Standard No.CEA/Hospital-003

Clinical Establishment Act Standard for Hospital (level 3)

Standard No.CEA/Hospital-003

Introduction

In 2010 Clinical Establishments (Registration and Regulation) Act, 2010 has been enacted by the Central Government to provide for registration and regulation of all clinical establishments in the country with a view to prescribe the minimum standards of facilities and services provided by them.

The Ministry has notified the "National Council for Clinical Establishments" and 'The Clinical Establishments (Central Government) Rules, 2012" under this Act vide Gazette. *This Act is applicable to all kinds of clinical establishments from the public and private sectors, of all recognized systems of medicine including single doctor clinics. The only exception will be establishments run by the Armed forces.*

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Categorization of Hospital

The minimum standards for hospital are developed on the basis of level of care provided as defined below:

Hospital Level 1-

Primary healthcare services provided by qualified doctors that include General Medicine, Pediatrics, First aid to emergency patient and Out Patient Services, Obstetrics & Gynecology Non-surgical and Minor Surgery and having a bed strength of not more than 30. The primary healthcare services can be provided through trained and qualified manpower; with support/supervision of registered medical practitioners with the required support systems for this level of care.

Hospital Level 2-

This level may include all the services provided at level 1 plus also have facility for Surgery and Anesthesia. Secondary healthcare services can be provided through registered medical practitioner under supervision and with support of specialists; it will have other support systems required for these services like pharmacy, laboratory, diagnostic facility etc.

Hospital Level 3-

This level may include all the services provided at level 1 and 2 plus the following: Multi-specialty clinical care with distinct departments, General Dentistry (this could be optional in case of independent Dental Hospital), Intensive Care Unit. Tertiary healthcare services can be provided through specialists; it will have other support systems required for these services like pharmacy, Laboratory, and Imaging facility.

Hospital Level 4 (Teaching) -

This level will include all the services provided at level 3. It will however have the distinction of being teaching/ training institution and it will have multiple super-specialties. Tertiary healthcare services that can be provided through specialists; It will have other support systems required for these services. It shall also include the requirements of MCI/other registering body.

1. Definition

A hospital is a clinical establishment providing patient treatment by qualified and trained staff and equipment through Allopathy - Modern system of medicine; where the patients are 'admitted' and stay overnight or more and they are referred as 'inpatients'; while some patients may go to a hospital just for diagnosis, treatment, or therapy and then leave, they are referred as 'outpatients' without staying overnight. In a hospital, treatment by staff from AYUSH may also be provided.

Hospitals usually have facility to admit and care for inpatients whilst the others often clinical establishments are described as clinics or day care centres. There are other exceptions too like Hospice etc.

The general hospital, may have multiple departments taking care of many kinds of disease and injury, and normally has an emergency department to deal with immediate and urgent care.

Specialized hospitals may include trauma centers, rehabilitation hospitals, children's hospitals, Mental hospitals or, and hospitals for dealing with specific medical needs such as psychiatric problems (psychiatric hospital) or Sanatorium, certain disease categories such as neuro, cardiac, oncology, or orthopedic, IVF and so forth.

Some hospitals are affiliated with universities for medical research and the training of medical personnel such as physicians and nurses, often called teaching hospitals. Guidelines laid down by MCI or other legal bodies shall be applicable to such hospitals

A hospital can be situated in rural or urban setting. It can be run by Public Sector (Central government/State government/Local government/Public Sector undertaking/Registered Society etc) or by Private Sector (Individual Proprietorship/ Registered Partnership/Registered Company /Co-operative Society/Trust /Charitable etc).

Hospital Level 3 is the clinical establishment that provide tertiary healthcare services by advanced specialists, laboratory and radiology along with the general surgery, paediatrics, general medicine, obstetrics and gynaecology services, emergency, intensive care unit etc. Tertiary health care is provided by public and private health care organisations both.

provide following specialized These hospitals may services Cardiology. Cardiothoracic surgery, Neuro medicine, Neurosurgery, Nephrology, Joint replacement, Plastic and reconstructive surgery, Rheumatology, Endocrinology, Respiratory Medicine, Oncology, Nuclear Medicine, Paediatric Surgery,

Gastroenterology, GI surgery, Transplantation Services, Blood Storage Centre/Blood Bank etc.

2. Scope

The scope of services that may be provided at a hospital level 3 practising Allopathy – Modern system of Medicine may include patient-care services in any or all of the following specialities, but not necessarily limited to:

Clinical Services:

- 2.1. General Medicine
- 2.2. General Surgery
- 2.3. Obstetrics and Gynaecology
- 2.4. Fertility and Assisted Reproduction
- 2.5. Paediatrics
- 2.6. Paediatric Intensive Care
- 2.7. Paediatric surgery
- 2.8. Neonatology
- 2.9. Orthopaedics
- 2.10. Orthopaedics with Joint Replacement
- 2.11. Anaesthesiology
- 2.12. Emergency Medicine & Trauma
- 2.13. Critical Care Medicine (e.g. HDU, ICU)
- 2.14. ENT
- 2.15. Ophthalmology
- 2.16. Neurology
- 2.17. Neurosurgery
- 2.18. Cardiology
- 2.19. Cardiothoracic surgery
- 2.20. Urology
- 2.21. Nephrology & Dialysis
- 2.22. Gastroenterology
- 2.23. GI Surgery (Surgical Gastroenterology)
- 2.24. Minimally Invasive Surgery or Minimal Access Surgery
- 2.25. Respiratory Medicine
- 2.26. Endocrinology
- 2.27. Rheumatology
- 2.28. Clinical Immunology
- 2.29. Psychiatry & Mental Health
- 2.30. Medical Oncology
- 2.31. Surgical Oncology
- 2.32. Radiation Oncology
- 2.33. Nuclear Medicine

