Wadia Hospitals

BAI JERBAI WADIA HOSPITAL FOR CHILDREN

ACCREDITATION STANDARDS

FOR

NEONATAL INTENSIVE CARE UNIT

(NICU)

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Introduction

The Neonatal Intensive Care Unit (NICU) plays a critical role in providing specialized care for the most vulnerable patients—newborns facing life-threatening conditions and complications. Ensuring that NICUs meet high standards of care is essential for improving patient outcomes and enhancing the overall quality of neonatal care. Bai Jerbai Wadia Hospital for Children has nearly a decade long legacy of catering to the healthcare needs of the neonatal and paediatric patients. The hospital has designed the accreditation standards for NICUs to serve as a benchmark for healthcare facilities, guiding them in implementing best practices, maintaining safety protocols, and fostering a nurturing environment for infants and their families.

The purpose of Neonatal Intensive Care Unit (NICU) accreditation standards is clearly documented, serving multiple critical functions within healthcare settings. These standards are meticulously crafted to meet accreditation requirements, ensuring that NICUs adhere to stringent criteria for excellence in neonatal care. Additionally, NICU accreditation standards play a vital role in facilitating quality improvement initiatives by providing a comprehensive framework for assessing and enhancing the quality and safety of neonatal healthcare delivery. By adhering to these standards, NICUs demonstrate their commitment to providing the highest standard of care to critically ill new-borns and their families, promoting consistency, transparency, and accountability in neonatal healthcare practices.

These standards are designed to evaluate various aspects of NICU operations, including staffing, equipment, clinical protocols, and family-centered care approaches.

The standards outline the key components and criteria of NICU accreditation standards, emphasizing their importance in promoting optimal care, supporting healthcare providers, and ultimately improving outcomes for newborns and their families.

The scope of accreditation standards for Neonatal Intensive Care Units (NICUs) is comprehensive and specific to the unique needs of caring for critically ill newborns.

These standards are meticulously designed to ensure the highest quality of care within NICU facilities. They encompass a wide range of criteria, including medical management, nursing care, diagnostic procedures, therapeutic interventions, infection control measures, and support services. Accreditation standards for NICUs are tailored to address the specialized equipment, staffing ratios, and protocols required to provide optimal care to premature infants, newborns with complex medical conditions, and those requiring intensive monitoring and intervention.

Additionally, these standards often include criteria related to family-centered care, ensuring that parents and families are actively involved in the care of their newborn and receive adequate support and education throughout their NICU stay.

By adhering to accreditation standards, NICU facilities demonstrate their commitment to excellence in neonatal care and provide assurance to patients, families, and stakeholders of the quality and safety of care provided.

Chapter 1 Governance, Leadership & Management (GLM)

Introduction:

Governance, leadership, and management are three interrelated concepts that play crucial roles in the success and effectiveness of organizations, whether they are in the public or private sector. Each concept has its distinct focus, but they are often interconnected and overlap in various ways.

Governance often sets the overarching framework for both leadership and management. Effective leadership is critical for inspiring and aligning the efforts of individuals within the organization to achieve the governance-established goals.

Management implements the strategies defined by governance and guided by leadership to ensure day-to-day operations are carried out efficiently.

The standards stipulate that there is a dynamic interplay between these three elements, with strong governance providing a foundation for effective leadership and management practices.

Standards & Objective Elements:

- **GLM.1 The healthcare facility is required to be governed by a designated team.**
    a. The roles and responsibilities of those responsible for governance are defined.
    b. The governing team defines the healthcare facility's mission, vision, values, and code of ethics.
- **GLM.2.The mission, vision, and values of the healthcare facility publicly displayed.**
    a. The mission, vision, and values of the healthcare facility should be made available for all the staff, patients, and visitors.
    b. The display of the mission, vision, and values of the healthcare facility should be in a bilingual manner.
    c. The staff should be trained mission, vision, and values of the healthcare facility.
- **GLM.3 The healthcare facility has embedded an ethical management framework.**
    a. There should be a defined code of ethics which includes an ethical management framework.
    b. The ethical management framework shall include the resolution of conflict of interest, defining the process of avoiding, disclosing, and managing ethical, legal, or financial conflicts.
    c. Staff is trained on the code of ethics such that the same is embedded and imbibed in the healthcare facility.

- **GLM.4 The healthcare facility has documented strategic and operational plans.**
    a. The governing team is responsible for approving the strategic and operational plans. The annual budget is prepared and approved in accordance with the strategic & operational plans.
    b. The strategic plan should include short-term and long-term plans to address major improvements/changes.
    c. The operational plan should include measurable objectives that can be monitored for progress, reported, and acted upon on an annual basis.
    d. The inputs should be taken from the stakeholders in the formulation of the strategic and operational plans. The plans can be linked to human resources, risk, and financial plans of the organization.
    e. An annual financial report is produced and approved by the governing team.
- **GLM.5 The healthcare facility has defined a financial governance framework.**
    a. The facility has delegated the authority of financial management to a financial director.
    b. The financial responsibilities, policies, and procedures to be adopted by the healthcare facility are detailed. These include procedures for the management of capital assets and investments that define how the capital investment program is managed. There is an asset register.
    c. An annual financial audit report is prepared and presented to the governing team.
- **GLM.6 The healthcare facility has defined an operational governance framework.**
    a. The facility has delegated the authority of operational management to an operations director.
    b. Operational management responsibilities may relate to,
        i. implementing policy,
        ii. setting targets or goals for the future through planning and budgeting for the organization's range of services,
        iii. establishing processes for achieving those targets,
        iv. Allocating resources to accomplish those plans and ensuring that plans are achieved.
- **GLM.7 The governing team of the healthcare facility is responsible for compliance with the laid down and applicable legislations, regulations, and notifications.**
    a. The healthcare facility shall ensure that the statutory and regulatory compliances shall be maintained.
    b. The healthcare personnel shall have a valid licensure.

- **GLM.8 The scope of services offered by the healthcare facility is defined and approved by the Top management.**
    a. The scope of services shall be in accordance with the strategic aims of the facility.
    b. The scope of services offered are defined by taking into account the needs of the community.
    c. The services provided should have appropriate diagnostic, therapeutic, preventive, rehabilitative service with suitably qualified personnel.
    d. The scope of services provided are displayed prominently in a bilingual manner for the knowledge of the general public.

Chapter 2 Clinical Service Protocols (CSP)

Introduction:

Clinical service protocols are systematic and standardized sets of guidelines or procedures designed to ensure consistency, safety, and quality in the delivery of healthcare services. These protocols are particularly important in clinical settings since patient care involves complex processes, collaboration among healthcare professionals, and adherence to evidence-based practices.

Clinical service protocols are integral to the delivery of safe and effective healthcare. They provide a framework for healthcare providers to deliver consistent, evidence-based care while promoting patient safety and positive health outcomes.

The standards aim to guide and encourage defined service protocols as the overarching principle for providing care to patients.

Standards & Objective Elements:

- **CSP.1 The healthcare facility has a defined registration and admission process**
    a. The healthcare facility registers and admits the patients following the healthcare facility's admission policy.
    b. The healthcare facility generates a unique hospital identification for every new patient and maintains medical records of the patient which are current, complete and accurate.
    c. There is a documented procedure for the identification of newborns while in the care of the healthcare facility.
    d. The healthcare facility admits the patient as per the available scope of service.
    e. The healthcare facility defines and displays the admission criteria in written format and must include clinical, physiological, and laboratory criteria.
- **CSP. 2 The healthcare facility has emergency treatment available at first contact.**
    a. First contact at the hospital should provide vacancy status & availability of ventilator vacancy.
    b. There is a process for reserving a bed in the NICU, which may be reserved for a specified time.
    c. Patients brought directly to the NICU without inquiry should be admitted to the NICU if indoor treatment is required.

d. In case of unavailability of bed and/or requirement to transfer to a higher level of care; basic care including resuscitation should be provided & arrangements made for the transfer.
e. The healthcare facility has established protocols to manage medico-legal cases in accordance with the statutory requirements.

