

The West Bengal Clinical Establishment Rules, 1951
As Modified up to 31st January, 2001
GOVERNMENT OF WEST BENGAL
Department of Health & Family Welfare

MEDICAL SERVICES

NOTIFICATION

No. :

In exercise of the power conferred by section 9 of the West Bengal Clinical Establishment Act, 1950 (West Ben. Act L VI of 1950), and in super session of all earlier rules on the subject, the Governor is pleased hereby to make the Following rules, namely :-

RULES

1. Short title and commencement

- (1) These rules may be called the West Bengal Clinical Establishment Rules, 2001.
- (2) They shall come into force from the date of their publication in the Official Gazette

2. Definitions

- (1) In these rules, unless there is any thing repugnant in the subject or context,-
 - (i) “The Act” means the West Bengal Clinical Establishment Act, 1950
 - (ii) Appendix means appendix to these rules;
 - (iii) “Appropriate authority” means the Council, the Body, the University or Board approved by the State or Central Government granting registration to particular discipline like Allopathic, Homeopathic, Ayurvedic, Acupuncture or Unani system of medicine for such purpose;
 - (iv) “C.M.O.H.” means the Chief Medical Officer of Health of the district with in which the local area is comprised ;
 - (v) “D.D.H.S.(Administration)” means the Deputy Director of Health Services or any other officer not below the rank of of Deputy Director of Health Services as the State Government may by Notification in the Official Gazette specify;
 - (vi) “D.H.C.” means the The District Health Committee constituted under section 5B of the Act;
 - (vii) “Kolkata” means the Kolkata as defined in the clause 9 of section 2 of the Calcutta Municipal Corporation Act, 1980 (west Ben. Act LIX of 1980);
 - (viii) “Package” means a group of facilities towards investigation, treatment or management with clear item wise explanation wrapped under a fixed price to be provided to the beneficiaries.
 - (ix) “R.M.O.” means the Residential Medical Officer, who will be engaged for a particular discipline like Allopathic, Homeopathic, and Ayurvedic or Unani system of medicine, with requisite qualifications and registration under Government recognized council, for the particular discipline for which the clinical establishment is set up;
 - (2) The words and expressions used in these rules and not defined shall have the meaning respectively arranged to them in the Act.
3. Each page of the **Register** shall be maintained and verified by the Licensing Authority in **Calcutta** and by Chief Medical Officer of Health elsewhere, in **FORM I**, as specified in the appendix to these rules.
 4. The names of the clinical establishments shall be **entered in the Register** in the order in which the applications of registration and for the grant of license are admitted and sufficient space shall be left for future additions and alterations in respect of the entries made about the establishment.
 5. The register shall be verified page wise by the Licensing Authority as prescribed in rule 7.

6. As soon as may be after the 1st day of April each year, each Chef medical officer of Health shall **inform** the Deputy Director of Health Services (Administration) and District Health Committee without delay of all the additions and alterations in the district register.
7. An officer not below the rank of Deputy of Health services shall be the **Prescribed Authority** hereinafter referred to as the **Licensing Authority** in Calcutta and the Chief Medical Officer of Health elsewhere, to whom the applications for registrations for and for the grant of License shall be made.
8. The application for registration and for the grant of License, or for their yearly renewal, or amendment, or for a duplicate of the license if the original is lost destroyed shall be in **FORM II** as specified in the appendix to these rules and shall be accompanied by a **fee** as hereinafter mentioned for each clinical establishment. The **approved plan** from appropriate authority for such purpose, of the premises where the establishment is run or proposed to be run or going to be modified, shall be attached to the new application or the new application for amendment. The **existing license must be surrendered** with the application for every renewal or amendment of the clinical establishment license on proper receipt from the licensing authority.

FEES PAYABLE WITH APPLICATION (in Rupees)

	For KMA*, Municipal Areas & Dist. HQs	For KMA*, Municipal Areas & Dist. HQs	Others	Others
	Registration	Renewal	Registration	Renewal
	Rs.	Rs.	Rs.	Rs.
1. Nursing Home and or Maternity Home, Dispensary (with bed) Day Care centers with beds and for Physical Therapy Establishment				
(a) Upto 10 beds	2000	1000	1500	750
(b) 11-20 beds	3500	1750	2500	1250
(c) 21-30 beds	4500	2250	3500	1750
(d) for each additional bed above 30 beds	150	75	100	50
2. PATHOLOGICAL LABORATORY				
(a) small	500	250	400	200
(b) medium	1000	500	800	400
(c) large	2500	1250	1500	750
Collection Centre for pathological labs	700	350	700	350

