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# OFFICIAL GAZETTE

## GOVERNMENT OF GOA

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### EXTRAORDINARY

### No. 2

GOVERNMENT OF GOA

Department of Public Health

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#### Notification

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In exercise of the powers conferred by sub section (1) and (2) of section 47 of the Goa Clinical Establishments (Registration and Regulation) Act, 2019 (Goa Act 19 of 2019), the Government of Goa hereby makes the following rules, namely:—

1. *Short title and commencement.*— (1) These rules may be called the Goa Clinical Establishments (Registration and Regulation) Rules, 2021.

(2) They shall come into force on the date of their publication in the Official Gazette.

2. *Definition.*— (A) In these rules, unless the context otherwise requires,—

(1) “Act” means the Goa Clinical Establishment (Registration and Regulation) Act, 2019 (Goa Act 19 of 2019);

(2) “Ambulance” means any privately or publicly owned motor vehicle or vessel or aircraft that is especially designed, constructed or modified, and equipped and is intended to be used and is maintained or operated for the overland, water or air transportation of patients upon the streets, roads, highways, waterways, river, airspace, or public ways in this state, or any other motor vehicles, vessels or aircraft used for such purposes;

(3) “Appendix” means Appendix appended hereto;

(4) “Applicant” means a person who has made an application;

(5) “Building” includes—

- (a) a house, out-house, stable, latrine, godown, shed, hut, wall (other than a boundary wall not exceeding two meters in height) and any other such structure, whether of masonry, bricks, wood, mud, metal or any other material whatsoever;
- (b) a structure on wheels or simply resting on the ground without foundations; and
- (c) a ship, vessel, boat (when outside the port limit of major ports as defined under the Indian Ports Act, 1908 (Central Act No. 15 of 1908), Aircraft, and
- (d) tent, van and any other structure used for human habitation, but do not include a temporary shed erected on ceremonial or festival occasions.
- (6) “care” means measures taken by a care provider or that are taken in a healthcare establishment in order to determine a service recipient’s state of health or to restore or maintain it;
- (7) “categorization” is the process in which ideas and objects are recognized, differentiated, and understood.
- (8) “Classification” means the action or process of classifying something according to shared qualities or characteristics.
- (9) “Clinics” means— a medical facility run by a single or group of physicians or health practitioners smaller than a hospital. Clinics generally provide only outpatient services and can have an observation bed for short stay.
- (10) “Collection Centre” means a Pathology Laboratory, other than Genetic laboratory providing services regarding collection of samples or specimen for the purpose of pathological, bacteriological, chemical, biological or other tests, examination, or analysis.
- (11) “Consultant” Registered Medical Practitioner in different fields of medicine having specialized knowledge, skill, expertise or experience who can act as specialist to provide expert medical care and services to the patients.
- (12) “Day care centre” means clinical establishment where persons to whom treatment of that kind/those kinds is provided are reasonably expected to be admitted and discharged on the same date;
- (13) “Dental clinics”- are places where dentists provide dental care with no inpatient facilities.
- (14) “Dental hospitals”- are places where dentists provide outpatient dental care with inpatient facilities
- (15) “Department” means department of health/health Speciality or any other Government department
- (16) “Diagnostic Centre” means-stand-alone organized facilities to provide simple to critical diagnostic procedures such as radiological investigation supervised by a radiologist and clinical laboratory services by laboratory specialist usually performed through referrals from physicians and other health care facilities.
- (17) “Director” means Director of Health Services, Goa.

(18) “Disaster” and “Disaster Management” shall have the meaning assigned to them under the Disaster Management Act, 2005 (Act 53 of 2005).

(19) “Display” means any form of display and includes any advertisement—

(a) printed in any medium for the communication of information;

(b) appearing in, communicated through or retrievable from, any mass media, elect otherwise; or

(c) contained in any medium for communication produced or for use by an institution.

(20) “Emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) of such a nature that the absence of immediate medical attention could reasonably be expected to result in (i) death of the person or; (ii) serious jeopardy in the health of the person (or in case of pregnant woman, in her health or health of the unborn child); (iii) serious impairment to bodily functions; or (iv) serious dysfunction of any organ or part of a body;

(21) “Emergency medical service” means the organization responding to a perceived individual need for immediate medical care in order to prevent loss of life or aggravation of physiological or psychological illness or injury;

(22) “emergency medical treatment” means’ the action that is required to be taken after screening a person who is in an emergency medical condition, as to the stabilization of the person and rendering of such further treatment as may be necessary for the purpose of preventing aggravation of the medical condition of the person or his death;

(23) “Employee” means a person wholly or principally employed in, or in connection with, a clinical establishment, whether working on permanent, periodical, contractual or piece-rate wages or on commission basis even though he receives no reward or payment for his labour.

(24) “Form” means the form appended hereto;

(25) “General Hospital” is a set up having facilities, medical staff and all necessary personnel to provide diagnosis, care and treatment of a wide range of acute conditions, including injuries, and normally has an emergency department to deal with immediate and urgent threats to health;

(26) “Genetic laboratory” means a laboratory as defined under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of sex selection) Act, 1994 (Central Act 57 of 1994).

(27) “Healthcare establishments” means any clinical establishment run by private or public sector agencies;

(28) “Hospital” means health care institutions that have an organized medical and other professional staff, and inpatient facilities, and deliver medical, nursing and related services 24 hours per day, 7 days per week, which offer a varying range of acute, convalescent and terminal care using diagnostic and curative services in response to acute and chronic conditions arising from diseases as well as injuries and genetic anomalies;

(29) ‘Hospital bed’ means a bed that is regularly maintained and staffed for the accommodation and full-time care of inpatients and is situated inwards or a part of the hospital where continuous medical care for inpatients is provided;

(30) “Imaging centre” means any establishment or premises used or intended to be used in production of images or visual display of structural or functional patterns of organs or tissues with the aid of any kind of electro-magnetic or sound wave for the purpose of diagnosis, treatment or research of diseases;

(31) “Indigent person” means a person who has no visible means of income or whose income is insufficient for the subsistence of his family and shall include,—

(i) a person who has received a ration card in the category of Below Poverty Line (BPL); and

(ii) a person not included in sub-clause (i) but has been identified as an indigent person by such designated authority as may be notified;

(32) “Informed consent” means consent given to a proposed specific intervention, without any force, undue influence, fraud, threat, mistake or misrepresentation, and obtained after disclosing to the person giving consent adequate information including risks and benefits of, and alternatives to the proposed intervention in a language and manner understood by such person with no binding to consent after being informed;

(33) “Inpatients”— residents hospitalized for indoor care across all types of hospital beds;

(34) “Inpatient facilities” means any establishment having beds for admission of patients;

(35) “Isolation” means the physical separation and confinement of an individual or groups of individuals who are infected or reasonably believed to be infected with a contagious or possibly contagious disease from non-isolated individuals, to prevent or limit the transmission of the disease to non-isolated individuals;

(36) “Large Laboratory” means as a Pathology Laboratory, other than Genetic laboratory performing all the Microbiology, and Morphological Pathology tests in addition to tests performed by the medium laboratory;

(37) “Local authority” means,—

(a) in any municipal area, the Corporation, or Municipal Council concerned;

(b) in notified area, the Notified Authority;

(c) in any other area, the Village Panchayat concerned.

(38) “Maternity Home”— means any premises used or intended to be used for reception of pregnant women or of women in labour or immediately after childbirth;

(39) “Medical device” means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article.

(40) “Medical Diagnostic laboratory” means a laboratory with one or more of the following where microbiological, serological, chemical, haematological, immune-hematological, immunological, toxicological, cytogenetic, exfoliative cytogenetic, histological, pathological or other examinations are performed of materials/fluids derived from the human body for the purpose of providing information on diagnosis, prognosis, prevention, or treatment of disease;

(41) "Medically Necessary" means a service or procedure that is scientific, appropriate and consistent with diagnosis and which, using accepted standard treatment protocol, standard operating procedures or any other standards of medical practice, could not be omitted without adversely affecting the patient's conditions;

(42) "Medical Record" means any paper, film, print out, slide, solution or medium, or any documentation of services performed at the direction of a service provider which can be deciphered or used to indicate and diagnose condition of the human body or a part of it or any material taken out of it and the course of treatment including nursing care administered to, or undergone by, the person;

(43) "Medical Superintendent" means a person by whatever name and designation he/she is called, who is a medical practitioner and is in charge of, or is entrusted with the running of, a clinic, hospital or nursing home;

(44) "Medical supplies" refers to the non-durable disposable health care materials ordered or prescribed by a physician, which is primarily and customarily used to serve a medical purpose and includes osteotomy supplies, catheters, oxygen, and diabetic supplies;

(45) "Medico-legal case" means any medical case which has legal implications either of a civil or criminal nature, and includes but is not limited to cases relating to accidents, assault, sexual assault, suicide, attempt to murder, poisoning, injuries on account of domestic violence, injuries on workers during course of employment;

(46) "Medium Laboratory" means a Pathology Laboratory, other than Genetic laboratory performing all the clinical pathology and haematology tests in addition to tests performed by the small laboratory but excluding Microbiology, and Morphological Pathology test;

(47) "Multi-specialty hospitals" are – hospitals offering specialized and tertiary care in single or multiple facilities segregated units each of which are devoted to a complexity of patient care defined in this sub-section;

(48) "Near relative" means any of the following relatives of the deceased (or patient) namely, a wife, husband, parent, son, daughter, brother and sister and includes any other person who is related to the deceased or any other person as may be defined under Indian Succession Act, 1925 [Act XXXIX of 1925];

(49) "Norm" means a statistical normative rate of provision or measurable target outcome over a specified period of time;

(50) "Nursing Home" means any premises used or intended to be used for reception of persons suffering from any sickness, injury or infirmity and providing of treatment and nursing for them and include a maternity home;

(51) "Outpatients" where care is provided without admission/hospitalization as inpatient;

(52) "Package of service" or "package" means a group of health care related services with clear item wise explanation wrapped under a fixed price to be provided to the service recipient;

(53) "Paramedical Professional" means any Technician like ECG Technician, Medical Laboratory Technician or Ophthalmic Assistant and includes such other technicians or any personnel, who helps in providing health care services, teaching or practice of medicine by a registered medical practitioner;

(54) "Patient" means a service recipient who has received any kind of service or care from any Clinical establishment with or without being registered by the patient registration system of that Clinical Establishment and shall include any child born to a patient and is entitled to enjoy all the rights, responsibilities and obligation of being a patient;

(55) "Patient Party" means a person willing to enjoy all the rights, responsibilities and obligation conferred upon a patient and is recognized as such by the clinical establishment or the service provider and includes,—

(i) a adult member of the family or near relatives; or

(ii) guardian of the service recipient, in case of service recipient being a minor; or

(iii) one of the friends, colleagues or any person authorized by the service recipient as his representative; or

(iv) guardian, legal heir or natural successor or near relatives of the service recipient in event of the death of the service recipient or his being incapacitated due to existing physical/mental/emotional state rendering him incapable to authorize a person as his Representative.

(56) "Personal care" means care which can be provided by a non-professional and shall include but not limited to-

(i) assistance with one or more of the following activities namely bathing, showering or personal hygiene; toileting; dressing or undressing; eating meals; or

(ii) assistance for persons with mobility problems; or

(iii) assistance for persons who are mobile but require some form of supervision or assistance; or

(iv) the provision of substantial emotional support; or

(v) assistance for summoning up on-duty nurse or medical officer; or

(vi) any such reasonable assistance expected of him subject to his skill, competency and experience;

(57) "Polyclinic" means a medical clinic where the proprietor and the service provider may be same or different persons;

(58) "Premises" means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance, vessels or aircraft;

(59) "Primary Consultant" means a Registered Medical Practitioner as defined;

(60) "Proprietor of clinical establishment" means a person who has been granted a license under the Act;

(61) "Public Health Emergency" means an occurrence or imminent threat, including owing to degraded environmental conditions, of an illness or health condition that:

(a) Poses a high probability of any of the following harms:

- (i) a large number of deaths or illness in the affected population;
  - (ii) a large number of serious or long-term disabilities in the affected population, including teratogenic effects, or;
  - (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial future harm to a large number of people in the affected population;
- (b) And can be caused by any of the following:
- (i) the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin, or;
  - (ii) any disaster, including major accidents.

*Explanation:*— Public health emergency can be due to communicable infectious diseases; chronic non-infectious, non-communicable conditions affecting large population, notified diseases, and conditions of public health importance or locally endemic diseases.

(62) “Quality assurance” means any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily, in compliance with quality control standards specified by the competent authority, and includes safety standards;

(63) “Quality control” means the set of operations (programming, coordinating, implementing) intended to maintain or to improve quality and includes monitoring, evaluation and maintenance at required levels of performance;

(64) “Qualified technician” means any paramedical professional who possesses a degree, diploma or certificate in any paramedical course of at least two years or equivalent, granted by any University established by law or any other institution recognized by the Department in this behalf.

(65) “Records” includes invoices, receipts, orders for the payment of money, bills of exchange, cheques, vouchers and other documents of prime entry and also includes such working papers and other documents as are necessary to explain the methods of calculations by which accounts are made up;

(66) “Reference laboratory” means a laboratory, registered under the law or accredited by National Accreditation Board for Testing and Calibration Laboratories or organization of similar repute, which accepts sample or Specimen from other clinical establishments for testing and examination;

(67) “Rehabilitation” means a goal-orientated and time-limited process aimed at enabling impaired persons to reach an optimum mental, physical or social functional level;

(68) “Resident Medical Officer” or “RMO” means the Duty Medical Officer;

(69) “Scientific” means anything that has been substantiated and proved on the protocol of evidence-based medicine;

(70) “Section” means a section of the Goa Clinical Establishment (Registration and Regulation) Act, 2019;

(71) "Service" means health care related services and non-health care related services including but not limited to ambulance service therapeutic service, diagnostic services, in/out patient & emergency services, dietary services, palliative services, and rehabilitative services;

(72) "Small Laboratory" means a Pathology Laboratory, other than Genetic laboratory performing only the Routine Clinical Pathology and Haematology tests e.g. Hb, TC, DC, ESR, BT, CT, PT, Routine examination of stool, urine, sugar (blood and urine), urea, and cholesterol;

(73) "Solo clinic" means a medical clinic used for consultation and treatment by a single doctor where the proprietor and the service provider is the same person;

*Explanation:* Single Doctor shall include any registered medical practitioner other than a dental practitioner.

(74) "Sonologist" means a qualified registered medical practitioner as defined under the Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of sex selection) Act, 1994 (Central Act 57 of 1994);

(75) "Specialty Hospital" are - hospitals having facilities, medical staff and all necessary personnel to provide diagnosis, tertiary care and treatment of a limited specialized group of acute or chronic conditions such as psychiatric problems, certain disease categories such as cardiac, oncology, or orthopaedic problems, and so forth;

(76) "Staff" means a service provider or other categories of employees or any other person who provides any service within the premises of the healthcare institution, whose services are utilized in the clinical establishment for providing any kind of service includes those working on part-time, temporary contractual, consultancy, honorary or on any other basis whether on payment basis or not;

(77) "Statutory FORM" means a form appended to these Rules;

(78) "Summary Medical Report" means a report to be provided by the Primary Medical Attendant containing such particulars which includes but not limited to—

(i) the reasons for admission, significant clinical findings, provisional diagnosis and results of investigations, treatment and the nature of the health service rendered; and

(ii) the final diagnosis and condition of the patient at the time of discharge;

(iii) follow-up advice, medication and other instructions and when and how to obtain urgent care when needed in an easily understandable manner; and

(iv) any other particulars which shall be useful for future health care of the patient.

The summary of Medical Records to be made available to the patient party at the time of Death to be known as Summary Medical Report (Death) and shall contain the following additional particulars:

(i) The terminal care given; and

(ii) a copy of death certificate issued as per Medical certification of Cause of Death guideline provided under the Birth and Death Registration Act, 1969 [Act No. 18 of 1969].

(79) "Table" means a table appended to these rules

(80) "Telemedicine" means the practice of medicine using audio, visual and data communications;

(81) "test" or "examination" means a medical test or procedure performed to detect, diagnose or monitor disease, disease processes, susceptibility or to determine a course of treatment;

(82) "Trade license": means a certificate of enlistment by whatsoever name called issued by the authority of the local self-government like Municipality or Panchayat;

(83) "treatment" means administration of any one or combination of therapies under any recognized system of medicine by a Registered Medical Practitioner to a person for restoring or maintaining his health;

(84) "University" means a University defined under clause (f) of section 2 of the University Grants Commission Act, 1956 (No. 30 of 1956) and includes an institution declared to be a deemed University under section 3 of the said Act;

(85) "Unwarranted public exposure" means a situation where the patient is subjected to exposure, private or public, either by photography, publication, videotaping, discussion, TV broadcasting or radio broadcasting, or by any other means that would otherwise tend to reveal his person or identity and circumstances under which he has or will be under medical or surgical treatment without his consent;

(B) The words and expressions used and not defined in these rules, but defined in the Act, shall have the same meaning respectively assigned to them in the Act.

3. *Allowance Payable to the members of the Council.*— The members of the Council other than ex-officio members shall be paid an allowance of Rs. 800/- for each sitting.

4. *Minimum standards of Facilities and Services.*— Every Clinical Establishment shall fulfil following minimum standards of facilities as specified in Tables hereto:

TABLE I  
(See Rule 4)

Standards to be maintained by doctor/medical practitioner practicing in Medicine/Dentistry in a clinical establishment

I) *Staff*

(1) The Medical Practitioner shall be assisted by para-medical staff, including qualified and/ or experienced Nurse/s and Technician/s (wherever required), with Attendants/ Servants, etc.

(2) They should be free from communicable or contagious diseases and medically examined at the time of appointment and thereafter every year.

(3) They should wear clean identifiable uniforms.

(II) *Facilities:*— The premises should include-

(1) A Consulting Room;

(2) A Patient Room/s in case of inpatient facility;

(3) A Reception/Lobby area;

(4) Equipment's and Instruments of good quality and in adequate quantity to carry out the various required tasks;

(5) Beds with mattresses and linen;

(6) Adequate number of toilets with water facility;

(7) Fully equipped Operation Theatre and Labour Room for hospitals as per speciality;

*Explanation:* list of essential drugs for each specialty may be laid down from time to time and each clinical establishment is expected to have all these drugs in store in addition to general list of essential drugs at any given point in time.

(8) Well equipped casualty room for hospitals.

(9) Proper method of disposal of Bio-Medical Waste as per the Bio-Medical Waste (Management) Rules, 2016, as amended from time to time.

(III) In case of Hospital/Nursing Home/Diagnostic Centre/Pathological Laboratory, names, contact number and license numbers of all the practicing doctors/medical practitioners including that of honorary doctors shall be displayed at conspicuous place.

(IV) Minimum standards as laid down under trade license issued by the Municipal Corporation/Municipal Council/Village Panchayat concerned shall be maintained.

(V) In addition to above, proper hygiene and cleanliness, adequate water and power supply quality equipment/instruments, beds with mattresses and linen, shall be provided and always maintained neat and clean.

## TABLE II Standards for Service Provider

### *Part I: General*

#### *1. Introduction*

1.1. The clinical establishment should maintain the Service Provider standards and norms as specified herein or any such standards and norms as may be notified from time to time.

1.2. The staff can be classified into the following categories: (a) Medical Staff; (b) Nursing staff; (c) Paramedical-Technical Staff; (d) General Duty attendant and other Gr-D staff; (e) Administrative-Managerial staff; (f) Non-medical technical staff; (g) Other staff.

1.3. Unless mentioned otherwise by the applicant, all staff requirement should be calculated on the basis of a routine 3 shift arrangement along with adequate number of reserve staff.

1.4. Any kind of trainee Medical/Nursing/paramedical staff should not be included while considering the manpower.

#### *2. Medical Staff*

2.1. In case of specialized service, it should have at least registered medical practitioner of modern medicine having minimum qualification of a post-graduate diploma/degree in relevant discipline to supervise/perform/conduct the test/procedure, to interpret and give the result or to examine and advice.

2.2. There should be one registered medical practitioner available on duty at each consultation room of the OPD clinic during the OPD hours to ensure the availability of services as described in the mandatory display by the clinical establishment.

2.3. IPD facilities should have two kinds of Medical staff or doctors: (a) Consultants and (b) Duty medical officers. As soon as a patient arrives at a clinical establishment he or she should immediately be attended by a Duty Medical Officer. A consultant should see the patient as soon as possible.

2.4. If it is medically necessary, the Duty Medical officer may refer the patient to the suitable speciality consultant who should be asked to render his opinion or advice or to perform a particular procedure in his capacity of being a Consultant having specialized knowledge, skill, expertise or experience. Any kind of trainee Doctor should not be considered as the service-provider for the purpose of the Act or rules.

2.5. There should be at least one Duty medical officer to act as RMO, in case of a Maternity/nursing home, available on duty round the clock.

2.6. In case of inpatient based facilities with more than 30 beds one duty medical officer should be available on duty round the clock.

2.7. In addition to the duty Medical officer, the number of consultants required in the Inpatient based Facilities should depend upon type of the services being provided (general /specialty/super-speciality etc.) there.

eg. A nursing home providing medical facilities should have a physician available on call round the clock. A nursing home providing surgical facilities should have a surgeon and anaesthetist available on call. In case Emergency Surgical Facilities are also provided then a surgeon and anaesthetist should be available on call round the clock.

eg. The resuscitation of new born should be under the supervision of a trained Registered Medical Practitioner preferably a paediatrician. Maternity home should have gynaecologist /surgeon, anaesthetist, and paediatrician.

### 3. *Nursing staff:*

*Nurses*— Diploma/degree in nursing/midwifery from any recognised institution and registered with the Goa Nursing Council. 70% of the nurses should possess the above mentioned qualification and 30% should be trained staff having minimum 10<sup>th</sup> standard pass and having experience of working in hospital for 02 years.

### 4. *Paramedical— Technical Staff:*

Depending upon the nature of service offered by the clinical establishment and the expected workload, at least one on duty qualified technical staff should be engaged.

In case of old establishment, the technical personnel who are found to be under qualified may continue to work in the same capacity but for further recruitment, properly qualified personnel are to be engaged. No paramedic should run the establishment without the supervision of a registered medical/Dental practitioner.

### 5. *Attendant:*

Minimum 6<sup>th</sup> class, shall have working knowledge of sepsis/asepsis and should be able to read English and read/write Konkani/Marathi.

### 6. *Administrative – Managerial staff*

This category of staff includes— Managers, receptionists, supervisors, security personnel etc. The requirement of this category of staff depends solely on the type of a hospital and its

size. As the size of a hospital increases the need for this category of staff also increases proportionately. Such staff should be provided in such number as per advise of the Authority.

#### *7. Non-Medical Technical Staff:*

Depending upon the type of facilities being offered, extent of outsourcing etc. Support staff like Dietician, Cook, Plumber, Electrician, telephone operator, Central heating/AC operators etc. should be at the disposal of the clinical establishment.

#### *Part II. Specific*

##### *1. ICU*

1.1 In case of nursing homes providing special care unit facilities, there should be at least two Duty Medical Officers exclusively for intensive care having post graduate diploma or degree or adequate working experience at a recognized hospital in the concerned discipline.