- **CSP.3 The healthcare facility has a defined transfer/referral process.**
  a. The healthcare facility has defined policies and protocols for neonatal transport.
  b. The healthcare facility has an adequately equipped ambulance for the transfer/referral onsite/outsourced.
     - The ambulance should have provisions for warmth, oxygenation, suction, and resuscitation.
     - Transport ventilator, incubator(s) are available for use during transport.
  c. The healthcare facility ensures that appropriately qualified personnel accompanies the patient during transfer and/or referral.
  d. The healthcare facility with Levels I and II neonatal intensive care units (NICUs), should have agreements with regional tertiary care centers about where they should transfer patients whom they are unable to care for.
  e. All relevant contact information and written guidelines and protocols should be easily accessible and reviewed periodically to ensure they are current.
  f. The healthcare facility provides a transfer summary to the patient.
- **CSP.4 The patients that avail treatment in the healthcare facility undergo a standardized initial assessment.**
  a. A standardized format is used for the initial assessment of out-patients, in-patients and emergency patients that reflects the baby's individual needs and is based on the observations and general condition of the patient at first point of contact.
  b. A suitably trained doctor and nurse carries out the initial assessment.
  c. The healthcare facility shall have processes to ensure that on admission to the facility, the duty doctor shall attend to the patient in a defined time frame.
  d. The contents of the initial assessment include a history and examinations
     - The immediate observations that need to be taken include measuring and recording of the APGAR score at birth, vitals, anthropometry, physical examinations.
  e. The clinical assessment leading to a documented care plan is counter-signed by the clinician in charge within 24 hours.
  f. There are procedures for the recognition and management of common problems of newborn babies, including hypothermia, jaundice, hypoglycaemia etc.

g. The care plans are made according to protocols in the unit & should be evidence-based.

- **CSP.5 The patients that avail treatment in the healthcare facility undergo a regular reassessment.**
  a. The out-patients, in-patients and emergency patients are reassessed at defined intervals.
  b. The response to the treatment is determined and documented.
  c. Ongoing clinical monitoring of the patient is undertaken and any deterioration is informed to the senior consultant. In case required senior consultant is available at all times on-call and to attend if required by the senior doctor on duty.
  d. The modification to the treatment plan wherever found necessary is documented.
  e. The healthcare facility shall have processes to identify need and arrange for sub-specialty reference wherever required.
- **CSP. 6 The healthcare facility ensures that patient care is coordinated in all care settings.**
  a. The healthcare facility has a standardized process of handover between each shift and during transfers.
  b. The handover communication is done on a standardised format by the staff providing clinical & nursing care.
  c. The healthcare facility ensures that patient is accompanied by an appropriately qualified individual during transfers.
- **CSP. 7 The healthcare facility has defined processes for level I neonatal care.**
  a. There is a policy defining the management, scope, and delivery of care of the level I neonatal care service.
     - Neonatal Resuscitation for each delivery. Stabilise and care for infants between 35 to 37 weeks and >1.8kg who are hemodynamically stable. Facility to stabilize and transport if unstable or <35 weeks and/or <1.8 kg.
  b. The healthcare facility can demonstrate that it meets all the requirements for a Level I neonatal service.
  c. The healthcare facility can demonstrate that suitably qualified personnel is available for patient care
     - Paediatrician : Desirable
     - Doctor: 1
     - Nurses: 1 RN & 1 ANM/Nursing aid
  d. The healthcare facility can demonstrate that it is adequately equipped for the provision of care
     - Oxygen support, warmer, and resuscitation equipments as per NRP guidelines.

e. Availability of NRP facilitators, modified new born screening, neonatal transport facility, Kangaroo Mother Care, Lactation support and immunization.

f. There is a documented procedure for the safe transfer of babies from level I care to a higher level of care, which includes the transportation requirements.

- **CSP. 8 The healthcare facility has defined processes for level II neonatal care.**

a. There is a policy defining the management, scope, delivery of care of the level II neonatal care service.

- All requirements of Level I and management of 32 -35 weeks of gestation and/or 1.5 to 1.8 kg. Respiratory support limited to CPAP. More than 35 weeks and/or more than 1.8 kg who need CPAP. Management of sepsis with IV antibiotics who are hemodynamically stable. Neonates needing phototherapy.

b. The healthcare facility can demonstrate that it meets all the requirements for a Level II neonatal service.

- Facilities for tube feeding. Facility to stabilise and transport to higher level of care.

c. The healthcare facility can demonstrate that suitably qualified personnel is available for patient care

- Pediatrician: Full-time mandatory with DCH/MD/DNB with 5/3/3 years of experience.
- RMO: DCH/MD/DNB with atleast 6/4 months of NICU experience. 1 per shift.
- Nurses (RN): 1 Senior nurse with adequate NICU experience. Nurse to patient ratio of 1:3

d. The healthcare facility can demonstrate that it is adequately equipped for provision of care

- Minimum 10 beds with 30% respiratory support beds. All the facilities and equipments of Level I and CPAP, continuous oxygen delivery, pulse oximeters, syringe pumps, NGT, warmers, phototherapy machines, suction facility, ABG analysis, exchange transfusion. 1 invasive ventilator in the unit is desirable.

e. Availability of NRP facilitators, modified new born screening, neonatal transport facility, Kangaroo Mother Care, Lactation support and immunization.

f. ROP, CCHD and hearing screen should made be available either in-house or MOU. There should be high risk follow up OPD.

g. There is a facility for the babies in level II special baby care to be fed with their mother's expressed milk.

h. There is a documented procedure for the safe transfer of babies from Level II care to a higher level of care, which includes the transportation requirements.

- **CSP. 9 The healthcare facility has defined processes for level III neonatal care.**
    a. There is a policy defining the management, scope and delivery of care of the level III NICU.
        - Management of <32 weeks and/or <1.5 kg. Neonates of any gestation requiring mechanical ventilation and/or hemodynamic support.
    b. The healthcare facility can demonstrate that it meets all the requirements for a Level III NICU.
        - Facilities for TPN, High risk OPD follow ups. Portable Xray, USG onsite. CT, MRI onsite or referrals with MOU.
    c. The healthcare facility can demonstrate that suitably qualified personnel is available for patient care
        - Specialist: Paediatrician MD/DNB(paediatrics) atleast 5 years experience and atleast one year fellowship/specialised neonatal training in neonatology from professional bodies/recognised institute in India/abroad.
        - JC/Clinical associate/Lecturer: post DCH/MD/DNB with atleast 2/1/1 year of NICU experience. 1 per shift.
        - RMO: 1 desirable.
        - Nurses (RN): 1 Senior nurse with adequate NICU experience. Nurse to patient ratio 1:1 for ventilated & 1:3 for non-ventilated will be desirable.
    d. The healthcare facility can demonstrate that it is adequately equipped for provision of care
        - Minimum 10 beds with 50% respiratory support beds. All the facilities and equipments of Level I, Level II and Incubators, Invasive ventilators, multi-para monitors, syringe pumps, T-piece resuscitators and Laminar flow.
    e. Availability of NRP facilitators, modified new born screening, neonatal transport facility, Kangaroo Mother Care, Lactation support and immunization.
    f. ROP, CCHD and hearing screen should made be available either in-house or MOU. There should be high risk follow up OPD.
    g. There is a documented procedure for the safe transfer of babies from Level III care to a higher level of care, which includes the transportation requirements.
    h. There is evidence that the healthcare facility provides support and information to families experiencing a neonatal death.
    i. There is psychosocial support available for staff working in the level III/IV NICU.
    j. Parents are given information about follow-up services including immunization and high-risk follow up programs and access to neurodevelopmental clinics.
- **CSP. 10 The healthcare facility has defined processes for level IV neonatal care.**

a. There is a policy defining the management, scope and delivery of care of the level IV NICU.
b. The healthcare facility can demonstrate that it meets all the requirements for a Level IV NICU.
    - Babies requiring multi-disciplinary care. All of the scope of level I,II, III with HFO, iNO, therapeutic hypothermia, Pediatric surgery and other medical and surgical sub-specialty. Portable Xray, USG onsite. CT, MRI onsite/outsourced. Neo BFHI and IBCLC trained lactation support. Milk bank and palliative support.
c. The healthcare facility can demonstrate that suitably qualified personnel is available for patient care.
    - Specialist: DM/DNB or appropriate qualification from abroad in Neonatology, should have atleast 5 years experience.
    - JC/Clinical associate/Lecturer: post DCH/MD/DNB with atleast 3/2/2 year of NICU experience. 1 per shift.
    - RMO: 1
    - Nurses: 1 Senior nurse with adequate NICU experience.
    - Nurse to patient ratio 1:2 for non-invasive & 1:1 for invasive ventilation will be desirable.
d. The healthcare facility can demonstrate that it is adequately equipped for provision of care
    - Minimum 10 beds. All the facilities and equipments of Level I, Level II, Level III and advanced ventilation (atleast 1 HFV facility), iNO therapy, therapeutic hypothermia.
e. Availability of NRP facilitators, modified new born screening, neonatal transport facility, Kangaroo Mother Care, Lactation support and immunization.
f. ROP, CCHD and hearing screen should made be available either in-house or MOU. There should be high risk follow up OPD.
g. Anaesthesia services are available, pre-anaesthesia assessment, anaesthesia plan is documented.
h. Surgical patients have a preoperative assessment, a documented pre-operative diagnosis, and pre-operative instructions are provided before surgery.
i. Informed consent for surgery and anaesthesia is obtained from the parents (in case the patient requires surgical intervention) by the person performing the procedure.
j. WHO Safe surgery checklist is implemented.

k. During anaesthesia, monitoring includes regular recording of temperature, heart rate, cardiac rhythm, respiratory rate, blood pressure, oxygen saturation and endtidal carbon dioxide.
l. The anaesthesiologist applies defined criteria to transfer the patient from the recovery area.
m. An operative note is documented before transfer out of patient from recovery.
n. Postoperative care is guided by a documented plan.

