

Notification
Health and Family Welfare Department
Sachivalaya, Gandhinagar
Dated the 13th March 2024

Gujarat Clinical Establishments (Registration and Regulation) Act, 2021.

No.GHY-04-2024-GCA-102021-1314-A.- WHEREAS certain draft rules were published as required by sub-section (1) of section 45 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj.18 of 2021) in the Gujarat Government Gazette, dated the 19th December 2023, inviting objection or suggestion from all persons likely to be affected thereby within a period of thirty days from the date of publication of the said notification in the Official Gazette.

AND WHEREAS objections or suggestions received by the Principal Secretary to the Government of Gujarat, Health and Family Welfare Department, Sachivalaya, Gandhinagar in respect of the said draft notification have been considered by the Government.

NOW, THEREFORE, in exercise of the powers conferred by sub-section (1) of section 45 of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 (Guj.18 of 2021) the Government of Gujarat hereby makes the following rules, namely:-

1. (1) These rules may be called the Gujarat Clinical Establishments (Registration and Regulation) (Amendment) Rules, 2024.

(2) They shall come into force from the date of their publication in the *Official Gazette*.
2. In the Gujarat Clinical Establishments (Registration and Regulation) Rules, 2022 (hereinafter referred to as "the said rules"), in rule 2, in sub-rule (1), after clause (a), the following clauses shall be added, namely:-
" (b) "Annexure" means annexure appended to these rules;

(c) "Blood bank" means a blood bank as defined in the Drugs and Cosmetic Rules, 1945 from time to time;

(d) "Clinic" means a clinical establishment providing examination, consultation, prescription to outpatients including dispensing of medicines by a single or general practitioner or specialist doctor or super-specialist doctor. "Polyclinic" means a clinical establishment with more than one doctor or general practitioner or specialist doctor or super-specialist doctor. A few minor procedures like dressing and administering injections etc. may be provided in the clinic or polyclinic.

(e) "Consulting Room" means a place where consultation including examination of the patients and issue of prescription is done and medical advice is provided;

- (f) "Council" means the State Council for Clinical Establishments;
- (g) "Dental Clinic" means a clinic where treatment for dental ailments is offered with or without injection, minor operation, dressing etc.;
- (h) "Dental Hospital" means a place where patients are treated as inpatient and treatment is given for dental ailments;
- (i) "Hospital" means and includes a Nursing Home or Health Centre or Treatment Centre or any other place where facilities for admission as in-patients for treatment of illness with or without surgery or conduct of delivery etc., with or without out-patient facilities and diagnostic facilities like laboratory etc., in any recognised system of medicine;
- (j) "Laboratory" means a place where bio-medical or bio-chemical or clinical pathology or biopsy or bacteriological or genetic investigation or any diagnostic test or investigative services are carried out;
- (k) "Patient" means a person who reports himself or brought to any clinical establishment including newly born child for treatment or consultation or seeking any other services rendered by the such clinical establishment;
- (l) "Pharmacist" means a person registered under the Gujarat State Pharmacy Council or any other such Council or Board in Gujarat recognised by the Government;
- (m) "Qualified Nurse" means a person who possesses the required qualification from any of the Nursing Teaching Institutions, recognised by the Indian Nursing Council and enrolled with the Gujarat Nursing Council under the Indian Nursing Council Act, 1947 (Central Act XLVIII of 1947). In case of Ayurveda or Unani or Homeopathic Nurse, it shall mean a person who possesses the required qualification from any of the Nursing Teaching Institutions, recognised by the Government and enrolled with respective Council or Board in Gujarat recognised by the Government.
- (n) "Registered Medical Practitioner" means a person who possess any of the Government recognised medical qualification and who has been enrolled in the register of the respective Council viz., Medical, Dental, Siddha, Ayurveda, Unani or Homeopathic Councils in Gujarat or the Board of Indian Medicine or any such Council, Board or any other statutory body in Gujarat established or recognised by the Government of Gujarat or Government of India;"

3. In the said rules, after rule 8, the following rule shall be inserted, namely:-

“8A. Minimum facilities of clinical establishment: –

- (1) The floor space and other facilities, the minimum number of staff and their minimum qualification, minimum equipment and other conditions required for a clinical establishment, for providing different medical services including specialized services shall be in accordance with the norms and conditions specified in Annexure-9.
- (2) If, at any time clinical establishment violates the conditions of registration or any of the provisions of the Act or rules made thereunder, the District Authority or the State Council, as the case may be, may take appropriate action under the Act.”.

4. In the said rules, in rule 9, for sub-rule (6), the following sub-rule shall be substituted, namely:—

“(6) In event of change of management or ownership, the clinical establishment shall inform in writing to the District Registering Authority regarding the change of management or ownership or RMP in-charge of Hospital within two months. The clinical establishment shall make an online application on the government portal in Annexure-1A for such changes along with payment of fees specified in Annexure 7.”

5. In the said rules, in rule 10, in sub-rule (1), after the words “necessary information filled”, the words “in Annexure-1A” shall be inserted.

6. In the said rules, in rule 12, after the words “provisional certificate”, the words “in Annexure-1A” shall be inserted.

7. In the said rules, after rule 10, following rule shall be added, namely:-

“10 A. Application for obtaining certificate of registration under rules 9 and 10 -

- (1) Every clinical establishment shall make an application under rule 9 and rule 10 as per Annexure-1A. If a clinical establishment is offering services in more than one recognised system of medicine, it shall make separate application for obtaining certificate for each system of medicine;

Provided that a laboratory or a diagnostic center which is a part of a clinical establishment shall not be required to get registered separately.

- (2) The clinical establishment shall be required to submit the documents specified in Annexure-1A along with the application for obtaining provisional certificate of registration and permanent certificate of registration.

(3) The amount collected by way of fees, fines and penalties by the Council and the Authority under section 35 and Section 36 shall be credited to such account as the State Government may, by order specified in this behalf.”

8. In the said rule, after rule 13, following rules shall be inserted, namely:-

“14. Duties of clinical establishment. - Every clinical establishment shall, -

- (a) display a copy of the Certificate of Registration of the clinical establishment in a prominent place of the premises open to public;
- (b) maintain records in electronic form showing the names, addresses and the qualifications of its employees and the equipment maintained by establishment and if any changes to it, report to the authority half yearly. However, Clinical establishments shall be permitted to maintain record in electronic or manual form for a transitional period of two years from the date of notification of this rules.
- (c) display of rates charged by Clinical Establishment. However while displaying rates chargeable for ICU rooms, different kinds of rooms for IPD, it shall not only display the room rent, but also average billing amount in respect of such rooms or ICU per day including cost of all medicines, doctor visit fees and all procedures charged on average per day to patients who stayed in such rooms over previous one year. Such display of rates shall be as per annexure-10.
- (d) maintain clinical records, preferably electronically-(i.e any paper, film, printout, slide, solution, medium which can be deciphered or used to indicate and diagnose the condition of the human body or a part of it or any material taken out of it and the course of treatment administered to or undergone by the person), of its activities relating to a patient. The patient shall be given case records containing name, age, gender and date of consultation, diagnosis (either provisional or final) and treatment advised including the laboratory and diagnostic results, and the investigation undertaken;
- (e) each record shall be kept open for inspection to the competent authority;
- (f) every clinical establishment shall facilitate to segregate and dispose the waste including biomedical waste as per the applicable norms or guidelines of the Government of India and Gujarat Pollution Control Board;
- (g) surrender of the Certificate of Registration, on ceasing to function as a clinical establishment.
- (h) It shall be the duty of every clinical establishment to provide a list of patients every month who are suffering from Tuberculosis or other notifiable diseases notified

under the Epidemic Disease Act, 1897 and getting diagnosed at the clinical establishment for the first time along with necessary details of communication address, contact number and other information to local Public Health Authority namely, Chief District Health Officer of a District or Municipal Health Officer of concerned urban local body in whatever way they are known.

- (i) It shall be the duty of every clinical establishment to follow directions related to public policy issued by the Government from time to time in respect of quality of care for specific categories of patients.

15. Maintenance of medical records. –(1) Every clinical establishment shall maintain records with particulars relating to the clinical observation, test, investigation, diagnostic opinion, advice and treatment given to the patient, who has visited the clinical establishment either as an in-patient or out-door patient in details to a broader extent as specified in Annexure-10. However, in respect of laboratory test or diagnostic investigation report, such records shall be maintained by concerned laboratory or diagnostic facility.

- (2) In case of unforeseen events, pandemic or any other disaster, the clinical establishment must provide information as required by the State Council or the District Registering Authority.
- (3) The record of OPD shall be maintained electronically for minimum period of two years, IPD record shall be maintained for minimum period of five years and in case of court-case/medico legal cases/consumer forum cases, the related record shall be maintained till the final disposal of the case.

16. Publication of list of clinical establishments–

- (1) The Authority/State Council shall display the list of clinical establishments registered in Gujarat and update the same on online platform every month in Form-A of Annexure-11.
- (2) The Authority shall display the list of the clinical establishments whose registration has expired and update the same on online platform in Form-B of Annexure-11.