1.2 In case of nursing homes providing special care unit facilities, there should be adequate number of nursing staff exclusively for critical care having certificate, diploma or degree or adequate working experience at a recognised hospital in the concerned discipline.

1.3 There should be one trained nurse available round the clock for every 3 beds in such special care units including post-operative wards. There should be one qualified critical care Technician available around the clock in such special care units.

##### *2. Eye Clinic with operating facility:*

Eye Clinic with operating facility should have (a) Doctors with post-graduation in ophthalmology, (b) minimum of two nurses for 10 beds and supportive staff preferably qualified O.T. Technician. Service of Anaesthetist should be available as and when required.

##### *3. Pathology Laboratory Facilities:*

3.1 Every Small Laboratory should have at least one registered medical practitioner of modern medicine having minimum qualification of a DCP or DTM&H or equivalent post-graduate or a MBBS degree with at least five years' experience in laboratory medicine to supervise the Laboratory work, to interpret and give the result. It should have one duly qualified medical technician on duty having minimum qualification in medical laboratory technology or equivalent.

3.2 Every Medium Laboratory should have (a) at least one registered medical practitioner as mentioned under the small laboratory and in addition to that, (b) one qualified person having a minimum qualification of a MSc (Biochemistry/Medical Micro-biology) or MD (Biochemistry) or equivalent post-graduate degree who can supervise those test. It should have two on duty qualified medical technicians.

3.3 Every large laboratory should have (a) at last one registered medical practitioner having minimum qualification of a MD (Pathology) or equivalent post-graduate degree; and (b) at least on registered medical practitioner having minimum qualification of a MD (Microbiology) or equivalent post-graduate degree; and (c) at least on registered medical practitioner having minimum qualification of a MD(Biochemistry) or equivalent post-graduate degree to supervise the Laboratory work, to interpret and give the result. It should have three on duty qualified medical technicians.

3.4 The histopathological, cytopathological and special haematological tests should be carried out personally by a MD (Pathology) or equivalent. Multi-disciplinary laboratories should identify a group leader, with specific qualification for each.

*Explanation:* A qualified person having Ph.D in the respective discipline should be considered as equivalent.

3.5 A collection centre should be under supervision of a Registered Medical Practitioner of modern medicine. The collection centre should have one— on duty qualified medical technician or support staff having higher secondary (with bioscience) certificate with a minimum five year experience in an established medium sized laboratory.

TABLE III  
Standards for Equipment, Medical Devices, Medical Supplies

Part I: *General*

1. *Introduction*

1.1. The clinical establishment should maintain the Equipment, Medical Devices, Medical Supplies standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

1.2. The clinical establishment should follow the IPHS guidelines regarding equipment and medical supplies for that category of establishment and Guidelines for Good Clinical Laboratory Practices by Indian Council of Medical Research.

1.3. The clinical establishment should provide adequate numbers of Equipment of good quality depending upon the service offered by that clinical establishment. The clinical establishment should be reasonably satisfied about the quality of the Equipment, Medical Devices, Medical Supplies before procurement of the same. It should procure Equipment, Medical Devices, Medical Supplies with BIS standard as far as possible. While commissioning or decommissioning such equipment, the clinical establishment should follow the manufacturer's guideline.

1.4. All equipment should be in good working condition at all times to meet workload requirement. Periodic inspection, cleaning, maintenance of equipment should be done as per manufacturer's guideline.

1.6. New equipment should be checked, calibrated and validated before routine use. Periodic performance check/calibration check for all equipment should be done using reference standard/reference material and records of such calibration maintained for inspection by the authorities

1.7. Under no circumstances should the completion of necessary equipment servicing or calibration be delayed or cancelled in order to accommodate further service provision.

2. *Medical Gas*

2.1. If central medical gas supply system is not available then (a) Oxygen cylinders should be provided as per the following norms: (i) Three cylinders for each Operating theatre; (ii) Two cylinders/8 beds for Wards; (iii) Two cylinders for each Delivery room; (iv) Two cylinders for Emergency area/ward. Stock for one week should be maintained. In each of these areas flowmeters and trolleys should be provided and (b) Suction apparatus should be provided as per the following norms: (i) One suction apparatus for operating theatre; (ii) One suction apparatus for delivery room; (iii) One suction apparatus for every eight beds; (iv) One suction apparatus for emergency and casualty patients. At least two of these should be foot operated.

2.2. If central medical gas supply system is available then (a) Oxygen outlet should be provided as per the following norms: (a) Two outlets per table for each Operating theatre; (b) Separate outlet per table/bed each Delivery room/Recovery room/Emergency area/ward; (b) vacuum outlet should be provided.

2.3. Nitrous oxide outlet should be provided as per the following norms: One outlet per table for each Operating theatre.

2.4. In all these areas one O<sub>2</sub> cylinder should be kept as spare. These three pipelines have to be of different colours conforming to a laid down standard and mounted on wall or ceiling surface. Precautions should be taken regarding the storage of oxygen and nitrous oxide.

### *Part II: Specific*

#### *1. Examination Treatment Dressing room*

1.1. Each Examination Room should be provided with equipment like: Chair for consultants (One for each consulting room); Chairs for patient and persons accompanying patient (Two or three per consulting room and casualty); Revolving stool (metallic - One for each consulting room); Doctor's table (One for each consulting room); Examination table with safe footsteps, mattress and pillow (One for each consulting rooms); Examination table for OBG clinic (with appropriate light fixture and stool for doctor); X-ray viewing box; Bowls; Wash basin with liquid soap dispenser and towel rail (One in each consulting room and in casualty), Weighing machine; Screens for every examination table.

1.2. Each Examination Room should be provided with instruments and medical supplies for patient examination like (torch, tongue depressor, stethoscope, Blood Pressure Apparatus, Thermometer, Kidney trays, Proctoscope (small medium and large for surgical OPD), Hammer (for eliciting tendon jerks), Tuning fork, Ant. vag wall retractor For OBG/OPD; Bivalved speculum, Sims speculum sterilizer (preferable); Gloves; Disposable Syringes, Gloves and Masks; Towels, Bedsheets post exposure Prophylactic kit, First Aid equipment's, emergency Drugs.

1.3. Treatment/Dressing room and Injection room should be provided with Equipment & Furniture like: (1) IV stands; (2) Examination table with mattress to carry out dressings (3) Dressing trolley; (4) Ambus bag; (5) Suction apparatus; (6) Oxygen cylinder with flowmeter; (7) One trolley for oxygen cylinder; (8) Laryngoscope with blades; (9) Dustbins with lids etc.

1.4. Treatment/Dressing room and Injection room should be provided with medical supplies like Hydrogen peroxide solution, Cetrimide solution, solvent ether spirit, Povidone iodine solution, Freshly prepared Eusol, Freshly prepared 1% Na Hypochlorite solution, Cheatles forceps, Drums with sterile gauze and bandages, Sterile packets of catgut, ethylon, prolene, silk, etc., autoclaved linen, sticking plaster, 2% Xylocaine without adrenaline, suture cutting scissors, Disposable syringes 5,10,20 ccs needles curved, cutting and round bodied small and medium sizes etc.

1.5. Emergency trolley tray should be provided with: Inj adrenaline,; Inj. soda bicarb; Inj aminophylline; chlorpheniramine; Inj calcium gluconate; Inj Frusemide; Inj vesopressor; Inj. 25% glucose I.V. fluids etc.

1.6. Catheters tray should be provided with: Endotracheal tubes tray (all sizes of cuffed tubes) with connectors; Oropharyngeal airway (all sizes); Spirit bottle. Syringes and needles; Foleys Catheters

1.7. Venesection tray should be provided with: Small plain forceps and small toothed forceps; Venesection scissors; Curved cutting needles medium sizes; Small mosquito forceps; Towels; One bowl; Lubricating jelly;

## 2. IPD facilities

2.1. The number and type of such Equipment's should vary with the services being provided and work load in the Nursing Home, but to provide the optimal services and to maintain the sterility of the equipment/instruments, each nursing Home should be provided with adequate quantity & quality of equipment and medical supplies like (a) equipment for emergency (b) equipment for ward (c) Trolley & Stretcher; (d) Hospital furniture; (e) Linen etc.

2.2. Each nursing Home should be provided with such equipment's for emergency like suction machine with generator connection & standby foot suction machine; all instruments /equipment's required for emergency & Basic life support (CPR); Emergency Tray; ECG Machine; Dressing trolley; Resuscitation tray.

2.3. In case of nursing home with more than 30 beds, each nursing station should be provided such equipment and medical supplies like: (1) Desk/counter; (2) Wall clock; (3) Wash basin with liquid soap dispenser and towel rail; (4) Sink unit; (5) Notice boards; (6) Fire fighting equipment; (7) Enema can-set (One per ten beds); (8) Vohler-Braun splint (for limb elevation); (9) Ophthalmoscope; (10) Torch (One large size -3 batteries & one small size -pin-point source); (11) Percussion hammer; (12) Laryngoscope with blades of all sizes; (13) Medicine trolley; (14) X-ray viewing box for one X-ray plate; (15) Refrigerator 300 litres; (16) Weighing machine; (17) Speculum & retractors; (18) Height scale (19) Stethoscope; (20) Glucometer; (21) Suture removal sets; (22) Dressing sets; (23) Cutdown sets etc

2.4. Each nursing Home should be provided with such Trolley & Stretcher for each ward: Minimum of two stretchers/trolleys and two wheel chairs should be provided. These stretchers/trolleys/wheel chairs (should always be functional in noiseless condition).

2.5. Each nursing Home should be provided with Hospital furniture (per bed one of each) like Bedside lockers with table top; Chair/Stool; urinal; bed-pan; sputum cup, kidney tray, Bedsteads (If provided with facility for IV sets, separate IV stands need not be provided); drip stand; One dustbin with lid; Indoor papers stand/holder.

2.6. Each IPD facilities should be provided with Linen adequate scale. Sheet and cover should be changed on daily basis. Fresh blankets and linen-set should be supplied at the time of admission.

2.7. Each Ward store should be provided such equipment and medical supplies like (1) Storage racks; (2) Oxygen cylinders; (3) IV stands; (4) Suction apparatus; (5) IV fluids and IV sets; (6) Foley's catheters with urine bags; (7) Naso-gastric tubes.

2.8. Each nursing home having Operation theatre should be provided with OT equipment's (1) Anaesthesia machine with complete accessories; (2) Multi Channel Monitor; (3) Pulse Oxymeter; (4) Suction apparatus – Electric/Battery/Foot operated; (5) Fix Operating Room lights with operation; (6) Bipolar Electro –Surgical Cautery; (7) Resuscitation Trolley; (8) Facilities for Blood Transfusion; (9) Surgical operating instruments for type of surgery which is being conducted in the Nursing Home; (10) High pressure autoclave with modern system of quick sterilization of surgical sterilization instruments and operating linen and other items; etc. In case of nursing home with more than 30 beds, each OT should be provided with Defibrillator with automatic external defibrillator and Ventilator.

2.9. Nursing station should be provided with Equipment & Furniture like: (1) Desk/counter; (2) Chairs; (3) Notice boards; (4) Communicating system; (5) Storage space; cupboards, etc

### 3. Maternity Home

3.1. All Maternity home should have the following instruments & equipment required for Emergency obstetric care: LSCS, Low mid cavity forceps/kiellandforcep, Vacuum extractor and suction machine); D&C sets; MTP set; Cervical exploration set; Uterine packing forceps; Post partum ligation set; Abdominal and Vaginal Hysterectomy set; Tuboplasty set; Electrocautery diathermy set; Anaesthetic equipment's

3.2. All Maternity home should have the following instruments & equipment Labour Room & Newborn corner: Delivery sets; Labour table; Doppler Foetal monitor; suction machine with generator connection & standby foot suction machine; Neonatal Resuscitation kit; oxygen cylinder; one infant warmer; weighing machine for the babies.

### 4. ICU

4.1. The beds should have a firm base to permit cardio-pulmonary resuscitation and should be movable easily. Provision should be there to alter height of the head and foot of the patient and the plank at the head end should be detachable to facilitate endotracheal intubation when required.

4.2. It should be provided with adequate quantity & quality of equipment's and oxygen (preferably central oxygen or one oxygen cylinder per bed with two standby cylinders) etc. An indicative List of Equipment (12 Bedded ICU and 8 Bedded HDU) is given below:—

(1) Bedside Monitors (at the rate of one per bed of ICU) with Modular-2 Invasive BP, SPO<sub>2</sub>, NIBP, ECG, RR, Temp Probes with trays;

(2) 6-12 Ventilators with paediatric and adult provisions, graphics and Non-Invasive Modes (Two Ventilators should be with inbuilt compressor. Each should have a heated Humidifier.

(3) 3 Non invasive Ventilators with Provision for CPAP and IPAP;

(4) Infusion Pumps (at least 2 per bed in ICU or 1 per Bed in HDU) with Volumetric with all recent upgraded drug calculations;

(5) Syringe Pumps (at least 2 per bed in ICU) with recent up gradation;

(6) Head End Panel (at the rate 1 per bed) with two O<sub>2</sub> Outlets, two vacuum, one compressed air and twelve electric outlets, provision for Alarm, trays for two monitors, Two Drip stands, one Procedure light;

(7) Defibrillator (2 with TCP facility- 1 standby) with Adult and paediatric pads with Transcutaneous pacing facility;

(8) ICU Beds (Shock Proof) (Fibre) Electronically Manoeuvred with all positions possible with mattress.

(9) Over Bed Tables (1 for each Bed) with all SS with 6 to 8 cupboards in each to store Drugs, side tray for x-rays, BHT, on wheels;

(10) ABG Machine (1 plus 1 standby) with facility for ABG and Electrolytes.

- (11) Crash/Resuscitation trolley to hold all resuscitation equipment and Medicines (at the rate of 2 for ICU and 1 for HDU);
- (12) Pulse Oxometer (Small Units 2 as stand-by units);
- (13) Refrigerator (1 per ICU) with freezer compartment;
- (14) HD Machines (2 per ICU) with user friendly so that even a Nurse can operate;
- (15) CRRT (1 per ICU) with high flow/Speed Model;
- (16) CO, SVR, ScvO<sub>2</sub> Monitor (1 per ICU)
- (17) Intermittent Leg Compressing Machine to prevent DVT (2 per ICU);
- (18) Airbeds to prevent Bed sores (1 per 2 beds);
- (19) Intubating Video scope to make difficult intubations easy (1 per 1CU);
- (20) Glucometer (2 for ICU, 1 for HDU);
- (21) ICU Dedicated Ultrasound and Echo machine (1 per ICU) with recent advances to look instantly even at odd hours. Vascular filling, central lines, etc,;
- (22) Bedside X ray (1 per ICU);
- (23) ETO sterilization to sterilize ICU disposables regularly (1 per ICU);
- (24) Spinal Board for spine trauma patients (2 per ICU);
- (25) Rigid Cervical Spine collars for stabilizing cervical spine (2 per ICU);
- (26) Ambu Mask different sizes Silicon, ETO sterilisable (10 sets including 2 for Pediatric use);
- (27) Pollution control buckets (1 set for each Bed);
- (28) Trays for Procedures For putting central lines, ICD, catheters etc
- (29) I A Balloon Pump (1 per ICU);
- (30) Fibroptic Bronchoscope (1 per ICU)
- (31) Computers with LAN, Internet facility and printer to be connected with all departments

#### 5. Nuclear Medicine Therapy Unit

5.1. There should be installation of "Type approved" PET-CT, SPECT-CT and GAMMA CAMERA for medical diagnostic purposes (Certificate of "Type Approval" to be obtained from AERB). Other equipment's like Gamma Probe, Thyroid uptake system etc. need to be purchased from approved vendor and to be AERB Draft The West Bengal Clinical Establishment (Registration and Regulation) Rules, 2012 45 approved. For the supplied isotopes, radiopharmaceuticals and blood products used in nuclear medicine from external suppliers.

5.2. Equipment for sedation and monitoring of sedated patient should be available on site. If intravenous sedation is performed there should be equipment for continuous pulseoxymetry.

Equipment's and drugs for the management of potential complication should be immediately available. For paediatric patient, sedation monitoring equipment should be capable of measuring saturating end tidal CO<sub>2</sub> and non invasive blood pressure. There should be equipment for endotracheal intubation of children in case of complication. If clinical exercise stress testing is performed, there should be equipment available for it.

5.3. Where appropriate to the patient population and procedure performed, equipment for general anaesthesia and monitoring of the patients should be available on site. Where warranted there should be appropriate resuscitation equipment available. Facilities should be available for cardio pulmonary resuscitation and basic life support appropriate to the level of cardiac stress testing performed.

5.4. In addition all the equipment should be checked and calibrated specifically for the following: (a) Dose calibration and constancy check; (b) Reproducibility and linearity checks of the dose calibrator; (c) Geometric correction factor check; (d) Calibration of energy window setting; (e) Check of signal uniformity, linearity, sensitivity and resolution; (f) Check of geometric distortion and spatial resolution; (g) Check of collimator absolute and relative sensitivity; (h) Centre of rotation check; (i) Pixel calibration; (j) SPECT phantom reconstruction check; (k) Crystal energy resolution check; (l) Molybdenum breakthrough check; (m) Ambient radiation dose management; (n) Radiopharmaceuticals sterility checks; (o) Film processor checks.

## 6. Pathology Laboratory

6.1. Equipment performance should be verified from Internal Quality Control results and External Quality Assessment results. Outlier parameter trend analysis record should be maintained in respect of its effect on the equipment. The frequency of performance check should be based on the day-to-day performance of the equipment

6.2. In case of large laboratory, all analytical equipment should be calibrated and calibration certificate provided by equipment company. Non-analytical equipment such as pipette, thermometer, weighing balance and centrifuge should be calibrated by accredited calibration laboratory or done in house.

6.3. The pathology laboratory should be provided with the Furniture & Fixtures as per norms:

6.4. Standard reagents of certified quality should be used for the purpose of analysis. The batch number of reagents should be recorded. The quality of the reagent viz. Analar grade, HPLC grade, etc. to be used for in house procedures should be defined in SOP. Those reagents are to be recorded in stock register.

6.5. Quality of newly purchased reagents should be validated against suitable control/reference material prior to use. Validation data should be properly documented. In-house prepared reagents should also be checked periodically for stability and a record of the same should be maintained.

6.6. Reagent label should contain name of reagent, concentration, date of preparation/opening, date of expiry, storage conditions and warnings eg. 'do not use if solution is turbid' where applicable. When individual bottles are small, this information can be recorded in a goods received ledger.

6.7. Microbiology laboratories should check activity/potency of each lot of antibiotic sensitivity discs before using and at least weekly thereafter with reference strains. Other microbiological consumables such as strips etc. used for identification should be checked

against reference strains. Laboratories testing microbiology specimens should check the quality of media by using appropriate reference strain and pH of the media.

6.8. All batches of culture containers should be checked for sterility before issuing to patients for collection of specimen.

6.9. Water quality should be checked for its grade and presence of interference elements. Reagent grade water according to IS1070:1992 of Bureau of Indian Standards (BIS) should be used for testing.

6.10. Depending upon the services available, the small, medium or large laboratory should be provided with (a) General equipment's for lab; (b) Equipment's for Clinical Pathology; (c) Equipment's for Histopathology; (d) Equipment's for Microbiology; (e) Equipment's for Haematology; (f) Equipment's for Biochemistry; (g) Equipment's for Serology.

6.11. General equipment for lab: Autoclave; Infection control coded bags and buckets; Equipment for collection and thereby transport of various specimens from outside the lab; Other miscellaneous necessary equipment depending upon the function of the lab, needle destroyer stopwatch, slid trays, test tube stands, stop watch etc

6.12. Equipment for Clinical Pathology: Binocular Microscopes; Auto-analyzer/multi-functional for haematology and biochemistry; Coagulometer; Colorimeter; Centrifuge; Water bath; Refrigerator; ESR tubes; Counting chambers; Micro pipettes; Preservative vials preferably vacutainers; Glass slides; Disposal methods for collections of specimen.

6.13. Equipment for Histopathology: Automatic tissue processor or standard methods of hand processing; Hot air oven; Hot Plate; Microtome (rotatory); Automatic knife sharpener or standard method; Water bath with thermostat; Glass specimen containers (small & large); Tissue cassettes with lids (steel made); L molds (large and small); Spirit lamps; Wax (paraffin with ceresin) melting point 58-600 c.; Slides and cover slips; Diamond pencils; Surgical grossing instruments eg. knife, scissors, forceps, blades etc; weighing machine (electronic preferred); Disposables gloves, masks and white coats; Kits for immunohisto chemistry and other necessary equipment; Stains and other reagents.

6.14. Equipment for Microbiology: Various media for culture and sensitivity; Swab sticks, transport media, universal containers, blood culture bottles; Antibiotics disks; Biological safety cabin II; Discard jars and disinfectants; Loops, wires, spirit lamps etc.

6.15. Equipment for Haematology: Microscope; Cell Chamber; Cell Counter (Preferable); Haemocytometer; Haemometer, etc.

6.16 Equipment for Biochemistry: Centrifuge; Colorimeter/Semi-autoanalyzer; Refrigerator; Micropipettes; Water bath etc.

6.17. Equipment's for Serology: Centrifuge; Refrigerator; Water bath; Incubator etc.

## 7. X-Ray lab

7.1. X-ray equipment for medical diagnostic purposes need to be purchased from approved vendor. There should be installation of "Type approved" X-ray equipment for medical diagnostic (Certificate of "Type Approval" to be obtained from AERB). Any radiation equipment/radiation installation should be commissioned only after all aspects including design, planning construction and operation have been duly approved by the AERB.

7.2. X ray machines should be of 100-1000 MA (as per scope of services), dental X-ray of 6MA and OPG X-ray of 4.5 to 10 MA. Each X-ray lab should be provided with the following protective accessories: Protection Screen; Lead apron 1-1.5 mm thickness upto 75 kV; Protective gloves; Protective goggles; Lead blocker for protection of generative organ or patients; Cones; film-badge etc.

7.3. The lab should be provided with: (1) Cassettes with intensifying screens; (2) Chair, (3) Dark room with safe light; (4) Dark room timer; (5) Film clips; (6) Film hanger and wall brackets; (8) Hanger for X-ray film; (9) Lead numbers for marking X-ray film; (10) Magnifying glass; (11) Step stools; (12) Revolving stool; (13) Tank thermometer; (14) Patients' trolley; (15) Wash basins with towel rail/liquid soap dispensers; (16) X-ray view box; (17) X-ray protection screen; (18) X-ray film processing tank; (19) X-ray film corner etc. An automatic film processor is desirable.

7.4. X-ray equipment's and protective clothing's should be checked from time to time. For this purpose, fluorescent screen should be used. Safe light provision and Developer tanks/tray is a should for Dark room. There should be appropriate resuscitation equipment and drugs available on site for management of contrast reactions.

7.5. All the equipment's should be checked and calibrated for at least the following: (a) Calibration of signal to noise ratio (wherever applicable); (b) Calibration of mA; (c) Calibration of kV; (d) Calibration of timer; (e) Check geometric distortion; (f) Check of Phantom image quality; (g) Check of functioning of film processing units etc.

