : INTENSIVE CARE			
Admission and discharge Criteria shall be documented and followed during transfer of patients. Staff shall be trained to comply with the criteria.			
All infection control measures shall conform to documented guidelines based on the established practices.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
HCO shall ensure that all relevant bio- medical equipment required in ICU is available. Medications shall be stored appropriately in refrigerators and temperature of refrigerator is monitored.			
Appropriate Isolation facility should be established for Infectious patient.			
Intensive Care Unit shall be manned by the competent staff round the clock.			
PR-14 : INFECTION CONTROL			
All high risk areas (OT, ICU, and CSSD) shall comply with the documented 'Good Infection Control Practices'.			
Staff shall be trained for all infection control practices, hand hygiene guideline, occupational risk and its prevention.			
Organization shall perform regular surveillance activity for infection control practices.			
PR-15 : CARDIO PULMONARY RESUSCITATION (CPR)			
Staff involved in direct patient care shall be trained in Cardio Pulmonary Resuscitation (CPR), Basic Life Support (BLS), and Advance Cardiac Life Support (ACLS). The training shall be periodically updated.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Neonatal advanced life support (NALS), Pediatric advanced life support (PALS) training shall also be done as per the scope of the services. .			
There shall be code blue protocol in the organization.			
Cardio Pulmonary Resuscitation (CPR) Algorithm should be displayed in all critical care areas. Cardio Pulmonary Resuscitation events are recorded and corrective and preventive measures are taken			
PR-16 : PAIN, BEDSORE AND FALL MANAGEMENT			
All the patients should be screened for pain.			
Pain management protocols shall be followed for patient in pain			
Patient and family members shall be educated about pain management.			
Patients shall be assessed and monitored for Bed sores and appropriate interventions are made. Staff shall be trained for pain, bedsore and fall management.			
PR-17 : PATIENT AND FAMILY EDUCATION / COMMUNICATION			
Patient and / or family shall be educated for their disease, progress, complication, cost and treatment			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Patients shall be educated for usage and effect of medication, diet and nutrition, immunizations, preventing infections as deemed appropriate.			
All matters related to patient education shall be documented and entered in the medical records.			
PR-18 : PATIENT RIGHTS AND RESPONSIBILITY			
Patients and families shall be made aware of their rights and responsibilities at the time of admissions. Educating patients should also be pursued through leaflets/posters at Out Patient Department (OPD) and other prominent waiting areas.			
Staff shall be trained in protecting patient rights.			
PR-19 : DISCHARGE/ DEATH SUMMARY			
Discharges shall be planned and discharge summary shall contain diagnosis, history, physical examination, investigation details, treatment provided and instructions thereof.			
When, where and how to obtain urgent care, should be mentioned in the discharge summary in easy to understand manner.			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
PR-20 : HUMAN RESOURCE MANAGEMENT			
Organization shall plan human resource with adequate number and with adequate mix of staff			
Staff shall be recruited after proper antecedent verification.			
Job responsibility shall be defined for all level of the staff.			
Annual Training Plan shall be prepared for all staff covering all training needs. Staff shall be trained for all safety related procedures (occupational hazards, fire and non-fire emergency etc.)			
Organization shall have a procedure to evaluate and monitor performance of the staff.			
Credentials of all clinical staff should be verified and documented in the files of the staff. Even telephone verification should be documented.			
Sexual harassment and grievance handling procedure shall be available and staff shall be trained for the same.			
PR-21 : FACILITY MAINTENANCE			
Facility shall be inspected for all safety related issues at regular intervals			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Organization shall develop plan for maintenance, testing, and inspection processes for critical utilities (Medical gases /Heating, Ventilation and Air Condition (HVAC) / water / electricity etc.)			
There shall be a documented preventive and breakdown maintenance plan for all facilities.			
PR-22 : MEDICAL EQUIPMENT MANAGEMENT			
Organization shall develop plan for regular testing, and inspection of all bio-medical equipment.			
Medical equipment shall be calibrated on a periodic basis.			
HCO shall ensure that preventive and breakdown maintenance plan for Bio-Medical equipment is followed.			
PR-23 : MEDICAL RECORD MANAGEMENT			
Medical records shall be retained as per the policies of HCO based on national and local law. It shall be stored in safe and secure place. Confidentiality of medical records shall be ensured.			
The medical records reviews are done regularly by the concerned stake holders and based on which appropriate corrective and preventive measures are taken			

PROCESS REQUIREMENT	Compliance	Partial Compliance	Non Compliance
PR-24 : SUPPORT SERVICE MANAGEMENT			
Documented policies and procedures shall be available for all support services including Laundry, Housekeeping, Security, Ambulance etc. The procedures shall take into considerations, all the appropriate provisions covered in this standard for their procurement, provisioning and maintenance.			
In case any of these services are outsourced, same procedures shall be applied on the outsourced organization(s).			

OUTCOME REQUIREMENTS

OUTCOME REQUIREMENT	Compliance	Partial Compliance	Non Compliance
OR -1 : PATIENT OUTCOME			
Monthly Out Patient Department (OPD) and In-Patient Department (IPD) admissions rates			
Mortality and Length of stay			
Infection Rates			
a. Surgical Site			
b. Urinary tract			
c. Blood Stream			
d. Ventilator Associated Pneumonia (VAP) / Hospital acquired Pneumonia			
Transfusion reaction			
OR-2 : SERVICE OUTCOME			
Bed occupancy			
Percentage of Patient satisfaction			
Percentage of Employee satisfaction			
Waiting time – Out Patient Department (OPD) and discharges			
Medical record documentation per the laid down policy			
OR-3 : RISK MANAGEMENT			
Reporting of sentinel events			
Reporting of Adverse events			

OUTCOME REQUIREMENT	Compliance	Partial Compliance	Non Compliance
Reporting of Falls, Percentage of Bedsores			
Reporting of Thefts / Security related incidents			
Reporting of Needle stick Injuries			
Reporting of Medication and adverse drug reactions			

SCORING SCHEME

Total Objective elements	:	155
Structural Requirement (SR)	:	055
Process Requirement (PR)	:	085
Outcome Requirement (OR)	:	015

All the objective elements can be assessed for compliance and be rated on the basis of implementation as 'compliance', 'non-compliance' and 'partial compliance'. The scoring can be done as below:

Compliance	:	10
Partial Compliance	:	5
Non Compliance	:	0

HCO can be considered compliant of 'ADVANCE LEVEL- PATIENT SAFETY STANDARD', if it gets 75% score in each of the category i.e. Structural, Process and Outcomes. The criteria for certification can however be modified based on the requirement of Empanelling/ Certification Agency, which can also put embargo on allowing only certain number of permissible non-compliance in each category.