17. Manner of inspection in case of a clinical establishment -

- (1) Entry and inspection or inquiry of the clinical establishment shall be done by the Authority or State Council or Health and Family Welfare Department or a team duly authorized by it subject to such general or special orders as may be made by the Authority or State Council or Health and Family Welfare Department.
- (2) The inspection team shall intimate in advance to the establishment about the visit.

(3) The inspection team shall examine premises used or proposed to be used for the clinical establishment and inspect the equipments and other accessories and enquire into the professional qualifications of the technical staff employed and may make any such other enquires, as it consider necessary to verify the statements made in the application for registration or grant of license or to ascertain factual veracity as to the complaint regarding patient care. All persons connected with the running of the establishment shall be bound to provide full and correct information to the inspection team.

(4) The inspection team shall submit a report in Annexure-12 within a week of the inspection to the authority and shall also forward a copy thereof to the State Council.

18. Disobedience of direction, obstruction and refusal of information.

(1) In case of disobedience of direction, obstruction and refusal of information required by any person of authority empowered under the Act, District Registering Authority or Council, shall hold an inquiry after giving the concerned person a reasonable opportunity of being heard for the purpose of imposing penalty.

(2) The person aggrieved by the decision of the Authority may prefer an appeal to the State Council within a period of three months from the date of receipt of such decision.

(3) State Council or the person authorised by the State Council on receipt of such appeal, if he considers that, an interim order is necessary in the matter, he may pass such an order.

(4) State Council or the person authorised by the State Council may pass such order as he deems fit after giving a reasonable opportunity of being heard.

(5) The decision of the appellate authority shall be communicated to the person concerned within fifteen days from the date of passing of such order.

(6) The decision of the appellate authority shall be final and binding.”

9. In the said rules, for Annexure 7, the following Annexure shall be substituted, namely:-

**“Annexure –7
(See rules 9, 10 and 12)**

Fees for Application of Registration/ Renewal of Different Clinical Establishment

Sr.	Establishment Type	Fees of application for provisional	Fees of application for permanent	Fees for appeal against District Authority
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		registration(in Rs)	registration(in Rs)	Order(in Rs)
1	Clinic/consulting room/ Polyclinic	1000/-	2000/-	1000/-
2	Establishment up to 15 beds	2000/-	8000/-	2000/-
3	Establishment with 16 to 30 beds	5000/-	20000/-	5000/-
4	Establishment with 31 to 50 beds	10000/-	40000/-	10000/-
5	Establishment with 51 to 100 beds	15000/-	60000/-	15000/-
6	Establishment with more than 100 beds	50,000/-	200000/-	15000/-
7	Standalone Lab/ Other diagnostic unit	2,000/-	8000/-	2000/-

- For late Application the amount would be double of the provisional or permanent registration fee as the case may be.
- For change of ownership, management or name of establishment would be half the amount of provisional or permanent registration fee as the case may be.
- For renewal of permanent registration would be half the amount of the permanent registration fee.
- For obtaining the duplicate certificate the fee amount would be 10 percent of the amount of provisional or permanent registration fee as the case may be”.

10. In the said rules, after Annexure 1, the following Annexures shall be inserted, namely:-

**“Annexure – 1A
(See rule 9, 10A, 12)**

**Application Form for Permanent Registration/
Renewal of Registration / Change of Management or Ownership of Clinical
Establishment**

Establishment Details

- 1. Name of the Clinical Establishment:** _____
 1. Registration Number (provisional/ permanent provided by the Authority if available): _____
 2. valid till: _____
- 2. Type of clinical Establishment** (Consulting Room, Clinic, Poly clinic, Hospital, Dental Clinic, Clinical Laboratory, X-ray Centre and imaging Centre): _____
- 3. Category of Clinical Establishment** (Allopathy, Ayurveda, Siddha, Homeopathy, Yoga, Naturopathy): _____
- 4. Address:**

Village/Town: _____	Taluka: _____
District: _____	State: _____ Pin code: _____
Telephone No.(with STD code): _____	Mobile: _____
Email ID: _____	Website URL address (if any): _____
- 5. Year of starting:** _____

6. Ownership of Services. (Fill/ Mark all whichever is applicable) -

Public Sector

Central Government	State Government	Local Government (please specify)
Public Sector Undertaking	Railways	Employees State Insurance Corporation
Grant-in-Aid institutions	Autonomous organization	Society/Not for profit Companies

Any other (please specify): _____

Private Sector

Individual Proprietorship	Partnership firm (Including LLP)	Registered Company
Corporation (including a society) registered under a Central, Provincial or State Act (Please specify)		
Trust (including Charitable) registered under a Central, Provincial or State Act (please specify)		
Branch of a Foreign Service provider (please specify)		

Any other (please specify): _____

7. Name of the owner(s) of Clinical Establishment:

Name: _____ Address: _____
 Village/Town: _____ Taluka: _____
 District: _____ State: _____ Pincode: _____
 Telephone No. (with STD code): _____ Mobile No.: _____ Email ID: _____

8. Name, Designation and Qualification of person-in-charge of the clinical establishment (it could be same as owner)

Designation: _____ Qualification: _____
 Registration No (GMC/IMC): _____
 Address: _____
 Village/Town: _____ Taluka: _____
 District: _____ State: _____ Pin code: _____
 Telephone No.(with STD code): _____ Mobile: _____ Email ID: _____
 Any other (please specify): _____

9. Type of clinical establishment: (Please mark/ tick whichever is applicable)

Clinic

Single Practitioner	Consulting Room	Polyclinic
Dental	Psychiatry	Any other please specify: _____

Hospital

General Practice Services	Maternity Home
Single speciality Services	Multi Speciality Services
Super speciality Services	ICU/ICCU

Emergency Causality	Drug de-addiction hospital
Psychiatry nursing home/ Hospital	Any other please specify: _____

10. Whether the clinical establishment-

(a) is attached with Laboratory (if so, please mark/tick whichever is applicable)

Pathology	Haematology	Histopathology
Cytology	Genetics	Samples Collection Centre
Biochemistry	Microbiology	Any other please specify

If answer to (a) above is yes, the following details may be furnished, namely:

- Tests that it proposes to carry out
- List of equipments available
- A list of technical staff (both technical and supervisory)
- List of personnel who are going to sign test reports.

(b) is attached with X-ray and Imaging Centre (if so, please tick whichever is applicable)

Portable X ray	Conventional X Ray	Digital X Ray
X Ray with computed Radiography system	Ultrasound	Ultra sound with Color Doppler
Mammography	Orthopentogram(OPG)	CT Scan
Magnetic Resonance Imaging (MRI)	Positron Emission Tomography (PET) Scan	Bone Densitometry
Uro-flowmetry	Any other (Please specify):	

(c) is attached with Blood Banks (if so, please tick whichever is applicable)

(A) Based on Location

Standalone	Hospital Based	Any other please specify: _____
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(B) Based on Facilities (please specify):

- Blood bank having whole blood facility only
- Blood bank/having whole blood and component facility
- Blood bank having whole blood and/or component facility with any other additional facility

11. List of the equipments (only provide list of such equipments with unit cost more than ten thousand rupees):-

12. System of Medicine: Services offered (please tick whichever is applicable)

(a) Allopathic Speciality

Medical and Allied	Surgical and Allied	Obstetrics and Gynecology
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Any other please specify: _____

(b) Ayurveda

Anusadh Chikitsa	Shalya Chikitsa	Shodhan Chikitsa	Rasayana
Pathya Vyavastha	Any other please specify: _____		

(c) Unani

Matab	Jarahat	Ilaj-bit-Tadbeer	Hifzan-e-Sehat
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Any other please specify: _____

(d) Siddha

Maruthuvam	Sirappu Maruthuvam	Varmam Thokknam & Yoga
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Any other please specify: _____

(e) Homeopathy

General Homeopathy	Any other please specify:-
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(f) Naturopathy

External Therapies with natural modalities	Internal Therapies
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Any other please specify:- _____

(g) Yoga

-Ashtang Yoga

Any other please specify:- _____

13. Area of the establishment (in square metres)

(a) Total area: _____ (b) Constructed Area: _____

14. Out-Patient Department

Total number of Out Patient Department Clinics

Sr.No.	Speciality	Number of Rooms

13. In-Patient Department

(a) Total number of beds:

(b) Specialty-wise distribution of beds, please specify:

Sr.No.	Speciality	Number of beds

15. Biomedical Waste Management

(a) Method of treatment and/or disposal of bio-medical waste:

- i. Through Common Facility
- ii. Onsite Facility
- iii. Any other (please specify)

(b) Whether authorization from Pollution Control Board obtained?