3. IMAGINE, X-RAY & OTHERS				
(a) USG only	1000	500	800	400
(b) ECHO	1000	500	800	400
(c) Color Doppler	1000	500	800	400
(d) CT scan	2000	1000	1800	900
(e) MRI	3000	1500	2800	1400
(f) X-Ray	1000	500	800	400
(g) Others: ECG, EEG, EMG, Scopy Procedures, Holter Monitoring & others not specified above	1000 each	500 each	800 each	400 each
(h) Angiography	5000	2500	4000	2000
4. ICCU/ITU/RCU/NCU Dialysis (each)	4500	2250	3000	1500
(a) up to 10 beds	6000	3000	4000	2000
(b) 10+ beds				
5. (a) Poly Clinics & other clinics	500/doctors	250/doctors	400/doctors	200/doctors
(b) Individual Clinic (Modern Medicine and Denal)				
(a) Graduates	300	150	200	100
(b) Post-graduate diploma and degree holder	1250	625	1000	500
(c) Ayurvedic / Homeo/ Unani/ Acupuncture therapist				
(a) Graduates	150	75	100	50
(b) Post-graduate diploma and degree holder	625	300	500	250
6. Hospitals having Specialty Clinic				
(a) 25-50 beds	1500/specialty	750/specialty	1000/specialty	500/specialty
(b) >50 beds	2500/specialty	1200/specialty	2000/specialty	1000/specialty
7. For diagnostic facilities in hospitals having more than 50 beds (excluding MRI and angiography)	12000	6000	10000	5000
8. Amendment fees	500		500	
9. Duplicate Copy of License	250		250	

*:KMA : Kolkata Metropolitan Area

Specialty Clinic:

1. Surgery / Eye/ ENT/ Orthopedics/ Cardiothoracic / Plastic surgery

2. Medicine /Pediatrics (Surgery / Medicine) / Cardiology / Endocrinology
3. Gyne and Obstetrics
4. Neurology / Skin / Dental
5. Any other discipline not included above

The licensure for a temporary camp **is hereby withdrawn. All operations should be performed in a fixed centre having OT facilities.**

The licensure for a temporary camp shall be valid for one month from the date of issue of the license.

The license for such temporary camp shall be renewed in any circumstance.

If the licensing authority rejects any application, the application fee shall be refunded after deduction of 25% of the fee.

The application for renewal of registration and license shall be submitted at least 30 days before the expiry of the date of license. No application for renewal of registration and license shall be entertained if made after the said period, unless the said application is filed before the date of expiry of such license with a fine which shall be 50% of the amount of renewal fee and, if so submitted the establishment shall be deemed to be duly registered and licensed until such date as the licensing authorities renews or refuses the registration and licensed.

If a licensee submits an application for renewal of license after expiry of the date of license, such application shall not be treated as a case of renewal of old license and shall be accompanied by up to date fee for original registration and license, and if any new license is issued on the basis of such application, the validity of such license shall be for one year from the date of issue of the license as usual. The intervening period that is from the date of expiry of the previous license up to the date before issue of the new license, shall be treated as irregular period of running the establishment by the licensee without providing any information the licensing authority about any closure of the establishment during that period, supposed to be done by the licensee, which is subsequently be regularized by the licensing authority after receiving the full payment toward the fee for original registration and license, unless affected by any other law of the land, under a notice mentioning the irregular period of running incorporated in the body of the license to be issued. If the last date of submitting an application is a gazetted holiday, the application shall be submitted on the immediate next working day.

9. The registration and the license granted under the Act **shall be valid for one year with** effect from the date of issue of the license will be issued accordingly.
10. The fees shall be paid in cash to the Reserve Bank of India in Calcutta and to the Treasury elsewhere under the Head—“**0210-MEDICAL & P.H. (Excluding P.H.)-OTHER RECEIPTS**’ under The West Bengal Clinical Establishment Act, 1950 and the refund of portion of application fees shall be given from the subordinate Head –“**DEDUCT-REFUND**’ under the appropriate receipt head. The licensing authority shall keep an account of the fees so deposit in the Reserve Bank of India in Calcutta or the Treasury, as the case may be on receipt of the Bank or Treasury Challan to be produce by the applicant. The licensing authority shall also keep an account of the refund of the fees.
11. No license for clinical establishment shall be granted unless the licensing authority is satisfied that the applicant and the **Clinical Establishment fulfills the following conditions;**