- 2.34. Plastic & Reconstructive Surgery
- 2.35. Dermatology
- 2.36. Community Health
- 2.37. Palliative Medicine
- 2.38. Geriatric Care
- 2.39. Family Medicine
- 2.40. Clinical Haematology
- 2.41. Organ transplantation
- 2.42. Genetics
- 2.43. Dentistry including sub specialities
- 2.44. Physical Medicine & Rehabilitation
- 2.45. Transfusion Medicine/Blood Storage Centre/Blood Bank
- 2.46. Other emerging sub-specialities in any of the above fields, or emerging independent specialities

Support services:

- 2.1. Registration / help desk and billing
- 2.2. Diagnostic Services:
 - a. Laboratory
 - b. Imaging Services
 - c. Non-imaging services e.g. Audiology Lab, TMT, Echocardiography, Neurophysiology, Urodynamics, PFT, Sleep Studies (Polysomnography), etc.
- 2.3. Pharmacy and Stores
- 2.4. CSSD / Sterilization Area
- 2.5. Linen and Laundry
- 2.6. Kitchen & Dietary Services
- 2.7. Waste Management Services (General and Biomedical)
- 2.8. Medical Gas Supply, Storage & Distribution
- 2.9. Ambulance services

3. Infrastructure Requirements:

3.1	Signage	
3.1.1	The Hospital shall display appropriate signage which shall be in at least two	
	languages	
3.1.2	The building shall have a board displaying the name of the hospital at a	
	prominent location	
3.1.3	Directional signage shall be placed within the facility to guide the patient.	
Follow	Following informative signage shall be displayed:	
3.1.4	Name of the care provider with registration number	
3.1.5	Registration details of the hospital as applicable	
3.1.6	Availability of fee structure of the various services provided (refer to CEA	

	2010 rules & regulation CG 4 Annexe)
3.1.7	Timings of the hospital and services provided
3.1.8	Mandatory information such as under PNDT Act etc. prominently as applicable.
3.1.9	Important contact numbers such as Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area.
3.1.10	Patients' rights & responsibilities.
Follow	ing safety signage shall be displayed:
3.1.11	Safety Hazard and Caution signs, for e.g. hazards from electrical shock, inflammable articles, radiation etc. at appropriate places, and as applicable under law.
3.1.12	Appropriate Fire exit signage.
3.1.13	Signage for "No Smoking" in prominent places.
3.2.	Other requirements
3.2.1	Access to the hospital shall be comfortable for the patient and/or attendants/visitors.
3.2.2	Access shall be provided within the requirements of "Persons with Disabilities Act" and shall be easy for all those whose mobility may be restricted due to whatever cause.
3.2.3	The hospital shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and visitors
3.2.4	The hospital shall have 24 hour provision of potable water for drinking & hand hygiene. It shall also have 24 hour supply of electricity, either through direct supply or from other sources.
3.2.5	The building shall be planned as such that sensitive areas, such as wards, consulting and treatment rooms and operation theatres are placed away from the outdoor source of noise. The hospital shall be well illuminated and ventilated
3.2.6	The hospital shall have clean public toilet(s) separate for males and females.
3.2.7	The hospital shall have mechanism for timely maintenance of the hospital building and equipment.
3.2.8	The hospital shall have appropriate internal and external communication facilities.
3.2.9	Furniture and fixtures shall be available in accordance with the activities and workload of the hospital. They shall be functional and properly maintained.
	For minimum space requirements refer to Annexure 1
	For indicative list of furniture and fixtures refer to Annexure 2

4. Medical Equipment and Instruments:

4.1	The hospital shall have adequate medical equipment and instruments, commensurate to the scope of service and number of beds.
4.2	There shall be established system for maintenance of critical equipment
4.3	All equipment shall be kept in good working condition through a process of periodic inspection, cleaning and maintenance. An equipment log-book shall

be maintained for all the major equipment.
For indicative list of medical equipment and instruments refer to Annexure 3 .

5. Drugs, Medical devices and Consumables:

5.1	The hospital shall have adequate drugs, medical devices and consumables commensurate to the scope of services and number of beds
5.2	Emergency drugs and consumables shall be available at all times.
5.3	Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations.
5.4	The hospital shall have defined procedures for storage, inventory management and dispensing of drugs in pharmacy and patient care areas
	For indicative list of drugs, medical devices and consumables refer to Annexure 4.

6. Human Resource Requirements:

6.1	The hospital shall have qualified and/or trained medical staff as per the scope of service provided and the medical care shall be provided as per the requirements of professional and regulatory bodies
6.2	The hospital shall have qualified and/or trained nursing staff as per the scope of service provided and the nursing care shall be provided as per the requirements of professional and regulatory bodies
6.3	The support/paramedical staff shall be qualified and/or trained as per the scope of services provided, and as per the requirement of the respective professional or regulatory bodies.
6.4	For every staff (including contractual staff), there shall be personal record containing the appointment order, documentary evidence of qualification and/or training (and professional registration where applicable).
6.5	Periodic skill enhancement/updation/refresher training shall be provided for all categories of the staff as relevant to their job profile, as prescribed by professional bodies and as per local law/regulations.
	For human resource requirements refer to Annexure 5

7. Support Services:

Registration/Help desk and Billing:

7.1.	The hospital shall have a Registration/ Help-desk & Billing counter, and the scope of this shall also include provision of patient guidance in matters like services available, cost estimation, healthcare insurance etc.	
Diagno	Diagnostic Services:.	
7.2.	Diagnostic services may be in-house or outsourced. For minimum standards for diagnostic services refer to CEA standards for Imaging and laboratory services.	
7.3.	Whether in house or outsourced, the services shall fulfil the requirements of	

	safe and timely patient care.		
7.4.	The diagnostic services, whether in house or outsourced, shall be		
	commensurate with the scope of services		
Pharm	Pharmacy Services		
7.5.	Pharmacy services in a hospital can be in-house or outsourced.		
7.6.	All applicable legal requirements shall be complied with.		
7.7.	Medicine storage shall be in a clean, well lit, and safe environment, and as		
	per manufacturer's requirements		
7.8.	Quality of drugs, medical devices and consumables shall be ensured		
CSSD	/ Sterilization Area		
7.9.	Provision for instrument and linen sterilization and storage of sterile items		
	shall be made available as per the scope of services.		
7.10.	Validation of Sterilization shall be done for ensuring the effectiveness of		
	sterilization process		
	management:		
7.11.	Soiled linen shall be collected, transported and washed separately in clean		
	and hygienic environment.		
7.12.	Where linen is contaminated, appropriate decontamination shall be carried		
	prior to despatch for washing.		
	Management Services:		
7.13.	Segregation, collection, transportation, storage and disposal of biomedical		
	waste shall be as per Bio Medical Waste Handling Rules.		
7.14.	Waste management guidelines shall be followed in the case of Mercury &		
	other toxic materials as per applicable local laws.		
7.15.	Segregation, collection, transportation, storage and disposal of general		
	waste shall be as per applicable local laws		
Medica			
7.16.	Oxygen for medical use shall be available. In addition other gases like		
	Nitrous oxide, Carbon dioxide etc. may be available in consonance with the		
- 4-	scope of services and bed strength.		
7.17.	Medical gases shall be stored and handled in a safe manner.		
7.18.	All applicable legal requirements shall be complied with.		
7.19.	Appropriate back-up and safety measures shall be in place to ensure patient		
	safety at all times.		
	ance services		
7.20.	The hospital shall have provision of transporting patients for		
	transfer/referral/investigations etc in safe manner.		
7.21.	The ambulance service shall be in-house and shall comply with the		
	applicable local laws.		
7.22.	Critical patient shall be transported under supervision of trained and qualified		
	staff.		
	For ambulance checklist please refer to Annexure 6.		

8. Legal/Statutory Requirements:

8.1 Every application must be accompanied with the documents confirming compliance with local regulations and law.

For indicative list refer to Annexure 7.

9. Record Maintenance and reporting:

9.1	The minimum medical records to be maintained and nature of information to be provided by the Hospitals shall be as prescribed in CG 2 Annexe as per Section 12 (1) (iii) of this Act
9.2	Medical Records may be maintained in physical or digital format.
9.3	Confidentiality, security and integrity of records shall be ensured at all times
9.4	The medical records of IPD patients shall be maintained in consonance with National or local law, MCI guidelines, and court orders.
9.5	Every Hospital shall maintain health information and statistics in respect of national programmes, notifiable diseases and emergencies/disasters/ epidemics and furnish the same to the district authorities in the prescribed formats and frequency.
	Content of medical record shall be as per Annexure 7

10. Basic Process:

Reaist	ration / help desk and billing services
10.1.	The hospital shall register all patients who visit the hospital except if the required services are not available in the facility, in which case the patient is guided to the appropriate nearest facility. (Please also see Emergency Services)
10.2.	Once registered, depending on the clinical need, patient is guided to appropriate service area like OPD, ER etc
10.3.	Patient shall be guided and informed regarding Patients' rights & responsibilities, cost estimates, third party services (e.g. Insurance) etc.
10.4.	The billing shall be as per the Hospital tariff list, which shall be available to patients in a suitable format.
Asses	sment and Plan of care
10.5.	Each patient shall undergo an initial assessment by qualified and/or trained personnel.
10.6.	Further management of patient shall be done by a registered medical practitioner on the basis of findings of initial assessment; for example, OPD treatment, admission, transfer/referral, investigation etc.
10.7.	At the time of admission of patient, General Consent for admission shall be taken. <i>Refer to Annexure 8.</i>
10.8.	In case of non-availability of beds or where clinical need warrants, the patient shall be referred to another facility along with the required clinical information or notes. There shall be appropriate arrangement for safe transport of patient.
10.9.	Reassessments of the admitted patients shall be done at least once in a day and/or according to the clinical needs and these shall be documented.
10.10.	Any examination, treatment or management of female patient shall be done in the presence of an employed female attendant/female nursing staff, if