Yes No Applied for

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

Number of permanent staff: _____

Number of temporary staff: _____

(A)

Category of Staff	Name	Qualification	Registration Number	Nature of Service Temporary/ Permanent
Doctors				
Nursing Staff				
Para-medical Staff				
Pharmacists				

(B) i. Number of Support Staff:

ii. Number of Administrative Staff:

iii. Others, Please specify

17. Clinical establishment shall upload following certificates as applicable:

- a) NOC or certificate as the case may be for Fire safety issued by competent authority
- b) Biomedical waste management certificate issued by GPCB
- c) Authorization from Atomic Energy Regulation Board (Radiology)
- d) Certificate under the Drug and Cosmetic Act, 1985
- e) Authorization under PC&PNDT Act, 1994
- f) Certificate of registration under Assisted Reproductive Technology (Regulation) Act, 2021
- g) Certificate of registration under Surrogacy (Regulation) Act, 2021
- h) License for blood bank or authorization for blood storage facility
- i) 5 to 10 photographs of clinical establishment taken from different angle.

18. Payment options for Registration Fees:

Payment option: Online Transaction

Online Transaction Id.:

Amount (in Rs.):

Date:

Details:

I / We hereby declare that the statement stated above are true and correct to the best of my/our knowledge and I/We shall abide by the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 and the Rules made thereunder.

I fully understand that in case any of the submitted documents are found to be false or if it is found that I have not fulfilled in accordance with any of the provisions of the Gujarat Clinical Establishments (Registration and Regulation) Act, 2021 and the Rules, the Competent Authority shall be at liberty to penalize me or cancel the registration as per the provisions of this Act.

Place:

Date:

Signature of the Authorized person of the clinical establishment

.....

Acknowledgment

Received Application for Registration from.....

Signature of CDMO/CDHO/Superintendent/Authorised person

Name:

Date with Seal:

11. In the said rules, after Annexure 8, the following Annexures shall be added, namely:-

**“Annexure-9
(See rule 8A)**

A. Allopathy System

I. Consulting Room. -

- (1) **Infrastructure** - Consulting room shall have sufficient space with light and ventilation. Separate space for the patients waiting for consultation has to be provided.
- (2) **Staff** - The examination of the patient and prescription of the treatment shall be done only by a registered medical practitioner as required under the Indian Medical Council Act/ National Medical Commission Act as applicable.
- (3) **Equipment** – The equipments and hospital accessories shall be available in the consulting room according to concerned speciality.
- (4) **Prescription slip**- Doctor shall sign the prescription slip with date and registration number with concern council and ABHA if agreed to by patient.

II. Clinic. - In addition to the norms prescribed for a consulting room, the following norms are required to be fulfilled, namely: -

- (1) **Building** - Sufficient space shall be available for keeping the patient under observation in case of anaphylaxis or for giving intravenous drip or for observation etc.,
- (2) **Staff** - Minimum of a Registered Medical Practitioner (RMP) and a qualified paramedical staff.
- (3) **Equipments**– Clinic should have all necessary equipments as per service provided.
- (4) **Waste Disposal**- Facilities to segregate and dispose the waste including biomedical waste as per the Government of India and Gujarat Pollution Control Board norms.
- (5) **Dispensation of Medicine**- If the clinic is also engaged in dispensing of medicines to the patients, the same shall be done only by a qualified pharmacist or by the Registered Medical Practitioner (RMP) of the clinic or under his direct supervision.

(6) **Laboratory in a Clinic-** If the clinic is providing laboratory services, the laboratory work shall be supervised and approved by a qualified person specified in Annexure-9.

(7) **X-ray/CT scan/MRI (radiograph)-** If the clinic is having radiograph unit, the radiograph shall be taken by a radiologist or a competent doctor or by a competent person complying with regulatory requirement.

(8) **Minor Surgeries-** In case of minor surgeries or minor surgical procedures like cyst excision, Medical Termination of Pregnancy (MTP), Dilatation and Curettage (D&C) are under taken it is advisable to have a sterile room for the purpose and facilities available as given for minor Operation Theatre.

III. Polyclinic- (1) In addition to the norms prescribed for clinic and consulting room, separate cubicles/rooms/spaces shall be made available for each specialties, if they are being attended simultaneously.

(2) Reasonable space for waiting room and provision of safe drinking water and toilet shall be made available for the patients. Names of different Registered Medical Practitioner (RMP) attending shall be exhibited in the waiting room.

IV. Hospital –

(1) **Infrastructure-** In addition to the norms prescribed for Clinic, Consulting room and Polyclinic, the waiting room shall be made available for the patients/those accompanying them, which shall have sufficient space

(2) **Ward or in-patient room clusters –**

(a) Space-

(i) Ward or in-patient room shall be spacious with good ventilation and light. Electric fan shall be provided to each room and one fan for at least two beds shall be provided for common rooms.

(ii) Toilets may be common or separate, but shall be clean and provided with water.

(iii) Cleaning arrangements shall be made to swab the clinical establishment atleast twice a day with antiseptic liquid.

(b) Staff-

-One Qualified RMP for every thirty beds

-One RMP shall be on call duty up to thirty beds during night and off duty hours.

- On duty RMP shall be available in the hospital physically for every thirty beds and above in general side round the clock.

- If the hospital is having less than thirty beds, but if an Intensive Care Unit (ICU) is functioning, one RMP per ten ICU beds shall be available on duty round the clock.

(ii) **Nurses-** Requisite number of qualified nurses for the bed capacity in accordance with the norms prescribed by Indian Nursing Council shall be provided.

The aforesaid human resource is the minimum requirement irrespective of the fact the availability of any number of trained personnel working in the hospital.

(iii) Attendant- Male and female attendants shall be engaged in sufficient number depending on the bed strength to assist the RMPs and nurses in their duties like dressings, enema and preparation of patients for surgery, delivery etc. but they shall not be given the task of giving injections or doing suturing etc. They shall work under the supervision of the nurse.

(iv) Infection control audit. - It shall be mandatory for hospitals with more than 30 beds to get infection control audit done through a third party agency once every 3 months. The audit report of infection control audit shall be displayed at a prominent place in the establishment.

(3) Other Services. -

(a) Pharmacy. - If a pharmacy is maintained in the hospital for dispensing medicines to the patients, it shall be done by a registered qualified pharmacist only and he should not prescribe any drugs.

(b) Laboratory. –

If the hospital is providing laboratory services, the laboratory work shall be supervise and approved by a qualified person specified in Annexure-9.

(c) X-Ray (Radiograph). - X-Ray department shall conform to the norms prescribed in part-VIII of this Annexure.

(d) Blood Bank. - If a blood bank is maintained by a hospital, it shall conform to the standards/requirements prescribed by the Government of India (i.e. Drugs and cosmetic Act 1940) from time to time.

(e) Ambulance. - It is desirable that, all Hospitals having more than fifty beds shall have an Ambulance with a driver available or alternatively they shall have tie up arrangement with another Hospital having Ambulance or some Ambulance service unit.

(f) Catering and Canteen. - If catering arrangements are available, the kitchen shall be clean and the cooks shall be periodically medically examined. FSSAI standards shall be followed as issued by time to time. Clean practices shall be maintained in the canteen and kitchen.

(g) lounge facility for admitted patients' attendants: every hospital with more than 50 beds shall provide a lounge where patients' attendants can quietly take meals or wait.

(g) General facilities-

(i) Bio-medical waste disposal – Bio-medical waste disposal shall be made as per the norms and Guidelines issued by Government of India or Gujarat Pollution Control Board from time to time. Proper segregation of the waste at the point is to be ensured.

(ii) Record Keeping –

All medical record should be maintained as per the code of medical ethics regulation 2002 published by National Medical commission and amended time to time.

(4) Mortuary room- A hospital having more than hundred beds shall have a mortuary room or room with freezer box facilities for the dead bodies.

(5) Water supply- Potable water supply shall be made available. Hot water supply also to be provided.

(6) Clothing and Linen- Bed sheets and other linen used for the patients shall be changed daily.

(7) Firefighting- Fire fighting system or equipments shall be installed as per government guidelines or fire NOC shall be obtained from competent authority, whichever applicable.

(8) Quality assurance- The names of the doctors working in the hospital and the facilities made available in the hospital shall be written and exhibited in the hospital at a prominent place or on hospital website. The Hospital shall strive to maintain quality in each of its services to be provided to the patients.

(9) Security- Due protective measures shall be under taken by the Hospital to ensure safety of the patients, visitors, staff and their properties.

(10) Hospital accessories- Sufficient number of wheel chairs, trolleys, stretchers etc. shall be made available in the hospital.

(11) Uninterrupted power supply - A generator or uninterrupted power system shall be provided to maintain essential services during power failure.

(12) Labour Room- If the Hospital is maintaining a labour room and is conducting deliveries it shall have the following norms, namely:-

(a) Building- There shall be a room for preparation of the patient for delivery, giving enema etc., with sufficient water supply. The labour room shall not be less than 120 square feet well ventilated with sufficient light. Space for keeping the newborn baby and for its resuscitation is essential.