7.6. In addition all the equipment should be checked and calibrated specifically for the following: (a) All X-ray machines should be calibrated as per AERB guidelines; (b) Calibration of mA; (c) Calibration of Kv; (d) Calibration of timer; (e) Check of collimeter/diaphragm/lead curtains; (f) Check of table movement and tilt; (g) Check phantom image quality; (h) Check of positioning accuracy; (i) Check of film processing unit etc.

### 8. *Mammography Lab*

8.1. There should be dedicated mammographic equipment with a grid and appropriate compression device. Mammographic biopsy attachment is desirable.

8.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Collimation alignment check; (b) Focal spot size measurement; (c) Beam quality half layer value HLV assessment; (d) Automatic exposure control(AEC) check; (e) Artefact evaluation; (f) Breast compression device check; (g) Screen cleanliness check.

### 9. *Ultrasonography*

9.1. The equipment should be registered under the PC-PNDT act as per rules and the certificate should be displayed. Registration of clinic is mandatory along with details of machine and radiologist/sonologist. The equipment should have convex, sector and linear probe with frequencies ranging from 3.5 MHz to 12MHz. Equipment for vascular studies should have colour Doppler imaging capability. There should be a trans-vaginal probe where pelvic imaging and obstetric imaging is offered and other endo-cavitary probes as per scope of services. Each USG Clinics should be provided with USG scanner, printer, CTV, table and couch for patient.

9.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Calibration of calipers; (b) Calibration of power output

### 10. Bone mineral densitometry

10.1. There should be a phantom/other calibration standards to evaluate the accuracy of Bone mineral density measurement. There should be software to compare with standards (specific to the equipment) which are age and gender related normal.

10.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Maintenance of QCT software, phantom and associated accessories; (b) Recalculation of LSC (least significant changes) in case of replacement of a CT scanner, CT X-ray tube, recalibration of CT scanner or modification to the QCT accessory components.

### 11. MRI

11.1. MRI equipment should meet the requirements for safety in medical diagnosis. MRI equipment should also meet safety requirements for machinery, electronic and medical devices associated with the unit. An automatic film processing unit should be linked to the MRI for documentation purposes.

11.2. In addition all the equipment should be checked and calibrated specifically for the following: (a) Calibration centre of frequency; (b) Check of shimming; (c) Check of gradient linearity; (d) Check of spikes; (e) Check of auditory noise level; (f) Check of ghost intensity; (g) Quench pipe of MR should be safely positioned; (h) Equipment in the unit should be MR compatible including trolleys; (i) Certificate of fitness for use by manufacturer for units more than 10yrs old.

11.3. The equipment should be registered under the PC-PNDT act as per rules and the certificate should be displayed. Registration of clinic is mandatory along with details of machine and radiologist/sonologist. Signages in local & English language should be displayed, indicating that "Sex determination is not done here. It is a punishable offence".

### 12. CT scan

12.1. Whole body CT Scan with scan cycle less than 1 sec (sub second). Installation of all equipment's should be approved by AERB. Basic life support and resuscitation equipment and drugs should be available on site.

12.2. The tube housing, Beam limiting devices, Beam filtration, scan plane accuracy couch position accuracy, Beam-ON indicators, scan increment accuracy, gantry aperture clearance, Image receptors, visual indicators, timer and warming conditions should be as per AERB Safety Code No. AERB/MED-20(Rev.1).

12.3. In addition all the equipment should be checked and calibrated specifically for the following: (a) Calibration of signal to noise ratio; (b) Calibration of mA; (c) Calibration of Kv; (d) Check of phantom image quality; (e) Check for radiation leakage wherever lead glass is installed; (f) Calculation of dose for each case and a log/record of the same should be maintained; (g) Certificate of fitness for use by the manufacturer for machines more than 10 yrs. old.

### 13. Interventional radiology

13.1. There should be fixed high resolution image intensification system with a minimum field of 25cms. Sites performing angiography should have digital acquisition and subtraction facilities. The angiographic injector should be capable of injecting varying rates and volumes and it should have appropriate safety mechanism to prevent over-injection.

13.2. Mobile intensifiers are not recommended for diagnostic angiography on a routine basis due to their limitation and image quality and data handling and also increased requirement of contrast and increased radiation dose and produces suboptimal images of thick body parts.

13.3. There should be facilities for patient monitoring by ECG/BP monitoring/pulse oxymetry /monitoring of direct pressure gradients as required by the scope of services listed.

13.4. The supply of diagnostic and therapeutic devices should be sufficient to support the range of services offered and for treatment of possible complications arising therein (e.g. transcutaneous ultrasound, intra arterial ultrasound, thrombectomy and arthrectomy devices, with associated catheters, tissue ablation devices).

13.5. There should be adequate protective measures as per AERB guideline.

TABLE IV  
Standards for Water, Sanitation, Hygiene, Safety and Security

*Part I: General*

*Introduction*

The clinical establishment should maintain the Water, Sanitation, Hygiene Safety & Security standards and norms as specified in this schedule or any such standards and norms as may be notified from time to time.

*1. Location and surroundings*

1.1 The clinical establishment should be situated in a site having clean & hygienic surroundings free from nuisance and should not be adjacent to an open sewer drain, filth, garbage bins or public lavatory or to a factory emitting smoke or obnoxious odor or public conveniences and any surrounding in unsanitary condition.

1.2 The clinical establishment should not be located in a dingy, damp or otherwise unsuitable building and premises in unsanitary condition. The site should be compatible with other considerations such as accessibility and availability of services and should be approved by the appropriate authority.

1.3 No clinical establishment shall be allowed to function from an unsafe building.

*2. Health, Clothing and Sanitary Requirements of staff*

The staff employed should be free from contagious disease and should be provided with clean uniforms suitable to the nature of their duties. The workers should be medically examined at the time of employment and periodically so examined thereafter. There should be facilities for medical checkup of hospital staff of all categories particularly cooks and staffs of the dietary department.

*3. Sanitation & Hygiene*

All the rooms/wards should be properly ventilated and have adequate lighting facilities. There should be adequate Sewage Disposal arrangement.

*4. General Water Supply:*

4.1 Arrangement should be made to supply adequate quantity and quality of water. The inpatient facilities with more than 30 beds should have supply of at least 350 litres of potable, wholesome water per day, per bed to meet all requirements (including laundry), except fire fighting.

4.2 The term “Wholesome water” means water that is: (a) free from pathogenic agents; and (b) free from harmful chemical substances; and (c) pleasant to the taste, i.e. free from colour and odour and (d) usable for domestic purposes.

4.3 Storage capacity for minimum 48 hours requirement should be made on the basis of above consumption. Arrangement should be provided to ensure uninterrupted water supply for operation theatre.

4.4 In case of inpatient facilities with more than 30 beds, hot water supply to wards and departments of the general hospital should be provided by means of electric storage type water heaters or centralized hot water system of capacity depending upon the need of hot water consumption.

#### 5. *Signage*

The clinical establishment should have: (a) properly displayed safety signs, for example, (a) signs of identification of safety equipment's such as fire extinguishers, (b) signs to identify hazards and hazardous activities, (c) signs to delineate public areas from area of restricted access.; etc.;

#### 6. *Standard Fire safety measures*

It should be provided as per The Goa Fire Safety Act/Rules and guidelines issued by that department.

#### 7. *Standard Biosafety Measures*

7.1. Entry into Laboratory/work area should be restricted. Staff should be attired with proper suitable clothing for working in the laboratory. Work surfaces should be disinfected when procedures are completed and at the end of each working day.

7.2 Gloves should be worn for all handling of infectious material. Examination gloves of vinyl or latex should be used in laboratory, ward, and operation theatre. General purpose utility gloves (i.e. rubber gloves or household gloves, reusable) should be used while cleaning instruments, decontamination procedures and other activities where manual dexterity is not required.

In operation theatres and delivery rooms, cleaning should be carried out every day. Cleaning with suitable disinfectant has to be carried out and swabs should be sent to laboratory for cultures regularly. Fumigation should be done as and when necessary. Records for the same should be maintained so that they can be scrutinized periodically. All horizontal surfaces including floor should be mopped between cases.

All medical instruments should be properly sterilized. Hepatitis vaccine should be provided for all personnel. Adequate arrangements for pest and rodent control should be provided by the clinical establishment.

#### 8. *Safety measures against Disaster*

It should be provided as per IPHS guideline.

### Part II. Specific

#### A. *Radiation safety*

Rooms housing diagnostic Xray units and related equipment should be located preferably on ground floor as far away as feasible from areas of high occupancy and general traffic, such as maternity and pediatric wards and other departments of the hospital. The X-Ray lab should take due safeguards against the radiation protection and should adhere to prescribed regulations of AERB which are amended from time to time.

### B. Water supply

Filtered and soft water supply should be arranged in pathology laboratories. Cold water supply should be arranged for processing tanks in film developing room, Water for Dialysis unit should be de-ionized using reverse osmosis process and disinfected by ultraviolet radiation.

### C. Biosafety Measures in clinical lab

(i) The lab should ensure Safety in laboratories therefore includes protection of both the staff and the environment from hazardous materials because (a) the Personnel working in laboratories is at risk from various chemicals, infectious materials, fire hazard, gas leak etc. and (b) The environment is also at risk of being contaminated by hazardous materials used and wastes generated in the laboratory.

(ii) Regarding biosafety, the labs should follow the Four levels of biosafety laboratories (BSL) developed by World Health Organization (WHO).

(iii) Goa State Pollution Control Board authorisation shall be mandatory.

(iv) Bio Medical Waste shall be disposed off as per the Bio Medical Waste Management Rules, 2016.

### 5. Minimum requirement of personnel shall be as follows:

Every Clinical Establishment shall fulfil following minimum requirement of personnel

(1) The Clinical establishment shall ensure that all service providers engaged or empanelled by him are registered under law regulating their registration and in the absence of such law, hold such qualifications and/or possess such experience as to provide care to patients.

(2) Each such engagement or empanelment shall be substantiated by an offer letter issued by the clinical establishment and an acceptance letter by the service provider: except where the proprietor and the service provider is the same person.

(3) The Clinical establishment shall ensure that any service providers engaged in the clinical establishment submits all particulars relating to his registration, qualification, training, experience and skill and the No Objection Certificate.

(4) The Clinical establishment shall retain such offer letter or acceptance letter and copies of such certificates of Registration and certificate of qualification and shall produce such documents at the time of inspection or enquiry or on demand by the authority.

*Explanation:* (i) "Certificate of registration" means the registration certificate awarded by the respective council in case of Registered Medical Practitioner, Registered Nurse or Midwife, and Registered Paramedical Technician.

(ii) "Certificate of qualification" means the certificate, diploma or degree awarded by university or any such competent authority.

(5) Every Clinical establishment shall comply with minimum qualification in respect of health service providers and other persons as specified in Table II in rule 4.

(6) The authority shall have the power to seek reasonable assistance from any authority to verify the authenticity, the applicability and appropriateness of any such qualification in such a manner as he deems fit.

(7) A patient or patient has the right to know-

(a) the method of identification of staff through uniforms, badges or other methods; and

(b) the names and professional status of the staff providing care or treatment to the patient.

(8) An identity card issued under the signature of the Proprietor of clinical establishment with more than 30 beds shall include but not limited to the following particulars-

- (a) the name of the clinical establishment and its License Number.
- (b) the name, designation, and prefix, suffix, where applicable.
- (c) a recent photograph of the staff; and
- (d) the signature.
- (e) any other relevant particulars.

(9) The identity card shall be worn by the staff when he is in the premises.

In case of clinical establishment with less than or equal to 30 beds, Tag mentioning name and designation of the staff shall be provided by proprietor of Clinical Establishment.

#### II *Availability of Manpower*

(1) Every Clinical establishment shall comply with the provisions of rule 5 and other norms with respect of health service providers.

(2) The Proprietor of clinical establishment shall—

(a) generate and maintain an up-to-date Staff Register in which names, designation, present and permanent addresses, qualification(s), date of engagement etc. of all staff of the clinical establishment shall be entered; and

(b) generate and maintain an up-to-date Register in which attendance of all staff of the clinical establishment are to be recorded daily.

(3) Failure to put signature in daily attendance by any staff shall be considered as contravention resulting in minor deficiency under the Act.

6. *Maintenance of medical record and reporting by Clinical Establishment.*— (1) The clinical establishment shall maintain the following medical records and submit following reports namely:

#### *Mandatory Record Keeping*

(i) clinical establishment shall generate and maintain,-

- (a) a record of health case sheet of every patient.
- (b) a register for in-patient.
- (c) a staff register.
- (d) a staff attendance register.

*Explanation:* In the in-patient register, the name and particulars of all the patients admitted including the child born to a woman admitted there have to be registered and recorded even if the new-born may not be sick. Child born to admitted women shall be registered as separate patient only if the child born is sick and requires special medical and nursing care.

(ii) Where an entry made in the IPD register referred in sub-clause (i) above relates to a woman who has been admitted for delivery, and a child born to such woman is removed with the consent of the clinical establishment and of the parents, or near relative then such clinical establishment shall in addition to the particulars specified in sub-clause (i), also specify in the register the name and address of the person who has taken custody of the child and the date on which and the reasons for which the child was so removed.

(iii) The hard copy of the registers shall have machined-pressed page number and shall be duly authenticated by the Proprietor.

(iv) The records and register shall bear the name of the clinical establishment along with the License number.

(v) Similarly all documents and stationary including treatment charts, reports, cash memo, bill etc. used by the clinical establishment shall bear the name of the clinical establishment.

(vi) Hard Copies of all records, register and documents shall be kept in the record room for at least five years or in the event of any proceeding till the final disposal of the proceeding.

(vii) The records, registers and documents shall be entered fully, chronologically and legibly and shall not be tampered with.

(viii) The Proprietor of the clinical establishment shall ensure that all the Registered Medical Practitioners of the clinical establishment are following the guideline of Medical record keeping issued by the Medical Council of India or the guidelines as may be notified from time to time.

(ix) Every record, register and document generated and maintained by the Clinical Establishment shall be open to inspection by the Authority or any other officer specifically empowered in his behalf.

(x) All reports, medical, medico-legal, mandatory or of any kind generated by the Clinical establishment shall be signed in ink and properly dated and shall be produced at the time of inspection or enquiry or on demand by the authority.

#### *B. Mandatory Display*

(i) At a conspicuous place in the premises of the clinical establishment be displayed the license in original so as to be visible to everyone visiting such establishment.

(ii) At reception area and other conspicuous place(s), the clinical establishment shall make available Information Display Board(s) containing appropriate, adequate and comprehensive information written in both the local and English language in a manner understood by a non technical person.

(iii) Information mentioned in clause (ii) shall include but not limited to-

(a) the name of the establishment with names of the Proprietors along with the license Number;

(b) the system(s) of medicine practiced, types and availability of health care and other services;

(c) name of empanelled service providers including visiting consultant, if any;

(d) availability of concession of rate of charges, if any;

(e) full contact details of the Grievance Officer with clear mention of the time of availability of the same;

(f) any other notice or information that may be required by the Authority or any Other statutory authority;

(g) in case of collection centre, the name and License Number of the mother laboratory and a certificate of affiliation; and

(h) Any other aspects of healthcare services, which may be of use to the public.

(iv) At reception area and other conspicuous place(s), the clinical establishment shall make available an Information Brochure containing appropriate, adequate and comprehensive information, written in both the local and English language for the benefit of the service recipient.

(v) Information mentioned under this sub clause (iv) shall include but not limited to-

(a) All information mentioned under sub-clause (iii);

(b) name, qualification, contact number of empanelled service provider including consultant, if visiting any;

(c) Schedules and timetables of visits of empanelled service providers including visiting consultant, if any;

(d) Working hours/timings of each Unit of the Clinical Establishment;

(e) Schedule of rate of charges payable for each type of services.

(vi) The clinical establishment shall submit a copy of Information, Brochure mentioned under sub-clause (iv) to the Authority along with the application for grant or renewal of license.

(vii) The clinical establishment shall inform the authority without delay on the amendments if any made in the information displayed.

(viii) Insurance empanelment.

(C) *Mandatory Reporting:*

(i) The clinical establishment shall report all births and deaths occurring in the clinical establishment to the appropriate authority within stipulated time. Reporting as regards various programmes, notified diseases and acts of Central/State Government shall be responsibility of the clinical establishment.

(ii) The clinical establishment shall submit a report regarding any unforeseeable or unanticipated events that has occurred at the clinical establishment to appropriate authority with a copy to the Authority by the next working day after the incident occurred or immediately after the incident occurred.

(iii) The reporting of unforeseeable or unanticipated events shall include, at a minimum, the following information:

(a) death of patient of the clinical establishment from unexplained cause or under suspicious circumstances, assault, battery or abduction of any patient, attempt of suicide by any patient; events of missing presumed to be absconding patient that are required to be reported to police;

(b) fire in the clinical establishment resulting in death or personal injury; or

(c) any act of violence or damage to the property; or

(d) malfunction or intentional or accidental misuse of patient care equipment that occurs during treatment or diagnosis of a patient of the clinical establishment and that did, or if not averted would, have significant adverse effect on the patient or staff of the clinical establishment; or

(e) confined or suspected outbreak of any disease; or

(f) any form of closure of suspension of work along with any follow up action taken or any other information whichever is relevant to the events.

(iv) The clinical establishment shall retain, for at least such period as specified under any written law pertaining to limitation period, all the information about investigation and findings regarding unforeseeable or unanticipated events so reported under clause (i).

(v) The Authority may demand further information of the unforeseeable or unanticipated events from the clinical establishment or any other person if he determines that the information is necessary for further investigation.

(vi) Clinical establishment shall not discriminate or retaliate against any person who in good faith provides any information under sub-clause (ii) or gives any evidence in any proceedings against the Clinical establishment or any person.

7. *Classification of Clinical Establishments.*— The Clinical Establishments of different systems shall be classified as under:

The Allopathic Hospitals will be broadly classified under following four levels:

(A) Hospital Level 1 (A) —

General Medical services with indoor admission facility provided by recognized allopathic medical graduate(s) and may also include general dentistry services provided by recognized BDS graduates.

*Example:* PHC, Government and Private Hospitals and Nursing Homes run by MBBS Doctors etc.

(B) Hospital Level 1 (B) —

This level of hospital shall include all the general medical services provided at level 1(A) above and specialist medical services provided by Doctors from one or more basic specialties namely General Medicine, General Surgery, Paediatrics, Obstetrics & Gynaecology and Dentistry, providing indoor and OPD services.

Level 1(A) and Level 1(B) Hospitals shall also include support systems required for the respective services like Pharmacy, Laboratory, etc.

*Example:* General Hospital, Single/Multiple basic medical Specialties provided at Community Health Centre, Sub Divisional Hospital, and Private Hospital of similar scope, Nursing Home, Civil/District Hospital in few places etc.

(C) Hospital Level 2 (Non-Teaching)

This level may include all the services provided at level 1(A) and 1(B) and services through other medical specialties given as under, in addition to basic medical specialty given under 1 (B) like:—

Orthopaedics

ENT

Ophthalmology

Dental

Emergency with or without ICU

Anaesthesia  
Psychiatry  
Skin Pulmonary Medicine  
Rehabilitation, etc.

And support systems required for the above services like Pharmacy, Laboratory, Imaging facilities, Operation Theatre etc.

*Example:* District Hospital, Corporate Hospitals, Referral Hospital, Regional/State Hospital, Nursing Home and Private Hospital of similar scope etc.

(D) Hospital Level 3 (Non-Teaching) Super-specialty services—

This level may include all the services provided at level 1(A), 1(B) and 2 and services of one or more or the super specialty with distinct department and/or also Dentistry if available. It will have other support systems required for services like pharmacy, laboratory, and Imaging facility, Operation Theatre etc.

*Example:* Corporate Hospitals, Referral Hospitals, Regional/State Hospital, Nursing Home and Private Hospital of similar scope etc.

(E) Hospital Level 4 (Teaching)—

This level will include all the services provided at level 2 and may also have Level 3 facilities. It will however have the distinction of being teaching/training institution and it may or may not have super specialties. Tertiary healthcare services at this level can be provided through specialists and may be super specialists (if available). It will have other support systems required for these services. It shall also include the requirement of MCI/other registering body for teaching hospitals and will be governed by their rules. However registration of teaching Hospitals will also be required under Clinical Establishment Act for purpose other than those covered under MCI such as, records maintenance and reporting of information and statistics, and compliance to range of rates for Medical and Surgical procedures, etc.

The categorisation of clinical establishments based on location, ownership, systems of medicine, type, size, services offered, specialty, etc. are as follows:

(a) *Location:*

Rural  
Urban  
Metro  
Notified/inaccessible areas (including Hilly/tribal areas)

(b) *Ownership:*

(a) Government/Public  
(i) Central Government  
(ii) State Government  
(iii) Local Government (Municipality, Zillaparishad, etc)  
(iv) Public Sector Undertaking  
(v) Other ministries and departments (Railways, Police, etc.)  
(vi) Employee State Insurance Corporation  
(vii) Autonomous organization under Government

(b) Non-Government/Private.

- (i) Individual Proprietorship
- (ii) Partnership
- (iii) Registered companies (registered under central/provincial/state Act)
- (iv) Society/trust (Registered a central/provincial/state Act)

(c) Systems of Medicine in the establishment

- (a) Allopathy (modern medicine)
- (b) Any one or multiple disciplines of AYUSH (as defined by the Ministry of AYUSH, GOI)

(d) Type/size:

The type and size of clinical establishments shall be as under:

(1) Clinics (outpatient)— The Clinics shall be categorized as follows:

- Single practitioner (Consultation services only/with diagnostic services/with shortstay)
- Polyclinic (Consultation services only/with diagnostic services/with shortstay)
- Dispensing
- Health Check up Centre

(2) Day Carefacility

- Medical/Surgical
- Medical SPA
- Wellness centres (where qualified medical professionals are available to supervise the services).

(3) Hospitals including Nursing Home (outpatient and inpatient)-a health care institution providing patient treatment by specialized staff and equipment.

The Hospitals including Nursing Homes should be categorized based on the following criteria.

- General Practice
- Single specialty
- Multi-specialty (including Palliative care Centre, Trauma Centre, Maternity Home)
- Super specialty

The fields of clinical medical and surgical specialty and super specialty shall be as per list of Medical Council of India regulation and currently it will cover following:

(a) *Medical Specialties*.— for which candidates must possess recognized post graduate degree of M.D. (DOCTOR OF MEDICINE) or Diploma (or its equivalent recognized degree/diploma)

- d) Anesthesiology
- e) Aviation Medicine
- f) Community Medicine
- g) Dermatology, Venerology and Leprosy

- h) Family Medicine
- i) General Medicine
- j) Geriatrics
- k) Immuno Haematology and Blood Transfusion
- l) Nuclear Medicine
- m) Paediatrics
- n) Physical Medicine Rehabilitation
- o) Psychiatry
- p) Radio-diagnosis
- q) Radio-therapy
- r) Rheumatology
- s) Sports Medicine
- t) Tropical Medicine
- u) Tuberculosis & Respiratory Medicine or Pulmonary Medicine

(b) *Surgical specialties*.— for which candidates must possess, recognized degree of M.S. (MASTER OF SURGERY) or Diploma (or its equivalent recognized degree).