	conducted by male personnel inside the hospital and vice versa.	
Inform	Informed Consent Procedure	
	Informed consent shall be obtained from the patient/ next of kin/ legal guardian as and when required as per the prevailing Guidelines / Rules and regulations in the language patient can understand (for e.g. before Invasive procedures, anaesthesia, Blood transfusion, HIV testing, Research, etc.).	
Care O	of Patient	
10.12.		
	notified by the Central /State Government/National & International professional bodies.	
	Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.	
10.14.	shall be maintained in the record, including the procedure safety checklist.	
10.15.	Monitoring of patient shall be done during and after all the procedures and same shall be documented (for example, after anaesthesia, surgical procedures, blood transfusion, etc.).	
10,16,	Staff involved in direct patient care shall receive basic training in CPR	
	ency Services:	
	Emergency patients shall be attended on priority. The Emergency	
-	department shall be well equipped with trained staff.	
10.18.	If emergency services are not available in the hospital, the hospital shall	
	provide first aid to the patients and arrange appropriate transfer/referral of	
	the patient.	
	ation Prescription, Administration And Monitoring	
10.19.	Prescription shall include name of the patient, date, name of medication, dosage, route, frequency, duration, name, signature and registration number of the medical practitioner in legible writing	
10.20.	Drug allergies shall be ascertained before prescribing and administration; if	
	any allergy is discovered, the same shall be communicated to the patient and recorded in the Case sheet as well.	
10.21.	Patient identity, medication, dose, route, timing, expiry date shall be verified prior to administration of medication	
	Safe injection practices shall be followed as per WHO guidelines.	
	High Risk Medicines shall be identified and verified by two trained healthcare personnel before administration.	
10.24.	Patients shall be monitored after medication administration and adverse drug reaction/events if any shall be recorded and reported (please refer http://cdsco.nic.in/adr3.pdf).	
Infection	on Control	
10.25.	The hospital shall follow standard precautions like practicing hand hygiene,	
	use of personal protection equipment etc. to reduce the risk of healthcare associated infections.	
	The hospital shall ensure adequate and proper spacing in the patient care area so as to prevent transmission of infections.	
10.27.	Regular cleaning of all areas with disinfectant shall be done as per	

	prescribed & documented procedure.
10.28.	Prescribed & documented Infection Control Practices shall be followed in
	High risk areas like Operation theatre, ICU, HDU, etc as per good clinical practice guidelines.
10.29.	Housekeeping/sanitary services shall ensure appropriate hygiene and
	sanitation in the hospital.
-	of the patient, staff, visitors and relative in a hospital
10.30.	Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures. E.g. identification of mother and baby in obstetric facility, etc
10.31.	The Hospital shall undertake all necessary measures, including demonstration of preparedness for fire and non-fire emergencies, to ensure the safety of patients, attendants, staff and visitors. (Please also see section on Infrastructure and Security and Fire)
10.32.	All applicable fire safety measures as per local law shall be adopted. This includes fire prevention, detection, mitigation, evacuation and containment measures. Periodic training of the staff and mock drills shall be conducted and the same shall be documented.
10.33.	In case of any epidemic, natural calamity or disaster, the owner/keeper of every Hospital shall, on being requested by the designated supervising Authority, cooperate and provide such reasonable assistance and medical aid as may be considered essential by the supervising authority at the time of natural calamity or disastrous situation
Patien	t Information and Education
10.34.	The patient and/or family members are explained about the disease condition, proposed care, including the risks, alternatives and benefits. They shall be informed regarding the expected cost of the treatment. They shall also be informed about the progress and any change of condition.
10.35.	Patient and/or family shall be educated about the safe and effective use of medication, food drug interaction, diet, and disease prevention strategies.
Discha	irge
10.36.	A Discharge summary shall be given to all patients discharged from the hospital. <i>For content of discharge summary refer to <u>Annexure 9</u>.</i>
10.37.	The discharge summary shall include the points as mentioned in the annexure in an understandable language and format
10.38.	Discharge summary shall also be given to patient and/or attendant in case of transfer LAMA/DAMA or death.

ANNEXURE 1

Minimum space requirements in a hospital level 3 shall be as follows:

Total Area		
1.	Total Area of hospital level 1 including 30 % area for circulation space for corridors, lobby, reception area	50 sq mt/bed as carpet area
Wards		
3.	Ward bed and surrounding space	6sq m/ bed; in addition circulation space of 30% as indicated in total area shall be provided for nursing station, ward store, sanitary etc.
Intensive C	are Unit	
4. Minor Opera	For ICU/CCU/Neuro ICU/HDU/Trauma ICU/Renal ICU bed and surrounding space	10.5 sq mt/ bed; in addition circulation space of 30% as indicated in the total area shall be provided for nursing station, doctors' duty room, store, clean and dirty utility, circulating area for movement of staff, trolley, toilet etc.
5.	OT for minor procedures	10.5 sq mt; in addition
		circulation space of 30% as indicated in total area shall be provided for nursing station, scrub station, clean and dirty utility, dressing room, toilet etc.
Labour roo		
<u>6.</u> 7.	Labour Table and surrounding space Other areas- nursing station, doctors' duty room, store, Clean and dirty utility, Circulating area, Toilets	10.5 sq m/ labour table 10.5 sq mt for clean utility and store and 7 sq mt for dirty utility and 3.5 sq mt for toilet.
Operation T	heatre (OT)	
8.	Operating Room Area	30.5 sq mt per operating room.
	& Casualty (if separate):	
9.	Emergency bed and surrounding space	10.5 sq mt/ bed: in addition circulation space of 30% as indicated in total area shall be

		provided for nurse station, doctor duty room store, clean and dirty utility, dressing area, toilet etc.	
Pharmacy			
10.	Pharmacy	The size should be adequate to contain 5 percent of the total clinical visits to the OPD in one session at the rate of 0.8 m2 per patient.	
Bio-medica	I Waste		
11.	<50 beds	5 sq m	
12.	50-100 beds	10 sq m	
13.	>100 beds	20 sq m	
Other functional areas(laboratory, diagnostics, front office/reception, waiting area, administrative area etc) should be appropriately sized as per the scope of service and patient load of the hospital.			