(b) Staff- Delivery shall be conducted preferably by a qualified RMP. Otherwise Qualified Nurse, Auxiliary Nurse Midwife may do the same. Untrained persons shall not be entrusted with the Job. Even if a Nurse / Auxiliary Nurse Midwife conduct the delivery, a RMP shall be on call for any emergency or newborn resuscitation. If the labour ward is in a maternity hospital and deliveries are taking place regularly, a duty RMP shall be available round the clock. It is desirable to have a Pediatrician on call.

(c) Equipment- The following equipments and hospital accessories shall be made available, namely:-

- Labour Table with lithotomy stand
- Oxygen Cylinder with Vent mask
- P.V. Tray with equipment
- Vacuum extractor / Forceps delivery set
- Sterile cord clamp
- Suction apparatus
- Baby resuscitation set

-Baby Warmer (a light may also do)

-any other necessary equipment or as prescribed by the State Government time to time under this rules.

(d) Drugs(Drugs/injections indicated below or their generic or otherwise equivalents in salt contents) -

- Inj. Methyl ergometrine	-Inj.Magnesiumsulphate
- Inj. Oxytocin	-Absorbable suture material
- Inj.carboprost tromethamine	- Inj.Diazepam
- I.V. Fluids	- 2% Lignocaine
-Tab.Misoprostol200mcg	- Inj. Vitamin K
- Inj. Phenytoin sodium	- Inj. Tetanus Toxoid

And any other drugs as prescribed by the State Government time to time under this rules.

(e) Records. -

- (i) Birth Register
- (ii) Birth intimation slip
- (iii) Case sheets and notes to be recorded
- (iv) Register for babies and mothers to prevent child changing.

(13) Operation Theatre. -

(a) Minor Operation Theatre. - Where septic cases and minor surgeries like abscess, Incision and Drainage (I&D) and other septic cases etc. are carried out.

(i) Space. - Sufficient space - not less than 100 square feet with adequate lighting and ventilation.

(ii) Staff. - All surgeries in minor operation theatre shall be carried out by qualified doctor only. However dressings can be done by a Qualified Nurse or a Trained Nurse.

(iii) Equipments-

- Operation table.
- Sterilizer/ Autoclave
- Minor surgical equipments
- Regional Anaesthesia equipment
- Drugs as required
- Drugs for emergency
- anesthesia apparatus with Oxygen cylinder, Nitrous Oxide Cylinder
- Suction apparatus
- Baby resuscitation set
- any other necessary equipment or as prescribed by the State Government time to time under this rules.

(iv) Records. - Records of all surgeries done in minor operation theatre shall be entered in a register.

(b) Major Operation Theatre. -

(i) Space. - Shall have sufficient space with a minimum of 150 square feet is essential, well lit preferably air-conditioned. Other than the operating room, there shall be provision for patient waiting and a cot provided for post-operative recovery. Sufficient space shall be available for autoclave and sterilization and for scrubbing. Running water from the tap shall be available in the scrub room sufficient arrangements for fumigation of operation theatre. Swab for culture to be taken from operation theatre at least once a month.

(ii) Staff - A qualified nurse shall be the head of nursing staff in the Operation Theatre. Anaesthesia to be provided by a qualified Anaesthetist. Surgeries shall be performed by qualified doctors only.

(iii) Equipments –

- Operating table

- Anaesthesia apparatus with sufficient oxygen, nitrous oxide cylinders

- Multipara monitors

- Defibrillator

- Suction apparatus (preferably two)

- Autoclave

- Surgical equipments for surgery as per speciality

- Resuscitation equipment and drugs

- any other necessary equipment or as prescribed by the State Government time to time under this rules.

(iv) Records. - Record of all surgeries performed shall be recorded in a register with name, age, gender, address of patient and names of Surgeon, Anaesthetist and Staff Nurse who performed surgery. Biopsy reports-if any, shall also be entered.

(14) Intensive Care Unit. - An Intensive Care Unit must be maintained in all Nursing Homes or Hospitals having more than hundred beds. The following norms are to be maintained, namely:-

(a) Space - A well ventilated preferably air conditioned room with sufficient lighting is essential. For upto four ICU beds, a minimum space of 240 square feet and proportionately higher if the number of ICU beds is more. Sufficient space for keeping ventilators and monitors to be available. Space for duty RMP and nurse shall also be available. There shall be provision for attendants outside the Intensive Care Unit.

(b) Staff - One doctor for every ten beds for day time. If there are more than ten beds, one additional doctor for every additional ten beds. Similar provision shall be made for night time.

(c) **Nurse** - Requisite number of qualified nurses for the bed capacity in accordance with the norms prescribed by Indian Nursing Council shall be provided.

(d) Equipments -

- Intensive Care Unit beds
- Ventilators
- Multipara Monitors
- Defibrillator
- Suction apparatus
- Oxygen supply (either Cylinder or central supply)
- Resuscitation equipment and drugs
- All necessary drugs
- Uninterrupted power supply
- any other necessary equipment or as prescribed by the State Government time to time under this rules.

(e) **Records.** - A record of in-patients in Intensive Care Unit shall be available either in a manual register or electronically as to their illness, treatment offered, specialists visited - Out come etc.,

(15) Medical Record Maintenance in a Hospital. - The following records shall be maintained-as applicable, namely:-

- (i) Admission and Discharge Register.
- (ii) Case sheets
- (iii) Referrals
- (iv) Infectious and Communicable disease Register.
- (v) Immunisation particulars
- (vi) Family Welfare Services
- (vii) Medico Legal Records
- (viii) Maternal Death Record
- (ix) Infant Death record
- (x) 1 to 5 years Child Death records
- (xi) Birth and Death Register(with cause of death)
- (xii) Any other record as may be required by the Government under any other Act/rules-regulations of Government of India or Government of Gujarat.
- (xiii) All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time.

V. Dental Clinic. –

(1) Building. - The consulting room if it accommodates the Dental Chair also shall be having sufficient space not less than 100 square feet. The room shall be well ventilated and shall have sufficient lighting arrangements. Space for keeping the Sterilizer and Trays to be provided. Sufficient space for patient waiting to be provided outside the consulting room.

(2) Staff. - Dental Surgery, Consultation and prescription shall be performed by a qualified Dental Surgeon only as per the Indian Dentist Act, 1948 (Central Act XVI of 1948). Injections and administration of local anesthesia may be done by the dental surgeon himself, besides an anesthetist. X-Ray shall be taken by a qualified Radiographer or by the Dentist.

(3) Equipments-

- (a) Dental Chair
- (b) Provision of water for surgery
- (c) Sterilizer
- (d) Bin for sterile cotton gauze etc.
- (e) Trays with instruments
- (f) Dental instruments
- (g) Dental X-Ray (desirable)
- (h) any other necessary equipments or as prescribed by State Government time to time under this rules.

(4) Records - A separate record shall be maintained as specified in the rules.

VI. Dental Hospitals - Out-patient department. - The outpatient department of a dental hospital shall conform to the norms prescribed to a Dental Clinic. In addition, sufficient waiting room shall be provided to the patients. Wards, Operation Theatre and other aspects shall be as per the norms prescribed to the nursing homes and hospitals.

VII. Clinical Laboratories- Clinical Laboratories includes clinical laboratories, pathological laboratories, radiological centres, genetic laboratories etc.

(1) Building—Sufficient space for sample collection, Processing, Report preparation etc. should be available. There shall be sufficient space for Microscopy and for Biochemical tests. The room shall be well ventilated with sufficient light. Space for keeping a hospital bed for the use of patient shall be available. If x-ray is also functioning, norms as for an X ray centre shall be followed. The laboratories shall ensure adequate space in relation to the following:-

- (a) Patient's reception
- (b) Sample collection
- (c) Isolation for Bio hazardous materials
- (d) Radioisotope related work as per the regulatory agency Atomic Energy Regulatory Board (AERB) requirement.
- (e) Lavatory for the patient's use

The Laboratories shall preferably follow standards prescribed by the National Accreditation Board for Testing and Calibration of Laboratories for the personnel qualification etc., quality assurance in Lab Service, Internal Quality and External Quality should be ensured.

(2) Staff. – The laboratory work shall be supervised and approved by a qualified person specified in Annexure-9

(3) Equipments -

Microscopes

Calorimeter
 Centrifuge
 Semi Auto Analyzer or Auto Analyzer
 Cell Counter
 Refrigerator
 Hot Air oven
 Bio safety cabinet
 Laminar air flow cabinet -Optional.

anyother necessary equipments or as prescribed by State Government time to time under this rules.

(4) Records. - A separate record shall be maintained as specified in the rules

The following minimum Records to be maintained: -

- (a) Daily Results Register
- (b) Internal Quality Control Register
- (c) Sample Collection Register
- (d) Participation in External Quality Assessment Schemes/ Programmes.

VIII. X-Ray (Radiograph) and Imaging Centres. - This Centre shall include all centres of Imaging Sciences namely, Ultra Sonography Scan Centres, Computed Tomography (C.T.) Scan Centres, Magnetic resonance imaging (MRI) Scan Centres, X-Rays (Radiograph) as well as and Treadmill Echocardiography etc.