- a) Otorhinolaryngology
- b) General Surgery
- c) Ophthalmology
- d) Orthopaedics
- e) Obstetrics & Gynaecology including MTP & Artificial Reproductive Techniques (ART) Centres

(c) *Medical Super specialties*—

- a) Cardiology
- b) Clinical Hematology including Stem Cell Therapy
- c) Clinical Pharmacology
- d) Endocrinology
- e) Immunology
- f) Medical Gastroenterology
- g) Medical Genetics
- h) Medical Oncology
- i) Neonatology
- j) Nephrology
- k) Neurology
- l) Neuro-radiology

d) *Surgical Super specialties*—

- a) Cardiovascular thoracic Surgery
- b) Urology

- c) Neuro-Surgery
- d) Paediatrics Surgery.
- e) Plastic & Reconstructive Surgery
- f) Surgical Gastroenterology
- g) Surgical Oncology
- h) Endocrine Surgery
- i) Gynecological Oncology
- j) Vascular Surgery

As regards to the definition of services provided at specialty and super specialty or multi-specialty allopathic hospitals the same shall be categorized based on level of care into:

- a) Hospital Level 1a
- b) Hospital Level 1b
- c) Hospital Level 2
- d) Hospital Level 3 (Non teaching)
- e) Hospital Level 4 (Teaching)

(4) *Dental Clinics and Dental Hospital:*

- a) Dental clinics
  - i) Single practitioner
  - ii) Poly Clinics (dental)
- b) Dental Hospitals (specialties as listed in the IDC Act)
  - i) Oral and Maxilla Facial Surgery
  - ii) Oral Medicine Andradiology
  - iii) Orthodontics
  - iv) Conservative Dentistry and Endodontics
  - v) Periodontics
  - vi) Pedodontics and Preventive Edentistry
  - vii) Oral Pathology and Microbiology
  - viii) Prosthodontics and Crownbridge
  - ix) Public Health Dentistry

(5) *Diagnostic Centers*

a) *Medical Diagnostic Laboratories:* There are two main types of labs that process the majority of medical specimens. Hospital laboratories are attached to a hospital, and perform tests on patients. Private (or community) laboratories receive samples from general practitioners, insurance companies, clinical research sites and other health clinics for analysis. These can also be called reference laboratories where more unusual and obscure tests are performed. Clinical Laboratories could be general Labs and/or Advanced Labs that provide services in the following fields:

- Pathology
- Bio-chemistry
- Microbiology

Molecular Biology and Genetic Labs

Virology

b) Diagnostic Imaging centres: Diagnostic Imaging centres could be general and/or Advanced that provide following services:

i) Radiology

General radiology

Interventional radiology

ii) Electromagnetic imaging (Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET)Scan)

iii) Ultrasound

c) Collection centres for the clinical labs and diagnostic centres shall function under registered clinical establishment

(6) *Allied Health professions*:— Allied health professions generally indicate that they are health professions distinct from medicine, dentistry, pharmacy and nursing. The list of allied health professions includes but is not limited to the following disciplines:

Audiology

Behavioural health (counselling, marriage and family therapy etc.)

Exercise Physiology

Nuclear medicine technology

Medical Laboratory Scientist

Dietetics

Occupational and Industrial Health

Optometry

Orthoptics

Orthotics and Prosthetics

Osteopathy

Paramedic

Podiatry

Health Psychology/Clinical Psychology

Physiotherapy

Radiation Therapy

Radiography/Medical Imaging

Respiratory Therapy

Sonography

Speech Pathology

(7) *AYUSH*

Ayurveda Ausadh Chikitsa, Shalya Chikitsa, Shodhan Chikitsa, Rasayana, Pathya Vyavastha  
Yoga Ashtang Yoga

Unani Matab, Jarahat, Ilaj-bit-Tadbeer, Hifzan-e-Sehat

Siddha Maruthuvam, Sirappu Maruthuvam, Varmam Thokknam & Yoga

Homeopathy General Homeopathy

Naturopathy External Therapies with natural modalities Internal Therapies

8. *Standards for different categories of Establishments.*— In Addition to the minimum standards of facilities and services as specified in rule 4, the Clinical Establishments of different categories shall have following standards, namely:—

(A) *Allopathy System*

The standards for Allopathic hospitals as classified in rule 7 shall be such as specified in Appendix I hereto.

(B) *Indian System of Medicine and Homoeopathy*

I. *Consulting Room/Clinic/Polyclinics*

1. *Building.*— The Consulting room shall be spacious, well ventilated and having sufficient light. The space shall be not less than 100 square feet. There shall be sufficient space for waiting of the patients etc., If it is a polyclinic, different cubicles shall be available for each doctor. The names of visiting doctors and their system of medicine shall be exhibited in front of the clinic.

2. *Staff.*— The clinics namely, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy Clinics shall be manned by the Registered Medical practitioner. If the pharmacy attached with the clinic, dispensing of medicines shall be done by a Pharmacist qualified under the respective system or by the doctor himself.

3. *Equipment.*— (a) Diagnostic equipment's ordinarily needed for all AYUSH, Indian System of Medicine and Homeopathy and Yoga and Naturopathy Clinics:

- (i) Thermometer
- (ii) Sphygmomanometer
- (iii) Stethoscope
- (iv) Knee hammer
- (v) Tongue Depressor
- (vi) Torch
- (vii) Weighing machine

4. *Drugs.*— The drugs dispensed to the patients shall contain a label indicating the name of medicine and the name of patient to whom it is given and quantity to be given etc., the date of expiry shall be specified in the label, if the drug has an expiry date. The drug to be given internally and the drug to be used externally shall be indicated and white and red labels to be provided respectively with clear writing as "For Internal use" or "For External Use" in vernacular.

5. *Records.*— A record of all patients seen as to their name, age, sex, diagnosis and treatment shall be available. The patient shall be provided with a slip with name, age, sex, diagnosis of treatment given.

(C) *General Conditions to be fulfilled by the hospitals under Allopathy and Ayush.*

(1) *Communication.*— A telephone connection shall be available for use by patients (on payment)

(2) *Security*.— Sufficient security shall be provided for the safety of inmates and to prevent theft.

(3) *Fire Fighting*.— Fire fighting equipment with I.S.I. mark shall be provided as per rules in the hospital.

(4) *Kitchen*.— If food is provided to inmates, the kitchen shall be clean and the cook(s) shall be periodically, medically examined for any infection or contagious diseases.

(5) *Clothing and Linen*.— It shall be clean and changed daily.

(6) *Water Supply*.— The potable water shall be provided to the patient.

(7) *Waste Disposal*.— It shall be as per the Government of India norms and shall follow the guidelines of Goa State Pollution Control Board.

(8) *Record Maintenance*.— (a) Every Clinical Establishment shall maintain the permanent records pertaining to details of the employees as well as the clinical records pertaining to the patients. The records shall be kept open for inspection by the competent authority or any other officer authorized in this behalf.

(b) Every Private Clinical Establishment shall make available a copy of list of observation, treatment etc., pertaining to the patient on payment of necessary charges within the reasonable time. Every Clinical Establishment shall display at a prominent place the charges for obtaining such information.

(c) Every Clinical Establishment may refuse to furnish such information, if such information is likely to cause injury to the person or his family members or if the treatment has been conducted on the direction of a public authority.

(D) *Diagnostic Labs*:

The minimum standards for Diagnostic Laboratories shall be as specified in Appendix II hereto.

9. *Form of Application, fee etc.*— (1) An application for certificate of provisional registration of the Clinical establishment shall be made in Form I hereto and it shall be accompanied by fees as specified in the table below:

The receipt of such application shall be acknowledge by acknowledgement in Form II hereto.

TABLE

Description	Urban		Rural	
	Fee for Provisional Registration	Fee for Permanent Registration	Fee for Provisional Registration	Fee for Permanent Registration
Out Patient Care	Rs. 500	Rs. 1000	Rs. 250	Rs. 500
In Patient Care	Rs. 1500	Rs. 3000	Rs. 750	Rs. 1500
Testing and Diagnostic	Rs. 2500	Rs. 5000	Rs. 1250	Rs. 2500

Other fees:

(i) For Renewal, fee will be same as registration fee (Provisional/Permanent).

(ii) For Late Application, enhanced fee equivalent to double of the registration fee for Provisional/Permanent registration shall be charged.

(iii) For Duplicate Certificate, the fee of Rs 1000/- shall be charged .

(iv) Change of Ownership, Management or Name of Establishment, the fee of Rs 2000/- shall be charged.

(v) For any appeal the fee shall be Rs. 1000/-.

If a laboratory or diagnostic centre is a part of a Establishment providing Outpatient/Inpatient care no separate registration is required if the management is same. However, fee as applicable above would have to be paid.

10. *Form of Certificate of Provisional registration.*— The Certificate of provisional registration shall be issued to the establishment in Form III hereto.

11. *Manner of Publication of Particulars of Clinical Establishment.*— The particulars of the Clinical Establishment registered provisionally shall be published by uploading the same on the official website of the respective Collector.

12. *Fee for duplicate certificate:*— A duplicate certificate shall be issued under section 16 on payment of fee as specified in rule 9.

13. *Manner of Informing change of ownership/management:*— The Clinical establishment shall inform the authority of any change in ownership or management in Form IV hereto within a period of one month from the date of such change and make application for fresh certificate of provisional registration, as the case may be, which shall be accompanied by fee as specified in rule 9.

14. *Publication of expiry of registration:*— The authority shall in the month of December of every year publish the names of all clinical establishments whose registration has expired, in atleast two local newspapers having wide circulation in the State and also on the official website of the respective Collector.

15. *Application for Certificate of Permanent registration:*— 1) Every application for certificate of permanent Registration shall be made in Form V hereto and it shall be accompanied by fee as specified in rule 9.

2) The receipt of such application shall be acknowledged in Form II hereto.

16. *Submission of Evidence:*— The Clinical Establishment shall submit evidence of having complied with the prescribed minimum standards in Form VI hereto.

17. *Display of information for filing objection:*— The evidence submitted by the Clinical Establishment of having complied with prescribed minimum standards shall be displayed on official website by the Authority by a public notice for inviting objections, if any, in form VII hereto.

18. *Certificate of Permanent registration:*— The Authority shall issue a certificate of permanent registration to the clinical establishment under sub-section (1) of section 27 of the Act in VIII hereto.

19. *Fee for renewal of permanent registration:*—

The renewal fee and the enhanced fee referred in sub-section (4) of section 27, shall be as specified in rule 9.

20. *Manner of Entry and Search:*— (1) Entry and search of the Clinical Establishment may be done by the Authority or an officer duly authorized by it or subject to such general or special orders as may be made by the authority.

(2) Such entry and search of clinical establishment can be conducted if anyone is carrying on a Clinical Establishment without registration or does not adhere to the prescribed minimum standards or has reasonable cause to believe that the Clinical Establishment is being used for purposes other than that it is registered or contravenes any of the provisions of the Goa Clinical Establishments (Registration and Regulations) Act, 2019 (Goa Act No. 19 of 2019) and the rules frame there under.

(3) The inspection team shall at all reasonable times enter and inspect any record, register, document, equipment and articles as deemed necessary.

(4) The inspection team shall normally intimate the Clinical Establishment in writing about the date of visit. The team shall examine all portions of the premises used or proposed to be used for the Clinical Establishment and inspect the equipments, furniture and other accessories and enquire into the professional qualifications of the technical staff employed or to be employed and shall make any such other enquires as they consider necessary to verify the statements made in the application for registration and grant of license.

(5) All persons connected with the running of the Clinical Establishment shall be bound to furnish full and correct information to the inspection team. Surprise inspections may also be conducted by the inspection teams.

(6) The Officer and/or inspection team so constituted by the authority shall submit a report in form 9 hereto within fifteen days of the inspection to the authority with a copy to the council.

21. *Fee for different category of Establishments:*— (1) The fee for different category of establishments shall be as specified in rule 9.

(2) All fees shall be paid either by a demand draft or bank challan or through online mode of payment.

(3) The fees shall be deposited by the Authority in an account opened by the Council in a nationalised bank and such sum be utilized by Council for the activities connected with the implementation of the provisions of the Act.

22. *Appeal:*— (1) An Appeal under section 33 shall be preferred to the Council within a period of 30 days from the date of passing of the Order by authority or from the date of receipt of Order by the Clinical Establishment, whichever is later.

(2) Such an appeal shall be filed in form X hereto and it shall be accompanied by fees as specified in rule 9.

(3) After receipt of the appeal, the Council shall fix the time and date for hearing and issue notice hereof to the appellant and the authority.

(4) The appellant may represent himself or through an authorized person or a Legal practitioner and submit the relevant documentary material, if any, in support of the appeal.

(5) The Council shall hear all the concerned, receive the relevant oral/documentary evidence submitted by them, consider the appeal and communicate its decision preferably within a period of ninety days from the date of filing of the Appeal.

(6) If the Council considers that an interim order is necessary in the matter, it may pass such order, pending final disposal of the appeal.

(7) The decision of State Council shall be final and binding.

(8) If no appeal is filed against the decision of the Authority within the specified period, the decision shall be final.

(9) The fees collected by the authorities shall be deposited in a nationalized bank account opened by the Council and shall be utilized by the Council for the activities connected with the implementation of the provisions of the Act.

23. *Register of Clinical Establishments:*— The Authority shall maintain a digital register of Clinical Establishments registered by it in form XI hereto.

24. *Returns, Statistics and Other information:*— A Clinical Establishment shall furnish returns, statistics to the authority in Form XII hereto within thirty days of end of every quarter of an year.

25. *Inquiry*.— The Authority shall issue a show cause notice to the Clinical Establishment and to the person who carries on Clinical Establishment seeking a reply within fifteen days of receipt of notice. The authority shall provide a hearing to such person before passing any order.

By Order and in the name of the Governor of Goa.

*Gautami Parmekar*, Under Secretary (Health-II).

Porvorim, 5th July, 2021.

FORM I

[See Rule 9(1)]

Application for Certificate of Provisional Registration of Clinical Establishment

1. Name of the Establishment/Doctor: \_\_\_\_\_  
(in case of Single Practitioner): \_\_\_\_\_
2. Address: \_\_\_\_\_  
Village/Town: \_\_\_\_\_ State: \_\_\_\_\_  
Pin Code: \_\_\_\_\_ Tele/Mobile No.: \_\_\_\_\_  
Website : \_\_\_\_\_
3. Name of the Owner:  
Address: \_\_\_\_\_  
Village/Town: \_\_\_\_\_ State: \_\_\_\_\_  
Pin Code: \_\_\_\_\_ Tele/Mobile: \_\_\_\_\_  
Website: \_\_\_\_\_
- 3a. Name of person in-charge and Qualification: \_\_\_\_\_  
\_\_\_\_\_
4. Ownership:
  - a) Public Sector: Central Government  
State Government  
Local Government  
Public Sector Undertaking  
Any other (Please specify)
  - b) Private Sector: Individual Proprietorship  
Registered Partnership  
Registered Company  
Co-operative Society  
Trust/charitable  
Any other (Please specify)
5. Systems of Medicine offered: (please tick whichever is applicable)
  - \* Allopathy
  - \* Ayurveda
  - \* Unani
  - \* Siddha
  - \* Homeopathy
  - \* Yoga & Naturopathy

6. Services provided: (Please tick whichever is applicable)
- \* Inpatient
  - \* Outpatient
  - \* Laboratory/Imaging Centre
  - \* Any other (Please specify)
- a) Category of Clinical Services:
- \* General
  - \* Single Specialty
  - \* Multi Specialty
  - \* Super Specialty
- 7 Type of Establishment: (please tick whichever is applicable)
- a) Inpatient
- \* Hospital
  - \* Nursing Home
  - \* Maternity Home
  - \* Primary Health Centre
  - \* Community Health Centre
  - \* Sanatorium
  - \* Day Care Centre
- b) No. of Beds: \_\_\_\_\_
- c) Outpatient: \* Single practitioner
- \* Polyclinic
  - \* Sub Centre
  - \* Physiotherapy Clinic
  - \* Dialysis Centre
  - \* Any other (please specify)
- d) Laboratory: \* Pathology
- \* Haematology
  - \* Biochemistry
  - \* Microbiology
  - \* Genetics
  - \* Collection Centre
  - \* Any other (please specify)
- e) Imaging Centre (Please specify)
- Special diagnostic: Please specify: \_\_\_\_\_

I hereby declare that the statements above are correct and true to the best of my knowledge and shall abide all the rules and declarations under the Clinical Establishment (Registration and Regulation) Act, 2010. I undertake that I shall intimate to the appropriate registering authority any change in the particulars given above.

Date:

*Signature of authorized signatory*

FORM II

[See Rule 9(2) and rule 16(2)]

ACKNOWLEDGMENT OF CERTIFICATE OF PROVISIONAL/PERMANENT  
REGISTRATION OF CLINICAL ESTABLISHMENT

The application in Form \_\_\_\_\_ for Grant/Renewal of Provisional/Permanent registration of the Clinical Establishment submitted by \_\_\_\_\_ (name and address of owner) has been received by the District Registration Authority on \_\_\_\_\_ (date) and found to be

Complete

Or

Incomplete

This acknowledgement does not confer any rights on the applicant for grant or renewal of registration.

Signature and Designation of Registration Authority or authorised person in the Office of the Appropriate Authority.

Seal

Designation of the Issuing Authority  
Place and Date

FORM III

[See Rule (10)]

CERTIFICATE OF PROVISIONAL REGISTRATION OF CLINICAL ESTABLISHMENT

Provisional Registration No. (Computer generated)

Date of Issue:(Computer generated)

Valid upto:(Computer generated)

1. Name of the Clinical Establishment: \_\_\_\_\_
2. Address: \_\_\_\_\_
3. Owner of the Clinical Establishment: \_\_\_\_\_
4. Name of Person In charge: \_\_\_\_\_
5. System of Medicine: \_\_\_\_\_
6. Type of Establishment: \_\_\_\_\_

Is hereby provisionally registered under the provisions of Clinical establishments (Registration and Regulation) Act, 2019 and the Rules made there under.

This authorization is subject to the conditions as specified in the said Act and rules made there under.

Seal

Designation of the Issuing Authority

Place and Date

District Registration Authority

Address:

Phone Number in case of Grievances

FORM IV

[See Rule (13)]

INFORMATION ON CHANGE OF OWNERSHIP/MANAGEMENT OF CLINICAL ESTABLISHMENT

To,  
The District Registering Authority  
Clinical Establishments Act & Rules

Sir/Madam,

I, Dr./Shri..... hereby inform you that there is change in the ownership/management of the establishment by name..... having permanent/provisional registration No. .... dated.....located at.....and owned/managed by.....

The new management/ownership is as under:

1. Name of the clinical establishment:
2. Address:
3. Owner of the clinical establishment:
4. Name of the person in charge:
5. System of medicine:
6. Type of establishment:

I hereby surrender the old certificate of Registration and request you to issue new certificate of Registration by incorporating the abovementioned changes.

I am enclosing herewith draft of Rs. ....

Thanking you,

Place  
Date

*Signature and Name*

\_\_\_\_\_

FORM V

[See Rule (15)]

APPLICATION FOR CERTIFICATE OF PERMANENT REGISTRATION

I. ESTABLISHMENT DETAILS

1. Name of the establishment: \_\_\_\_\_
2. Address: \_\_\_\_\_  
 Village/Town: \_\_\_\_\_ Block: \_\_\_\_\_  
 District: \_\_\_\_\_ State \_\_\_\_\_ Pincode \_\_\_\_\_  
 Tel No.(with STD code): \_\_\_\_\_ Mobile: \_\_\_\_\_ Fax: \_\_\_\_\_  
 Email ID: \_\_\_\_\_ Website(if any) \_\_\_\_\_
3. Month and Year of starting: \_\_\_\_\_  
 (From 4 to 11 mark all whichever are applicable)
4. Location:  
 Rural                      Urban                      Metro  
 Notified/inaccessible areas (including Hilly/tribal areas)
5. Ownership of Services

Government/Public Sector Central Government State Government Local Government  
(Municipality, Zilla parishad, etc.)

Public Sector Undertaking Other ministries and Departments (Railways, Police, etc.) Employee  
State Insurance Corp Autonomous organization under Government.

Non-Government/Private Sector

Individual Proprietorship Partnership Registered companies (registered under central/provincial/  
/State Act) Society/trust (Registered under central/provincial/state Act)

6. Name of the owner of Clinical Establishment: \_\_\_\_\_

Address: \_\_\_\_\_

Village/Town: \_\_\_\_\_ Block: \_\_\_\_\_ District: \_\_\_\_\_ State: Pin code: \_\_\_\_\_

Tel No (with STD code): \_\_\_\_\_ Mobile: \_\_\_\_\_ Fax: \_\_\_\_\_

Email ID: \_\_\_\_\_

7. Name, Designation and Qualification of person in-charge of the Clinical Establishment: \_\_\_\_\_

Qualification(s): \_\_\_\_\_

Registration Number: \_\_\_\_\_

Name of Central/State Council (with which registered): \_\_\_\_\_

Tel. No. (with STD code): \_\_\_\_\_ Fax: \_\_\_\_\_ Mobile: \_\_\_\_\_

E-mail ID: \_\_\_\_\_

8. Systems of Medicine offered: (please tick whichever is applicable)

Allopathy Ayurveda Unani Siddha Homoeopathy Yoga Naturopathy Sowa-Rigpa

9. Type of establishment: (please tick whichever is applicable)

(I). Clinic (Outpatient)

- Single practitioner  
(Consultation services only/with diagnostic services/with short stay facility)
- Polyclinic  
(Consultation services only/with diagnostic services/with short stay facility)
- Dispensary
- Health Checkup Centre

(II). Day Care facility

Medical Surgical Medical SPA Wellness centers (where qualified medical professionals are available to supervise the services).

(III). Hospitals including Nursing Home (outpatient and inpatient):

- Hospital Level 1a
- Hospital Level 1b
- Hospital Level 2
- Hospital Level 3 (Nonteaching)
- Hospital Level 4 (Teaching)

(IV). Dental Clinics and Dental Hospital:

- a. Dental clinics
  - i. Single practitioner
  - ii. Poly Clinics(dental)
- b. Dental Hospitals (specialties as listed in the IDC Act.)