- **CSP.11 Prescription, administration, and storage of medicines is done in a safe and rational manner.**
  a. The healthcare facility ensures that medicines are prescribed on Drug sheets/ Drug Kardex.
  b. The minimum requirements of a prescription are adhered to. Defined processes govern the use of controlled drug use and management.
  c. The prescription is legible, dated, timed and signed by prescribing doctor.
  d. The healthcare facility has defined process for verbal orders.
  e. The healthcare facility ensures that safe administration of medication.
  f. Patients undergo appropriate monitoring during and after medication administration.
  g. Medication are stored as per manufacturer(s) recommendation.
- **CSP.12 Treatment plans made are shared with parents.**
  a. The parents are counselled on the progress and course during the stay on a daily basis.
  b. There is a dedicated quiet room for counselling parents and to provide distressed parents with privacy.
  c. Multi-disciplinary counselling is done when appropriate.
- **CSP.13 Resuscitation services are available.**
  a. The healthcare facility ensures that NRP facilitators are available in each shift.
  b. There is a defined protocol to be followed during an event requiring resuscitation.
  c. The events during resuscitation are recorded.
  d. A post-event analysis is performed to identify areas of improvement.
- **CSP. 14 The healthcare facility has processes in place to ensure that clinical procedures are performed in a safe manner.**
  a. The healthcare facility ensures clinical procedures are carried out based on evidence-based practices in neonatal care.
  b. Qualified and trained personnel carry/assist the clinical procedures as per their privileges.
  c. The healthcare facility ensures that care is taken to prevent adverse events.
  d. Procedural sedation is administered in a consistent manner.
  e. Competent and trained personnel are responsible to administer sedation.

f. Informed consent is taken from the parent by the person performing the procedure.
g. Adherence to standard precautions is done.
h. Patients are appropriately monitored during and after the procedure.

- **CSP. 15 The healthcare facility has a defined process for discharge**
  a. The healthcare facility ensures that discharge process is planned with consultation of the parents.
  b. The healthcare facility provides a discharge summary for all patients including those leaving against medical advice.
  c. The discharge summary provided has a pre-defined standardized format.
  d. In case of death, a death summary is provided which includes the cause of death.
  e. The discharge/death summary includes details of the implantable medical device used.
  f. The healthcare facility ensures education/information to parents by healthcare professionals before discharge about:
     - Basic newborn care.
     - Care during travel.
     - Kangaroo mother care.
     - safe sleeping environment.
     - breastfeeding.
     - no smoking environment.
     - Danger symptoms and signs of illness in their infant and response.
     - Significance of vaccination of infants and in special cases household contacts.
     - Training for resuscitation of high risk neonates.
  g. The healthcare facility ensures that patients are briefed about the follow-up schedule for growth, vision, neurodevelopment, hearing assessment and ongoing medical problems and high risk OPD follow ups.
  h. Parents receive ongoing psychosocial support (when required) that is adapted to their individual needs and resources.
  i. In case of neonates with life limiting illness, appropriate pre discharge pain and comfort care medication and measures taught to parents. Ongoing psychosocial support after discharge to home by good collaboration with palliative services if present or health care worker or medical social worker for life limiting disability or grief rituals.

- **CSP.16 There is a process for the creation of a neonatal care record for every patient, in which the observations are documented.**
  a. Patient service records are maintained and updated to ensure continuity of care (E.g. Handover process, time to initial assessment, continuation sheet, discharge summary and advice on when to seek medical advice etc).

b. All records are legible, timed, dated and signed by competent authorities & noted in chronological manner.
c. The reports of investigations – laboratory & imaging and other invasive procedures etc. are maintained.
d. The records are maintained in a safe, secure and confidential & are retained and destroyed as per local governing laws & regulations.
e. The healthcare facility complies with the government requirements of notifiable diseases.

Chapter 3 Patient-Centered Care (PCC)

Introduction:

Patient-centered care is an approach to healthcare that prioritizes the needs, preferences, and values of individual patients. It emphasizes active collaboration between healthcare providers and patients to ensure that decisions about the patient's care are aligned with their unique characteristics and goals. This approach recognizes the importance of treating patients with respect, dignity, and compassion.

Patient-centered care is essential for achieving positive health outcomes and enhancing the overall healthcare experience for patients. It requires a shift in mindset, organizational culture, and healthcare delivery processes to prioritize the individual needs and preferences of patients in every aspect of care.

The standards require the healthcare facilities to imbibe a patient centered culture in their operations.

Standards & Objective Elements:

- **PCC.1 The clinical care pathways are developed with evidence-based clinical practice guidelines and/or clinical protocols to guide uniform patient care.**
    a. The clinical care is provided in consonance with applicable laws and regulations.
    b. The clinical care pathways are adapted from evidence-based clinical practice guidelines and/or national/international guidelines.
    c. The clinical care pathways are consistently followed.
    d. The clinical care pathways are reviewed on an annual basis to incorporate changes in the national/international guidelines.
- **PCC.2 The healthcare facility has defined a clinical governance framework that exhibits a systematic approach to maintaining and improving the quality of care.**
    a. The clinical governance framework is developed by a multi-disciplinary committee.
    b. The terms of reference and roles and responsibilities of the multi-disciplinary committee are defined. The frequency of the meeting is atleast quarterly.
    c. At minimum the multi-disciplinary committee reviews and updates the following:
        i. Adherence to clinical care pathways
        ii. Credentialing and privileging of personnel
        iii. Competency assessments
        iv. Clinical audits
        v. Risk management framework including risk register
        vi. Quality improvement plan and activities
        vii. Education and training

viii. Information management
ix. Research and development
x. Clinical & Operational performance data

- **PCC.3 Clinical protocols should be made in line with accepted national or international guidelines.**
  a. Standard protocols should be available and followed for uniformity of care in the unit
  b. There is evidence that standard protocols are derived from national or international guidelines like NNF, WHO etc.
  c. If departmental clinical protocols are not available national guidelines by appropriate authority should be followed
- **PCC.4 The healthcare facility shall involve patients and/or patient next of kin in the decision making process.**
  a. Shared decision-making could include discussing their options for care and treatment, the discussion of benefits and risks. A clinical basis for decisions is backed by recent evidences and available medical knowledge.
  b. Information could be available in different languages and formats to facilitate the shared decision-making process.
  c. Parents are updated about the daily clinical situation of the child in the standard state/ native language or the language they best understand. This could also include communication about any adverse events that has occurred.
  d. Choices could include the type of treatment, who they want involved in their care or service and end of life wishes.
  e. The decision-making process could make use of decision aids.
  f. Appropriate medical information is given and parents/ family are involved as much as possible in decision making and the family's choices are recorded.
  g. For important decisions such as denying further care in case of life limiting illness, sufficient time is given for appropriate reflection and multiple multi-speciality opinions may be required.
  h. There is evidence that the healthcare facility provides support and information to families experiencing a neonatal death.
  i. In case the decision is taken to withdraw treatment and care in view of life limiting illness in infant, the same should be accepted, documented and appropriate psychosocial support should be provided.
- **PCC.5 The healthcare facility shall identify and respect patient's and/or patient next of kin's preferences or choices.**
  a. Preferences may relate to
     - how individuals are addressed.

- their care and treatment options.
- their personal effects.
- their clothing and self-care routines
- drinks and meals.
- activities, interests, privacy, visitors

b. Parents are involved in daily care procedures, e.g. changing nappies, measuring temperature, hygiene of the mouth, bathing etc.