1. Buildings. - Sufficient space as the equipment in use demands. Sufficient space shall be provided for patient waiting and resuscitation of the patient in case of anaphylaxis occurring. X-ray and imaging centres shall fulfill the "*Atomic Energy Regulatory Board*" (AERB) norms.

2. Staff. - All tests shall be carried out by qualified technical persons only as follows:-

X-Ray	Radiographer with Clinical Research Associate (CRA) Qualification or Diploma in Medical Radiology Imaging Technology or BSC in Imaging Technology Or Degree or Diploma Course approved by AERB or Certificate/Diploma/Degree course as approved by the State Government/University recognised by UGC.
Ultra Sonogram	by a qualified Doctor or by a Radiologist or Concerned Specialist as per the provisions of the Pre-Conception And Pre-Natal Diagnostic Techniques (Prohibition of Gender Selection) Act, 1994
Electro Cardiogram (ECG)	by an Electro Cardiogram (ECG) Technician trained in Electro Cardiogram (ECG) or by doctor
Electroencephalography (EEG)	Electroencephalography (EEG) Technician trained in Electroencephalography (EEG) or by doctor

Computed Tomography (CT) scan	By a Radiographer/ X-ray technician and report by a Radiologist or by the concerned specialist.
Treadmill	Concerned Technician. A doctor shall be present during the Test.
Echo Cardiograph	by a Qualified Doctor preferably a Cardiologist or by a Qualified Doctor (Post Graduate in field of Radiology, Medicine, Pediatric, Anesthesia, Emergency, Critical care, Clinical Cardiology with adequate experience preferably a Cardiologist (Super Specialist in field of Cardiology)
Contrast Studies	Radiologist or by the Concerned Specialist
Magnetic resonance imaging (MRI)	Radiologist or by the Concerned Specialist

Scan. – MRI/CT scan/PET scan/USG scan Ultra sonography scan reporting shall be performed by a Radiologist or by the Concerned Specialist.

2. Equipments. - Equipments according to the concerned speciality tests.

3. Records. - A separate record shall be maintained as specified in the rules.

IX. Laboratories:

S. No.	Laboratory type	Basic Composite	Medium	Advanced
(1)	(2)	(3)	(4)	(5)
I	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 biochemistry based rapid	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

		test.		
	(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	Immuno Cytochemistry. Other biological fluid cytology; Ultrasound or CT guided FNAC.
	(f)Immuno-histopathology	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 Bacteria. (b) Real Time Polymerase Chain Reaction (RTPCR) tests. (c) Tissue diagnosis test for infectious diseases.
II INFRASTRUCTURE				
		Basic Composite	Medium	Advanced
	1. Signage			
	(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
(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
2.Safety Signage (Wherever applicable)			
(a) Safety hazard and caution signs- Biomedical waste segregated in coloured bins and bags as per Biomedical Waste Management Rules, 2016 including	Essential	Essential	Essential

	radioactive materials, toxic chemicals, microbial agents, infected biological material.			
	(b) Appropriate Fire exit signages - Minimum one fire extinguisher	Desirable	Desirable	Essential
3. Spacerequirement				
	(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
	(j) Temperature control for specialized	Essential	Essential	Essential

	equipment like flow cytometry and chemiluminescence equipment, ELISA test equipment etc.			
	(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) Darkroom for Immunofluorescence	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
III. HUMAN RESOURCE				
	a) Minimum Qualification of Technical Head of Laboratory or Specialist or* Authorised Signatories. NOTE: 1. *The authorised signatory will be liable for authenticity of the laboratory report only. 2. Medical tests should normally be undertaken on	Essential – 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. Those working in Government sector shall be exempted from the aforesaid	Essential – 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. Or 2. MBBS with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or	Essential – 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. Or 2. MBBS

<p>the advice of a registered medical practitioner.</p>	<p>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 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>Note: <i>Laboratory technician with qualification as mentioned in Part III (b) of this tableworking in a Medical Diagnostic Laboratory registered under a Central or State Clinical Establishments Registration Act, as applicable, and a</i></p>	<p>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, sign and issue test reports in respect of tests of their respective specialty.</p> <p>Or</p> <p>M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics 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</p>	<p>with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology conduct the tests, generate, sign and issue test reports in respect of tests of their respective specialty.</p> <p>Or</p> <p>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</p>
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		<p><i>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</i></p>	<p>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>Note: 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</p>	<p>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>Note: 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</p>
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			<p>microbiology tests as listed in basic composite laboratory.</p> <p>Illustration: (i) Special Tests pertaining to Bio-Chemistry and Micro-biology 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.</p> <p>(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>medical microbiology tests as listed in basic composite laboratory.</p> <p>Illustration: Special Tests pertaining to Bio-Chemistry and Micro-biology 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.</p> <p>(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>(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</p>	Essential: 1	Essential: 2	Essential: 4

(M.Sc) Bio-chemistry or Micro biology qualification from a recognised university or institution.			
(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”.

B. AYUSH

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 Homeopathy 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. - Diagnostic equipments 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.

II. NURSING HOMES AND HOSPITALS.-

1. Building. - The norms prescribed for consulting room or outpatient in the Allopathy system of medicine shall be fulfilled. It shall also have sufficient space for patient waiting separate cubicles for each doctors to work. The names of the doctors and then Specialists and different facilities available in the hospital shall be put up in a board.

2. Wards or inpatient rooms. - Inpatient wards shall be spacious with ventilation and lighting. Electric fan shall be provided to each room and in common rooms one fan for at least four beds shall be provided. Toilets be common or separate but shall be clean and provided with water from tap. Cleaning arrangements shall be made to swab daily the wards with antiseptic lotion.

3. Staff. - (a) Doctors. - The hospital shall employ only registered medical practitioner to treat the patients. The doctor shall also be registered in the Council under his respective system of medicine or in the Council/Board for Indian System of Medicine.

(b) Nurse. - A qualified nurse shall be available at the ratio of one nurse and two trained nurses for up to thirty beds.

(c) Pharmacist/Therapist. - Pharmacist/Therapist qualified or trained in the respective system of medicine shall be employed for dispensing of medicines. If the hospital has more than thirty beds, for less than thirty beds the doctor himself can dispense the medicines or employ a qualified or trained pharmacist/Therapist.

(d) Other Staff. - Other staff shall be employed as per need. Sufficient number of cleaning staff shall be available at least one for every thirty beds.

4. Equipment.-

(a) On need basis, following equipments may be considered for all Siddha Hospitals, namely:-

- (i) Traction Kit
- (ii) Walker
- (iii) IR light
- (iv) TFT and Ultrasound Therapy Instrument
- (v) Vibrator (Manual and Electronic)

(b) On need basis, following equipments may be considered for all Siddha Hospitals, namely:-

- (i) Thokkanam table
- (ii) Vedhu Chamber
- (iii) Wax bath machine
- (iv) Karanool
- (v) Kazhichal endhiram
- (vi) Vaanathi maruthuvam Chair
- (vii) Nasiyam Chair
- (viii) Peetchuendiram-Disposal Packs
- (ix) Kidney Tray
- (x) Motion tray
- (xi) Nebuliser Set
- (xii) Moving Stretcher
- (xiii) Disposable Syringes
- (xiv) Surgical instruments for common procedures, First Aid
- (xv) Parenteral drugs and infusion related equipments
- (xvi) Equipments needed for specific Aga maruthuvam, puramaruthuvam procedures.

(c) Equipments for Yoga and Naturopathy.-

On need basis, following equipments may be considered for yoga therapy:-

- (i) Carpets /coir mats
- (ii) Jala neti pot

- (iii) Eye wash cup
- (iv) Yoga charts
- (v) Sutra neti rubber catheter

Hydrotherapy.-

- (i) Enema can
- (ii) Steam bath cabin with Automatic steam generator
- (iii) Facial sauna
- (iv) Fomentation bag
- (v) Ice bag
- (vi) Packs – Chest, Leg, Arm, Knee, Abdomen, GH Pack, Renal, Full wet sheet pack
- (vii) Linen cloth for compress
- (viii) Epsom salt-packets
- (ix) Hip bath tub
- (x) Spinal bath tub
- (xi) Spinal Spray
- (xii) Foot and arm bath tub
- (xiii) Small and Big towels

Mud Therapy.-

- (i) Mud storer-100 lts barrel-2
- (ii) Linen cloth- for preparing mudpacks
- (iii) Mud trays
- (iv) Bucket and mug-2

Magneto Therapy.-

- (i) High, Medium, Low power magnets with keepers
- (ii) Magnetic belt – Neck, Abdomen, Knee, Wrist

Massage Therapy.-

- (i) Massage table-cushioned and covered with rexin
- (ii) Foot stepper
- (iii) Vibratory massager
- (iv) Roller massager

Chromotherapy.-

- (i) Colour lamps
- (ii) Colour glass bottles
- (iii) Color Thermoleum

Electrotherapy.-

Infra-red lamp (IRR) Acupuncture/Acupressure.-

- (i) Moxa stick
- (ii) Electronic Acu – stimulator
- (iii) Reflexology chart
- (iv) Acu-Roller-Spinal, Spinal, Palm, Soles, Legs, Fingers
- (v) Acupuncture needles- copper-(0.25x25)

5. Physical fitness

- (i) Static cycle
- (ii) Manual Treadmill
- (iii) Rowing machine
- (iv) Overhead pulleys

6. Infrastructure. - Clinic shall have the consultation items and minimum equipments to give out patient treatments. Hospital shall have all the equipments along with diet centre to prepare bland diet, natural diet, herbal juice and other special diet therapy for various diseases. In addition to above, first aid and emergency management need to be provided. Sufficient number of Wheel Chairs, Stretchers shall be available at least one per every thirty beds.