- i. Oral and maxilla facials surgery
- ii. Oral medicine and radiology
- iii. Orthodontics
- iv. Conservative dentistry and Endodontics
- v. Periodontics
- vi. Pedodontics and preventive dentistry
- vii. Oral pathology and Microbiology
- viii. Prosthodontics and crown bridge
- ix. Public health dentistry

## (V) Diagnostic Centre

A. Medical Diagnostic Laboratories:  
Pathology                      Biochemistry  
Molecular Biology and Genetic Labs

Microbiology  
Virology

## B. Diagnostic Imaging center's

**i. Radiology**

- General radiology
- Interventional radiology

**ii. Electromagnetic imaging**

- Magnetic Resonance Imaging(MRI)
- Positron Emission Tomography (PET)Scan

**iii. Ultrasound**

## C. Miscellaneous

- Electro Cardio Graphy (ECG)
- Eco cardiography
- Tread Mill test
- Electro MyoGraphy (EMG)
- Electro Encephalo Graphy (EEG)
- Electrophysiological studies
- Mammography

## D. Collection centres

For the clinical labs and diagnostic centres shall function under registered clinical establishment

Yes/No

If yes, then No. of Collection Centre:

## VI) Allied Health Professions:

- Audiology
- Behavioural health (counselling, marriage and family therapy etc.)
- Exercise physiology
- Nuclear medicine technology
- Medical Laboratory Scientist
- Dietetics
- Occupational therapy
- Optometry
- Orthoptics
- Orthotics and prosthetics
- Osteopathy
- Paramedic

- Podiatry
- Health Psychology/Clinical Psychology
- Physiotherapy
- Radiation therapy
- Radiography/Medical imaging
- Respiratory Therapy
- Sonography
- Speech pathology

**(VII) AYUSH****Ayurveda**

Ausadh Chikitsa      Shalya Chikitsa      Shodhan Chikitsa      Rasayana Pathya Vyavastha

**Yoga**

Ashtang      Yoga

**Unani**

MatabJarahaat      Ilaj-bit-Tadbeer      Hifzan-e-Sehat

**Siddha**

Maruthuvam      Sirappu Maruthuvam      Varmam Thokknam & Yoga

**Homoeopathy**

General Homoeopathy

**Naturopathy**

External Therapies with natural modalities      Internal Therapies

**II. TYPES OF SERVICE**

- TYPE
  - General Practice Services
  - Single Specialty Services
  - Multi Specialty Services (including Palliative care Centre, Trauma Centre, Maternity Home - applicable for hospitals only)
  - Super Specialty Services
- SPECIALITY SPECIFIC
  - Medical Specialties – for which candidates must possess recognized PG degree (MD/Diploma/DNB or its equivalent degree)
    - i. Anesthesiology
    - ii. Aviation Medicine
    - iii. Community Medicine
    - iv. Dermatology, Venerology and Leprosy
    - v. Family Medicine
    - vi. General Medicine
    - vii. Geriatrics
    - viii. Immuno Haematology and Blood Transfusion
    - ix. Nuclear Medicine
    - x. Paediatrics
    - xi. Physical Medicine Rehabilitation
    - xii. Psychiatry
    - xiii. Radio-diagnosis
    - xiv. Radio-therapy

- xv. Rheumatology
- xvi. Sports Medicine
- xvii. Tropical Medicine
- xviii. Tuberculosis & Respiratory Medicine or Pulmonary Medicine

Surgical specialties - for which candidates must possess, recognized PG degree (MS/Diploma/DNB or its equivalent degree)

- i. Otorhinolaryngology
- ii. General Surgery
- iii. Ophthalmology
- iv. Orthopedics
- v. Obstetrics & Gynecology

Medical Super specialties –

- i. Cardiology
- ii. Clinical Hematology including Stem Cell Therapy
- iii. Clinical Pharmacology
- iv. Endocrinology
- v. Immunology
- vi. Medical Gastroenterology
- vii. Medical Genetics
- viii. Medical Oncology
- ix. Neonatology
- x. Nephrology
- xi. Neurology
- xii. Neuro-radiology

Surgical Super-specialities-

- i. Cardiovascular thoracic Surgery)
- ii. Urology
- iii. Neuro-Surgery
- iv. Paediatrics Surgery.
- v. Plastic & Reconstructive Surgery
- vi. Surgical Gastroenterology
- vii. Surgical Oncology
- viii. Endocrine Surgery
- ix. Gynecological Oncology
- x. Vascular Surgery
- xi.

**III INFRASTRUCTURE DETAILS**

10. Area of the establishment (in sq. ft.):

a) Total area: \_\_\_\_\_ b) Constructed area: \_\_\_\_\_

11. Out Patient Department:

11.1 Total No. of OPD Clinics \_\_\_\_\_

11.2 Specialty-wise distribution of OPD Clinic

S.No.	Specialty

12. In Patient Department:

12.1. Total number of beds: \_\_\_\_\_

12.2. Specialty-wise distribution of beds, please specify:

S.No.	Specialty	Beds

13. Biomedical Waste Management

13.1 Method of treatment and/or disposal of Bio-medical waste

Through Common Facility  Onsite Facility

Any other (please specify): \_\_\_\_\_

13.2. Whether authorization from Pollution Control Board/Pollution Control Committee obtained?

Yes  No  Applied For  Not Applicable

#### IV HUMAN RESOURCES

14. Total number of Staff (as on date of application):

No. of permanent staff : \_\_\_\_\_ No. of temporary staff : \_\_\_\_\_

Please furnish the following details:-

Category of staff	Name	Qualification	Registration No.	Nature of service Temporary/Permanent
Doctors				
Nursing staff				
Para-medical staff				
Pharmacists				
Administrative staff				
Others, please specify				

Separate annexure may be attached

Support staff

Category	Total No.	Remark

15. Payment options for Registration Fees:

Online payment  Demand Draft  Bank Challan

Amount (in Rs.): \_\_\_\_\_

Details: \_\_\_\_\_

Receipt No. \_\_\_\_\_

I,.....on behalf of myself and the company/society/  
/association/body hereby declare that the statements above are correct and true to the best of my  
knowledge and I shall abide by all the provisions made under the Clinical Establishment (Registration  
and Regulation) Act, 2019 and the rules framed thereunder.

I undertake that I shall inform the District Registering Authority of any changes in the particulars  
given above.

I shall comply with the minimum standards prescribed under the said Act, 2019 for the services provided by us and also all other conditions of registration as stipulated under the aforesaid Act and Rules made there-under.

Place:  
Date:

*Signature of the Authorized Signatory*  
Office Seal

FORM VI  
[See Rule (16)]

FORM OF EVIDENCE OF COMPLIANCE OF PRESCRIBED MINIMUM STANDARDS BY CLINICAL ESTABLISHMENT

1. Name, Designation and Qualification of person in-charge of the Clinical Establishment: \_\_\_\_\_  
 Qualification(s): \_\_\_\_\_  
 Registration Number: \_\_\_\_\_  
 Name of Central/State Council (with which registered): \_\_\_\_\_  
 Tel. No. (with STD code): \_\_\_\_\_ Fax: \_\_\_\_\_ Mobile: \_\_\_\_\_  
 E-mail ID: \_\_\_\_\_
2. Systems of Medicine offered: (please tick whichever is applicable)  
 Allopathy Ayurveda Unani Siddha Homoeopathy Yoga Naturopathy Sowa-Rigpa
3. Type of establishment: (please tick whichever is applicable)
  - (I) Clinic (Outpatient)
    - Single practitioner  
(Consultation services only/with diagnostic services/with short stay facility)
    - Polyclinic  
(Consultation services only/with diagnostic services/with short stay facility)
    - Dispensary
    - Health Check-up Centre
  - (II) Day Care facility  
 Medical Surgical Medical SPA Wellness centers (where qualified medical professionals are available to supervise the services).
  - (III) Hospitals including Nursing Home (outpatient and inpatient):
    - Hospital Level 1a
    - Hospital Level 1b
    - Hospital Level 2
    - Hospital Level 3 (Non teaching)
    - Hospital Level 4 (Teaching)
  - (IV) Dental Clinics and Dental Hospital:
    - (a) Dental clinics
      - (i) Single practitioner
      - (ii) Poly Clinics (dental)
    - (b) Dental Hospitals (specialties as listed in the IDC Act)
      - a) Oral and maxilla facials surgery
      - b) Oral medicine and radiology
      - c) Orthodontics

- d) Conservative dentistry and Endodontics
- e) Periodontics
- f) Pedodontics and preventive dentistry
- g) Oral pathology and Microbiology
- h) Prosthodontics and crown bridge
- i) Public health dentistry

(V) Diagnostic Centre

A. Medical Diagnostic Laboratories:

Pathology	Biochemistry	Microbiology
Molecular Biology	Genetic Labs	Virology

B. Diagnostic Imaging centers

**i. Radiology**

- General radiology
- Interventional radiology

**ii. Electromagnetic imaging**

- Magnetic Resonance Imaging (MRI),
- Positron Emission Tomography (PET) Scan

**iii. Ultrasound**

C. Miscellaneous

- a) Electro cardio Graphy (ECG)
- b) Eco cardiography
- c) Tread Mill test
- d) Electro MyoGraphy (EMG)
- e) Electro EncephaloGraphy (EEG)
- f) Electrophysiological studies
- g) Mammography

D. Collection centres

For the clinical labs and diagnostic centres shall function under registered clinical establishment

Yes/No

If yes, then No. of Collection Centre:

VI) Allied Health Professions:

- a) Audiology
- b) Behavioural health (counselling, marriage and family therapy etc.)
- c) Exercise physiology
- d) Nuclear medicine technology
- e) Medical Laboratory Scientist
- f) Dietetics
- g) Occupational therapy
- h) Occupational & Industrial Health
- i) Optometry
- j) Orthoptics
- k) Orthotics and prosthetics
- l) Osteopathy
- m) Paramedic
- n) Podiatry
- o) Health Psychology/ Clinical Psychology

- p) Physiotherapy
- q) Radiation therapy
- r) Radiography/Medical imaging
- s) Respiratory Therapy
- t) Sonography
- u) Speech pathology

**(VII) AYUSH**

Ayurveda

AusadhChikitsa Shalya Chikitsa ShodhanChikitsa Rasayana Pathya Vyavastha

**Yoga**

Ashtang                      Yoga

**Unani**

MatabJarahat Ilaj-bit-Tadbeer Hifzan-e-Sehat

**Siddha**

Maruthuvam Sirappu Maruthuvam Varmam Thokknam &amp; Yoga

**Homoeopathy**

General Homoeopathy

**Naturopathy**

External Therapies with natural modalities Internal Therapies

**II. TYPES OF SERVICE**

## • TYPE

General Practice Services

Single Specialty Services

Multi-Specialty Services (including Palliative care Centre, Trauma Centre, Maternity Home - applicable for hospitals only)

Super Specialty Services

## • SPECIALITY SPECIFIC

Medical Specialties – for which candidates must possess recognized PG degree (MD/Diploma/DNB or its equivalent degree)

- a) Anesthesiology
- b) Aviation Medicine
- c) Community Medicine
- d) Dermatology, Venerology and Leprosy
- e) Family Medicine
- f) General Medicine
- g) Geriatrics
- h) Immuno Haematology and Blood Transfusion
- i) Nuclear Medicine
- j) Occupational & Industrial Health
- k) Paediatrics
- l) Physical Medicine Rehabilitation
- m) Psychiatry
- n) Radio-diagnosis
- o) Radio-therapy
- p) Rheumatology
- q) Sports Medicine
- r) Tropical Medicine
- s) Tuberculosis & Respiratory Medicine or Pulmonary Medicine

*Surgical specialties for which candidates must possess, recognized PG degree (MS/Diploma/DNB or its equivalent degree)*

- a) Otorhinolaryngology
- b) General Surgery
- c) Ophthalmology
- d) Orthopedics
- e) Obstetrics & Gynecology

*Medical Super specialties—*

- a) Cardiology
- b) Clinical Hematology including Stem Cell Therapy
- c) Clinical Pharmacology
- d) Endocrinology
- e) Immunology
- f) Medical Gastroenterology
- g) Medical Genetics
- h) Medical Oncology
- i) Neonatology
- j) Nephrology
- k) Neurology
- l) Neuro-radiology

*Surgical Super-specialities—*

- a) Cardiovascular thoracic Surgery)
- b) Urology
- c) Neuro-Surgery
- d) Paediatrics Surgery.
- e) Plastic & Reconstructive Surgery
- f) Surgical Gastroenterology
- g) Surgical Oncology
- h) Endocrine Surgery
- i) Gynecological Oncology
- j) Vascular Surgery
- k)

(III) INFRASTRUCTURE DETAILS

4. Area of the establishment (in sq. ft.):

a) Total Area: \_\_\_\_\_ b) Constructed area: \_\_\_\_\_

5. Out Patient Department:

5.1 Total No. of OPD Clinics: \_

5.2 Specialty-wise distribution of OPD Clinic

S.No.	Specialty

6. In Patient Department:

6.1 Total number of beds: \_\_\_

6.2 Specialty-wise distribution of beds, please specify:

S.No.	Specialty	Beds

7 Biomedical Waste Management

7.1 Method of treatment and/or disposal of Bio-medical waste

Through Common Facility                       Onsite Facility

Any other (please specify): \_\_\_\_\_

7.2. Whether authorization from Pollution Control Board/Pollution Control Committee obtained?

Yes     No                       Applied     For Not Applicable

IV. HUMAN RESOURCES

8. Total number of staff (as on date of application):

No. of permanent staff : \_\_\_\_ No. of temporary staff : \_\_\_\_

Please furnish the following details:—

Category of staff	Name	Qualification	Registration No	Nature of service Temporary/ Permanent
Doctors				
Nursing staff				
Para-medical staff				
Pharmacists				
Administrative staff				
Others, please specify				

Separate annexure may be attached

Support staff

Category	Total No.	Remark

9. List of legal requirements

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

Sr. No.	Name of Document	Valid from	Valid till	Send for renewal	Remark (Expired/valid/NA)
1	Provisional Registration under Medical Establishment Act				
2	Biomedical Waste Management licenses				
3	No objection certificate under Pollution Control Act (Air/Water)				
4	NOC from Fire Department				
5	NOC from sanitary point of view from concerned PHC				
6	Ambulance: Commercial vehicle permit Permit from Directorate of Health Services				
7	Building completion licenses				
8	Food safety license				
9	Medical Gases Licenses/Explosives Act				
10	Blood Bank licenses				
11	MOU/Agreement with outsourced Human resource agencies as per labour laws.				
12	Provident Fund/ESI Act				
13	MTP Act				
14	PNDT Act				
15	PAN				
16	Ownership document or Lease agreement if premises are taken on rent.				

Any other requirements to be complied in accordance with the prevailing law of the State.

UNDERTAKING

I, ..... on behalf of myself and the company/  
/society/association/body hereby declare that the statements above are correct and true to the best of  
my knowledge and I shall abide by all the provisions made under the Clinical Establishment  
(Registration and Regulation) Act, 2019 and Rules, 2020.

I undertake that I shall inform the District Registering Authority of any changes in the particulars  
given above.

I shall comply with the minimum standards prescribed under Clinical Establishment Act for the  
services provided by us and also all other conditions of registration as stipulated under the aforesaid Act  
and Rule there-under.

Place:

*Signature of the Authorized Signatory*

Date:

Office Seal

FORM VII  
[See Rule (17)]

PUBLIC NOTICE

The public in general is hereby informed that the Clinical Establishments as specified in column (2) of  
the Table below have made applications for certificate of Permanent Registration under section 21, the  
Goa Clinical Establishments (Registration and Regulation) Act, 2019 (Goa Act 19 of 2019), and submitted  
evidence of prescribed minimum standards in the Forms appended in Annexure hereto.

Objections for granting Certificate of Permanent Registration may be forwarded to the Registering  
Authority before expiry of thirty days from the date of issue of this notice.

TABLE

Sr. No.	Name of Clinical Establishment with address	Ownership/ /in charge	System of medicine	Date on which application was submitted	Category and standards complied with
(1)	(2)	(3)	(4)	(5)	(6)

Place:

Date:

SEAL

North/South Goa District

Registering Authority

FORM VIII  
[See Rule (18)]

CERTIFICATE OF PERMANENT REGISTRATION OF CLINICAL ESTABLISHMENT

Permanent Registration No.

Date of Issue:

Valid upto:

1. Name of the Clinical Establishment: \_\_\_\_\_
2. Address: \_\_\_\_\_
3. Owner of the Clinical Establishment: \_\_\_\_\_
4. Name of Person In charge: \_\_\_\_\_
5. System of Medicine: \_\_\_\_\_
6. Type of Establishment: \_\_\_\_\_

Is hereby registered under sub section (1) of section 27 of the Clinical Establishments (Registration and Regulation) Act, 2019 (Goa Act 19 of 2019).

This authorization is subject to the conditions as specified in the Clinical Establishments (Registration and Regulation) Rules, 2021.

Seal

Designation of the Issuing Authority

Place and Date

District Registration Authority

Address:

Phone Number in case of Grievances

FORM IX

[See Rule 20]

FORMAT FOR SUBMISSION OF INSPECTION REPORT

Number of visits made with date: \_\_\_\_\_

Name and details of members of the inspection team: \_\_\_\_\_

Address and contact details of Clinical Establishment visited: \_\_\_\_\_

Process followed for inspection (eg. Kindly outline who was met: \_\_\_\_\_  
With. What records were examined etc.)

Salient Observations/findings conclusions: \_\_\_\_\_

Specific Recommendations: \_\_\_\_\_

1) To the Clinical Establishment: \_\_\_\_\_

2) To the District Registering Authority: \_\_\_\_\_

\*In case of lack of consensus amongst members of the inspection team, the same may be kindly indicated.

Signature(of all members of the inspection team)

Date:

Place:

Form X

[See Rule 22(2)]

APPEAL MEMO

(Name of the Clinical Establishment)

(Detailed Address)

Contact Nos: \_\_\_\_\_

(Landline) \_\_\_\_\_

Mobile \_\_\_\_\_

Email id: \_\_\_\_\_

Dated: \_\_\_\_\_

To,  
The Chairman  
Goa Council for Clinical Establishments,  
(Detailed Address)

Sir/Madam,

I, Dr./Mr./Mrs./Ms.Name \_\_\_\_\_ of the Clinical establishment, namely \_\_\_\_\_ had applied for:-

- Grant of certificate of provisional registration in respect of the Clinical establishment, namely \_\_\_\_\_

- Grant of certificate of permanent registration in respect of the Certificate of provisional registration bearing No. \_\_\_\_\_ dated \_\_\_\_\_.

However, \_\_\_\_\_ Authority vide Order No. \_\_\_\_\_ dated \_\_\_\_\_ has refused to grant certificate of provisional registration/permanent registration.

----OR----

I, Dr./Mr./Mrs./Ms. \_\_\_\_\_ Name \_\_\_\_\_ of the Clinical establishment, namely, \_\_\_\_\_ and holding a Certificate of provisional registration/permanent registration bearing No. \_\_\_\_\_ dated \_\_\_\_\_.

- Vide Application dated \_\_\_\_\_ I had requested the \_\_\_\_\_ authority to renew the said Certificate of permanent registration, however, the \_\_\_\_\_ Authority vide Order No. \_\_\_\_\_ dated \_\_\_\_\_ has refused to renew the said Certificate of permanent registration.
- The \_\_\_\_\_ Authority vide Order No. \_\_\_\_\_ dated \_\_\_\_\_ has cancelled/revoked the said Certificate of provisional registration/permanent registration.
- The \_\_\_\_\_ Authority vide Order No. \_\_\_\_\_ dated \_\_\_\_\_ has directed to stop running the Clinical Establishment.
- The \_\_\_\_\_ Authority vide Order No. \_\_\_\_\_ dated \_\_\_\_\_ has directed to pay a penalty of Rs. \_\_\_\_\_ for an offence under section \_\_\_\_\_ the \_\_\_\_\_ Act, \_\_\_\_\_ (Goa N. of \_\_\_\_\_).
- Any other grievance

The above decision of the district authority appears to be not valid. I request you to consider my application as per the justifications mentioned below:

i) \_\_\_\_\_ ii) \_\_\_\_\_ iii) \_\_\_\_\_

I am willing to appear before you for personal hearing, if necessary, I am enclosing herewith a draft of 1000/-

Thanking you

Place:

Date:

Signature:

Name:

FORM XI  
[See Rule (23)]

REGISTER OF CLINICAL ESTABLISHMENTS

Sr. No.	Name of Clinical Establishment	Ownership/ /incharge	System of medicine	Provisional Registration No. and date	Permanent registration No. and date	Date of expiry of permanent registration	Remarks if any

FORM XII  
[See rule(24)]

RETURNS AND STATISTICS

**Information and Statistics to be collected Monthly from Clinical Establishments under the Clinical Establishment Act**

A. General Information:

1. Name of the Clinical Establishment \_\_\_\_\_
2. Registration Number of the Clinical Establishment \_\_\_\_\_
3. Address \_\_\_\_\_  
 Village/Town/City \_\_\_\_\_ Block \_\_\_\_\_ District \_\_\_\_\_  
 \_\_\_\_\_ State \_\_\_\_\_ Pincode \_\_\_\_\_  
 Tel No. (with STD code): \_\_\_\_\_ Mobile: \_\_\_\_\_ Email  
 ID Website (if any): \_\_\_\_\_
4. Name of Contact Person \_\_\_\_\_ Contact  
 Details(Cell/Landline/email)
5. Clinical establishment Type:
  - \* General practice
  - \* Specialty practice
  - \* Super-Specialty practice
  - \* Psychiatric practice
  - \* Obstetrics-Gynae Practice
  - \* Pediatric practice

B. Category-wise Monthly Reporting forms for following categories (separate form for each category to be filled up)

General Hospitals

Stand Alone Super Specialty Hospital Multiple Super Specialty Hospital Stand Alone Specialty Hospital Multiple Specialty Hospital

Out Patient and In Patient information (as applicable)

i. General Information:

S.No.	Description	Male	Female
1.	Total OPD patients		
2.	Total IPD Patients		
3.	Total Deaths		
4.	Number of Maternal Deaths		
5.	Live Births		
6.	Still Births		
7.	No. of Neonatal Deaths (within 24 hours of Birth) No of Deaths of children (0 to 28 days) No. of Deaths of children (0 to 1 year) No. of Deaths of children under 5 years of age		

## ii. Communicable Diseases:

S. No.	Disease	Old patients	New patients
1	Malaria		
2	Tuberculosis		
3	Dengue Hemorrhage fever		
4	Chikungunya		
5	Meningitis		
6	Typhoid		
7	Diphtheria		
8	Whooping cough		
9	Tetanus		
10	Measles		
11	Poliomyelitis		
12	Japanese Encephalitis		
13	Cholera		
14	Syphilis		
15	Gonorrhoea		
16	Leprosy (Multi bacillary)		
17	Leprosy(Pauci bacillary)		
18	Gastroenteritis		
19	Leptospirosis		
20	Hepatitis		
21	Conjunctivitis		
22	Trachoma		
23	Rabies		
24	Dog Bite (including Domestic /wild animal)		
25	Snake Bite		

## iii. Non Communicable Diseases:

S. No.	Disease	Old patient	New patient
1	Diabetes* (moderate and above)		
2	Hypertension**		
3	Ischemic Heart Disease		
4	Mental Illness		
5	Osteoarthritis		
6	Stroke		

\*Criteria for diagnosing Diabetes

Diagnosis	Fasting Glucose(mg/dl)	2-hour Post –Glucose Load(mg/dl)
Diabetes Mellitus	> = 126	> = 200
Impaired Glucose Tolerance	< 110	> 140 to < 200
Impaired Fasting Glucose	> = 110 to < 126	