- **PCC.6 The healthcare facility respects the values, beliefs, any special preferences, cultural needs and responding to requests related to the spiritual needs of the patient and their family.**
  a. The healthcare facility provides access to spiritual care or advice that is solicited by the patient and their families.
  b. Parents could be permitted to bring family support or in special circumstances, a spiritual adviser to meetings. There is a defined timeframe to handle any ethical dilemmas.
  c. The healthcare facility provides facilities which are culturally appropriate and ensuring the personal dignity of the patient and family.
- **PCC.7 The healthcare facility shall ensure that informed consent is obtained from the patient and family about their care**.
  a. Provision of consent forms in multiple languages including state and national languages with parents as signing authority as legal guardians of neonates.
  b. Informed consent includes information regarding the procedure; it's risks, benefits, alternatives.
  c. Consent forms should be mandatory for but not restricted to the below mentioned aspects:
     - Procedures like umblical catheterization, PICC insertion and central line insertion, surfactant administration.
     - Blood and blood product transfusions.
     - Use donor human milk in case of availability of milk bank.
  d. In case of refusal of care for personal or spiritual reasons, the same should be adequately documented after emphasising the due need for care in the parent's native language.
  e. The situations where consent can be waived off are outlined.
- **PCC.8 The healthcare facility shall provide appropriate education to maintain and improve their own health and wellbeing.**
  a. Education and support regarding importance and early initiation of breast feeding and early skin to skin contact in antenatal period.

b. Continued lactation education and support by lactation consultants and health care professionals after delivery.
c. In case of neonate kept nil by mouth, education about need and support for continued expression of milk and use of services of milk bank.
d. Family Integrated care in NICU where mother and if possible remaining family members are encouraged to come inside NICU and actively participate in care of the baby.
e. Training of mothers to maintain basic hygiene like ensuring adequate hand hygiene while handling of baby.
f. Training in basic care of newborn with regards to cord care, bathing, massage and other cultural customs.

- **PCC.9 There is a mandatory training programme on person centered care, which includes but not limited to,**
  a. Handover and takeover mechanisms during transition of care.
  b. the Patients' Rights,
  c. patient choice and preferences including spiritual and cultural beliefs
  d. effective communication
  e. patient feedback and complaint management process including resolution within defined timeframe.
  f. informed consent
- **PCC.10 The healthcare facility protects the patient and family rights.**
  a. There is a documented charter of the rights of the patients.
  b. The rights of the patients includes privacy, dignity, respect, confidentiality of information, personal safety, complaint management and access to all information about their care.
  c. The patient are made aware of the rights through prominently display in a bilingual manner.
  d. Any violation of patient rights are reported and analysed for improvements.
  e. The staff is trained to protect and promote the rights of the patient.
- **PCC.11 The healthcare facility identifies and informs the patient and family about their responsibilities.**
  a. There is a documented charter of the responsibilities of the patients and the family.
  b. The responsibilities of the patients and family includes providing accurate information to care providers, facilitating the delivery of care and respecting the rights of the staff.
  c. The responsibilities of the patient and family are prominently displayed in a bilingual manner.

Chapter 4 Infection Prevention & Control (IPC)

Introduction:

Infection prevention and control (IPC) is a critical aspect of healthcare that involves implementing measures to prevent the spread of infections within healthcare settings. Effective IPC practices are essential for protecting both patients and healthcare workers from healthcare-associated infections (HAIs).

Infection prevention and control require a comprehensive and multidisciplinary approach to minimize the risk of infections in healthcare settings. It involves a combination of standard precautions, transmission-based precautions, and adherence to guidelines and protocols to create a safe and hygienic environment for both patients and healthcare providers.

The standards describe the key components that are essential to ensure infection prevention and control.

Standards & Objective Elements:

- **IPC 1. The healthcare facility has a documented infection control plan, and policy.**
    a. The infection control plan is aimed at the reduction and mitigation of risks to patients, parents, and healthcare providers.
    b. Adequate measures are undertaken for infection control activities for staff, patients and visitors.
    c. The infection control plan identifies high-risk activities and procedures.
    d. The infection control comprises procedures for surveillance and control of infection.
    e. The infection control plan is reviewed at least once a year to incorporate the current best practices as per international guidelines.
    f. The healthcare facility has a designated individual to oversee the infection control plan.
- **IPC. 2 The healthcare facility has a defined budget for infection control activities.**
    a. The governing team has earmarked adequate funds from its annual budget for infection prevention and control activities.
    b. The budget shall include adequate personal protective equipments, hand wash facilities, cleaning, and disinfectants.
- **IPC 3. Infection control activities are guided by available national/international standards of care and safety.**
    a. The healthcare facility adheres to standard precautions.
    b. The healthcare facility adheres to hand-hygiene guidelines including steps of hand washing.

c. The healthcare facility adheres to transmission-based precautions.
d. The healthcare facility adheres to isolation precautions
e. The healthcare facility adheres to safe injection & infusion practices.
f. Appropriate zoning is maintained where required.
g. Appropriate antimicrobial usage policy is established and implemented.

- **IPC. 4 The infection prevention and control activities cover the support services of the healthcare facility.**
  a. The healthcare facility a defined process for housekeeping activities.
  b. Biomedical waste management is done as per local applicable laws and there is appropriate infrastructure for carrying out these activities.
  c. The healthcare facility as processes for cleaning, sterilization and disinfection.
  d. The healthcare facility has processes for reuse of single use devices.
  e. Facilities are adequate for clean and dirty utilities.
  f. The infection prevention and control activities encompass the management of linen.
  g. The infection prevention and control activities encompass the management of kitchen sanitation and food-handling.
- **IPC. 5 The healthcare facility identifies and monitors key processes and indicators to oversee the infection control activities.**
  a. Surveillance incorporates tracking and analysing of infection risks, rates and trends.
  b. Surveillance is directed towards the identified high-risk activities.
  c. Surveillance includes monitoring compliance with hand-hygiene guidelines.
  d. Surveillance includes mechanisms to capture the occurrence of multi-drug resistant organisms and highly virulent infections.
  e. Surveillance includes monitoring the effectiveness of housekeeping services.
  f. The healthcare facility identifies and takes appropriate action to control outbreaks of infections.
  g. The routine surveillance includes air settle plate, swab to check for sterility, water surveillance and specialised surveillance (dialysis water – Endotoxin testing).
  h. Surveillance data is verified, analysed, and appropriate corrective and preventive actions are taken.
- **IPC 6. The healthcare facility monitors and mechanisms to prevent hospital acquired infections.**
  a. The healthcare facility has implemented care bundles to monitor catheter-associated urinary tract infections(CAUTI), ventilator associated complication/ventilator-associated pneumonia (VAP), Surgical Site Infections (SSI) and Central line associated blood stream infections (CLABSI).
  b. The healthcare facility monitors catheter-associated CAUTI rate.
  c. The healthcare facility monitors VAP rate.
  d. The healthcare facility monitors CLABSI rate.

e. The healthcare facility monitors SSI rate.

- **IPC 7. The organisation ensure the safety of healthcare workers by preventing healthcare associated infections in staff.**
  a. Implementation of occupational health and safety practices to reduce the risk of transmitting microorganisms among health care providers.
  b. The healthcare facility has defined an immunization policy.
  c. Implementation of work restrictions for health care providers with transmissible infections.
  d. Kitchen and food handling staff are appropriately tested and immunized.
  e. There is a defined process for management for blood and body fluid exposure and needle stick injury prevention.
  f. Appropriate post-exposure prophylaxis is provided to staff.
- **IPC. 8 The organisation ensures the continuous training is provided to the healthcare workers.**
  a. The healthcare workers are trained on the infection prevention and control activities both at time of induction and continuous on job trainings.
  b. The surveillance date is shared regularly with the healthcare provider as a feedback regarding the infection prevention and control activities.
- **IPC. 9 The organization implements engineering controls for prevention of infection in healthcare facility**.
  a. The design of patient care areas is done taking into account prevention of cross contamination.
  b. The operation room air quality and water supply are monitored and tested.
  c. The air conditioning plant and equipment maintenance and HEPA validation is done as per defined frequency.
  d. Filter and air conditioning duct cleaning/maintenance and replacement as per wear and tear is evidenced.
  e. Preventive measures are in place for fungus colonization on walls, ceilings of hospital premises.
  f. The microbial analysis of water supply is conducted atleast once a month.
  g. The healthcare facility ensures adequate risk assessment and corrective actions for engineering controls for prevention of infections.

Chapter 5 Quality Improvement & Safety (QIS)

Introduction:

Quality improvement and patient safety are integral components of healthcare that focus on enhancing the effectiveness, efficiency, and safety of healthcare services. Both concepts emphasize continuous assessment, monitoring, and improvement to ensure the delivery of high-quality, safe, and patient-centered care.

Quality improvement and patient safety are ongoing, collaborative efforts that require commitment at all levels of a healthcare organization. By continuously monitoring, analyzing, and improving processes, healthcare providers can enhance the quality and safety of care, ultimately leading to better patient outcomes.

The standards are designed to promote evidence-based practices, reduce errors, and improve overall healthcare outcomes.