7. Records. - (1) A record of all patients admitted / treated shall be available along with the investigations diagnosis and treatment. The patient shall be provided with a discharge slip containing the details of investigation, diagnosis, treatment and follow up etc.,

(2) The following register shall be maintained. It is the duty of the clinical establishment to give all the relevant particulars to the patients on demands.

(i) Admission and Discharge Register

(ii) Contagious and infectious disease register.

(iii) Medico legal cases register (in case medico legal cases are brought there for treatment at any stage), if applicable

(iv) Birth and Death Register, if applicable

Records with full address shall be kept ready for verification by the District Authority/State Council/Health and Family Welfare Department.

C. GENERAL CONDITIONS TO BE FULFILLED BY THE HOSPITALS UNDER AYUSH.

1. Security. - Sufficient security shall be provided for the safety of inmates and to prevent theft.

2. Fire Fighting: - Firefighting equipment with I.S.I. mark shall be provided as per rules in the hospital.

3. 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.

4. Clothing and Linen. - It shall be clean and changed daily.

5. Water Supply. - 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 Gujarat Pollution Control Board.

Annexure-10

(see rule 15)

Part A

Display of rates charged by clinical establishment		
Room Type	Only Room Rate per day	Average billing amount per day per person for those who occupied such rooms in last one year, including cost of doctor fees, medicines, diagnostics tests etc.
ICU Room		
Deluxe Room		
Super-Deluxe Room		
AC Room		
Sharing Room		

Note: Hospital can maintain this record in physical or in electronic format with minor modification as deemed necessary for types of diseases treated at the establishment.

- The hospital shall maintain individual case sheets for the patients.

Part D
Register of Out door Patients

System of Medicine **Clinic / Consulting Room** **Gujarat Clinical Establishment Regulation Act Registration no.:**

Name of the Doctor:

Date:

Serial No	Name of the Patient and address	Mobile No./ Contact No. if available	Age	Gender	Provisional Diagnosis
(1)	(2)	(3)	(4)	(5)	(6)
1.					
2.					
3.					
4.					

Note: Hospital can maintain this record in physical or in electronic format with minor modification as deemed necessary for types of diseases treated at the establishment.

Part E
Operation Register

System of Medicine: **Hospital / Nursing Home** **Gujarat Clinical Establishment Regulation Act Registration no.:**

Form-B
List of Clinical Establishments with Expiry of Registration

Serial No.	Name and Address of Clinical Establishment	GCERA No. and Date	District	Type of Establishment	Type of Registration	Registration Expired on
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.						
2.						
3.						
4.						
5.						
6.						
7.						

Annexure-12
(Check list for inspection)
(See rule 17)

A. Allopathy System

I. Consulting Room. -

(1) Infrastructure –

Adequate space Yes/No

Adequate light Yes/No

Adequate ventilation Yes/No

Patients waiting area facility Yes/No

(2) Staff. - registered medical practitioner available. **Yes/No**

registered qualified nurse available. **Yes/No**

(3) Equipment. –Requisite equipments and hospital accessories are available in the consulting room? **Yes/No**

(4) Records. – Patients' Register with details as per Annexure 10 (preferably electronically) **Yes/No**

(5) Prescription slip–date, name of patient, legible recommendation of drug/drugs with dose and duration, stamp/seal of RMP. **Yes/No**

II. Clinic. - In addition to consulting room, the following checklist are require to be fulfilled

(1) Infrastructure -

Sufficient space for two hospital beds for managing emergency/ primary treatment of patient **Yes/No**

(2) Staff. –

1	Registered Medical Practitioner (RMP)	Yes/No
2	Qualified nurse	Yes/No
3	cleaning personnel	Yes/No

(3) Equipments. – Requisite equipments and hospital accessories are available in the consulting room? **Yes/No**

(4) Waste Disposal. – Facilities as per the Government of India and Gujarat Pollution Control Board norms. **Yes/No**

(5) Dispensation of Medicine. –done by

1	Doctor himself	Yes/No
2	Qualified Pharmacist	Yes/No

(6) Laboratory in a Clinic. - By Qualified technical person **Yes/No**

(7) X-ray Unit. –By Qualified technical person. **Yes/No**

(8) Minor Surgeries–(refer to minor Operation Theater)In case of minor surgeries like cyst excision, Medical Termination of Pregnancy (MTP), Dilatation and Curettage (D&C) are under taken it is advisable to have a sterile room for the purpose and facilities available as given for minor Operation Theatre.

III. Polyclinic. –

(1) Infrastructure - (1) In addition to the norms prescribed for clinic and consulting room, separate cubicles/rooms/spaces available **Yes/No**

(2) Reasonable space for waiting room **Yes/No**

(3) safe drinking water. **Yes/No**

(4)Names of different Registered Medical Practitioner (RMP) attending shall be exhibited in the waiting room. **Yes/No**

IV. Hospital. –

(1) a. Infrastructure- In addition to the norms prescribed for Clinic, Consulting room and Polyclinic, the waiting room shall be made available for the patients/those accompanying them, which shall have sufficient space. **Yes/No**

b.Wards or in-patient room clusters. –

1	adequate space	Yes/No
2	adequate light	Yes/No
3	adequate ventilation	Yes/No

4	Electric fan/Air cooler/Air conditioner in each room	Yes/No
5	one electric fan per two bed in common room/Air cooler/Air conditioner	Yes/No
6	Toilets common/separate provided with adequate water supply	Yes/No
7	Cleaning of Toilets twice a day with antiseptic liquid.	Yes/No
8	Cleaning of the wards twice a day with antiseptic liquid.	Yes/No

(2) Staff. – Specialist doctors for each specialist services provided in hospital.
Yes/No

(i) One RMP for every thirty beds physically available on duty

During day Yes/No,

during night Yes/No and

- One RMP shall be on call duty up to thirty beds during night and off duty hours. Yes/No

- On duty RMP is available in the hospital physically for thirty beds and above in general side for all the 24 hours. Yes/No

- If the hospital is having a functional Intensive Care Unit then, one RMP is be available physically in ICU for every 10 ICU beds for 24/7 Yes/No

(ii) Nurses-Requisite number of qualified nurses for the bed capacity in accordance with the norms prescribed by Indian Nursing Council shall be provided. Yes/No

The aforesaid human resource is the minimum requirement irrespective of the fact the availability of any number of trained personnel working in the hospital.

(iii) Cleaning Services-Is daily cleaning twice a day with antiseptic fluid done? Yes/No

(3) Other Services. -

(a) Pharmacy. - If a pharmacy is maintained in the hospital for dispensing medicines to the patients, Does the pharmacy unit follow the rules and guidelines of government? Yes/No.

(b) Laboratory. - If a Laboratory is maintained by the hospital, other than urine albumin, sugar, blood hemoglobin, all other Laboratory Tests shall be performed by a qualified Laboratory Technician. Yes/No

(c) X-Ray (Radiograph).- X-Rays taken by a qualified Technician. Yes/No

(d) Scan. – MRI/CT scan/PET scan/Doppler/ Ultra sonography scanning shall be performed by a Doctor only. Yes/No

(e) Blood Bank - If a blood bank is maintained by a hospital, it shall confirm to the standards/requirements as issued by the Government of India from time to time. Yes/No

(f) Ambulance–(Hospital having fifty or more beds)

Own ambulance with qualified driver is available. Yes/No

Or

tie up (MoU) arrangement with another Hospital having Ambulance or some Ambulance service unit. **Yes/No**

(g) Catering and Canteen. - If available,

(1) Cleaning of the Kitchen daily **Yes/No**

(2) the cooks periodically medically examined **Yes/No.**

(3) FSSAI standards followed as issued by government time to time. **Yes/No**

(h) lounge facility for admitted patients' attendants in case of hospital with than 50 beds, available or not ? Yes/No

(i) General facilities:-

(i) Waste disposal—(Government of India norms and Guidelines issued by Pollution Control Board). Proper segregation of the waste at the point **Yes/No.**

(ii) Record Keeping.—as prescribe in the form of A,B,C,D,E in Annexure-10 and as per guidelines of state and central government time to time. **Yes/No**

(b) A medical case record shall be maintained for in the form of a register or electronically in the clinical establishment in respect of each patient, which shall include the following particulars, namely: -

(i) A detailed daily statement of the patient's health and condition.