WHO Definition 1999

\*\*Hypertension

A Blood pressure record of > 140/90 mm Hg

iv. Specialty/Department wise Reports : General Information

Name of Specialty	No. of OPD Patients	No. of Bed (indicate ICU Beds also)	No. of Admissions (indicate No. admitted in ICUs separately)	Bed Occu-pancy Rate	No. of Deaths	No. of Basic Procedure done	No. of Advance Procedure done	No. of Malignancy cases (if applicable)
Ophthalmology								
Mental Health								
Orthopaedic								
Gynae and Obstetrics								
Pediatrics								
CTVS								
Cardiology								
Neurology								
Gastroenterology								
Endocrinology								
Cancer Hospital								
Urology								
Nephrology								
Trauma Hospital								

V. Specialty/Department wise Reports : Specific Information

Name of Specialty	Name of Disease/Procedure	No of Cases
Ophthalmology	Cataract operations done	
	Glaucoma cases	
	Corneal Transplants done	
Mental Health	No. of Psychosis cases under treatment	
Gynae and Obstetrics	No. of deliveries conducted (including Caesarian deliveries)	
	No. of Still Births	
	No. of Maternal Deaths	
Neurology	No. of Strokes	
	Epilepsy	
CTVS		

Cardiology		
Gastroenterology	No. of Cirrhosis cases	
Trauma Hospital	No. of Major Head Injuries	
	Coma cases	
	No. of Brain Stem Death Certified	
Cancer Hospital	Type of Cancers	
Nephrology	Chronic Kidney Diseases (indicate Grade)	
	CRF	
	No. of Patients on Dialysis	

C. Information to be collected Monthly from Diagnostic Medical Laboratory under Clinical Establishment Act

Category of Laboratory:

- General
- General with single specialty
- General with multispecialty

1) No. of tests performed in the following departments:

S. No.	Department	Tests Number
1	Hematology	
2	Biochemistry	
3	Immunology	
4	Serology	
5	Pathology	
6	Cytology & Histopathology	
7	Molecular Biology	
8	Virology	
9	Genetics	

2) Number of tests done and reported positive for the following communicable diseases:

S. No.	Disease & Name of Test	Total No. of Tests performed	Number of positive
1	HIV		
2	Tuberculosis		
3	Malaria falciparum		
4	Dengue		
5	Chikungunya		
6	Japanese Encephalitis		
7	Others		
(i)	HAV		
(ii)	HBV		
(iii)	HCV		
(iv)	HDV		
(v)	Malaria vivax		

(vi)	Leptospirosis		
(vii)	H <sub>1</sub> N <sub>1</sub> /Influenza		
(viii)	Meningococcal Meningitis		
(ix)	Shigella		
(x)	Typhoid		
(xi)	Paratyphoid A		
(xii)	Paratyphoid B		
(xiii)	Plague		
(xiv)	Cholera		
(xv)	Syphilis		
(xvi)	Gonorrhoea		

D. Information to be collected Monthly from Diagnostic Imaging Centres under Clinical Establishments Act:

No. of tests performed in the following departments:

S. No.	Department	Tests Number
1.	X ray	
2.	USG	
3.	CT Scan	
4.	MRI	
5.	Mammography	
6.	Bone Densitometry	
7.	Doppler	
8.	ECG	
9.	ECHO cardiography	
10.	Holter monitoring	

Appendix I  
[see rule 8(A)]

I Standards for hospitals (level 1A and 1B )

1. Scope

The scope of services that may be provided at a hospital(level 1A &1B)practising Allopathy – Modern system of Medicine may include patient-care services in any or all of the following specialities:

- 1.1. General Medicine
- 1.2. Obstetrics & Gynaecology (Non-surgical)
- 1.3. Paediatrics
- 1.4. Community Health and Family Medicine
- 1.5. General Dentistry
- 1.6. Basic Support services
  - a) Registration/help desk and billing
  - b) Diagnostic Services: (Can be own/outsourced/Tie up)
    - Collection centre/Laboratory
    - X-ray
    - USG
  - c) Waste Management Services (General and Biomedical)

## 2. Infrastructure

### 2.1 Signage

- 2.1.1 The Hospital shall display appropriate signage which shall be in at least two languages. A board stating "24 hours emergency available" is desirable.
- 2.1.2 The building shall have a board displaying the name of the hospital at a prominent location.
- 2.1.3 Directional signage shall be placed within the facility to guide the patient(s).  
The directional signages should be permitted outside in the nearby vicinity of the hospital/  
/Nursing Home to facilitate easy access

*Following informative signage shall be displayed:*

- 2.1.4 Name of the care provider with registration number.
- 2.1.5 Registration details of the hospital as applicable.
- 2.1.6 Availability of fee structure of the various services provided (refer to CEA 2010 rules & regulation).
- 2.1.7 Timings of the facility and services provided.
- 2.1.8 Mandatory information such as under PNDT Act etc.
- 2.1.9 Important contact numbers such as Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area.

*Following safety signage shall be displayed:*

- 2.1.11 Safety Hazard and Caution signs, for e.g. hazards from electrical shock, inflammable articles, radiation etc. shall be displayed at appropriate places, and as applicable under law.
- 2.1.12 Appropriate Fire exit signage.
- 2.1.13 Signage for "No Smoking" at prominent places.

### 2.2. Other requirements

- 2.2.1 Access to the hospital shall be comfortable for the patient and/or attendants/visitors.
- 2.2.2 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.
- 2.2.3 The hospital shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and visitors hygiene.
- 2.2.4 The hospital shall have 24 hr provision of potable water for drinking & hand. It shall also have 24 hour supply of electricity, either through direct supply or from other sources.
- 2.2.5 The hospital shall have clean public toilet(s).
- 2.2.6 Furniture and fixtures shall be available in accordance with the activities and workload of the hospital. They shall be functional and properly maintained.

*The minimum space requirements shall be as stated in Annexure 1 and Annexure 11*

*Furniture and fixtures shall be as stated in Annexure 2 and Annexure 12*

## 3. Medical Equipment and Instruments:

- 3.1 The hospital shall have adequate medical equipment and instruments, commensurate to the scope of service and number of beds.
- 3.2 There shall be established system for maintenance of critical equipment.
- 3.3 Equipment shall be kept in good working condition through a process of periodic inspection, cleaning and maintenance. Annual maintenance.

*Medical equipment and instruments shall be as stated in Annexure 3.*

## 4. Drugs, Medical devices and Consumables:

- 4.1 The hospital shall have adequate drugs, medical devices and consumables commensurate to its scope of services and number of beds.

- 4.2 Emergency drugs and consumables shall be available at all times.
- 4.3 Drug storage shall be in a clean, well lit, and safe environment and shall be in consonance with applicable laws and regulations.
- 4.4 The facility shall have defined procedures for storage, inventory management and dispensing of drugs in pharmacy and patient care areas.

*List of drugs, medical devices and consumables shall be as stated in Annexure 4.*

5. *Human Resource Requirement*

- 5.1 The hospital shall have qualified and/or trained medical and nursing staff as per the scope of service provided and the medical/nursing care.
- 5.2 The support/paramedical staff shall be qualified and/or trained as per the scope of services provided, and as per requirement.
- 5.3 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). Human resource requirements shall be as stated in Annexure 5.

6. *Support Services:*

- 6.1 The Hospital shall have a Registration/Help-desk & Billing counter.
- 6.2 The diagnostic services, whether in house or outsourced, shall be commensurate with the scope of service of the hospital.
- 6.3 Segregation, collection, transportation, storage and disposal of general waste shall be done as per applicable local laws.
- 6.4 Segregation, collection, transportation, storage and disposal of biomedical waste shall be done as per Bio medical waste handling rules.
- 6.5 The Hospital shall arrange transportation of patients for transfer/referral/investigations etc. in safe manner. The arrangement can be out sourced or self owned.

7. *Legal/Statutory Requirements*

- 7.1 Compliance with local regulations and law.  
*legal requirement shall be as stated in Annexure 6.*

8. *Record Maintenance and reporting:*

- 8.1. The minimum medical records to be maintained and nature of information to be provided by the Hospitals shall be as prescribed by the Clinical Establishment Act.
- 8.2. Medical Records shall be maintained in physical or digital format.
- 8.3. The hospital shall ensure confidentiality, security and integrity of records.
- 8.4. The medical records of IPD patients shall be maintained in consonance with National or local law, MCI guidelines, and court orders.
- 8.5. The 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.

*The content of medical record shall be as stated in Annexure 7.*

9. *Basic Processes*

- 9.1. The hospital shall register all patients who visit the hospital except if the required service is not available in the facility, in which case the patient is guided to the appropriate nearest facility.
- 9.2. Patient shall be guided and informed regarding Patients' rights and responsibilities, cost estimates, third party services (e.g. Insurance) etc., as per Annexure 8.
- 9.3. The billing shall be as per the Hospital tariff list, which shall be available to patients in a suitable format.
- 9.4. Each patient shall undergo an initial assessment by qualified and/or trained personnel.

- 9.5. 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.
- 9.6. The hospital shall ensure adequate and proper spacing in the patient care area so as to prevent transmission of infections.
- 9.7. Regular cleaning of all areas with disinfectant shall be done.
- 9.8. Housekeeping/sanitary services shall ensure appropriate hygiene and sanitation in the establishment.
- 9.9. At the time of admission of patient, general consent for admission shall be taken.
- 9.10. 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.
- 9.11. 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.
- 9.12. Any examination, treatment or management of female patient shall be done in the presence of an employed female attendant/female nursing staff, if Clinical Establishment Act conducted by male personnel inside the hospital and vice versa.
- 9.13. The patient and family shall be treated with dignity, courtesy and politeness.
- 9.14. The Hospital shall provide care of patient as per Standard Treatment Guidelines that may be notified by the Central /State Government (Desirable).
- 9.15. The Clinical Establishment shall undertake to provide within the staff and facilities available, such medical examination and treatment as may be required to stabilize the emergency medical condition of any individual who comes or is brought to such clinical establishment.
- 9.16. 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.
- 9.17. 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.
- 9.18. Patient identity, medication, dose, route, timing, expiry date shall be verified prior to administration of medication.
- 9.19. Patients shall be monitored after medication administration and adverse drug reaction/events if any shall be recorded and reported.
- 9.20. The hospital shall follow standard precautions like practicing hand hygiene, use of personal protection equipment etc. so as to reduce the risk of healthcare associated infections.
- 9.21. Security and safety of patients, staff, visitors and relatives shall be ensured by provision of appropriate safety installations and adoption of appropriate safety measures.
- 9.22. The patient and/or family members are explained about the disease condition, proposed care, including the risks, alternatives and benefits. They shall be informed on the expected cost of the treatment. They shall also be informed about the progress and any change of condition.
- 9.23. 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, Blood transfusion, HIV testing, etc.) in the manner as stated in Annexure 9.
- 9.24. A Discharge summary shall be given to all patients discharged from the hospital.
- 9.25. Discharge/Death summary shall also be given to patient and/or attendant incase of transfer LAMA/DAMA or death.
- 9.26. The discharge summary shall include the points as mentioned in the Annexure 10 in an understandable language and format.  
*Content of discharge summary shall be as stated in Annexure 10.*

ANNEXURE 1 (Level 1 Hospitals)  
(see clause 2.2 of Appendix I)

Minimum space requirements in a hospital level 1 shall be as follows:

Note: Structural changes should be applicable to the Nursing home/Hospitals constructed after the implementation of CEA since it is not possible to change the existing structures, especially with restrictions of building bye-laws

Area (Desirable)

*Wards*

1. Ward bed and surrounding space 6 sq. m./bed; Desirable: in addition circulation space of 30% as indicated in total area shall be provided for Nursing station, Ward store, Sanitary etc., Minor Operation Theatre/Procedure room.

2. OT for minor procedures (where applicable) 10.5 sq.m. (Desirable).

*Labour room*

3. Labour Table and surrounding space 10.5 sq. m./labour table.

4. Other areas-nursing station, doctors' duty room, store, Clean and dirty utility, Circulating area, Toilets 10.5 sq.m. for clean utility and store and 7 sq.m. for dirty utility and 3.5 sq.m. for toilet.

5. Bio-medical Waste 5 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 1 working counter and 1 handwash basin shall be provided.

3. Distance between beds shall be 1.0 metres (Desirable).

4. Space at the head end of bed shall be 0.25 metres.

5. Door width shall be 1.2 metres (Desirable) and corridor width 2.5 metres (Desirable).

*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.

*Emergency room (if available)*

1. Emergency bed and surrounding space shall have minimum 10.5 sq. m./bed area (Desirable).

## ANNEXURE 2

(See clause 2.2 of Appendix I)

## FURNITURE AND FIXTURES

*S.N ARTICLES*

2. Examination Table

3. Writing tables

4. Chairs
5. Almirah
6. Waiting Benches
7. Medical/Surgical Beds
8. Labour Table- if applicable
9. Wheel Chair/Stretcher
10. Medicine Trolley, Instrument Trolley
11. Screens/curtains
12. Foot Step
13. Bed Side Table
14. Baby Cot- if applicable
15. Stool
16. Medicine Chest
17. Examination Lamp
18. View box
19. Fans
20. Tube Light/lighting fixtures
21. Wash Basin
22. IV Stand
23. 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  
(See clause 3 of Appendix I )

EQUIPMENTS

a. EMERGENCY EQUIPMENT

1	Resuscitation equipment including laryngoscope, endotracheal tubes, suction equipment, xylocainespary, oropharyngeal and nasopharyngeal aiways, Ambu- bags/ asult and pediatric (neonatal if indicated)
2	Oxygen cylinders with flow meter/tubing/catheter/face mask/nasal prongs
3	Suction Apparatus
4	Defibrillator with accessories (Desirable)
5	Equipment for dressing/bandaging/suturing
6	Basic diagnostic equipment- Non mercury Blood Pressure Apparatus, Stethoscope, weighing machine, thermometer (Non mercury)
7	ECG Machine
8	Pulse Oximeter (Desirable)
9	Nebulizer with accessories

b. Other equipment and consumables, 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 1A	Level 1B	Level 2	Level 3
<b>NON MEDICAL</b>					
<i>Administration</i>					
	Office equipment	Yes	Yes	Yes	Yes
	Office furniture	Yes	Yes	Yes	Yes
<i>Electricity</i>					
	Emergency lights	Yes	Yes	Yes	Yes
<i>Water Supply</i>					
	Hand-washing sinks/taps/bowls on stands in all areas	Yes	Yes	Yes	Yes
	Storage tank	Yes	Yes	Yes	Yes
	Water purification chemicals or filter	Yes	Yes	Yes	Yes
	Water source for drinking water	Yes	Yes	Yes	Yes
<i>Waste Disposal</i>					
	Buckets for contaminated waste in all treatment areas	Yes	Yes	Yes	Yes
	Drainage system	Yes	Yes	Yes	Yes
	Rubbish bins in all rooms	Yes	Yes	Yes	Yes
	Sanitation facilities for patients	Yes	Yes	Yes	Yes
	Separate Bio-medical waste disposal	Yes	Yes	Yes	Yes
	Sharps containers in all treatment areas	Yes	Yes	Yes	Yes
<i>Safety</i>					
	Fire extinguisher	Yes	Yes	Yes	Yes
<i>Vehicle (Own/ /Outsourced)</i>					
	Vehicle 4 wheeler	Desirable	Desirable	Yes	Yes
	Ambulance	Yes	Yes	Yes	Yes
<i>Medical Stores</i>					
	Lockable storage	Yes	Yes	Yes	Yes
	Refrigeration	Yes	Yes	Yes	Yes
<i>Kitchen (Own/ /Outsourced)</i>					
	Cooking pots and utensils	Yes	Yes	Yes	Yes

	Cooking stove	Yes	Yes	Yes	Yes
	Food refrigeration	Yes	Yes	Yes	Yes
	Plates, cups & cutlery	Yes	Yes	Yes	Yes
	Storage	Yes	Yes	Yes	Yes
	Washing and drying area facilities	Yes	Yes	Yes	Yes
Laundry(Own/ /Outsourced)					
	Detergent/soap	Yes	Yes	Yes	Yes
	Washing and rinsing equipment/bowls	Yes	Yes	Yes	Yes
	Housekeeping brooms, brushes and mops	Yes	Yes	Yes	Yes
Housekeeping(Own/ Outsourced)					
	Buckets	Yes	Yes	Yes	Yes
	Soap and disinfectant	Yes	Yes	Yes	Yes
<b>MEDICAL</b>					
<i>Outpatient Rooms</i>					
	Non Mercury Blood Pressure Apparatus and Stethoscope	Yes	Yes	Yes	Yes
	Container for sharps disposal	Yes	Yes	Yes	Yes
	Desk and chairs	Yes	Yes	Yes	Yes
	Examination gloves	Yes	Yes	Yes	Yes
	Examination table	Yes	Yes	Yes	Yes
	Hand washing facilities	Yes	Yes	Yes	Yes
	Light source	Yes	Yes	Yes	Yes
	Minor surgical instruments	No	Yes	Yes	Yes
	Ophthalmoscope	No	No	Yes (as applicable)	Yes
	Otoscope	No	No	Yes (as applicable)	Yes
	Patellar hammer	Yes	Yes	Yes	Yes
	Receptacle for soiled pads, dressings, etc.	Yes	Yes	Yes	Yes
	Separate biohazard disposal	Yes	Yes	Yes	Yes
	Sterile equipment storage	Yes	Yes	Yes	Yes
	Sutures	Yes	Yes	Yes	Yes

	Thermometer(Non mercury)	Yes	Yes	Yes	Yes
	Torch with extra batteries	Yes	Yes	Yes	Yes
	Weighing scale	Yes	Yes	Yes	Yes
Women and Child health examination room					
	Non Mercury Blood Pressure Apparatus and Stethoscope	Yes	Yes	Yes	Yes
	Contraceptive supplies	Yes	Yes	Yes	Yes
	Birth register	Yes	Yes	Yes	Yes
	Examination gloves	Yes	Yes	Yes	Yes
	Examination table with stirrups	Yes	Yes	Yes	Yes
	Fetal stethoscope	No	Yes	Yes	Yes
	Doppler	No	No	No	Yes
	Hand washing facility	Yes	Yes	Yes	Yes
	Height measure	Yes	Yes	Yes	Yes
	IUD insertion set	Yes	Yes	Yes	Yes
	Pregnant woman Register	Yes	Yes	Yes	Yes
	Speculum and vaginal examination kit	Yes	Yes	Yes	Yes
	Syringes and needles	Yes	Yes	Yes	Yes
	Tape measure	Yes	Yes	Yes	Yes
	Tococardiograph	No	Yes	Yes	Yes
Labour room					
	Baby scales	Yes	Yes	Yes	Yes
	Non Mercury Blood Pressure Apparatus and stethoscope	Yes	Yes	Yes	Yes
	Clean delivery kits and cord ties	Yes	Yes	Yes	Yes
	Curtains if more than one bed	Yes	Yes	Yes	Yes
	Delivery bed and bed linen	Yes	Yes	Yes	Yes
	Fetal stethoscope	Yes	Yes	Yes	Yes
	Hand washing facility	Yes	Yes	Yes	Yes
	Instrument trolley	Yes	Yes	Yes	Yes
	IV treatment sets	Yes	Yes	Yes	Yes
	Latex gloves and protective clothing	Yes	Yes	Yes	Yes

	Linens for newborns	Yes	Yes	Yes	Yes
	Mucus extractor	Yes	Yes	Yes	Yes
	Oral airways, various sizes	Yes	Yes	Yes	Yes
	Oxygen cylinder/concentrator	Yes	Yes	Yes	Yes
	Partograph charts	Yes	Yes	Yes	Yes
	Self inflating bag and mask-adult and neonatal size	Yes	Yes	Yes	Yes
	Suction machine	Yes	Yes	Yes	Yes
	Suturing sets	Yes	Yes	Yes	Yes
	Thermometer(Non mercury)	Yes	Yes	Yes	Yes
	Tray with routine & emergency drugs syringes and needles	Yes	Yes	Yes	Yes
	Urinary catheters and collection bags	Yes	Yes	Yes	Yes
	Vacuum extractor set	Yes	Yes	Yes	Yes
	Work surface near bed for newborn resuscitation	Yes	Yes	Yes	Yes
Inpatient Wards					
	Basic examination Equipment (stethoscope, Non mercury BP Apparatus (etc.))	Yes	Yes	Yes	Yes
	Beds, washable mattresses and linen	Yes	Yes	Yes	Yes
	Curtains	Yes	Yes	Yes	Yes
	Dressing sets	Yes	Yes	Yes	Yes
	Dressing trolley/Medicine trolley	Yes	Yes	Yes	Yes
	Gloves	Yes	Yes	Yes	Yes
	IV stands	Yes	Yes	Yes	Yes
	Medicine storage cabinet	Yes	Yes	Yes	Yes
	Oxygen cylinder and concentrator	Yes	Yes	Yes	Yes
	Patient trolley on wheels	Yes	Yes	Yes	Yes
	PPE kits	Yes	Yes	Yes	Yes
	Suction machine	Yes	Yes	Yes	Yes
	Urinals and bedpans	Yes	Yes	Yes	Yes

Operation Theatre	If available				
	Adequate storage	Yes	Yes	Yes	Yes
Ambu resuscitation set with adult and child masks	Yes	Yes	Yes	Yes	Yes
Defibrillator				Yes	Yes
Electro cautery	No	Yes	Yes	Yes	Yes
Fixed operating lights	No	No	No	No	Yes
Fixed suction machine	No			No	Yes
Hand washing facilities	Yes	Yes	Yes	Yes	Yes
Instrument tray	Yes	Yes	Yes	Yes	Yes
Instrument trolley	Yes	Yes	Yes	Yes	Yes
Laryngoscope set	No			Yes	Yes
Mayo Stand	Yes	Yes	Yes	Yes	Yes
Mobile operating light	Yes	Yes	Yes	Yes	Yes
Ophthalmic Operating Microscope	No	No		Yes (as applicable)	Yes (as applicable)
Oral airways, various sizes	No			Yes	Yes
Oxygen cylinder and concentrator	Yes	Yes	Yes	Yes	Yes
Patient trolley on wheels	Yes	Yes	Yes	Yes	Yes
Portable suction machine	Yes	Yes	Yes	Yes	Yes
Safety Box	No			Yes	Yes
Sphygmomanometer (Non Mercury) and stethoscope	Yes	Yes	Yes	Yes	Yes
Stool adjustable height	No	Yes	Yes	Yes	Yes
Operating table	No	Yes	Yes	Yes	Yes
IV Therapy Equipment No					
Anesthesia Equipment Anesthetic trolley/machine	No	Yes	Yes	Yes	Yes
CO2 Monitor	No			Yes	Yes
O2 Monitor	No			Yes	Yes
Endoscopic equipment and necessary accessories	No	No	No	No	Yes
Bronchoscope	No	No	No	Desirable	Yes
Colonoscope	No	No	No	Desirable	Yes
Endoscope	No	No	No	Desirable	Yes
Fiber Optic Laryngoscope	No	No	No	Desirable	Yes

Central Supply					
	Amputation set	No	No	No	Yes
	Caesarean/hysterectomy set	No	No	Yes	Yes
	Dilatation and curettage set	No	No	Yes	Yes
	Endoscopic instrument cleaning machines and solutions	No	No	No	Yes
	Hernia set	No	No	Yes	Yes
	Laparotomy set	No	No	Yes	Yes
	Linens	Yes	Yes	Yes	Yes
	Locked storage	Yes	Yes	Yes	Yes
	Operating drapes	No	Yes	Yes	Yes
	Ophthalmic instrument	No	No	Yes	Yes
	Protective caps, aprons, shoes and gowns etc	Yes	Yes	Yes	Yes
	Pelvic/fistula repair set	No	No	No	Yes
	Sterile gloves	Yes	Yes	Yes	Yes
	Sterilization equipment for instrument and linens	Yes	Yes	Yes	Yes
	Surgical supplies (e.g., sutures, dressings etc.)	Yes	Yes	Yes	Yes
	Thoracocentesis set	No	No	No	Yes
	Thoracostomy set with appropriate tubes and water seal bottles	No	No	No	Yes
	Thoracotomy set	No	No	No	Yes
	Thyroid/Parathyroid set	No	No	No	Yes
	Tracheostomy set	No	No	Yes	Yes
	Tubal ligation set	No	No	Yes	Yes
	Vascular repair set	No	No	Yes	Yes

Other equipment as per the specialized services available shall also be there

#### ANNEXURE 4

(see clause 4 of Appendix I)

#### DRUGS, MEDICAL DEVICES AND CONSUMABLES

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

Sl. No.	Name of the Drug
	<i>INJECTIONS</i>
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
	OTHER
22	NEB. SALBUTAMOL 2.5 ML
23	NEB. BUDESONIDE
24	LIGNOCAINE JELLY 2%
25	ACTIVATED CHARCOAL
26	CALCIUM (INJ or TAB)
	FLUIDS
27	RL 500 ML
28	NS 500 ML
29	NS 250 ML
30	NS 100 ML
31	DNS 500 ML
32	DEXTROSE 5% 500 ML
33	DEXTROSE 10% 500 ML
34	PEDIATRIC IV INFUSION SOLUTION 500 ML

b. Other drugs and consumables shall be available as per the scope of services, bed strength and patient turnover.