A. General (For all Clinical Establishments):

- I.** The person or person associated with the clinical establishment are considered fit and proper person.
- II.** Application (**FORM II**) shall be filled in with the particular name of the applicant and not with the name of Registered Firm, Company or Partnership Organization so that responsibility of the clinical establishment shall be fixed upon a particular person. So in case of a Firm, Company or a Partnership Organization, the name of a **person from amongst the Directors, Partners or Owners**, that may be the Applicant, shall be specified through a resolution of the personnel in the management of such Firm, Company or Partnership Organization.
- III.** The premises and equipments are reasonably suitable and adequate with a **stock emergency and lifesaving drugs.**

- IV. The premises where the clinical establishment is actually located, **shall have no communication, such as common passage, common stare cases etc**, with any residential quarter of persons not connected with the clinical establishment i.e. there should be no free access
- V. The plan for construction of new clinical establishment must follow the measurement as laid down in Annexure A. The plan should be duly certified by the Government Approved Engineer / Architect on the body of the plan and to be submitted with the application for registration.
- VI. A plan of construction of the premises **duly approved** by the Municipal or Corporation Authority as the case may be shall be furnished to show that the construction is exclusively meant for a clinical establishment to run there and if the construction is approved for residential purpose, it should be **converted** accordingly with due approval of the respective Municipal or Corporation Authority concerned, as the case may be before it is submitted with the application for grant of license under the West Bengal Clinical Establishment Act,1950 .**Ownership towards the premises must be supported by deed, records or tax documents. In case of lease Deed with Landlord a**, no objection certificate must be produced with application. Current Receipt of rent payment to the landlord in case of rented building is required in case of renewal of license.
- VII. In the premises **there should be** a Reception **counter** an Office with an airproof and waterproof Record room a, Waiting room with proper ventilation, lighting, drinking water supply, cooling arrangement, sanitary arrangement and separate toilets for male and female.
- VIII. Clinical Establishment having **identical names** in the jurisdiction of a particular licensing authority shall not be allowed to avoid biasness amongst the beneficiaries.
- IX. The word **“RESEARCH”** cannot be used **in the nomenclature of a clinical** establishment under this act, unless the subject of definite Recherche proposal (s) is are submitted along with the application for registration and if such a proposal is submitted at all, yearly progress in that filed with the observation of an expert in that specialty must be submitted to the licensing authority for onward transmission to the Ethical Committee.
- X. The word **“HOSPITAL”** can be inserted in nomenclature of a clinical establishment having not less than 25 beds where treatment facilities in all the discipline or a particular discipline are sufficiently available with necessary infrastructure for **any type of emergency management during day and night**.
- XI. **The naming** of a clinical establishment **shall** conform and the facility to made available for treatment or diagnostic observation.
- XII. **The general cleanliness** of the **premises** including sanitary arrangement, furniture and equipments must be properly maintained along with 24 hours adequate **potable water** supply for the beneficiaries with an arrangement for safe and hygienic disposal of clinical waste products as per provisions laid down in the **Bio-medical Waste (Management and Handing) Rules, 1998**.
- XIII. Every application for clinical establishment must be supported with astride license and Clinical Waste Disposal license (if available) from the respective Corporation, Municipal Authority or Pantheist Body as the case may be.
- XIV. The persons employed to conduct the clinical establishment must be properly **qualified, trained and sufficient in number**, as provided in rules.
- XV. Every application for registration shall contain Appointment and Acceptance letter of the staff proposed to be engaged and Bio-data with documentary evidence of their qualification (**Technical and non –Technical**) and particulars salaries including yearly increment and ex-gratia for overtime duty to be drawn by them.
- XVI. All clinical establishments should preserve the Xerox Copy of certificates of Consultants / Specialists, as the case may be to be, produced to the licensing authority on demand. A list of such consultants / specialists stating their qualifications is to be provided with Form II during application.
- XVII. If any employee or a consultant of a clinical establishment is employed in Government Services, details must be submitted to the licensing authority in this regard with **no-objection certificate**

from the Head of the Institution. No Government employee shall be employed as RMO or full time employee of a clinical establishment.