(ii) Details of any investigations made, surgical operations carried out and treatment given and

(iii) Records of all medical prescriptions, Copy of detail reporting of any scan X-Ray reports, laboratory reports or any other report with full name, qualifications of the doctor.

(iv) In the case of a maternity home or a maternity case, the said person shall keep a case record of each child born to a patient. Full and detail record of pregnancy must be maintained for at least a period of ten years.

In non MLC case if patient or his or her relative demand scan (USG/CT/MRI) you can give it in writing form in case paper but same time clinical establishment have to keep reporting of same scan in case paper

(iii) Medico Legal Cases.—record keeping of medico legal case as per government guidelines **Yes/No,**

(4) Mortuary room. – (A hospital having more than hundred beds) a mortuary room. **Yes/No,**

or

room with freezer box facilities for the dead bodies. **Yes/No**

(5) Water Supply. –

(1) Potable water supply is available. **Yes/No.**

(2) Hot water supply is available. **Yes/No**

(6) Clothing and Linen. - Bed sheets and other linen used for the patients changed daily **Yes/No.**

(7) Fire Fighting. – Fire safety related certificate or NOC available or not? **Yes/No**

- (8) Quality Assurance.** - The names of the RMPs working in the hospital and the facilities made available in the hospital shall be written and exhibited in the hospital. **Yes/No**
- (9) Security.** –Security measure for safety of patients and their properties **Yes/No**
- (10) Hospital accessories.** - Sufficient number of wheel chairs, trolleys, and stretchers shall be made available in the hospital. **Yes/No**
- (11) Uninterrupted power supply** - A generator or uninterrupted power system to maintain essential services during power failure is available or not? **Yes/No**
- (12) Labour Room.** - If the Hospital is maintaining a labour room and is conducting deliveries it shall have the following norms, namely:-

(a) Infrastructure –

- (1) There shall be a room for preparation of the patient for delivery, giving enema etc., with sufficient water supply. **Yes/No**
- (2)The area of Labour room is equal or more than 120 square feet.**Yes/No**
- (3) With well-ventilated and sufficient light. **Yes/No.**
- (4)Space for keeping the newborn baby with resuscitation.**Yes/No**

(b) Staff. –Delivery conducted by (tick right in available)

1	a qualified RMP	
2	Staff Nurse	
3	Auxiliary Nurse Midwife	

- (1) RMP available on call for any emergency or newborn resuscitation. **Yes/No**
- (2) If the labour ward is in a maternity hospital and deliveries are taking place regularly, a duty RMP shall be available round the clock. **Yes/No.**
- (3) Paediatrician on call available. **Yes/No**

(c) Equipment. - The following equipments and hospital accessories shall be made available, namely :-(tick right in available)

Labour Table with lithotomic stand	
Oxygen Cylinder with Vent mask	
P.V. Tray with equipment	
Vacuum extractor / Forceps delivery set	
Sterile cord clamp	
Suction apparatus	
Baby resuscitation set	
Baby Warmer (a light may also do)	

(d) Drugs. (Drugs/injections indicated below or their generic or otherwise equivalents in salt contents) -(tick right in available)

Drugs	Remarks
-------	---------

- Inj. Methyl ergometrine	
- Inj. Oxytocin	
- Inj.carboprost tromethamine	
- Inj. Methyl ergometrine	
- Inj. Oxytocin	
-Inj.Magnesium sulphate	
-Absorbable suture material	
- Inj.Diazepam	
- 2% Lignocaine	
- Inj. Vitamin K	
- Inj. Tetanus Toxoid	
- I.V. Fluids	
-Tab.Misoprostol200mcg	

(e) Records-(tick right in available)

(i) Birth Register	
(ii) Birth intimation slip	
(iii) Case sheets and notes to be recorded	
(iv) Register for babies and mothers to prevent child changing.	

(13) Operation Theatre. -

(a) Minor Operation Theatre. - Where septic cases and minor surgeries like abscess, Incision and Drainage (I&D) and other septic cases etc., are carried out.

(i) Infrastructure-

- (1) Space - not less than 100 square feet. **Yes/No**
- (2) Adequate lighting. **Yes/No**
- (3) Adequate ventilation. **Yes/No**

(ii) Staff. –

- (1) Surgeries carried out by qualified RMP. **Yes/No**
- (2) Qualified Nurse allocated. **Yes/No**

(iii) Equipments. –

Operation table.	
Sterilizer Autoclave	
Minor surgical equipments	
Regional Anaesthesia equipment	

Drugs as required	
Drugs for emergency tray	
Anesthesia apparatus with Oxygen cylinder, Nitrous Oxide Cylinder	
Suction apparatus	
Baby resuscitation set	

(iv) Records. –

Register of Records of all surgeries done in minor OT available. **Yes/No**

(b) Main Operation Theatre. -

(i) Space. –

- (1) Space with a minimum of 150 square feet. **Yes/No**
- (2) well air-conditioned available in main OT. **Yes/No**
- (3) Patient waiting area available. **Yes/No**
- (4) Acot (bed) provided for postoperative recovery. **Yes/No**
- (5) Sufficient space for autoclave and sterilization and for scrubbing. **Yes/No**
- (6) Running water from the tap in the scrub room. **Yes/No**
- (7) Sufficient arrangements for fumigation of operation theatre. **Yes/No**
- (8) Swab for culture to be taken from operation theatre at least once a month (register available). **Yes/No**

(ii) Staff. –

- (1) A qualified Anaesthetist or a doctor only who is trained in anaesthesia. **Yes/No**
- (2) Surgeries shall be performed by qualified doctors only. **Yes/No**
- (3) Head of nursing staff in the Operation Theatre. **Yes/No**

(iii) Equipments. –

Operating table	
Anesthesia apparatus with Oxygen cylinder, Nitrous Oxide Cylinder	
Multipara monitors	
Suction apparatus (preferably two)	
Autoclave	
Surgical equipments for surgery as per speciality	
Resuscitation equipment and drugs	
Defibrillator	

(iv) Records as per form part-D of Annexure-10 (operation register). **Yes/No**

(1) Record of Biopsy reports (In cases where as required) entered in register. **Yes/No**

(14) Intensive Care Unit. - An Intensive Care Unit may be maintained in all Nursing Homes / Hospital having more than hundred beds. The following norms are to be maintained, namely:-

(a) Space. –

- (1) For up to four hospital beds, a minimum space of 240 square feet and proportionately higher if the number of hospital beds is more. **Yes/No**
- (2) A well ventilated preferably air conditioned room. **Yes/No**
- (3) Sufficient lighting. **Yes/No**
- (4) Sufficient space for keeping ventilators and monitors available. **Yes/No**
- (5) Space for duty RMP available. **Yes/No**
- (6) Space for duty nurse/nurses available. **Yes/No**
- (7) Provision for attendants outside the Intensive Care Unit. **Yes/No**

(b) Staff. –

- (1) One doctor for every ten beds for day time physically available. **Yes/No**
- (2) If there are more than ten beds, one additional doctor for every additional ten beds physically available. **Yes/No**
- (3) Similar provision for night time physically available. **Yes/No**

(c) Nurse. –

- (1) Requisite number of qualified nurses for the bed capacity in accordance with the norms prescribed by Indian Nursing Council is available? **Yes/No**
- (2) An another qualified nurse available for every additional three beds. **Yes/No**

(3) Similar arrangement available for night time. **Yes/No**

(d) Equipments. -

Intensive Care Unit hospital beds	
Ventilators	
Multipara Monitor	
Defibrillator	
Suction apparatus	
Oxygen supply (either Cylinder or central supply)	
Drugs	

(e) Records—Maintainence of record of in-patients in Intensive Care Unit as to their illness, treatment offered, specialists visited - Out come etc. available. **Yes/No**

(15) Medical Record Maintenance in a Hospital. - The following records shall be maintained, namely:-

Medical Record Maintenance in a Hospital	Electronically	Manually
(i) Admission and Discharge Register.		
(ii) Case sheets		

(iii) Referrals		
(iv) Infectious and Communicable disease Register.		
(v) Immunisation particulars		
(vi) Family Welfare Services		
(vii) Medico Legal Records		
(viii) Maternal Death Record		
(ix) Infant Death record		
(x) 1 to 5 years Child Death records		
(xi) Any other record as may be required by the Government, from time to time.		
Any other record as may be required by the Government under any other Act/rules-regulations of Government of India or Government of Gujarat.		