Standards & Objective Elements:

- **QIS.1 The healthcare facility evaluates and monitors the performance of service.**
    a. Various inputs are considered by the healthcare facility to denote the performance of the service including the following:
        i. Patient feedback and complaints received.
        ii. Observations from internal audits.
        iii. Observations from proactive risk assessments
        iv. Incident reporting
        v. Patient reported outcome measures
        vi. Infant mortality rate
        vii. Employee feedback
        viii. Training need identification

- **QIS.2 The healthcare facility identifies and monitors the key performance indicators.**
    a. The healthcare facility identifies and monitors key indicators to oversee the clinical structures, processes and outcomes.
    b. The healthcare facility identifies and monitors key indicators to oversee the infection control activities.
    c. The healthcare facility identifies and monitors key indicators to oversee the managerial structures, processes and outcomes.

d. The healthcare facility identifies and monitors key indicators to oversee the patient safety activities.
e. The data of indicators is analysed for trends, verified and the performance of the indicators is measured in relations to industry/ evidence based benchmarks. Opportunities for improvements are identified
f. There is evidence of appropriate corrective and preventive actions taken for outliers.
g. The healthcare facility is required to make the clinical performance data public including outcomes, this can be done by display in the facility and/or on the website.

- **QIS.3 The healthcare facility develops and implements quality improvement plan focusing on continual improvement in the quality of care provided.**
  a. The quality improvement plan is developed, implemented and maintained by a multi-disciplinary committee.
  b. The quality improvement plan includes clearly defined goals, objectives and allocated responsibilities.
  c. The plan is reviewed regularly atleast annually.
  d. The staff is trained on the quality improvement plan and programme.
  e. The quality improvement performance data including trends and quality improvement activities are discussed and deliberated upon in the management review committee by the top management.
  f. The quality improvement performance data including trends and quality improvement activities are reviewed at minimum on a quarterly basis by the top management.
  g. There is a defined budget for the quality improvement related activities.
  h. A comprehensive continual quality improvement report including but not limited to the plan, budget, audit observations, clinical audits, quality improvement projects, performance data and quality improvement activities are presented to the governing body on an annual basis.
- **QIS.4 The healthcare facility ensures proactive risk management**
  a. The healthcare facility follows risk management process and it is evidenced in both proactive and reactive manner.
  b. The risk management framework is supported by objective evidence in form of plan, policies, procedures and processes and relevant with scope of services of organization.
  c. The healthcare facility undertakes surveillance at regular intervals for risk identification.
  d. The identified risks are discussed at specified intervals & monitoring is done to incorporate the improvements.
  e. Staff is trained on a regular interval on risk management.
- **QIS.5 The healthcare facility has policies and processes implemented for the incident reporting.**

a. There is a defined process for reporting of incidents ranging from 'no harm' to 'sentinel events'.
b. The reported incidents are analyzed to identify opportunities for improvements.
c. Appropriate corrective and preventive actions are undertaken for the identified opportunities.

- **QIS.6 The healthcare facility adheres to international guidelines on patient safety.**
  a. The healthcare facility has processes to ensure medication safety.
  b. The healthcare facility has processes to ensure safe transition of care.
  c. The healthcare facility has processes to ensure safe surgical practices.
  d. The healthcare facility has processes to ensure safe environment of care.
  e. The healthcare facility has processes to ensure infection control.
- **QIS.7 The healthcare facility plans and implements mechanisms for the care of patients during internal and external emergency/disaster situation.**
  a. The healthcare facility has adequate measures for early detection, abatement and containment of the fire related emergencies.
  b. The healthcare facility has adequate measures for prevention and management of the non-fire related emergencies like workplace violence, baby abduction, and mass casualty events.
  c. The healthcare facility has documented process of response measures to be undertaken in case of such events.
  d. Mock drills are held at least twice a year.
  e. Variations observed in the mock drills are analysed and appropriate measures are taken for improvements in response.
- **QIS.8 The healthcare facility conducts clinical and audits at regular intervals.**
  a. Clinical audits are designed in order to improve the quality of patient care.
  b. Appropriate healthcare personnel participate in the clinical audits.
  c. The remedial measures identified from the clinical audits are implemented.
- **QIS. 9 The healthcare facility conducts nursing audits at regular intervals.**
  a. Nursing audits are designed in order to improve the quality of patient care.
  b. Appropriate healthcare personnel participate in the nursing audits.
  c. The remedial measures identified from the nursing audits are implemented.

Chapter 6 Clinical Support Services (CSS)

Introduction:

Clinical support services encompass a range of healthcare services and functions that provide essential support to clinical care delivery. These services contribute to the overall efficiency, effectiveness, and quality of patient care.

These clinical support services play crucial roles in delivering comprehensive and patient-centered care. They collaborate with clinical professionals to address the diverse needs of patients and contribute to positive health outcomes. Effective coordination and integration of these services enhance the overall quality and continuity of healthcare delivery.

The standards help healthcare organizations establish best practices, meet regulatory requirements, and provide consistent, high-quality care.

Standards & Objective Elements:

- **CSS. 1 Laboratory services are provided as per the requirements of the scope of services.**
    a. The healthcare facility ensures that adequate infrastructure (physical and equipment) is available to provide the defined scope of services.
    b. Qualified and trained personnel perform and supervise the investigations and report the results.
    c. There are defined processes for test requisition, sample collection, identification, handling, safe transportation, processing and disposal of a specimen.
    d. There is a standardized format for reporting of results.
    e. The time-frame for reporting of results is defined for each test.
    f. The critical results are intimated to the clinician at the earliest.
    g. Critical results are intimated to the person concerned at the earliest.
    h. There is a defined process to address the recall / amendment of reports whenever applicable.
- **CSS. 2 There is an established laboratory quality assurance and safety programme.**
    a. The laboratory quality assurance and safety programme is implemented.
    b. The programme addresses verification and/or validation of test methods.
    c. The equipments in the laboratory are periodically calibrated and maintained.
    d. The programme includes the documentation of corrective and preventive actions.
    e. Laboratory personnel are provided with appropriate safety measures and trained in safe practices.

- **CSS. 3 Imaging services are provided as per the requirements of the scope of services.**
    a. The legal and regulatory compliances related to imaging services are maintained.
    b. The healthcare facility ensures that adequate infrastructure (physical and equipment) is available to provide the defined scope of services.
    c. Qualified and trained personnel perform and supervise the investigations and report the results.
    d. There are defined processes for test requisition, identification, handling, and safe transportation.
    e. There is a standardized format for reporting of results.
    f. The time-frame for reporting of results is defined for each test.
    g. The critical results are intimated to the clinician at the earliest.
    h. Critical results are intimated to the person concerned at the earliest.
    i. There is a defined process to address the recall / amendment of reports whenever applicable.
- **CSS. 4 There is an established imaging quality assurance and safety programme.**
    a. The imaging quality assurance and safety programme is implemented.
    b. Patients are appropriately screened for safety/risk before imaging.
    c. Imaging personnel and patients use appropriate radiation safety and monitoring devices where applicable.
    d. The programme addresses periodic internal/external peer review of imaging results using appropriate sampling.
    e. The equipments including radiation-safety and monitoring devices in the imaging services are periodically calibrated and maintained.
    f. The programme includes the documentation of corrective and preventive actions.
    g. Imaging personnel are provided with appropriate safety measures and trained in safe practices.
- **CSS. 5 Transfusion services are available as per the scope of the service.**
    a. There are defined protocols for transfusion of blood and blood components safely.
    b. The healthcare facility ensures rational use of blood and blood components.
    c. Informed consent is obtained for transfusion of blood and blood components.
    d. There is evidence that the healthcare facility promotes blood donation.
    e. Blood/blood components are available for use in emergency situations within a defined time-frame.
    f. Patients are monitored appropriately during and after blood transfusion.
    g. Post-transfusion form is collected, reactions if any identified and are analysed for preventive and corrective actions.
- **CSS. 6 The healthcare facility has immunization and OPD services.**

a. The national guidelines on immunization are implemented for all levels of NICU.
b. The healthcare facility takes measures to create awareness regarding the immunization.
c. Appropriate staff are responsible to administer the vaccines.
d. Vaccines are stored as per manufacturer recommendations.
e. High risk follow up OPD services are available for all patients from level II onwards.

- **CSS. 7 The healthcare facility has ambulance service to ensure safe patient transportation of patients with appropriate care.**
  a. The healthcare facility has ambulance service either onsite/outsourced.
  b. The healthcare facility has a dedicated ambulance bay area.
  c. The ambulance is appropriately equipped and operated by trained personnel.
  d. The ambulance complies with the requisite statutory compliances.
  e. There is a defined timeframe to check the ambulance, equipments and emergency medicines.
- **CSS. 8 Rehabilitation services are provided in a collaborative manner.**
  a. Rehabilitation services are provided in collaboration with the treating consultant.
  b. Qualified and trained personnel are available for provision of care.
  c. Early intervention is provided to ensure improved outcomes.
  d. Care is guided by functional assessment and periodic re-assessments which are done and documented.
  e. Care is provided adhering to infection control and safety practices.
- **CSS. 9 Pharmacy services are available.**
  a. The healthcare facility has developed and implemented a drug formulary.
  b. The formulary is revised annually to ensure that an updated list is available for clinical use.
  c. Medications and consumables are procured as per a defined process.
  d. Medications and consumables are stored as per the manufacturer's recommendation(s) in a clean and secure location.
  e. The healthcare facility has protocols for the safe usage of medicines as per the international guidelines.
  f. Appropriate inventory control mechanisms are in place.
  g. Near-expiry medicines and consumables are recalled from the location of use as per a defined process.
  h. The healthcare facility implements a process for the usage of the implantable medical devices.
- **CSS. 10 The healthcare facility has requisite information technology support.**

a. Information management and technology acquisitions are commensurate with the identified information needs.
b. A maintenance plan for information technology and communication network is implemented.
c. Contingency plan ensures continuity of information capture, integration and dissemination.
d. The organisation ensures that information resources are accurate and meet stakeholder requirements.
e. The organisation contributes to external databases in accordance with the law and regulations.