Other requirements:

Wards:

- 1. The ward shall also have designated areas for nursing station, doctors' duty room, store, clean and dirty utility, janitor room, toilets and this shall be provided from circulation area.
- 2. For a general ward of 12 beds, a minimum of 2 WC and 1 hand wash basin shall be provided.
- 3. Distance between beds shall be 1.0 metres
- 4. Space at the head end of bed shall be 0.25 metres.
- 5. Door width shall be 1.2 metres and corridor width 2.5 metres

Intensive Care Unit:

- 1. The unit is to be situated in close proximity of operation theatre, acute care medical and surgical ward units.
- 2. Suction, oxygen supply and compressed air to be provided for each bed.
- 3. Adequate lighting and uninterrupted power supply shall be provided.
- 4. Adequate multi-sockets with 5 ampere and 15 ampere sockets and/or as per requirement to be provided for each bed.

- 5. Nurse call system for each bed.
- 6. ICU shall have designated area for nursing station, doctors' duty room, store, clean and dirty utility, circulating area for movement of staff, trolley, toilet, shoe change, trolley bay, janitor closet etc

Labour room:

- 1. The obstetrical unit shall provide privacy, prevent unrelated traffic through the unit and provide reasonable protection of mothers from infection and from cross-infection.
- 2. Measures shall be in place to ensure safety and security of neonates.
- 3. Resuscitation facilities for neonates shall be provided within the obstetrical unit and convenient to the delivery room.
- 4. The labour room shall contain facilities for medication, hand washing, charting, and storage for supplies and equipment.
- 5. The labour room shall be equipped with oxygen and suction

Operation Theatre

- 1. The operation theatre complex shall have appropriate zoning.
- 2. The operation theatre complex shall provide appropriate space for other areas- nursing station, doctors' duty room, scrub station, sterile store, Clean and dirty utility, Dress change room, Toilets:
 - *a.* Sterile area consists of operating room sterile store and anesthesia room
 - *b.* Clean zone- consists of equipment/medical store, scrub area, pre and/or post-operative area and linen bay
 - c. Protective zone- consists of change room, doctors room and toilets
 - d. Dirty area
 - e. Due considerations are to be given to achieve highest degree of asepsis to provide appropriate environment for staff and patients.
- 3. Doors of pre-operative and recovery room are to be 1.5 m clear widths.
- 4. Air Conditioning to be provided in all areas. Window AC and split units should preferably be avoided as they are pure re circulating units and become a source of infection.
- 5. Appropriate arrangements for air filtration to be made.

- 6. Temperature and humidity in the OT shall be monitored.
- 7. Oxygen, Nitrous Oxide, suction and compressed air supply should be provided in all OTs.
- 8. All necessary equipment such as shadow-less light, Boyle's apparatus shall be available and in working condition.
- 9. Uninterrupted power supply to be provided.

Note: For Eye Hospitals only where procedures are done in local and/or regional anaesthesia, Minor OT criteria may be applicable.

Emergency room

- 1. Emergency bed and surrounding space shall have minimum 10.5 sq m/ bed area.
- 2. There shall be designated space for nurse station, doctor duty room store, clean and dirty utility, dressing area, toilet etc.

Clinical Laboratory

- 1. The laboratory area shall be appropriate for activities including test analysis, washing, biomedical waste storage and ancillary services like Storage of records, reagents, consumables, stationary etc eating area for staff.
- 2. For detail please refer to NABH CEA LAB

Imaging

- 1. The department shall be located at a place which is easily accessible to both OPD and wards and also to emergency and operation theatre.
- 2. As the department deals with the high voltage, presence of moisture in the area shall be avoided.
- 3. The size of the department shall depend upon the type of equipment installed.
- 4. The department/room shall have a sub-waiting area preferably with toilet facility and a change room facility, if required.
- 5. For detail please refer to NABH CEA IMAGING

Central Sterilization and Supply

1. Department (CSSD) — Sterilization, being one of the most essential services in a hospital, requires the utmost consideration in planning.

- 2. Centralization increases efficiency, results in economy in the use of equipment and ensures better supervision and control.
- 3. The materials and equipment dealt in CSSD shall fall under three categories: a) those related to the operation theatre department,
 - b) common to operating and other departments, and
 - c) pertaining to other departments alone.

Other Departments

Other departments shall have appropriate infrastructure commensurate to the scope of service of the hospital.

ANNEXURE 2

FURNITURE AND FIXTURES

S.N	ARTICLES
3.	Examination Table
4.	Writing tables
5.	Chairs
6.	Almirah
7.	Waiting Benches
8.	Medical/Surgical Beds
9.	Labour Table- if applicable
10.	Wheel Chair/Stretcher
11.	Medicine Trolley, Instrument Trolley
12.	Screens/curtains
13.	Foot Step
14.	Bed Side Table
15.	Baby Cot- if applicable
16.	Stool
17.	Medicine Chest
18.	Examination Lamp
19.	View box
20.	Fans
21.	Tube Light/ lighting fixtures
22.	Wash Basin
23.	IV Stand
24.	Colour coded bins for BMW

*this is an indicative list and the items shall be provided as per the size of the hospital and scope of service.