ANNEXURE 5  
(See clause 5 of Appendix I)

HUMAN RESOURCE

The Human Resource requirement for any hospital depends on the scope of services provided by the hospitals, bed strength and workload of the hospital.

However on the basis of level of care provided the minimum staffing requirements for Hospital level 1 shall be as follows:

1.	Doctor	Qualified doctor shall be available round the clock on site (Desirable for 1A). Level 1A shall have a MBBS qualified doctor. (Qualified doctor is a MBBS approved as per State government rules & regulations as applicable from time to time). Level 1B shall have MBBS doctor with required post-graduation qualification.
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.(Desirable)
3.	Pharmacist (If in house pharmacy available)	1 in a hospital
4.	Lab Technician (if in house laboratory service available)	1 in a hospital (minimum DMLT) BSc, MSc, MLT (Desirable)
5.	X-ray Technician (if in house X-ray facility available)	1 in a hospital (minimum Diploma in X Ray Technician course)
6.	Multi Task staff	Minimum 1

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

#### ANNEXURE 6

(See clause 7 of appendix I )

#### LIST OF LEGAL REQUIREMENTS

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

Sl. No.	Name of Document	Valid From	Valid Till	Send for Renewal by	Remark (Expired/valid/NA)
1	2	3	4	5	6
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 (As per AERB regulations)				
4.	NOC from Fire Department				
5.	NOC from sanitary point of view from concerned PHC				
6.	Ambulance Commercial Vehicle Permit Commercial Driver License Pollution Control Licenses				
7.	Building Completion Licenses				
8.	Lift license for each lift				

1	2	3	4	5	6
9.	DG Set Approval for Commissioning*				
10.	Diesel Storage Licenses*				
11.	Retail and bulk drug license (pharmacy)				
12.	Food Safety Licenses*				
13.	Narcotic Drug License				
14.	Medical Gases Licenses/Explosives Act*				
15.	Clinical Establishments and Registration (if applicable)				
16.	Blood Bank Licenses				
17.	MoU/agreement with outsourced human resource agencies as per labor laws				
18.	Spirit License				
19.	Electricity rules				
20.	Provident fund/ESI Act				
21.	MTP Act				
22.	PNDT Act				
23.	Sales Tax registration				
24.	PAN				
25.	No objection certificate under Pollution Control Act (Air/Water)				
26.	Arms Act, 1950 (if guards have weapons)				

\* (as per regulations of State)

#### ANNEXURE 7

(See clause 8 of Appendix I )

#### CONTENT OF MEDICAL RECORD

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

S. 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)

## ANNEXURE 8

(See clause 9 of Appendix I)

Patients' rights and responsibilities:

## Patients' Rights

A patient and his/her representative has the following rights with respect to the clinical establishment-

1. To adequate relevant information about the nature, cause of illness, proposed investigations and care, expected results of treatment, possible complications and expected costs;
2. To information on the rates charged for each type of service provided and facilities available. Clinical Establishment shall display the same at a conspicuous place in the local as well as in English language.
3. To access a copy of case papers, patient records, investigations reports and detailed bill.
4. To informed consent prior to specific tests/treatment (e.g. surgery, chemotherapy).
5. To seek second opinion from an appropriate clinician of patients' choice, with records and information being provided by treating hospital.
6. To confidentiality, human dignity and privacy during treatment.
7. To have ensured presence of a female person, during physical examination of a female patient by a male practitioner.
8. To non-discrimination about treatment and behaviour on the basis of HIV status.
9. To choose alternative treatment if options are available.

## Patients' Responsibilities:

- Provide all health related information.
- Cooperate with Doctors during examination, treatment.
- Follow all instructions.
- Pay hospitals agreed fees on time.
- Respect dignity of doctors and other hospital staff.
- Never resort to violence.

## ANNEXURE 9

(See clause 9.23 of Appendix I)

## INFORMED CONSENT/CONSENT GUIDELINES

The informed consent shall at the least contain the following information in an understandable language and format (desirably which a lay person can easily understand)

Sl. 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 and potential complications should be explained
6	Signature of patient/guardian with date and time

## ANNEXURE 10

(See clause 9.26 of Appendix I )

## DISCHARGE SUMMARY

The discharge summary shall at the least contain the following information in any understandable language and format:

Sl. 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

## II Standards for Hospital (Level 2)

1) *Scope*

The scope of services that may be provided at a hospital level 2 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:*

- 1.1. General Medicine
- 1.2. General Surgery
- 1.3. Obstetrics and Gynaecology
- 1.4. Paediatrics including new born care
- 1.5. Orthopaedics
- 1.6. Anaesthesiology
- 1.7. Emergency Medicine & Trauma
- 1.8. Critical Care Medicine (e.g. HDU, ICU)
- 1.9. ENT
- 1.10. Ophthalmology
- 1.11. Psychiatry
- 1.12. Dermatology
- 1.13. Community Health
- 1.14. Palliative Medicine
- 1.15. Geriatric Care
- 1.16. Family Medicine
- 1.17. Dentistry including sub specialities
- 1.18. Physical Medicine & Rehabilitation
- 1.19. Transfusion Medicine/Blood Storage Centre/Blood Bank
- 1.20. Other emerging sub-specialities in any of the above fields.

*Support services:*

- 1.21. Registration/help desk and billing
- 1.22. Diagnostic Services:
  - a. Laboratory
  - b. Imaging Services
  - c. Non-imaging services
- 1.23. Pharmacy and Stores
- 1.24. CSSD/Sterilization Area
- 1.25. Linen management
- 1.26. Kitchen & Dietary Services
- 1.27. Waste Management Services (General and Biomedical)
- 1.28. Medical Gas Supply, Storage & Distribution
- 1.29. Ambulance services

2) Infrastructure Requirements:	21	<i>Signage</i>
	2.1.1	The Hospital shall display appropriate signage which shall be in at least two languages.
	2.1.2	The building shall have a board displaying the name of the hospital at a prominent location.
	2.1.3	Directional signage shall be placed within the facility to guide the patient.
	<i>Following informative signage shall be displayed:</i>	
	2.1.4	Name of the care provider with registration number.
	2.1.5	Registration details of the hospital as applicable.
	2.1.6	Availability of fee structure of the various services provided (refer to CEA 2010 rules & regulation CG 4 Annexe).
	2.1.7	Timings of the facility and services provided.
	2.1.8	Mandatory information such as under PNDT Act etc. prominently as applicable.
	2.1.9	Important contact numbers such as Blood Banks, Fire Department, Police and Ambulance Services available in the nearby area.
2.1.10	Patients' rights & responsibilities.	
Following safety signage shall be displayed:		
2.1.11	Safety Hazard and Caution signs, for e.g. hazards from electrical shock, inflammable articles, radiation etc. at appropriate places, and as applicable under law.	
2.1.12	Appropriate Fire exit signage.	
2.1.13	Signage for "No Smoking".	
2.2.	Other requirements.	
2.2.1	Access to the hospital shall be comfortable for the patient and/or attendants/visitors.	
2.2.2	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.	

2.2.3	The hospital shall be developed and maintained to provide safe, clean and hygienic environment for patients, their attendants, staff and visitors.
2.2.4	The hospital shall have 24 hr provision of potable water for drinking & hand hygiene. It shall also have 24 hr supply of electricity, either through direct supply or from other sources.
2.2.5	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.
2.2.6	The hospital shall have clean public toilet(s) separate for males and females.
2.2.7	The hospital shall have mechanism for timely maintenance of the hospital building and equipment.
2.2.8	The hospital shall have appropriate internal and external communication facilities.
2.2.9	Furniture and fixtures shall be available in accordance with the activities and workload of the hospital. They shall be functional and properly maintained.
	<i>Minimum space requirements shall be as stated in Annexure 11.</i>
	<i>Furniture and fixtures shall be as stated in Annexure 12.</i>

3. *Medical Equipment and Instruments:*

3.1	The hospital shall have adequate medical equipment and instruments commensurate to the scope of service and number of beds.
3.2	There shall be established system for maintenance of critical Equipment.
3.3	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.
	<i>Medical equipment and instruments shall be as stated in Annexure 13.</i>

4. *Medical Equipment's and Instruments*

4.1	The hospital shall have adequate drugs, medical devices and consumables commensurate to the scope of services 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.
	<i>Drugs, medical devices and consumables shall be as stated in Annexure 14</i>

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 facility has defined procedures for storage, inventory management and dispensing of drugs in pharmacy and patient care areas.
	<i>Drugs, medical devices and consumables shall be as stated in Annexure 14.</i>

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. Human resource requirements shall be as per Annexure 15.
	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).

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.
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.
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.
CSSD/Sterilization Area:	
7.8	Provision for instrument and linen sterilization and storage of sterile items shall be made available as per the scope of services.
7.9	Validation of Sterilization shall be done for ensuring the effectiveness of sterilization process.
Linen management:	
7.10	Soiled linen shall be collected, transported and washed separately in clean and hygienic environment.
7.11	Where linen is contaminated, appropriate decontamination shall be carried prior to despatch for washing.

Waste Management Services	
7.12	Segregation, collection, transportation, storage and disposal of biomedical waste shall be as per Bio medical waste handling rules.
7.13	Waste management guidelines shall be followed in the case of Mercury & other toxic materials as per applicable local laws.
7.14	Segregation, collection, transportation, storage and disposal of general waste shall be as per applicable local laws.
Medical Gas	
7.15	Oxygen for medical use shall be available. In addition other gases like Nitrous oxide, Carbon dioxide etc. may be available in consonance with the scope of services and bed strength.
7.16	Medical gases shall be stored and handled in a safe manner.
7.17	All applicable legal requirements shall be complied with. Legal requirements shall be as stated in Annexure 16
7.18	Appropriate back-up and safety measures shall be in place to ensure patient safety at all times.
Ambulance services	
7.19	The establishment shall have provision of transporting patients for transfer/referral/ investigations etc., in safe manner.
7.20	Ambulance Services may be in-house or outsourced. The Ambulance services shall comply with the applicable local laws, even if they are outsourced.
<b>8. Legal/Statutory Requirements:</b>	
8.1	Every application must be accompanied with the documents confirming compliance with local regulations and law.
<b>9. Record Maintenance and reporting:</b>	
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.
	<i>Medical record shall be as stated in Annexure 17.</i>
<b>10. Basic Processes:</b>	
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.
Assessment 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 which shall be stated in Annexure 18.
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.
Informed Consent Procedure	
10.11	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 of Patient	
10.12	The Hospital shall provide care of patient as per the best clinical practices and reference may be made to Standard Treatment Guidelines that may be notified by the Central/State Government/National & International professional bodies.
10.13	Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.
10.14	All the relevant documents pertaining to any invasive procedures performed 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.
Emergency Services:	
10.17	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.
Medication 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.
10.22	Safe injection practices shall be followed as per WHO guidelines.
10.23	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 <a href="http://cdsco.nic.in/adr3.pdf">http://cdsco.nic.in/adr3.pdf</a> ).
Infection 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.
10.26	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 establishment.
Safety 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.
Patient Information and Education	
10.34	The patient and/or family members shall be 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 are educated about the safe and effective use of medication, food drug interaction, diet, and disease prevention strategies.

Discharge	
10.36	A Discharge summary shall be given to all patients discharged from the hospital. <i>For content of discharge summary refer to Annexure 9.</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 11

(See sub clause 2.2.9 of clause II of Appendix I)

Minimum space requirements in a hospital Level 2 shall be as follows:

Total Area		
1.	Total Area of hospital level 1 including 30 % area for circulation space for corridors, lobby, reception area	40 sq.mt./bed as carpet area
Wards		
2.	Ward bed and surrounding space	6 sq. mt./bed; in addition circulation space of 30% as indicated in total area shall be provided for Nursing station, Ward store, Sanitary etc.
Intensive Care Unit (if available)		
3.	For medical/surgical ICU/HDU 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.
Minor Operation Theatre/Procedure room		
4.	OT for minor procedures (where applicable)	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 room		
5.	Labour Table and surrounding space	10.5 sq. mt./labour table.
6.	Other areas- nursing station, doctors' duty room, store, clean and dirty utility, circulating area, toilets	10.5 sq. mt. for clean utility and store and 7 sq. mt. for dirty utility and 3.5 sq. mt. for toilet.
Operation Theatre (OT)		
7.	Operating Room Area	24.5 sq. mt. per operating room.
Emergency & Casualty (if separate):		

8.	Emergency bed and surrounding space	10.5 sq. m./ bed
9.	Other areas- nursing station, doctors' duty room, store, clean and dirty utility, dressing area, toilets	Nurse station out of circulation. Doctor duty room of 7 sq. m. and a toilet of 3.5 sq. m. Store of 7 sq. m.
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 m <sup>2</sup> per patient.
Bio-medical 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 (if available)*

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 should 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.

#### *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,
- c) pertaining to other departments alone

*Other Departments*

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

## ANNEXURE 12

(See sub clause 2.2.9 of clause II of Appendix I)

## FURNITURE AND FIXTURES

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

(See sub-clause 3 and 4 of clause II of Appendix I)

## 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
1	2	3	4	5
<b>NON MEDICAL</b>				
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
	Water source for drinking water	Yes	Yes	Yes
Waste Disposal				
	Buckets for contaminated waste in all treatment areas	Yes	Yes	Yes
	Drainage system	Yes	Yes	Yes
	Incinerator or burial pit	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

1	2	3	4	5
	Separate Bio-medical waste disposal	Yes	Yes	Yes
	Sharps containers in all treatment areas	Yes	Yes	Yes
<b>Safety</b>				
	Fire extinguisher			
<b>Vehicle</b>	Vehicle 4—wheel drive	No	Yes	Yes
	Ambulance 4-wheel drive	No	No	Yes
<b>Medical Stores</b>				
	Lockable storage	Yes	Yes	Yes
	Refrigeration	Yes	Yes	Yes
<b>Kitchen</b>				
	Cooking pots and utensils	No	Yes	Yes
	Cooking stove	No	Yes	Yes
	Food refrigeration	No	Yes	Yes
	Plates, cups & cutlery	No	Yes	Yes
	Storage	No	Yes	Yes
	Washing and drying area facilities	Yes	Yes	Yes
<b>Laundry</b>				
	Detergent/soap	Yes	Yes	Yes
	Washing and rinsing equipment/bowls	No	Yes	Yes
	Housekeeping Brooms, brushes and mops	Yes	Yes	Yes
<b>Housekeeping</b>				
	Buckets	Yes	Yes	Yes
	Soap and disinfectant	Yes	Yes	Yes
<b>MEDICAL</b>				
<b>Outpatient Rooms</b>				
	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	No	Yes (as applicable)	Yes
	Patellar hammer	No	Yes	Yes
	Receptacle for soiled pads, dressings, etc.	Yes	Yes	Yes

1	2	3	4	5
	Receptacle for soiled pads, dressings, etc	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 health 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
	BP machine and stethoscope	Yes	Yes	Yes
	Clean delivery kits and cord ties	Yes	Yes	Yes
	Curtains if more than one bed	Yes	Yes	Yes
	Delivery bed and bed linen	Yes	Yes	Yes
	Fetal stethoscope	Yes	Yes	Yes
	Hand washing facility	Yes	Yes	Yes
	Instrument trolley	Yes	Yes	Yes
	IV treatment sets	Yes	Yes	Yes
	Latex gloves and protective clothing	Yes	Yes	Yes
	Linens for newborns	Yes	Yes	Yes
	Mucus extractor	Yes	Yes	Yes
	Oral airways, various sizes	Yes	Yes	Yes
	Oxygen tank and concentrator	Yes	Yes	Yes
	Partograph charts	Yes	Yes	Yes
	Self inflating bag and mask - adult and neonatal size	Yes	Yes	Yes

1	2	3	4	5
	Suction machine	Yes	Yes	Yes
	Suturing sets	Yes	Yes	Yes
	Thermometer	Yes	Yes	Yes
	Tray with routine & emergency drugs, syringes and needles	Yes	Yes	Yes
	Urinary catheters and collection bags	Yes	Yes	Yes
	Vacuum extractor set	Yes	Yes	Yes
	Work surface near bed for newborn resuscitation	Yes	Yes	Yes
<b>Inpatient Wards</b>				
	Basic examination equipment (stethoscope, BP machine, etc)	Yes	Yes	Yes
	Beds, washable mattresses and linen	Yes	Yes	Yes
	Curtains	Yes	Yes	Yes
	Dressing sets	Yes	Yes	Yes
	Dressing trolley/Medicine trolley	Yes	Yes	Yes
	Gloves	Yes	Yes	Yes
	IV stands	Yes	Yes	Yes
	Medicine storage cabinet	Yes	Yes	Yes
	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
<b>Operation Theatre</b>				
	Adequate storage	No	Yes	Yes
	Ambu resuscitation set with adult and child masks		Yes	Yes
	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
	Instrument tray	No	Yes	Yes
	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

1	2	3	4	5
	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 accessories	No	No	Yes
	Bronchoscope	No	No	Yes
	Colonoscope	No	No	Yes
	Endoscope	No	No	Yes
	Fiber Optic Laryngoscope	No	No	Yes
Central Supply	Amputation set	No	No	Yes
	Caesarean/hysterectomy set	No	Yes	Yes
	Dilatation and curettage set	No	Yes	Yes
	Endoscopic instrument cleaning machines and solutions	No	No	Yes
	Hernia set	No	No	Yes
	Laparotomy set	No	Yes	Yes
	Linens	Yes	Yes	Yes
	Locked storage	Yes	Yes	Yes
	Operating drapes	No	Yes	Yes
	Ophthalmic instrument	No	Yes	Yes
	Protective hats, aprons, shoes and gowns etc	Yes	Yes	Yes
	Pelvic/fistula repair set	No	No	Yes
	Sterile gloves	Yes	Yes	Yes
	Sterilization equipment for instruments and linens	Yes	Yes	Yes
	Surgical supplies (e.g., sutures, dressings, etc)	Yes	Yes	Yes
	Thoracentesis set	No	No	Yes
	Thoracostomy set with appropriate tubes and water seal bottles	No	No	Yes
	Thoracotomy set	No	No	Yes
	Thyroid/Parathyroid set	No	No	Yes
	Tracheostomy set	No	Yes	Yes
	Tubal ligation set	No	Yes	Yes
	Vascular repair set	No	Yes	Yes
Other equipment as per the specialized services available shall also be there				

## Annexure 14

(See sub-clause 4 and 5 of clause II of Appendix I)

## DRUGS, MEDICAL DEVICES AND CONSUMABLES

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

Sl. No.	Name of the Drug
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
	<b>OTHER</b>
23	NEB. SALBUTAMOL 2.5 ML
24	NEB. BUDESONIDE
25	LIGNOCAINE JELLY 2%
26	ACTIVATED CHARCOAL
27	CALCIUM (INJ or TAB)
<b>FLUIDS</b>	
28	RL 500 ML
29	NS 500 ML
30	NS 250 ML
31	NS 100 ML
32	DNS 500 ML
33	DEXTROSE 5% 500 ML
34	DEXTROSE 10% 500 ML
35	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 15

(See sub-clause 6 of Clause II of Appendix I)

## HUMAN RESOURCE

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

Hospital employs varieties of personnel with different levels of skill and competency mix. Health Workforce is the most critical component of the hospital resources. This is not only because it consumes 60 to 70% of the recurrent budget allocation but also because of the skills, competency, capacity and commitment of the human resources that determine the efficiency, effectiveness and quality of medical care.

The requirement mentioned below is the minimum requirement for upto 50 bedded Hospital Level 2 and it shall be prorated as required:

Sl. No.	Human Resource	Requirement
1	Doctor	MBBS doctor shall be available round the clock on site per unit. And 1 Doctor with specialization in the subject concerned as per scope of service (Full-Time/Part-Time or visiting).
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 (If in house pharmacy available)	1 in a hospital
4	Lab Technician (if in house laboratory service available)	1 in a hospital (minimum DMLT)
5	X-ray Technician (if in house X-ray facility available)	1 in a hospital (minimum Diploma in X Ray Technician course)
6	Multi-purpose Worker	Minimum 2 (minimum 12th pass)

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

## Annexure 16

(See sub-clause 7.17 of clause II of Appendix I)

## 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):

Sl.	Name of Document	Valid From	Valid Till	Send for renewal by	Remark (Expired/valid/NA)
1	2	3	4	5	6
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				

1	2	3	4	5	6
4	NOC from Fire Department				
5	NOC from sanitary point of view from concerned PHC				
6	Ambulance				
	Commercial Vehicle Permit				
	Commercial Driver License				
7	Pollution Control Licenses				
8	Building Completion Licenses				
9	Lift license for each lift				
10	DG Set Approval for Commissioning				
11	Diesel Storage Licenses				
12	Retail and bulk drug license (Pharmacy)				
13	Food Safety Licenses				
14	Narcotic Drug Licenses				
15	Medical Gases Licenses/ Explosives Act				
16	Clinical Establishments and Registration (if applicable)				
17	Blood Bank Licenses				
18	MoU/agreement with outsourced human resource agencies as per labor laws				
19	Spirit Licence				
20	Electricity rules				
21	Provident fund/ESI Act				
22	MTP Act				
23	PNDT Act				
24	Sales Tax registration				
25	PAN				
26	No objection certificate under Pollution Control Act (Air/Water)				
27	Arms Act, 1950 (if guards have weapons)				

Annexure 17

(See sub-clause 9 of clause II of Appendix I )

CONTENT OF MEDICAL RECORD

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

Sl. No.	Content
1	2
1	Name & Registration number of treating doctor
2	Name & Registration number of Name, demographic details & contact number of patient
3	Relevant Clinical history, Assessment and re-assessment findings, nursing notes and Diagnosis

1	2
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)

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Annexure 18

(See sub-clause 10.7 of clause II of Appendix I )

INFORMED CONSENT/CONSENT GUIDELINES

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

Sl. 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 19

(See sub clause 10.36 of clause II of Appendix I )

Discharge Summary

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

Sl. 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.