- XVIII.** Any **examination, treatment or management of female patients** must be conducted in the presence of an employed female attendant / female nursing staff, if conducted by male personnel inside the clinical establishment.
- XIX.** An up –to –date register shall be maintained in which **Name, Present and Permanent Address and qualifications of all the employees (both temporary and permanent)** of the clinical establishment are to be noted.
- XX.** An **attendance register** of all employees of the establishment shall be maintained.
- XXI.** Proper **accounts** shall be maintained of all receipts and expenditure.
- XXII.** A clinical establishment shall not **conduct any training course** in medical or Para-medical subjects or **register any person to provide degree or diploma** on such subject unless the **Appropriate Authority** affiliates such training course.
- XXIII.** No organization registered under the society Registration Act will be allowed to cater clinical treatment or accommodate any center for clinical investigation facilities, unless and until, it obtains a clinical lincese/licenses accordingly from the Licensing Authority concerned. In case of Partnership firm or Association, Deeds /Documents in this respect along with **Power of Attorney to the Applicant from amongst the Proprietors** must be submitted with the Application of clinical establishment license and registration.
- XXIV.** **Free treatment** facilities for 40% of the patients at Out-Patient Departments that is, in Out door and 10%of the patients at in Patient Department that, in door, must be provided by the clinical establishment having equipments procured with the help of Custom Duty Exemption Certificate as per Central Government norm and declaration by the clinical establishment in this respect .A month-wise repot extension of such free treatment must be submitted with the application for renewal of registration and license.
- XXV.** If any clinical establishment receives any land for the purpose under some special consideration from the Government of West Bengal or from the Government of India or from any charitable trust, a copy of agreement towards the facilities to be the patients in the from of free treatment or other must be submitted with the application for registration and license.
- XXVI.** The clinical establishment that has received reduction or exemption from payment of application fees as the case may be, under sub-section 1 Section 4(i) of the Act, will be required to provide treatment facilities (both In-door and Out-door) free of cost to 20% Out-door and 15% In-door Patients, if not fall under the jurisdiction of sub-rule (xxiv) and below of such percentage of free treatment during any agreement under sub-rule (xxv) of this rule, and must submit a monthly report of such free treatment to the Licensing Authority failing which their license shall be suspended until they pay the full license fee along with a fine of equal amount.
- XXVII.** An **information booklet** in local languages must be provided to the beneficiaries. The clinical establishment will offer an estimate of expenditure likely to be incurred to the in-door patients either for the whole Package for investigations. Treatment and Management or by furnishing item wise estimate for investigations, treatment or management, separately.
- XXVIII.** All payments should be supported by receipts.
- XXIX.** All charitable institutions /Doctors doing service should submit application in Form II of CE Rules asking the licensing authority (Dy. DHS (Admn.) in case of Kolkata and CMOH in case of a district) to waive or to reduce the fees as the case may be. Secretary, Health & Family Welfare will ultimately decide on the matter.
- XXX.** The license granted to an establishment under these Rules is not transferable. In the event of change of ownership or change of management or when the establishment ceases to function the license shall be surrendered to the licensing authority and the new owner or management should apply afresh for grant of license.