- **CSS. 11 The healthcare facility ensures security services are available.**
  a. Operational planning identifies areas which need to have extra security.
  b. The access to different areas in the healthcare facility are controlled.
  c. There is use of CCTV surveillance where required.
  d. There are defined policies for visitor management, parents staying in the premises.

Chapter 7 Human Resource Management (HRM)

Introduction:

Human Resource Management (HRM) is a crucial function within organizations that focuses on managing the people aspects of the workforce. It encompasses a wide range of activities aimed at attracting, developing, motivating, and retaining employees to contribute effectively to the organization's goals.

Effective human resource management is essential for creating a productive, engaged, and satisfied workforce. HR professionals play a critical role in aligning human capital strategies with organizational goals and ensuring that employees have the support and resources needed to contribute to the overall success of the organization.

The standards provide a set of best practices to ensure the effective management of an organization's workforce.

Standards & Objective Elements:

- **HRM.1 The healthcare facility has strategies and plans for the management of its human resources.**
    a. The healthcare facility has a manpower plan where the current and future human resources strategies are outlined. The plan defines the staffing requirements to meet the healthcare facility's strategic objectives.
    b. The healthcare facility has a defined recruitment process.
    c. The healthcare facility maintains a personnel file for each member of staff. The personnel file is kept in a strictly confidential manner.
- **HRM.2 The healthcare facility has defined plans for promotion of staff well-being.**
    a. The healthcare facility has procedures in place to promote staff well-being by means of annual health check-ups and staff education on healthy lifestyle programme.
    b. The healthcare facility in addition monitors factors that contribute to the occupational health and safety of the personnel in the facility.
    c. Appropriate measures are taken to prevent occupational hazards and related injuries.
- **HRM.3 The healthcare facility has defined procedures for resolution of workplace issues including prevention of sexual harassment at workplace, grievance handling and disciplinary actions.**
    a. The staff should be made aware of the procedures for grievance handling and disciplinary actions.

b. The grievance handling and disciplinary action procedures are in consonance with the prevailing laws and are based on principles of natural justice.

- **HRM.4 The healthcare facility should have medical and paramedical staff with recent and relevant education and/or experience.**
  a. Neonatal training programs with state-wide or country-wide recognition that promote evidence-based practices should be the minimum criteria for consultant neonatologists.
  b. Certified neonatal nursing training program should be encouraged and implemented.
  c. The credentialing & privileging committee shall determine the scope of practice based on safety and available expertise including operating of equipments of the medical and paramedical staff backed by current evidence.
- **HRM.5 The healthcare facility should have medical and paramedical staff with recent and relevant skills and competency.**
  a. The healthcare facility should encourage simulation based learning to upgrade skills and competencies.
  b. The staff should undergo orientation or induction training on the protocols of NICU.
  c. Continuous inter professional education and practice to provide complex care by a multidisciplinary team.
  d. Annual neonatal resuscitation training and certification to provide safe and effective care to new-borns.
  e. Continuous professional development (CPD) with authentication by respected state / national medical council shall be mandatory to keep updated with the scientific and newer technological changes.
  f. Annual appraisals by a credentialing and privileging committee of medical and paramedical staff with regards to skills and competencies.
- **HRM.6 The healthcare facility evaluates the ongoing performance of all staff in line with their job description on an annual basis.**
  a. For the nursing staff observations of performance should be made daily by Senior Neonatologist while doing daily rounds.
  b. Doctors' performance shall be reviewed on the following parameters:
     - Cases treated/operated on in the past year
     - Workshops attended to improve & upgrade skills & knowledge
     - Research done & publications made
     - Conducted any workshops /CME for training other trainees & neonatologists
  c. Attendance to the ward should be noted daily
  d. Trainee doctors should keep Log books, recording following:
     - Duration of Posting
     - Areas of posting including NICU, Labour Ward, Postnatal Wards & OPD

- Details of cases treated
- Procedures performed
- Case presentations made
- Seminars presented
- Conferences & workshops attended

e. Assessment of trainee doctors should be made regularly in a formal examination including case presentation & Viva Voce & marks awarded

- **HRM.7 The healthcare facility should have an ongoing training and development programme.**

a. Training of trainee Neonatologist.
   - On ward rounds- Daily bedside case discussions.
   - Training for procedures by simulation.
   - Joint meeting of all doctors to discuss difficult & complex cases.
   - Joint meeting with other specialities for cases requiring management by multiple teams.
   - Lectures taken & workshops conducted by Senior faculty for trainees.
   - Journals & books should be made available to trainees with easy access to online search platforms.

b. Training of Consultant Neonatologist
   - Should attend workshops & conferences regularly to be update with recent advances

c. Training of nursing staff

d. Training of paramedical staff

- **HRM. 8 The healthcare facility conducts satisfaction survey for the employees.**

a. The employee satisfaction survey is conducted at least once a year.

b. The results of the survey are analysed and areas of improvements are identified.

c. Appropriate corrective and preventive actions are undertaken.

Chapter 8 Facility & Equipment Management (FEM)

Introduction:

Facility and equipment management involves the effective planning, maintenance, and optimization of physical assets within an organization. This encompasses a broad range of activities related to managing buildings, infrastructure, machinery, and other assets to ensure they contribute to the organization's goals efficiently and effectively.

Effective facility and equipment management contribute to operational efficiency, cost-effectiveness, and the overall well-being of an organization. By implementing best practices in these areas, organizations can create and maintain optimal working environments that support their core functions and strategic objectives.

Facility and equipment management standards provide guidelines and best practices for organizations to effectively manage their physical assets. Adhering to these standards can help ensure the safety, reliability, and efficiency of facilities and equipment.

Standards & Objective Elements:

- **FEM. 1 The healthcare facility has defined processes for the facility, engineering support, medical equipments and utility systems.**
    a. The healthcare facility plans for utility, medical and engineering equipment in accordance with the level of NICU and the strategic plan.
    b. All the equipments have asset control.
    c. The equipments have a documented preventive and operational maintenance plan.
    d. The equipments have a documented plan in case of breakdown.
    e. Round the clock support is available for emergency repairs.
    f. The equipments are inspected and calibrated at a pre-defined interval.
    g. The equipments are replaced, condemned and disposed as per a defined process.
- **FEM. 2 The healthcare facility has a training programme on use of equipments.**
    a. The healthcare facility ensures the training is provided to the end-users.
    b. The healthcare facility ensures the training is provided in case of change/upgradation of equipment and/or change in the end user.
    c. The competency of staff for handling the appropriate equipment is evaluated.
    d. Competent staff operates the specialized equipment.
- **FEM. 3 The healthcare facility ensures that appropriate control mechanisms are available for critical equipments.**

a. The critical equipments in the healthcare facility are identified.
b. Downtime for critical equipment breakdowns is monitored from reporting to inspection and implementation of corrective actions.
c. Appropriate measures are undertaken to reduce the downtime of equipments.

- **FEM. 4 The healthcare facility ensures that all local laws for safety of building, equipment, spaces, supplies for stated services are adhered to.**
  a. Updated drawings are maintained as per statutory requirements.
  b. There are internal and external sign postings in the organisation in a manner understood by the patient, families and community.
  c. The fire related signages, radiology related signages are available as per statutory requirements. The signages are bilingual.
  d. There are defined processes in place for calibration and preventive maintenance of all equipments to prevent safety related incidents like fire or injury risks.
  e. Potable water and electricity are available round the clock.
  f. Back-ups of water and electricity are available in case of shortage of supply.
- **FEM. 5 The healthcare facility is designed in a manner to promote comfort to the patient attendants.**
  a. There is a dedicated space for expression of milk and breastfeeding.
  b. There is a facility for waiting area/room. The facility is physically accessible for patients in terms of availability of ramps, wide spaces, clear signage to direct the parents.
  c. The healthcare facility has access to basic necessities for the parents.
- **FEM. 6 The healthcare facility is designed in a manner to promote healthy work environment for the staff.**
  a. There is a designated space for staff work area.
  b. There is a duty room for staff providing round the clock services.
  c. There are designated changing rooms for males & females.
- **FEM. 7 The healthcare facility is designed in a manner to promote a safe and secure environment to patients.**
  a. The healthcare facility ensures that adequate measures are in place for maintaining the ambient temperature of the NICU.
  b. The facility is inspected at a pre-defined interval.
  c. The healthcare facility conducts electrical safety audits.
  d. Hazardous materials are identified and used safely.
  e. The MSDS sheets for the hazardous materials are available.
  f. The plan for managing the spills of hazardous materials is implemented.