Annexure 3

EQUIPMENTS

a. Emergency Equipment

Sr No	Name of Emergency Equipment
1	Resuscitation equipment including Laryngoscope, endotracheal tubes, suction equipment, xylocaine spray, oropharyngeal and nasopharyngeal airways, Ambu Bag- Adult & Paediatric (neonatal if indicated)
2	Oxygen cylinders with flow meter/ tubing/catheter/face mask/nasal prongs
3	Suction Apparatus
4	Defibrillator with accessories
5	Equipment for dressing/bandaging/suturing
6	Basic diagnostic equipment- Blood Pressure Apparatus, Stethoscope,, weighing machine, thermometer
7	ECG Machine
8	Pulse Oximeter
9	Nebulizer with accessories

b. Other equipment which shall also be available in good working condition as per the scope of services and bed strength (some of the emergency equipment are already mentioned above).

Department Equipment		Level 1	Level 2	Level 3
	AL			
Administration				
	Office equipment	Yes	Yes	Yes
	Office furniture	Yes	Yes	Yes
Electricity				
Emergency lights		Yes	Yes	Yes
Water Supply				
Hand-washing sinks/taps/bowls on stands in all areas		Yes	Yes	Yes
Storage tank		Yes	Yes	Yes
	Water purification chemicals or filter	Yes	Yes	Yes

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	Water source for drinking water	Yes	Yes	Yes			
Waste Disposal	Waste Disposal						
	Buckets for contaminated waste in all treatment areas	Yes	Yes	Yes			
	Drainage system	Yes	Yes	Yes			
	Incinerator or burialpit	Yes	Yes	Yes			
	Protective boots and utility gloves	Yes	Yes	Yes			
	Rubbish bins in all rooms	Yes	Yes	Yes			
	Sanitation facilities for patients	Yes	Yes	Yes			
	Separate Bio-medical waste disposal	Yes	Yes	Yes			
	Sharps containers in all treatment areas	Yes	Yes	Yes			
Safety							
	Fire extinguisher						
Vehicle							
	Vehicle 4—wheel drive	No	Yes	Yes			
	Ambulance 4-wheel drive	No	No	Yes			
Medical Stores							
	Lockable storage	Yes	Yes	Yes			
	Refrigeration	Yes	Yes	Yes			
Kitchen							
	Cooking pots and utensils	No	Yes	Yes			
	Cooking stove	No	Yes	Yes			
	Food refrigeration	No	Yes	Yes			
	Plates, cups & cutlery	No	Yes	Yes			
	Storage Washing and drying area facilities	No Yes	Yes Yes	Yes Yes			
Laundry							
	Detergent/soap	Yes	Yes	Yes			
	Washing and rinsing equipment/bowls	No	Yes	Yes			
	Housekeeping Brooms, brushes and mops	Yes	Yes	Yes			
Housekeeping							
	Buckets	Yes	Yes	Yes			
	Soap and disinfectant	Yes	Yes	Yes			
	MEDICAL						
Outpatient Rooms							

			•=	105pitai- 005
	Blood pressure machine and stethoscope	Yes	Yes	Yes
	Container for sharps disposal	Yes	Yes	Yes
	Desk and chairs	Yes	Yes	Yes
	Examination gloves	Yes	Yes	Yes
	Examination table	Yes	Yes	Yes
	Hand washing facilities	Yes	Yes	Yes
	Light source	Yes	Yes	Yes
	Minor surgical instruments	No	Yes	Yes
	Ophthalmoscope	No	Yes (as applicable)	Yes
	Otoscope	No	Yes (as applicable)	Yes
	Patellar hammer	No	Yes	Yes
	Receptacle for soiled pads, dressings, etc	Yes	Yes	Yes
	Separate biohazard disposal	Yes	Yes	Yes
	Sterile equipment storage	Yes	Yes	Yes
	Sutures	Yes	Yes	Yes
	Thermometer	Yes	Yes	Yes
	Torch with extra batteries	Yes	Yes	Yes
	Weighing scale	Yes	Yes	Yes
Women and Child h	ealth examination room			
	BP machine and stethoscope	Yes	Yes	Yes
	Contraceptive supplies	Yes	Yes	Yes
	Child register	Yes	Yes	Yes
	Examination gloves	Yes	Yes	Yes
	Examination table with stirrups	Yes	Yes	Yes
	Fetal stethoscope	No	Yes	Yes
	Doppler	No	No	Yes
	Hand washing facility	Yes	Yes	Yes
	Height measure	Yes	Yes	Yes
	IUD insertion set	Yes	Yes	Yes
	Pregnant woman Register	Yes	Yes	Yes
	Speculum and vaginal examination kit	Yes	Yes	Yes
	Syringes and needles	Yes	Yes	Yes
	Tape measure	Yes	Yes	Yes
	Tococardiograph	No	Yes	Yes
Labour room				
	Baby scales	Yes	Yes	Yes