B. For Nursing Homes and/or Maternity Homes, Dispensaries and Day Care Centers (With Beds)

- (I) Formation for rooming of the patient should be as :-
- a) Ward-a room having not less than 4(four) patients with acceptable floor space vide Annexure-A of these rules per patient and must be separated for male and female.
 - b) Cubical- a long room divided for each patient with curtains up to an acceptable height of 2.5 meters to provide privacy to the patients of three sides with a screen in open side having acceptable floor space vide Annexure-A of these rules per patient.
 - c) Cabin-a single room to provide complete privacy to a patient with acceptable floor space vide Annexure-A of these rules for the patient with an attached toilet exclusively for the patient.
- (II) **Provision for sanitary fittings:-**
Acceptable norms to be followed as laid down in Annexure-A of these rules.
- (III) **Except for Intensive Therapy Unit and Intensive Cardiac Care Unit with provision of curtains,** no male patient is allowed to stay with female patient inside a ward. There shall be separate male or female ward.
- (IV) **Operation Theatre Complex :-** Minimum floor space for an operation Theatre as specified in “Annexure -A” of these rules shall be provided apart from area provided, scrubbing, dirty linen, store, Doctor’s room, Nurses room, Recovery and Sterilization. Such a complex must be treated as a **sterile zone** and a sepsis of such complex shall be regularly maintained. All operation theatres must be equipped with proper instruments like shadow less lamp, anaesthetics apparatus with oxygen cylinder, diathermy etc.
- (V) Proper **ventilation, lighting and water supply** must be provided.
- (VI) Fans operated by electricity must be provided with, where electricity is available, or other means of cooling must be adopted.
- (VII) Sufficient number of **water closets, bathrooms and washbasins** must be provided as per acceptable norms laid down in Annexure-A of these rules.
- (VIII) Adequate number of bedpans and slop sinks with flushing arrangements must be provided.
- (IX) Floor and other parts of the rooms must be kept clean and in proper repairs regularly.
- (X) The rooms and the building are all while washed every year and if washable paint used should be painted once in every three years.
- (XI) Adequate and wholesome diet must be provided to the patients as per advice of the attending Doctor and cleanliness is to be maintained in preparation of diet and it’s service to the patients.
- (XII) Proper arrangements for attending the patients and prompt answering to their calls must be made available round the clock.
- (XIII) No person, other than those who are directly connected with the running of the establishment or who are members of their family, shall be allowed to reside in the premises except with the special permission of the authorities of the establishment shall be responsible for the action of any person whom they grant such special permission.
- (XIV) No person shall be allowed to sleep on the floor where the patients are accommodated.
- (XV) In case of a maternity home the **delivery room** must be provided as per specification laid down in Annexure A of these rules. **The delivery room must be equipped** with obstetric table, suction apparatus, and shadow less lamp, weighing machine for the babies and other instruments for the purpose with adequate emergency management facilities.
- (XVI) A room with proper sanitary arrangements with provision for drinking water must be provided for Residential Medical Officers, to be called as Residential Medical Officers room, and with the same arrangements a room must be provided for nursing personnel to be called as Nurses changing Room., in a new establishments.
- (XVII) All clinical establishments having indoor facilities shall maintain proper bed head tickets with the time of admission of the patient, provisional diagnosis and the prescription of the doctor

attending the patient during admission with proper date, time and signature. It will be obligatory on the part of such clinical establishments to submit bed head ticket of any patient, whenever required with details, that is, with copy of, all investigations reports done after advice of attending doctor/s, diet chart, input-output chart, temperature chart, prescriptions, clinical findings, and final diagnosis or cause of death if occurred, of the patient, during the course of treatment in such clinical establishments, by the licensing authority or his nominated person/s. Any refusal or inability or failure to submit the same, by any clinical establishment, if required with in a stipulated time as fixed up by the licensing authority, shall be considered as a gross violation of the rules.

- (XVIII) All corridors must be adequately spacious and wide to provide safe movements of ambulatory patients with the help of stretchers or wheel chairs and so to the stair cases for movements of stretchers where there is no provision of electrically operated lift.

C. For Physical Therapy Establishments

- (I) A physical therapy establishment provides treatment facilities to patients suffering from crippling diseases and disabilities. The treatment may be classified as physical and electro-therapy, hydrotherapy, occupational therapy and exercise (Gymnasium). Physiotherapy demands complete privacy. Accommodations should, therefore, be provided in the forms of booths. A long room with curtains, which could be drawn, to form cubicles and afford adequate privacy shall be provided. The minimum area that could be provided in such an establishment for different items shall be as per with Annexure-A of these rules with adequate equipments for the purpose.
- (II) Such establishments shall be under direct supervision of a properly qualified expert on the particular type of treatment to be provided by the establishment.
- (III) Save as hereinafter provided, the employees of the establishment and the person/s giving the actual treatment shall have the proper qualifications from institutions approved by the appropriate authority for imparting such treatment.
- (IV) Male or female employees providing such therapy under direct supervision of properly qualified person /s shall possess a **minimum qualification** of Secondary Education (10+) or equivalent education from any recognized board of secondary education and must possess practical experience for a period of at least 5 years as a trainee or work assistant under a Physiotherapist in Physiotherapy department of a Government hospital or a hospital recognized for such purpose by the appropriate authority to achieve a satisfactory **Knowledge** on (a)basic anatomy specially of bones joints and muscle (b)basic physiology with rudimentary knowledge of diseases in which massage is indicated or contraindicated (c) mechanism and use of remedial apparatus (d) physics and application of electrical appliances used in modern physiotherapy.
- (V) To provide complete separate arrangement shall be provided for the therapy of male and female patients by the male or female employees respective under proper supervision of qualified person/s in this respect.

DIAGNOSTIC FACILITIES:

All diagnostic facilities employing consultant / full time specialist /MBBS as the case may be, in various departments will display in a prominent place the time of the visit of the consultant / full time specialist / MBBS for the interest of the patient. If the consultant /full time specialist / MBBS is not available on 2 successive occasions during the stipulated time, necessary measures will be taken as per rule. The consultant / full time specialist / MBBS, as the case may be, should put their signature and date in the report issued by the diagnosis unit.