DEFINITIONS & TERMS

Accreditation	Accreditation is self-assessment and external peer review process used by health care organisations to accurately assess their level of performance in relation to established standards and to implement ways to improve the health care system continuously
Accreditation assessment	The evaluation process for assessing the compliance of an organisation with the applicable standards for determining its accreditation status.
Assessment	All activities including history taking, physical examination, laboratory investigations that contribute towards determining the prevailing clinical status of the patient.
APGAR	Apgar stands for Appearance, Pulse, Grimace, Activity and Respiration
Breakdown maintenance	Activities which are associated with the repair and servicing of site infrastructure, buildings, plant or equipment within the site's agreed building capacity allocation which have become inoperable or unusable because of the failure of component parts
Calibration	Set of operations that establish, under specified conditions, the relationship between values of quantities indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realised by standards.
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
Clinical care pathway	Clinical care pathways are standardised evidence-based, multidisciplinary management plans. They identify an appropriate sequence of clinical interventions, timeframes, milestones and expected outcomes for a homogenous patient group.

Clinical Governance	'a system through which hospitals are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish"
Clinical practice guidelines	Clinical practice guidelines are systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.
Competence	Demonstrated ability to apply knowledge and skills (para 3.9.2 of ISO 9000: 2015). Knowledge is the understanding of facts and procedures. Skill is the ability to perform a specific action.
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 the privacy of information related to his/her healthcare records.
Consent	The willingness of a party to undergo examination/procedure/ treatment by a healthcare provider. It may be implied (e.g. patient registering in OPD), expressed which may be written or verbal. Informed consent is a type of consent in which the healthcare provider has a duty to inform his/her patient about the procedure, its potential risk and benefits, alternative procedure with their risk and benefits so as to enable the patient to make an informed decision of his/her health care. In law, it means active acquiescence or silent compliance by a person legally capable of consenting. In India, the 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.
Correction	Action to eliminate the detected non-conformity (Reference: ISO 9000:2015)
Corrective action	Action to eliminate the cause of a non-conformity and to prevent recurrence. (Reference: ISO 9000:2015)
CPAP	Continuous positive airway pressure
Credentialing	The process of obtaining, verifying and assessing the qualification of a healthcare provider.
Developmental supportive care	A broad category of interventions designed to minimize the stress of a neonatal intensive care unit. Strategies include control of external stimuli (vestibular, auditory, visual, tactile), clustering of nursery care activities and minimal handling, intentional positioning (nesting, prone position, swaddling) and protection of sleep.

Discharge summary	A part of a patient record that summarises the reasons for admission, significant clinical findings, procedures performed, treatment rendered, patient's condition on discharge and any specific instructions given to the patient or family (for example follow-up medications).
Disciplinary procedure	A sequence of activities to be carried out when staff does not conform to the laid-down norms, rules and regulations of the healthcare organisation.
Emergency care area	A designated room or unit in a facility where immediate care and resuscitation are provided for severe or sudden illness, trauma or injury
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.
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.
Feedback	Information or comments about something that you have done which tells you how good or bad it is
Formulary	An approved list of drugs. Drugs contained in the formulary are generally those that are determined to be cost-effective and medically effective.
Governing Body	A group that manages or controls the activities of country, region, or organization
Grievance-handling procedures	The sequence of activities carried out to address the grievances of patients, visitors, relatives and staff.
Guideline	Rule or instruction on the best way of doing something.
Hazardous materials	Substances dangerous to human and other living organisms. They include radioactive or chemical materials.
Health professional or provider	A trained individual with knowledge and skills to provide preventive, curative, promotional or rehabilitative health care in a systematic way to people, families and communities. They include doctors, nurses, midwives, pharmacists and paramedical staff.
High-risk procedures / treatment	High-risk operations have been defined as those with a high mortality rate.

	Any procedure or treatment where there is a known risk of harm.
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 operations of the healthcare facility.
Indicator	A statistical measure of the performance of functions, systems or processes over time. For example, hospital acquired infection rate, mortality rate, caesarean section rate, absence rate, etc.
Information	Processed data which lends meaning to the raw data.
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 an adequate supply without stock-outs/excessive storage. It is also the process of balancing ordering costs against carrying costs of the inventory so as to minimise total costs.
Isolation	Separation of an ill person who has a communicable disease (e.g.,measles, chickenpox, mumps, SARS) from those who are healthy. Isolation prevents transmission of infection to others and also allows the focused delivery of specialised health care to ill patients. The period of isolation varies from disease-to-disease. Isolation facilities can also be extended to patients for fulfilling their individual, unique needs.
Job description	It entails an explanation pertaining to duties, responsibilities and conditions required to perform a job.
Job specification	The qualifications/physical requirements, experience and skills required to perform a particular job/task.
Kangaroo mother care	Early, continuous, prolonged skin-to-skin contact between a mother and her newborn, frequent and exclusive breastfeeding and early discharge from hospital.
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. (Reference: British Standard 3811:1993)
Medical equipment	Any fixed or portable non-drug item or apparatus used for diagnosis, treatment, monitoring and direct care of a patient.
Medication Order	A written order by a physician, dentist, or other designated health professionals for a medication to be dispensed by a pharmacy for administration to a patient
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.
MOU	Memorandum of Understanding
Multidisciplinary	A generic term which includes representatives from various disciplines, professions or service areas.
Near-miss	A near-miss is an unplanned event that did not result in injury, illness, or damage--but had the potential to do so
Newborn/Neonate	Infant < 1 month of age (neonate).
NGT	A nasogastric tube (NG tube)
Notifiable disease	Certain specified diseases, which are required by law to be notified to the public health authorities.
NRP	Neonatal Resuscitation Program
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.
Occupational health hazard	The hazards to which an individual is exposed during the course of the performance of his job. These include physical, chemical, biological, mechanical and psychosocial hazards.
Operational plan	The 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 the sustainability of the organisation's achievements.
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. When an activity is outsourced to other institutions, there should be a memorandum of understanding that clearly lays down the obligations of both organisations: the one which is outsourcing and the one who is providing the outsourced facility. It also addresses the quality-related aspects.
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
Patient-reported outcome measures (PROMs)	Patient-reported outcome measures are questionnaires measuring the patients' views of their health status.
Patient Satisfaction	Patient satisfaction is a measure of the extent to which a patient is content with the health care which they received from their health care provider. Patient satisfaction is thus a proxy but a very effective indicator to measure the success of Health care providers.
Performance appraisal	It is the process of evaluating the performance of staff during a defined period of time with the aim of ascertaining their suitability for the job, the potential for growth as well as determining training needs.
Policies	They are the guidelines for decision-making,e.g. admission, discharge policies, antibiotic policy,etc.
Preventive maintenance	The maintenance carried out at predetermined intervals or according to prescribed criteria and intended to reduce the probability of failure or the degradation of the functioning of an item.
Prescription	A prescription is a document given by a physician or other healthcare practitioner in the form of instructions that govern the care plan for an individual patient. Legally, it is a written directive, for compounding or dispensing and administration of drugs, or for other service to a particular patient.
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.
Procedural sedation	Procedural sedation is a technique of administering sedatives or dissociative agents with or without analgesics to induce a state that allows the patient to tolerate unpleasant procedures while maintaining cardiorespiratory function. Procedural sedation and analgesia (PSA) is intended to result in a depressed level of consciousness that allows the patient to maintain oxygenation and airway control independently.
Procedure	A specified way to carry out an activity or a process (Para 3.4.5 of ISO 9000: 2015). 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.
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 assurance	Part of quality management focussed on providing confidence that quality requirements will be fulfilled
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.
Re-assessment	It implies a 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 the efficient and effective functioning of an organisation.
Risk assessment	Risk assessment is the determination of the 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 mitigation	Risk mitigation is a strategy to prepare for and lessen the effects of threats and disasters. Risk mitigation takes steps to reduce the negative effects of threats and disasters.
ROP	Retinopathy of prematurity
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.
Sedation	The administration to an individual, in any setting for any purpose, by any route, moderate or deep sedation.
Sentinel events	A relatively infrequent, unexpected incident, related to system or process deficiencies, which leads to death or major and enduring loss of function for a recipient of healthcare services. Major and enduring loss of function refers to sensory, motor, physiological, or psychological impairment not present at the time services were sought or begun. The impairment lasts for a minimum period of two weeks and is not related to an underlying condition.
Staff	All personnel working in the organisation including employees, "fee-for service" medical professionals, part-time workers, contractual personnel and volunteers.