	P machi	ne	and	Yes	Yes	14
	ethoscope		and	165	res	Yes
	lean delive	ry ties	kits	Yes	Yes	Yes
th	urtains Ian one	if bed	more	Yes	Yes	Yes
D	elivery bed	and be	ed linen	Yes	Yes	Yes
F	etal stethos	cope		Yes	Yes	Yes
H	and washii	ng facil	lity	Yes	Yes	Yes
In	strument	trolley	,	Yes	Yes	Yes
IV.	/ treatment	sets		Yes	Yes	Yes
	atex gloves			Yes	Yes	Yes
Li	nens for ne	wborn	S	Yes	Yes	Yes
M	lucus extrac	ctor		Yes	Yes	Yes
	ral airway zes	vs, vari	ous	Yes	Yes	Yes
	xygen oncentrator	tank	and	Yes	Yes	Yes
	artograph	charts		Yes	Yes	Yes
m	elf inflating ask - adult eonatal size	and	ld	Yes	Yes	Yes
S	uction mach	nine		Yes	Yes	Yes
S	uturing sets	;		Yes	Yes	Yes
T	hermomete	r		Yes	Yes	Yes
ei	ray with mergency /ringes and	routine drugs needle	,	Yes	Yes	Yes
U	rinary cathe	eters a		Yes	Yes	Yes
V	acuum extra	actor s	et	Yes	Yes	Yes
	/ork surfac or newborn			Yes	Yes	Yes
Inpatient Wards						
	asic exami quipment (s P machi	tethos	cope, etc)	Yes	Yes	Yes
	eds, washa attresses a		n	Yes	Yes	Yes
	urtains			Yes	Yes	Yes
	ressing	sets		Yes	Yes	Yes
	ressing troll olley	ley/Me	dicine	Yes	Yes	Yes
G	loves			Yes	Yes	Yes
	/ stands	3		Yes	Yes	Yes
1.						Yes

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				-
	Oxygen tank and concentrator	Yes	Yes	Yes
	Patient trolley on wheels	Yes	Yes	Yes
	PPE kits	Yes	Yes	Yes
	Suction machine	Yes	Yes	Yes
	Urinals and bedpans	Yes	Yes	Yes
OperationTheatre		1.00		
oporationmodato	Adequate storage	No	Yes	Yes
	Ambu resuscitation set	110	Yes	Yes
	with adult and child masks		100	100
	Defibrillator	No	No	Yes
	Electro cautery	No	No	Yes
	Fixed operating lights	No	No	Yes
	Fixed suction machine	No	No	Yes
	Hand washing facilities	No	Yes	Yes
		No	Yes	Yes
	Instrument tray			
	Instrument trolley	No	Yes	Yes
	Laryngoscope set	No	Yes	Yes
	Mayo Stand	No	Yes	Yes
	Mobile operating light	No	Yes	Yes
	Ophthalmic Operating Microscope	No	Yes (as applicable)	Yes (as applicable)
	Oral airways, various sizes	No	Yes	Yes
	Oxygen tank and concentrator	No	Yes	Yes
	Patient trolley on wheels	No	Yes	Yes
	Portable suction machine	No	Yes	Yes
	Safety Box	No	Yes	Yes
	Sphygmomanometer and stethoscope	No	Yes	Yes
	Stool adjustable height	No	Yes	Yes
	Operating table	No	Yes	Yes
	IV Therapy Equipment	No		
	Anesthesia Equipment Anesthetic trolley/machine	No	Yes	Yes
	CO2 Monitor	No	Yes	Yes
	O2 Monitor	No	Yes	Yes
	Endoscopic equipment and necessary	No	No	Yes
	accessories	No	No	Vaa
	Bronchoscope	No	No	Yes
	Colonoscope	No	No	Yes
	Endoscope	No	No	Yes
	Fiber Optic Laryngoscope	No	No	Yes
Central Supply				

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Amputation	set	No	No	Yes
Caesarean/h set	ysterectomy	No	Yes	Yes
Dilatation and set	d curettage	No	Yes	Yes
Endoscopic cleaning mac solutions		No	No	Yes
Hernia set		No	No	Yes
Laparotomy	set	No	Yes	Yes
Linens		Yes	Yes	Yes
Locked stora	ge	Yes	Yes	Yes
Operating dra	apes	No	Yes	Yes
Ophthalmic	instrument	No	Yes	Yes
Protective ha shoes and go		Yes	Yes	Yes
Pelvic/fistula	repair set	No	No	Yes
Sterile gloves	6	Yes	Yes	Yes
Sterilization for instument linens		Yes	Yes	Yes
Surgical supp sutures, etc)		Yes	Yes	Yes
Thoracentesi	s set	No	No	Yes
Thoracostom appropriate water seal b	tubes and	No	No	Yes
Thoracotomy	set	No	No	Yes
Thyroid/Para		No	No	Yes
Tracheostom	y set	No	Yes	Yes
Tubal ligation	n set	No	Yes	Yes
Vascular repa	air set	No	Yes	Yes
Other equipment as per the specia	alized services	available	shall also be t	there

ANNEXURE 4

DRUGS, MEDICAL DEVICES AND CONSUMABLES

a. List of Emergency Drugs and consumables (Essential in all hospitals)

SI. No.	Name of the Drug
	INJECTIONS
1.	INJ. DIAZEPAM 10 MG
2.	INJ. FRUSEMIDE 20 MG
3.	INJ. ONDANSETRON 8 MG/4ML
4.	INJ. RANITIDINE
5.	INJ NOR ADRENALINE 4 MG
6.	INJ. PHENYTOIN 50 MG
7.	INJ DICLOFENAC 75 MG
8.	INJ. DERIPHYLLINE
9.	INJ CHLORPHENIRAMINE MALEATE
10.	INJ. HYDROCORTISONE 100 MG
11.	INJ. ATROPINE 0.6 MG
12.	INJ. ADRENALINE 1 MG
13.	INJ. KCL
14.	STERILE WATER
15.	INJ. SODA BICARBONATE
16.	INJ. DOPAMINE
17.	INJ. NALAXONE 400 MCG
18.	INJ. LIGNOCAINE 50 ML
19.	TAB. SORBITRATE
20.	TAB. ASPIRIN
21.	INJ. TETANUS
22.	INJ. ADENOSINE
	OTHER
23.	NEB. SALBUTAMOL2.5 ML
24.	NEB. BUDESONIDE

LIGNOCAINE JELLY 2%
ACTIVATED CHARCOAL
CALCIUM (INJ or TAB)
FLUIDS
RL 500 ML
NS 500 ML
NS 250 ML
NS 100 ML
DNS 500 ML
DEXTROSE 5% 500 ML
DEXTROSE 10% 500 ML
PEDIATRIC IV INFUSION SOLUTION 500 ML

- b. The other drugs and consumables shall be available as per the scope of services, bed strength and patient turnover.
- c. Medical devices shall be available as per the scope of services, bed strength and patient turnover.