D. For Clinical Laboratories

- (I) It shall be under a properly qualified person to conduct the test, examination or analysis **and the preparation** of cultures, vaccines, serum or other biological or bacteriological product undertaken by the laboratory.

- (II) The clinical laborites shall be provided with 600 mm 900 mm high bench of length about 2 meters per technician and to full width of the room for pathology in charge of the laborites Each **laboratory bench** shall have laborite sink with swan neck fittings, reagent shelving, gas and power point under counter cabinet .Top of the laboratory bench shall be of acid alkali proof.
- (III) The **room size** shall be provided for such purpose shall be as per Annexure-A of these rules apart from pathologist room, sample collection room report delivery room and laboratory waste material for disposal.
- (IV) All clinical laboratories are liable to **keep the records** the name of the patients, their address and the name of the referral doctor with detail of invention results. The clinical laboratories will have **to inform** the licensing authority about the notifiable diseases, if detected, within 24 hours with a copy to Chief Health Officers, Calcutta Metropolitan Urban Health Organization in case of Calcutta and Deputy Chief Medical Officer of Health –II in case of a district.

(A) Laboratory :

- a) The large and super-specialty laboratory shall be manned by the medical persons with post-graduate qualification in pathology, microbiology and biochemistry /PhD in the respective discipline.
- b) The small laboratory may be manned by a DCP or DTM&H or an MBBS with at least five years experience in laboratory medicine.
- c) The medium laboratory may be manned by a DCP or DTM&H or an MBBS with at least five years experience in laboratory medicine along with MSc: Biochemistry / Medical Micro-biology provided the laboratory performs the special tests.
- d) Any laboratory that performs histopathological, cytopathological and special hematological tests must be manned by an MD in pathology and in the specialty.
- e) Multi-disciplinary laboratories shall identify a group leader, with specific qualification for each.

(B) Technical Personnel:

The technical person performing the tests and reporting the results should have one of the following qualifications:

- a) Science graduate with five years experience in an established medium sized laboratory. (to be approved by the Govt. of West Bengal).
- b) Graduate in Medical Laboratory Technology.
- c) Diploma in Medical Laboratory Technology (with a course of at least of one year duration) awarded by a University, State Government, Central Technical Board, or Indian Medical Association with 2 years experience in an established medium – sized laboratory.
- d) A Laboratory may employ upto 25% of the staff without experience but which requisite qualifications or a person with more than ten years of laboratory experience with at least matriculation with science.

The laboratory shall have a system for imparting necessary training to technical staff at various levels. There shall be a system so that a technical person receives adequate training in the operation of a new analytical equipment and performance of a new test before he/she is assigned to such work.

(C) Collection Centre:

A blood collection center should be manned by an MBBS. The qualification of technician is as mentioned in (B) above. The collection center should have an adequate waiting space and a room having at least 80 sq.ft. floor area. **No collection center should be operated by any pathological laboratory in any medicine shop.** If any laboratory is found to operate through a medicine shop the authority may cancel the license of such laboratory.

(D) Laboratory Specification:

Small: Routine Clinical Procedures e.g. Hb, TC,DC,ESR,BT,CT,PT, Routine examination of stool, urine, sugar (blood and urine), urea, cholesterol.

Medium: As above + Special tests e.g. LFT, Lipid profile, Renal Function, Cardiac Function, Common Hormone Assay: T3, T4, TSH, Prolactin, 17 ketosteroids, Urine and blood culture, Elisa Test, Use of Semi Auto Analyser & Electrolytes estimation.

Large: As above and others.

Laboratories doing investigations by radio-immunoassay techniques need clearance from the BARC.