Standard precautions	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
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 a market leader in the provision of cardiothoracic and vascular services. The resource allocation will have to follow the pattern to achieve the target.
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.
Top management	Top management refers to the executive arm of the governing body in an organization, typically responsible for making key decisions that affect the overall direction and strategy of the company. This group includes executives such as the Chief Executive Officer (CEO), Chief Financial Officer (CFO), Chief Operating Officer (COO), and other senior leaders.
Values	The fundamental beliefs that drive organisational behaviour and decision-making. This refers to the guiding principles and behaviours that embody how an organisation and its people are expected to operate. Values reflect and reinforce the desired culture of an organisation.
Verbal order	Verbal orders are those orders given by a physician with prescriptive authority to a licensed person who is authorised by the organisation.
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.

Workplace violence	Incidents where staff are abused, threatened or assaulted in circumstances related to their work, including commuting to and from work, involving an explicit or implicit challenge to their safety, well-being or health.

Annexure I - Key performance indicators

Key Performance Indicators (KPIs) for a Neonatal Intensive Care Unit (NICU) are essential for monitoring and assessing the quality of care provided to critically ill newborns and ensuring optimal outcomes. These KPIs help healthcare professionals track performance, identify areas for improvement, and maintain high standards of care. Here are some key performance indicators relevant to NICU settings:

Sr. No.	Standards	Indicator	Formula	Unit	Frequency	Remarks
i.	QIS 2a	Proportionate Neonatal Mortality Rate	The number of deaths / Total number of discharges and deaths	Percentage	Monthly	This KPI helps assess the effectiveness of medical interventions and overall care quality.
ii.	QIS 2a	NICU Readmission Rate	Total number of patients returning to NICU within 48 hours / Total number of discharges.	Percentage	Monthly	This KPI reflects the success of post-discharge care and follow-up.
iii.	QIS 2a	Reintubation rate	Total number of patients reintubated within 48 hours. / Total number of patients extubated.	Percentage	Monthly	Reintubation is often considered a significant event, as it indicates a deterioration in the patient's respiratory status or other health complications.
iv.	QIS 2b	Catheter associated Urinary tract infection rate	Number of urinary catheter associated UTIs in a Month * 1000 / Number of urinary	/1000 urinary catheter days	Monthly	Monitoring infection rates is crucial for ensuring infection prevention and control.

			catheter days in that month			
v.	QIS 2b	Ventilator associated Pneumonia rate	Number of Ventilator Associated Pneumonia in a month * 1000 Number of ventilator days in that month	/1000 Ventilator days	Monthly	Monitoring infection rates is crucial for ensuring infection prevention and control.
vi.	QIS 2b	Central line - associated Blood stream infection rate	Number of central line - associated blood stream infections in a month * 1000 No. of central line days in that month	/1000 central line days	Monthly	Monitoring infection rates is crucial for ensuring infection prevention and control.
vii.	QIS 2b	Surgical site infection rate	Number of surgical site infections in a given month Number of surgeries performed in that month	Percentage	Monthly	Monitoring infection rates is crucial for ensuring infection prevention and control.
viii.	QIS 2b	Hand Hygiene Compliance Rate	Total number of Hand hygiene	Percentage	Monthly	Monitoring infection rates is crucial for ensuring infection prevention and control.

			actions performed Total number of hand hygiene opportunities			
ix.	QIS 2c	Average Length of Stay	Total inpatient days Total number of discharges and deaths	Number	Monthly	Monitoring this KPI helps assess the efficiency of care delivery and resource utilization.
x.	QIS 2c	Parent/Patient Satisfaction Scores	Achieved Score Maximum score achievable	Percentage	Monthly	Surveys and feedback mechanisms can be used to measure this KPI.
xi.	QIS 2d	Critical Equipment Downtime:	Total amount of downtime	Hours	Monthly	Ensuring the availability and reliability of medical equipment is vital for providing continuous care.
xii.	QIS 2d	Adherence to Patient Identification protocols	Total number of patient identification errors reported Total of number incident reported	Percentage	Monthly	Accurate patient identification is essential to prevent errors in treatment, medication administration, and other aspects of care.
xiii.	QIS 2d	Medication Errors Rate	Total number of medication errors Total number of opportunities of medication	Percentage	Monthly	The medication error rate refers to the frequency or percentage of errors that occur during the medication process, including prescribing, dispensing, administering, and monitoring medications.

			errors			
xiv.	QIS 2d	Phlebitis/Extra vasation rate	Total number of cases of phlebitis or extravasation Total number of patients with peripheral access	Percentage	Monthly	Monitoring of phlebitis/extravasation rate is an integral part of a continuous improvement in IV therapy practices
xv.	QIS 2d	Adherance to WHO Safe Surgery Checklist	Number of surgeries where the procedure was followed Number of surgeries performed	Percentage	Monthly	Monitoring adherence to a safe surgery checklist is a critical component of a comprehensive patient safety program, contributing to improved outcomes, reduced complications, and a culture of continuous quality improvement in surgical care

Annexure II – Levels of Neonatal Intensive Care Unit

	Scope of care	Manpower	Facilities & Equipments
Level I	Neonatal Resuscitation for each delivery. Stabilise and care for infants between 35 to 37 weeks and >1.8kg who are hemodynamically stable. Facility to stabilise and transport if unstable or <35 weeks and/or <1.8 kg	Pediatrician : Desirable Doctor: 1 Nurses: 1 RN & 1 ANM/Nursing aid	Oxygen support, warmer, resuscitation equipments as per NRP guidelines.
Level II	All of the above and management of 32 -35 weeks of gestation and/or 1.5 to 1.8 kg. Respiratory support limited to CPAP More than 35 weeks and/or more than 1.8 kg who need CPAP. Management of sepsis with IV antibiotics who are hemodynamically stable. Neonates needing phototherapy.	Pediatrician: Full-time DCH/MD/DNB with 5/3/3 years of experience. Mandatory RMO: DCH/MD/DNB with atleast 6/4 months of NICU experience. 1 per shift. Nurses (RN): 1 Senior nurse with adequate NICU experience. Nurse to patient ratio of 1:3	Minimum 10 beds with 30% respiratory support beds. All the facilities and equipments of Level I and CPAP, continuous oxygen delivery, pulse oximeters, syringe pumps, RT, warmers, phototherapy machines, suction facility, ABG analysis, exchange transfusion. *1 invasive ventilator in the unit is desirable

	Facilities for tube feeding. Facility to stabilise and transport to higher level of care.		
Level III	Management of <32 weeks and/or <1.5 kg. Neonates of any gestation requiring mechanical ventilation and/or hemodynamic support. Facilities for TPN, High risk OPD follow ups Portable Xray, USG onsite. CT, MRI onsite or referrals with MOU.	Specialist: Paediatrician MD/DNB(paediatrics) atleast 5 years experience and atleast one year fellowship/specialised neonatal training in neonatology from professional bodies/recognised institute in India/abroad. JC/Clinical associate/Lecturer: post DCH/MD/DNB with atleast 2/1/1 year of NICU experience. 1 per shift. RMO: 1 desirable. Nurses (RN): 1 Senior nurse with adequate NICU experience. Nurse to patient ratio 1:1 for ventilated & 1:3 for non-ventilated will be desirable.	Minimum 10 beds with 50% respiratory support beds. All the facilities and equipments of Level I, Level II and Incubators, Invasive ventilators, multi-para monitors, syringe pumps, T-piece resuscitators. Laminar flow
Level IV	Any of the above requiring multi-disciplinary care.	Specialist: DM/DNB or appropriate qualification from	Minimum 10 beds

	All of the above with HFO, iNO, therapeutic hypothermia, Pediatric surgery and other medical and surgical sub-specialty Portable Xray, USG onsite. CT, MRI onsite/outsourced. Neo BFHI and IBCLC trained lactation support. Milk bank and palliative support.	abroad in Neonatology, should have atleast 5 years experience. JC/Clinical associate/Lecturer: post DCH/MD/DNB with atleast 3/2/2 year of NICU experience. 1 per shift. RMO: 1 Nurses: 1 Senior nurse with adequate NICU experience. Nurse to patient ratio 1:2 for non-invasive & 1:1 for invasive ventilation will be desirable.	Minimum 10 beds All the facilities and equipments of Level I, Level II, Level III and advanced ventilation (atleast 1 HFV facility), iNO therapy, therapeutic hypothermia.

For all levels: NRP facilitators, modified new born screening, neonatal transport facility, KMC, Lactation support and immunization should be available.

From level II onwards: ROP, CCHD and hearing screen should made be available either in-house or MOU. There should be high risk follow up OPD.

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