Annexure 5

HUMAN RESOURCE

The Human Resource requirement for any hospital shall be as per the scope of services provided by the hospital.

The requirement mentioned below is the minimum requirement for a multispecialty hospital with <u>less than 50 beds</u> and it can be prorated as required.

Based on the levels of care provided, the minimum staffing requirements for Hospital level 3 shall be as follows:

SI.	Human Resource	Requirement		
No.				
1.	Doctor	MBBS doctor shall be available		
		round the clock on site per unit		
		1 Doctor with specialization in the		
		subject concerned as per scope of		
		service (Full-Time / Part-Time or		
		visiting)		
		In ICU, 1 MBBS for every 6 beds ,		
		on- site for 24X7		
2.	Nurses	Qualified nurses per unit per shift		
		shall be available as per		
		requirement laid down by "The		
		Indian Nursing Council, 1985",		
		occupancy rate and distribution of		
		bed.		
		(Qualified nurse is a nursing staff		
		approved as per state government		
		rules & regulations as applicable		
		from time to time).		
3.	Pharmacist	2 in a hospital		
4.	Lab Technician	2 in a hospital (minimum DMLT)		
4.				

5.	X-ray Technician	2 in a hospital (minimum Diploma in X Ray Technician course)		
6.	Other Technicians	As per requirement		
7.	Nutritionist	As per requirement		
8.	Social worker	As per requirement		
9.	Administrative Assistant	As per requirement		
10.	Medical Record Technician	As per requirement		
11.	Driver	As per requirement		
12.	Security Guard	As per requirement		
13.	Multi-purpose Worker	Minimum 2 (minimum 12 th pass)		

*Requirement of other staff (Support and administrative) will depend on the scope of the hospital.

Annexure 6

LIST OF LEGAL REQUIREMENTS

Below is the list of legal requirements to be complied with by a hospital a applicable by the local/state health authority (all may not be applicable):

SI.	Name of Document	Valid From	Valid Till	Send for renewal by	Remark (Expired/ valid/NA)
1.	Registration under Nursing Home Act/ Medical Establishment Act				
2.	Bio-medical Waste Management Licenses				
	Authorization of HCO by PCB				
	MOU with Vendor				
3.	AERB Licenses				
	Type approval				
	Layout Approval				
	License for CT- interventional/ Registration for other machines				
4.	NOC from Fire Department				
5.	Ambulance				
	Commercial Vehicle Permit				
	Commercial Driver License				

	Pollution Control Licenses		
6.	Building Completion Licenses		
7.	Lift licences for each lift		
8.	DG Set Approval for Commissioning		
9.	Diesel Storage Licenses		
10.	Retail and bulk drug license (pharmacy)		
11.	Food Safety Licenses		
12.	Narcotic Drug Licenses		
13.	Medical Gases Licenses/ Explosives Act		
14.	Clinical Establishments and Registration (if applicable)		
15.	Blood Bank Licenses		
16.	Boilers Licenses		
17.	MoU / agreement with outsourced human resource agencies as per labor laws		
18.	Spirit Licence		
19.	Electricity rules		

20.	Provident fund/ESI Act			
21.	MTP Act			
22.	PNDT Act			
23.	Transplantation of Human organs Act			
24.	Salex Tax registration			
25.	PAN			
26.	No objection certificate under Pollution Control Act (Air/Water)			
27.	Wireless operation certificate from Indian P&T	-		
28.	Arms Act, 1950 (if guards have weapons)			

Annexure 7

CONTENT OF MEDICAL RECORD

Medical record shall contain, at the least, the following information:

SI. No.	Content
1.	Name & Registration number of treating doctor
2.	Name, demographic details & contact number of patient
3.	Relevant Clinical history, Assessment and re-assessment findings, nursing notes and Diagnosis
4.	Investigation reports
5.	Details of medical treatment, invasive procedures, surgery and other care provided
6.	Applicable consents
7.	Discharge summary
8.	Cause-of-death certificate & Death Summary (where applicable)

<u>Annexure 8</u>

INFORMED CONSENT/CONSENT GUIDELINES

The informed consent shall at the least contain the following information in an understandable language and format.

SI. No.	Content
1.	Name of the patient/ guardian (in case of minor/mentally disabled).
2.	Registration number of patient
3.	Date of admission
4.	Name & Registration number of treating doctor
5.	Name of procedure/operation/investigation/blood transfusion /anaesthesia/ potential complications
6.	Signature of patient/guardian with date and time

Annexure 9

Discharge Summary

The discharge summary shall at the least contain the following information in an understandable language and format.

SI. No.	Content		
1.	Name & Registration number of treating doctor		
2.	Name, demographic details & contact number of patient, if available		
3.	Date of admission and discharge		
4.	Relevant clinical history, assessment findings and diagnosis		
5.	Investigation results,		
6.	Details of medical treatment, invasive procedures, surgery and other care provided		
7.	Discharge advice (medications and other instructions).		
8.	Instruction about when and how to obtain urgent care.		