E. For Radiology

- (I) The role of radiology department shall be radio diagnostic and radiotherapy; hence it shall be **under properly qualified person/** conduct the radio diagnosis or radiotherapy, as the case may be.
- (II) The Radiotherapy diagnostic units generally deal with Radiography, Ultrasound, Nuclear medicine, and Computed Axial Topography Scanner, Magnetic Resonance Image etc.
- (III) The **Radiotherapy** units including treatment with various types of **radiations** ranging from superficial therapy to mega voltage therapy.
- (IV) The size of the department depends on the load the scope of work and the type of the equipment employed. However the room housing X-ray equipment must be spacious enough to permit installation, use and servicing of the equipment with safety and convenience for the operating personnel, the servicing personal and the patients. The room size must be provided as per Annexure –A of these rules for a general purpose X-ray machine. Fluoroscopy room shall be completely cut off from direct light through provisions of air locks.
- (V) The rooms housing diagnostic X-ray units and related equipments shall be **located** as far away as feasible from areas of high occupancy and general traffic.
- (VI) **The radiography units should be operated from separate control room or behind a lead mobile protection screen of 1.5 mm lead equivalent wherever necessary.**
- (VII) All establishments having X-Ray and imaging facilities MUST fulfill the clauses as laid down in the SAFETY MANUAL prepared by ATOMIC ENERGY REGULATORY BOARD, Govt. of India.
- (VIII) All establishments doing Ultrasonography via a portable machine should have license under the Act and PNDDT Act. Ultrasonologist having portable machine, who have no fixed establishments should be registered under PNDDT act. No ultrasonologist should perform USG in an establishments who has no license under CE and or PNDDT Act. No ultrasonologist should perform in any establishment without having license under PNDDT Act.

F. For Medical Clinics (Doctors' Chambers for any discipline)

- (I) Minimum **floors space** to be provided for an examination rooms shall have the specification as specified in Annexure 'A' of these rules.
- (II) Adequate waiting space and reception area. Airy, ventilated, comfortable and well lighted. Only fees to be displayed and toilet for patients.
- (III) Doctor's chamber of any registered medical practitioner inside a medicine shop is not permitted. However 6 months time, from the date of issuance of Gazette is allowed for withdrawal of such chambers. An owner may apply to the licensing authority, in case of difficulty for consideration, which will be judged on merit. The total period in any case should not exceed 12 months.

12. On receipt of the application the licensing authority shall depute any officer or officers of the State Government duly authorized by him in writing in this behalf **to make an enquiry and report as per**

FORM III as specified in the appendix to these rules about the eligibility of the establishments for registration and license under the Act.

13. The enquiring officer/s **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 qualification of the technical staff employed or to be employed and shall make such other enquires as he /they considered necessary to verify the statements made in the application for registration and grant of license.
14. All persons connected with the running of the establishment shall be bound to supply **full and correct information** to the enquiring officer/s.
15. (a) The license authority may register the applicant and grant a license under the act for the establishment if satisfied on the report of the enquiring officers/s that all the conditions are fulfilled.

All new Clinical Establishment should be inspected normally within 60 days of application. All objections, after inspection of the new establishment, should be communicated in writing to the applicant and 30 days time will be given to the establishment to correct minor deficiencies and in case of major 180 days. The Clinical Establishment will not function in the meantime. In case of old establishments one year time will be given to correct structural deficiencies, if any on receipt of a declaration from the licensee. In case of failure to meet the deficiencies in old and new establishments the application shall deemed to be rejected and the cause will be written in register as prescribed in the rules.

- (b) After receiving application from a new establishment or for installation of a new equipment (except individual clinic) the Clinical Establishment should be inspected within 60 days of application. Meanwhile the clinical establishment or the machinery should not function. The clinical establishment should not advertise through print or any other media without obtaining a valid license. If the inspection could not be done within 90 days then the clinical establishment or the machinery will automatically get the license if all other criteria are fulfilled.

16. Any applicant aggrieved by the rejection of an application for registration and license may appeal for reconsideration of registration and license to the Secretary, Department of Health and Family Welfare, Government of West Bengal Writer's Buildings, Kolkata –I in case of Kolkata and to the Chairman District Health Committee in case of a district, within 30 days from the date of rejection of such application, in the form of a memorandum, setting forth the relevant facts of the case along with the copy of information provided to the applicant by the license authority towards correction of the anomalies detected during inspection or processing the case. The appellant may represent his case before the appellate authority either by him or herself or through a duly authorized agent or legal practitioner, The appellate authority shall inform the appellant of the date when the appeal will be heard and may call for any information or require the production of any document which may be necessary for the disposal of the appeal.

17. Every license granted under the Act shall be in **FROM IV** as specified in the appendix of these rules and on the terms indicated on the backside of the license.

18. A keeper of the clinical establishment shall keep the following registers of the patients received or accommodated or both at the clinical establishment as an out-door or in-door patient namely:-
 - a) Register of admission and discharge /death of the patient;
 - b) Register of expenditure incurred by the patients for treatment in the clinical establishment;
 - c) Records of treatment.