V. Dental Clinic. –

(1) Infrastructure-

- (1) Sufficient space of the consulting room not less than 100 square feet if it accommodates the Dental Chair. **Yes/No**
- (2) Well ventilated consulting room. **Yes/No**
- (3) Sufficient lighting arrangements. **Yes/No**
- (4) Space for keeping the Sterilizer and Tray. **Yes/No**
- (5) Sufficient space for patient waiting outside the consulting room. **Yes/No**

(2) Staff. –

- (1) Qualified Dental Surgeon or Dentist available or not? **Yes/No**
- (2) Qualified nurse available or not ? **Yes/No**

(3) Equipments. –

(a) Dental Chair	
(b) Provision of water for surgery	
(c) Sterilizer	
(d) Bin for sterile cotton gauze etc.	
(e) Trays with instruments	
(f) Dental instruments	
(g) X-Ray (desirable)	
(h) Disposable (optional) / autoclaved syringes.	

(4) Records. -

A record of the patients treated along with name, age, gender, disease and treatment given shall be available. A slip shall be given to the patient with all the above particulars. All the records as mentioned above may be kept electronically and to be

linked with the public health record keeping as determined by Govt. authorities from time to time Available? **Yes/No**

VI. Dental Hospitals. - Out-patient department- The outpatient department of a dental hospital shall conform to the norms prescribed to a Dental Clinic. In addition, sufficient waiting room shall be provided to the patients. Wards, Operation Theatre and other aspects shall be as per the norms prescribed to the nursing homes and hospitals.

VII. Clinical Laboratories. - They shall include clinical laboratories, pathological laboratories, radiological centres, genetic laboratories etc.

- (1) Infrastructure- (1) Sufficient space for sample collection, Processing, Report preparation etc. **Yes/No**
- (2) Lavatories for the patients use with sufficient water. **Yes/No**
- (3) Sufficient space for Microscopy and for Biochemical tests. **Yes/No**
- (4) The room with well ventilated and sufficient light. **Yes/No**
- (5) Space for keeping a hospital bed for the use of patient available. **Yes/No**
- (6) If X-ray is also functioning, norms as for an X ray centre shall be followed. **Yes/No**
- (7) The laboratories shall ensure adequate space in relation to the following:-
 - (a) Patient's reception area available. **Yes/No**
 - (b) Sample collection area available. **Yes/No**
 - (c) Area available for Isolation for Bio hazardous materials. **Yes/No**
 - (d) Radioisotope related work as per the regulatory agency Atomic Energy Regulatory Board (AERB) requirement.(if apply) **Yes/No**

The Laboratories shall preferably follow standards prescribed by the National Accreditation Board for Testing and Calibration of Laboratories for the personnel qualification etc., quality assurance in Lab Service, Internal Quality and External Quality should be ensured.

(2) Staff. –

(a) Examination/Reporting

- (a) The Biopsy examination and reporting shall be done by a Pathologist or by a Trained Doctor. (If applicable) **Yes/No**
- (b) Culture and sensitivity tests carried out, a Microbiologist either Medical or non-Medical? (If applicable) **Yes/No**
- (c) Cytology reports given by a Pathologist only. **Yes/No**

(b) Qualification for technical staff. - The staff performing the technical tests shall have the

- (i) Diploma in laboratory technician; or
- (ii) Medical Laboratory Technician course; or
- (iii) Medical Technology; or
- (iv) Post graduate diploma in medical Laboratory Technology; or
- (v) One year medical laboratory technician training course; or
- (vi) Laboratory Technician Trainig course from any of Government recognised institution or University established or incorporated by or under the Central or State Act in India or any other educational

institution recognised as such or declared to be deemed as a University under section 3 of the University Grant Commission Act,1956.

- (c) In a genetic laboratory, all tests shall be carried out and reporting done by a qualified Genetist or qualified doctor only. If amniocentesis is done as permitted by law it shall be done only in a Minor Operation Theatre and all facilities as needed for a Minor Operation Theatre shall be available and it shall be done by a qualified doctor under sterile conditions only.

(3) Equipments. -

(a) Microscopes	
(b) Calorimeter	
(c) Centrifuge	
(d) Semi Auto Analyser or Auto Analyser	
(e) Cell Counter	
(f) Refrigerator	
(g) Hot Air oven	
(h) Biosafety cabinet	
(i) Laminar air flow cabinet -Optional.	

- (4) Records. -** All tests carried out on the Laboratory shall be recorded in a Register along with name, age, gender, investigation done report, date, etc., All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time.(As per prescribed in form part A of Annexure-10 Available? **Yes/No**)

The following minimum Records to be maintained: -

- (a) Daily Results Register. **Yes/No**
- (b) Internal Quality Control Register. **Yes/No**
- (c) Sample Collection Register. **Yes/No**
- (d) Participation in External Quality Assessment Schemes Programmes. **Yes/No**

VIII. X-Ray (Radiograph) Centres. - This Centre shall include all centres of Imaging, Sciences namely, Ultra Sonogram Scan Centres, Computed Tomography (C.T.) Scan Centres, Magnetic resonance imaging (MRI) Scan Centres, X-Rays (Radiograph) as well as Electro Cardiogram (ECG), Electroencephalography (EEG) and Treadmill Echocardiography.

- 1. Buildings. -** Sufficient space as the equipment in use demands. Sufficient space shall be provided for patient waiting and resuscitation of the patient in case of anaphylaxis occurring. X ray and imaging centres shall fulfil the "*Atomic Energy Regulatory Board*" (AERB) norms
- (1) Sufficient space. **Yes/No**
 - (2) Sufficient space for patient waiting. **Yes/No.**
 - (3) Sufficient space for patient resuscitation. **Yes/No**
 - (4) X-ray and imaging centre fulfill AERB norms. **Yes/No**

2. Staff. - All tests shall be carried out by qualified technical persons only as follows:-

Name of Test	Carried out by	Yes/No
X-Ray	Radiographer with Clinical Research Associate (CRA) Qualification or Diploma in Medical Radiology Imaging Technology or BSC in imaging Technology Or Degree or Diploma Course approved by AERB or Certificate/Diploma/ Degree course as approved by State Government/ University recognised by UGC.	
Ultra-Sonogram	By a qualified Doctor or by a Radiologist or Concerned Specialist as per the provisions of the Pre-Conception And Pre-Natal Diagnostic Techniques (Prohibition of Gender Selection) Act, 1994	
Electro Cardiogram (ECG)	By an Electro Cardiogram (ECG) Technician trained in Electro Cardiogram (ECG) or by doctor	
Electroencephalography (EEG)	Electroencephalography (EEG) Technician trained in Electroencephalography (EEG) or by doctor	
Computed Tomography (CT) scan	By a Radiographer and report by a Radiologist or by the concerned specialist.	
Treadmill	Concerned Technician. A doctor shall be present during the Test.	
Echo Cardiograph	By a Qualified Doctor preferably a Cardiologist By a Qualified Doctor (Post Graduate in field of Radiology, Medicine, Pediatric, Anesthesia, Emergency, Critical care, Clinical Cardiology with adequate experience preferably a Cardiologist (Super Specialist in field of Cardiology)	
Contrast Studies	Radiologist or by the Concerned Specialist	
Magnetic resonance imaging (MRI)	Radiologist or by the Concerned Specialist	

2. Equipments. - Equipments according to the concerned machine. **Yes/No**


3. Records. - Name, age, gender, address of patient, the nature of investigation done referral doctor, and result of the investigation shall be available in a register. Number of cases treated free of charges shall also be available along with name, age, gender, address and result etc. All the records as mentioned above may be kept electronically and to be linked with the public health record keeping as determined by Govt. authorities from time to time.

Above record maintained as above electronically and/or manually. **Yes/No.**

Signature/Name/Designation/Seal of the Authorized person of inspecting team

- (1)
- (2)
- (3)

By order and in the name of the Governor of Gujarat,


(R.A.Prajapati)

Under Secretary to the Government.

Copy to :

1. The Secretary to the Hon'able Governor(By letter)
2. The Principal Secretary to the Hon'able Chief Minister, Sachivalaya, Gandhinagar
3. PS to Hon'able Minister, Health & Family Welfare Department, Sachivalaya, Gandhinagar
4. Chief Secretary, Government of Gujarat , Sachivalaya, Gandhinagar
5. Principal Secretary, Health & Family Welfare Department, Sachivalaya, Gandhinagar
6. Secretary, Legal Department, Sachivalaya, Gandhinagar
7. Commissioner, Health , Medical Services & Medical Education, 5 Dr. Jivraj Mehta Bhavan, Gandhinagar
8. Additional Director Medical Services, 5 Dr. Jivraj Mehta Bhavan , Gandhinagar
9. Additional Director Medical Education 5 Dr. Jivraj Mehta Bhavan , Gandhinagar
10. The Director of Information, Dr. Dr. Jivraj Mehta Bhavan, Gandhinagar with request to give suitable press note.
11. The manager, Government Press, Sector-30, Gandhinagar-with a request to publish in Gujarat Government Gazette.
12. The System Manager, Health and Family Welfare Department, Sachivalay, Gandhinagar to upload this Notification on Website.
13. Select file
14. Deputy Section Officer's file