## II Standards for Hospital (Level 3)

### 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:

<b>3.1</b>	<b>Signage</b>
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.
<b>Following informative signage shall be displayed:</b>	
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.
<b>Following safety signage shall be displayed:</b>	
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.
<b>3.2.</b>	<b>Other requirements</b>
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.
	<i>Minimum space requirements shall be as stated in Annexure 20</i>
	<i>Furniture and fixtures shall be as stated in Annexure 21</i>

**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.
	<i>Medical equipment and instruments shall be as stated in Annexure 22</i>

**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.
	<i>Drugs, medical devices and consumables shall be as stated in Annexure 23.</i>

**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.
	<i>Human resource requirements shall be as stated in Annexure 24</i>

**7. Support Services:**

<b>Registration/Help desk and Billing:</b>	
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.
<b>Diagnostic Services:</b>	
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.
<b>Pharmacy Services</b>	
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.
<b>CSSD/Sterilization Area:</b>	
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.
<b>Linen management:</b>	
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.
<b>Waste Management Services:</b>	
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.
<b>Medical Gas:</b>	
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 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.
<b>Ambulance Services:</b>	
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.

<b>8. Legal/Statutory requirements:</b>	
8.1	Every application must be accompanied with the documents confirming compliance with local regulations and law.
	<i>Legal requirements shall be as stated in Annexure 25.</i>
<b>9. Record Maintenance and reporting:</b>	
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 Annexure 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.
	<i>Medical record shall be as stated in Annexure 26</i>
<b>10. Basic Process:</b>	
<b>Registration/help desk and billing Services</b>	
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.
<b>Assessment and Plan of care</b>	
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	General Consent for admission shall be as stated in Annexure 27.
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.
<b>Informed Consent Procedure</b>	
10.11	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.).
<b>Care of Patient</b>	
10.12	The Hospital shall provide care of patient as per the best clinical practices and reference may be made to Standard Treatment Guidelines that may be notified by the Central/State Government/National & International professional bodies.
10.13	Patient and/or families shall be educated on preventive, curative, promotive and rehabilitative aspects of care either verbally, or through printed materials.

10.14	All the relevant documents pertaining to any invasive procedures performed 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.
<b>Emergency Services</b>	
10.17	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.
<b>Medication Prescription, Administration And Monitoring</b>	
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.
10.22	Safe injection practices shall be followed as per WHO guidelines.
10.23	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 <a href="http://cdsco.nic.in/adr3.pdf">http://cdsco.nic.in/adr3.pdf</a> ).
<b>Infection Control</b>	
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.
10.26	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.
<b>Safety of the patient, staff, visitors and relative in a hospital</b>	
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.

<b>Patient Information and Education</b>	
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.
<b>Discharge</b>	
10.36	A Discharge summary shall be given to all patients discharged from the hospital. <i>Content of discharge summary shall be as stated in Annexure 28.</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 20

(See sub-clause 3 of clause III of Appendix I )

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

<b>Total Area</b>		
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.
<b>Wards</b>		
3.	Ward bed and surrounding space	6 sq. m./bed; in addition circulation space of 30% as indicated in total area shall be provided for nursing station, ward store, sanitary etc.
<b>Intensive Care Unit</b>		
4.	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.
<b>Minor Operation Theatre/Procedure room</b>		
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.
<b>Labour room</b>		
6.	Labour Table and surrounding space	10.5 sq m/labour table.
7.	Other areas- nursing station, doctors' duty room, store, clean and dirty utility, Circulating area, Toilets	10.5 sq.mt. for clean utility and store and 7 sq.mt. for dirty utility and 3.5 sq.mt. for toilet.
<b>Operation Theatre (OT)</b>		
8.	Operating Room Area	30.5 sq.mt. per operating room.

<b>Emergency &amp; Casualty (if separate):</b>		
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.
<b>Pharmacy</b>		
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 m <sup>2</sup> per patient.
<b>Bio-medical Waste</b>		
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 anaesthesia 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.
1. 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.

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**Annexure 21**

(See sub-clause 3 of clause III of Appendix I)

**FURNITURE AND FIXTURES**

Sr. No.	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 22

(See sub-clause 4 of clause III of Appendix I)

## 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
1	2	3	4	5
<b>NON MEDICAL</b>				
<b>Administration</b>				
	Office equipment	Yes	Yes	Yes
	Office furniture	Yes	Yes	Yes
<b>Electricity</b>				
	Emergency lights	Yes	Yes	Yes
<b>Water Supply</b>				
	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
	Water source for drinking water	Yes	Yes	Yes
<b>Waste Disposal</b>				
	Buckets for contaminated waste in all treatment areas	Yes	Yes	Yes
	Drainage system	Yes	Yes	Yes
	Incinerator or burial pit	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

1	2	3	4	5
	Separate Bio-medical waste disposal	Yes	Yes	Yes
	Sharps containers in all treatment areas	Yes	Yes	Yes
<b>Safety</b>				
	Fire extinguisher			
<b>Vehicle</b>	Vehicle 4—wheel drive	No	Yes	Yes
	Ambulance 4-wheel drive	No	No	Yes
<b>Medical Stores</b>				
	Lockable storage	Yes	Yes	Yes
	Refrigeration	Yes	Yes	Yes
<b>Kitchen</b>				
	Cooking pots and utensils	No	Yes	Yes
	Cooking stove	No	Yes	Yes
	Food refrigeration	No	Yes	Yes
	Plates, cups & cutlery	No	Yes	Yes
	Storage	No	Yes	Yes
	Washing and drying area facilities	Yes	Yes	Yes
<b>Laundry</b>				
	Detergent/soap	Yes	Yes	Yes
	Washing and rinsing equipment/bowls	No	Yes	Yes
	Housekeeping Brooms, brushes and mops	Yes	Yes	Yes
<b>Housekeeping</b>				
	Buckets	Yes	Yes	Yes
	Soap and disinfectant	Yes	Yes	Yes
<b>MEDICAL</b>				
<b>Outpatient Rooms</b>				
	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

1	2	3	4	5
	Separate bio hazard 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
<b>Women and Child health examination room</b>				
	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
<b>Labour room</b>				
	Baby scales	Yes	Yes	Yes
	BP machine and stethoscope	Yes	Yes	Yes
	Clean delivery kits and cord ties	Yes	Yes	Yes
	Curtains if more than one bed	Yes	Yes	Yes
	Delivery bed and bed linen	Yes	Yes	Yes
	Fetal stethoscope	Yes	Yes	Yes
	Hand washing facility	Yes	Yes	Yes
	Instrument trolley	Yes	Yes	Yes
	IV treatment sets	Yes	Yes	Yes
	Latex gloves and protective clothing	Yes	Yes	Yes
	Linens for newborns	Yes	Yes	Yes
	Mucus extractor	Yes	Yes	Yes
	Oral airways, various sizes	Yes	Yes	Yes
	Oxygen tank and concentrator	Yes	Yes	Yes
	Partograph charts	Yes	Yes	Yes
	Self inflating bag and mask - adult and neonatal size	Yes	Yes	Yes

1	2	3	4	5
	Suction machine	Yes	Yes	Yes
	Suturing sets	Yes	Yes	Yes
	Thermometer	Yes	Yes	Yes
	Tray with routine & emergency drugs, syringes and needles	Yes	Yes	Yes
	Urinary catheters and collection bags	Yes	Yes	Yes
	Vacuum extractor set	Yes	Yes	Yes
	Work surface near bed for newborn resuscitation	Yes	Yes	Yes
<b>Inpatient Wards</b>				
	Basic examination equipment (stethoscope, BP machine, etc.)	Yes	Yes	Yes
	Beds, washable mattresses and linen	Yes	Yes	Yes
	Curtains	Yes	Yes	Yes
	Dressing sets	Yes	Yes	Yes
	Dressing trolley/Medicine trolley	Yes	Yes	Yes
	Gloves	Yes	Yes	Yes
	IV stands	Yes	Yes	Yes
	Medicine storage cabinet	Yes	Yes	Yes
	Oxygen tank and concentrator Patient trolley on wheels	Yes	Yes	Yes
	PPE kits	Yes	Yes	Yes
	Suction machine	Yes	Yes	Yes
	Urinals and bedpans	Yes	Yes	Yes
<b>Operation Theatre</b>				
	Adequate storage	No	Yes	Yes
	Ambu resuscitation set with adult and child masks		Yes	Yes
	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
	Instrument tray	No	Yes	Yes
	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

1	2	3	4	5
	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	Yes	Yes
	Anesthesia Equipment Anesthetic trolley/machine	No	Yes	Yes
	CO2 Monitor	No	Yes	Yes
	O2 Monitor	No	Yes	Yes
	Endoscopic equipment and necessary accessories	No	No	Yes
	Bronchoscope	No	No	Yes
	Colonoscope	No	No	Yes
	Endoscope	No	No	Yes
	Fiber Optic Laryngoscope	No	No	Yes
Central Supply	Amputation set	No	No	Yes
	Caesarean/hysterectomy set	No	Yes	Yes
	Dilatation and curettage set	No	Yes	Yes
	Endoscopic instrument cleaning machines and solutions	No	No	Yes
	Hernia set	No	No	Yes
	Laparotomy set	No	Yes	Yes
	Linens	Yes	Yes	Yes
	Locked storage	Yes	Yes	Yes
	Operating drapes	No	Yes	Yes
	Ophthalmic instrument	No	Yes	Yes
	Protective hats, aprons, shoes and gowns etc.	Yes	Yes	Yes
	Pelvic/fistula repair set	No	No	Yes
	Sterile gloves	Yes	Yes	Yes
	Sterilization equipment for instruments and linens	Yes	Yes	Yes
	Surgical supplies (e.g. sutures, dressings, etc.)	Yes	Yes	Yes
	Thoracentesis set	No	No	Yes
	Thoracostomy set with appropriate tubes and water seal bottles	No	No	Yes
	Thoracotomy set	No	No	Yes
	Thyroid/Parathyroid set	No	No	Yes
	Tracheostomy set	No	Yes	Yes
	Tubal ligation set	No	Yes	Yes
	Vascular repair set	No	Yes	Yes
Other equipment as per the specialized services available shall also be there				

## Annexure 23

(See sub-clause 5 of clause III of Appendix I)

## DRUGS, MEDICAL DEVICES AND CONSUMABLES

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

Sl. No.	Name of the Drug
<b>INJECTIONS</b>	
01	INJ. DIAZEPAM 10 MG
02	INJ. FRUSEMIDE 20 MG
03	INJ. ONDANSETRON 8 MG/4ML
04	INJ. RANITIDINE
05	INJ NOR ADRENALINE 4 MG
06	INJ. PHENYTOIN 50 MG
07	INJ DICLOFENAC 75 MG
08	INJ. DERIPHYLLINE
09	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
<b>OTHER</b>	
23	NEB. SALBUTAMOL 2.5 ML
24	NEB. BUDESONIDE
25	LIGNOCAINE JELLY 2%
26	ACTIVATED CHARCOAL
27	CALCIUM (INJ or TAB)
<b>FLUIDS</b>	
28	RL 500 ML
29	NS 500 ML
30	NS 250 ML
31	NS 100 ML
32	DNS 500 ML
33	DEXTROSE 5% 500 ML
34	DEXTROSE 10% 500 ML
35	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 24

(See sub-clause 6 of clause III of Appendix I)

## 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 less than 50 beds 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. No.	Human Resource	Requirement
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).
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 12th pass).

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

## Annexure 25

(See sub-clause 8 of clause III of Appendix I)

## LIST OF LEGAL REQUIREMENTS

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

Sl.	Name of Document	Valid From	Valid Till	Send for renewal by	Remark (Expired/valid/NA)
1	2	3	4	5	6
01	Registration under Nursing Home Act/ Medical Establishment Act				
02	Bio-medical Waste Management Licenses				
	Authorization of HCO by PCB				
	MOU with Vendor				
03	AERB Licenses				
	Type approval				
	Layout Approval				
	License for CT-interventional/ Registration for other machines				
04	NOC from Fire Department				
05	Ambulance				
	Commercial Vehicle Permit Commercial Driver License				
06	Pollution Control Licenses				
07	Building Completion Licenses				
08	Lift licences for each lift				
09	DG Set Approval for Commissioning				
10	Diesel Storage Licenses				
11	Retail and bulk drug license (pharmacy)				
12	Food Safety Licenses				
13	Narcotic Drug Licenses				
14	Medical Gases Licenses/ Explosives Act				
15	Clinical Establishments and Registration (if applicable)				
16	Blood Bank Licenses				
17	MoU/agreement with outsourced human resource agencies as per labor laws				

1	2	3	4	5	6
18	Spirit Licence				
19	Electricity rules				
20	Electricity rules				
21	MTP Act				
22	PNDT Act				
23	Transplantation of Human organs Act				
24	Sales Tax registration				
25	PAN				
26	No objection certificate under Pollution Control Act (Air/Water)				
27	Arms Act, 1950 (if guards have weapons)				

Annexure 26

(See sub-clause 9 of clause III of Appendix I)

CONTENT OF MEDICAL RECORD

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

Sl. 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)

Annexure 27

(See sub-clause 10.7 of clause III of Appendix I)

INFORMED CONSENT/CONSENT GUIDELINES

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

Sl. 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 28

(See sub-clause 10.36 of clause III of Appendix I)

**Discharge Summary**

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

Sl. 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.

Appendix II

[See rule 8(d)]

S. No.	Type of Laboratory Advanced	Basic	Medium	Composite
(1)	(2)	(3)	(4)	(5)
1	Scope of Services	These tests (as mentioned below) can be performed in mobile laboratory at field locations also	In addition to the tests performed in basic composite laboratory, including tests mentioned as under	In addition to tests performed in medium laboratory, additional tests mentioned as under
	(a) Biochemistry	Routine Biochemistry tests like Blood Sugar, Renal Function Tests, Liver Function Tests, Amylase, Lipase, Lipid profile, Cerebro -Spinal Fluid (CSF) and other biological fluids (glucose and protein), Oral Glucose Tolerance Test, Electrolytes, Calcium or Phosphate, HbA1c, any bio chemistry based rapid test	Hormone Bioassay, Tumor markers, plasma protein electrophoresis	(a) coagulation profile, Drug monitoring and toxicology assay  (b) Molecular genetics, tests for detection of inborn errors of metabolism

(1)	(2)	(3)	(4)	(5)
	(b) Haematology	Haemogram, Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping and matching	Coagulation Assay	All other Haematology tests also
	(c) Histopathology	Nil	May do, subject to availability of equipment and specialist	Histopathology Examination
	(d) Molecular Genetics	Nil	May do, subject to availability of equipment and specialist	Molecular genetics
	(e) Cytopathology	Nil	PAP smear, Fine Needle Aspiration Cytology (FNAC), sputum and CSF cytology	ImmunoCytochemistry. Other biological fluid cytology; Ultrasound or CT guided FNAC.
	(f) Immunohistopathology	Nil	Nil	Immunohistochemistry:
	(g) Medical Microbiology & Immunology	Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova, cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory.	(a) Serological tests for viruses, bacteria, fungi, parasites (b) Cultural Sensitivity tests: Bacterial or fungal (c) Other special stains besides Gram's stain.	(a) Culture sensitivity tests for viruses. (b) Real Time Polymerase Chain Reaction (RT-PCR) tests. (c) Tissue diagnosis test for infectious diseases.
II	INFRASTRUCTURE			
		Basic Composite	Medium	Advanced
	<b>1. Signage</b>			
	(a) Basic signage- A signage within or outside the facility should be made available containing the following information.	Essential	Essential	Essential
	(b) Name of the person in-charge with qualification and registration number	Essential	Essential	Essential

(1)	(2)	(3)	(4)	(5)
	(c) Broad services provided i.e. Haematology, Biochemistry, Clinical Pathology, Histology, Cytology, Molecular Genetics- whichever is applicable	Essential	Essential	Essential
	(d) Timings of the different consultants	Desirable	Essential	Essential
	(e) Internet facility or Telephone and mobile number for appointment	Desirable	Desirable	Desirable
	(f) Fee structure: To be displayed separately including type of investigation and charges i.e. Special and routine tests	Essential	Essential	Essential
<b>2. Safety Signage (Wherever applicable)</b>				
	a) Safety hazard and caution signs - Biomedical waste segregated in coloured bins and bags as per Biomedical Waste Management Rules, 2016 including radioactive materials, toxic chemicals, microbial agents, infected biological material	Essential	Essential	Essential
	(b) Appropriate Fire exit signages - Minimum one fire extinguisher	Desirable	Desirable	Essential
<b>3. Space requirement</b>				
	(a) Registration and waiting room, public utilities, safe drinking water etc.	Desirable	Essential	Essential
	(b) Sample collection area	Essential	Essential	Essential
	(c) Laboratory with adequate diffuse and spot lighting	Essential	Essential	Essential
	(d) Toilet	Essential	Essential	Essential
	(e) Reporting and billing area	Essential	Essential	Essential
	(f) Staff room and doctor's duty room - Male and female different where 24 hours services available	Desirable	Desirable	Essential
	(g) Washing room	Essential	Essential	Essential
	(h) Preservation of the specimens and slides	Essential	Essential	Essential
	(i) Electrical facilities	Essential	Essential	Essential

(1)	(2)	(3)	(4)	(5)
	(j) Temperature control for specialized equipment like flow cytometry and chemiluminescence equipment, ELISA test equipment etc.	Essential	Essential	Essential
	(k) Counselling room for HIV	Essential, if HIV test is done	Essential, if HIV test is done	Essential, if HIV test is done
	(l) FNAC room for all patients for sample collection	Desirable	Desirable	Desirable
	(m) Dark room for Immuno-fluorescence	Not required	Not required	Essential
	(n) Frozen Section facilities	Not applicable	Essential	Essential
	4. Furniture and fixtures	Essential	Essential as per scope of services	Essential as per scope of services
	5. Communication system- Telephone and mobile number for appointment	Desirable	Desirable	Desirable
	6. Wash Basins	Essential	Essential	Essential
<b>III Human Resource</b>				
	<p>a) Minimum qualification of Technical Head of Laboratory or Specialist or *Authorised Signatories.</p> <p>NOTE:</p> <p>1. *The authorised signatory will be liable for authenticity of the laboratory report only.</p> <p>2. Medical tests should normally be undertaken on the advice of a registered medical practitioner.</p>	<p>Essential –</p> <p>1. MBBS registered with MCI or State Medical Council with at least one year training or work experience in a Medical Diagnostic Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation.</p> <p>Those working in Government sector shall be exempted from the aforesaid training or experience</p> <p>or</p> <p>2.M.Sc in Pathology or Medical Microbiology or Medical Biochemistry from a recognised university or institution with at least three years training or work experience in a Medical Diagnostic Laboratory of same or higher level in a</p>	<p>Essential –</p> <p>1. Doctor of Medicine (MD) or Diplomate of National Board (DNB) in Pathology or Biochemistry or Medical Microbiology or Laboratory Medicine or Diploma in Clinical Pathology (DCP), registered with MCI or State Medical Council.</p> <p>Or</p> <p>2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three</p>	<p>Essential –</p> <p>1. Doctor of Medicine (MD) or Diplomate of National Board (DNB) in Pathology or Biochemistry or Medical Microbiology or Laboratory Medicine or Diploma in Clinical Pathology (DCP), registered with MCI or State Medical Council.</p> <p>Or</p> <p>2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a</p>

(1)	(2)	(3)	(4)	(5)
		<p>Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of laboratory results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p><i>Note:</i> Laboratory technician with qualification as mentioned in Part III (b) of this Notification working in a Medical Diagnostic Laboratory registered under a Central or State Clinical Establishments Registration Act, as applicable, and a Health care worker in a Government National Health program trained for conducting identified specific tests, may conduct the tests and generate test results which shall be submitted to the signatory authority at Sl. Nos. 1 or 2 as applicable.</p>	<p>years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate, sign and issue test reports in respect of tests of their respective specialty.</p> <p>Or</p> <p>3. M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.</p> <p>All such test reports generated must</p>	<p>recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate, sign and issue test reports in respect of tests of their respective specialty.</p> <p>Or</p> <p>3. M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or</p>

(1)	(2)	(3)	(4)	(5)
			<p>necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p><i>Note:</i> Interpretation of lab results or opinion there on, wherever required by the signatory authority at Sl. No.3, such test reports may be co-signed by the signatory authority at Sl. Nos. 1 or 2, after recording opinion or interpretation. Co-signee medical doctor shall be responsible only for the opinion or interpretation given.</p> <p>Desirable: If any special test of other speciality is done, it is desirable that specialist of that subject needs be there on full time or part time or outsourced basis.</p> <p>*Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory.</p> <p>Illustration: (i) Special Tests pertaining to Bio-</p>	<p>organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.</p> <p>All such test reports generated must necessarily bear a disclaimer to the effect that the reports are strictly for the use of medical practitioners and are not medical diagnosis as such.</p> <p><i>Note:</i> Interpretation of lab results or opinion there on, wherever required by the signatory authority at Sl. No. 3, such test reports may be co-signed by the signatory authority at Sl. Nos. 1 or 2, after recording opinion or interpretation.</p> <p>Co-signee medical doctor shall be responsible only for the opinion or interpretation given.</p>

(1)	(2)	(3)	(4)	(5)
			<p>Chemistry and Microbiology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively. (ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology</p>	<p>Desirable:</p> <p>If any special test* of other speciality is done, it is desirable that specialist of that subject needs be there on full time or part time or outsourced basis.</p> <p>*Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory.</p> <p>Illustration:</p> <p>(i) Special Tests pertaining to Bio-Chemistry and Microbiology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in BioChemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively (ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board</p>

(1)	(2)	(3)	(4)	(5)
				(DNB) or Ph.D in Pathology
	(b) Number of laboratory technicians with Diploma in Medical Laboratory Technology (DMLT) or Bachelor of Science (B.Sc.) Medical Laboratory Technology (MLT) or Master of Science (M.Sc) Bio-chemistry or Micro biology qualification from a recognised university or institution	Essential: 1	Essential: 2	Essential: 4
	(c) Support staff (Laboratory Assistant or Laboratory Attendant) Roster of salary of staff. Periodic health check-ups and vaccination of staff	Essential: 1.	Essential: 1	Essential: 2

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