These registers shall be entered fully, cholerically and legibly. The formats of 'Register of admission and discharge / death of the patients 'and the: Register of expenditure incurred by the patients for treatment in the clinical establishment 'have been shown in FROM V FROM VI respectively as specified in the appendix to these rules. Copies of which shall be kept in the record room of the clinical establishment concerned as stated in rules VII of rule –11 under the heading "AGENERAL". (For all Clinical Establishment0"of these rules for at least 5 years. The information in this regard shall be supplied to the license authority, as and when required.

19. The keeper of the clinical establishment other than a clinical liberty shall ;-

- (i) Within 24 hours of the death at the establishment of any patient or any child born to a patient send to the local register of birth and death, in this behalf a notice on writing by registered post or through a messenger stating-
 - a) The date and hour of birth;
 - b) The date and hour of death and ;
 - c) If a medical certificate of the cause of death has been signed by a registered medical practitioner –the name and registration number of such medical practitioner, or,
 - d) If such certificate has not been given or obtained, the cause of death to the best of Knowledge.
 - (ii) If an inquest is held in respect of any such death, send within 24 hours of the conclusion thereof to such authorities as may be prescribed by the Director of Health Services, West Bengal and in this behalf a notice in writing by registered post or, in an equally suitable manner, stating the date of inquest and the cause of death as found by the Coroner or Jury thereat.
- 20.** The keeper of every clinical establishment shall maintained and their a bound **Inspection book** and a **Complain Register (for the patients party)**, which shall be produced before the inspecting officer/s as and when required.
- 21.** The Keeper of every clinical establishment shall furnished to the license authority a copy of the **compiled Yearly Report on the working of the establishment** on and before 1st April each year by registered post or through a messenger.
- 22.** Any **officer authorized under sub-section (1) of section 6 of the Act** may enter any establishment and inspect any document subject to the following Regulation namely :

Regulations

- (i) The officer authorized under sub-section (1) section 6 of the Act **may enter with or without notice**, any premises license for Physical therapy or Maternity home admitting general and or maternity cases at any time of the day and night, and, any premises license for other kinds of clinical establishment during working hours, and may consider necessary, for the purpose of ascertaining, whether the provision of the Act and the rules there under are being properly complied within the establishment.
- (ii) The officer authorized under sub-section (1) of section 6 of the Act, **may call upon the officer-in-charge of a police station** for rendering such assistance as may be necessary for proper discharge of his duties.
- (iii) It shall be **obligatory** on the party of a license of a clinical establishment to **inform** to the nearest police station about all suspicious cases of injury and legal cases treated in the clinical establishment.
- (iv) If any license desires **to close down the clinical establishment**, which was running under the West Bengal Clinical Establishment Act, 1950, at any time before expire of the license, or on the expiry of the license, he shall send a closure notice in writing by registered post or through a messenger to the licensing authority, at least one month before the date of such closure. The license shall also **surrender the license** to the licensing authority immediately after closure of the clinical establishment.
- (v) All emergency patients attending a clinical establishment, where ever registered medical practitioner /s are engaged, must be attended primarily without considering the financial capability of the patient **to save the life**, and then, may be **referred with suitable medical report** about the ailments, as early as possible to the nearest Government hospital if necessary. It is also the responsibility of the patient or his party to pay all the dues before being released from the clinical establishment.
- (vi) No clinical establishment either curative or diagnostic shall refuse **the treatment or investigation** of patient suffering from HIV if it does not have a Voluntary Testing and Counseling Centre. Cases which need further investigation should be referred to the nearest VTCC.
- (vii) All clinical establishments should report Family Welfare cases i.e. tubectomy, vasectomy, Oral Pill users and other users of contraceptive methods, Immunization Programme and Acute Flaccid Paralysis cases monthly to the respective Deputy CMOH III in district and District Family Welfare Officer in case of Kolkata. All malaria cases detected in the laboratory and or treated in clinical

establishment to be reported to Deputy CMOH II in case of a district and Kolkata Metropolitan Urban Health Organisation (KMUHO) in case of Kolkata.

- (viii) All clinical establishments performing medical termination of pregnancy (MTP) should submit monthly report in proper form under MTP Act to the State Welfare Officer: West Bengal with a copy to the Chief Medical Officer of Health in the districts.
- (ix) A report in the form of **hospital statistics** will have to be submitted month wise to the Director, **State Bureau of Health intelligence** as per prescribed Form of that bureau by the license of the clinical establishment in case of Kolkata and to the District Inspector of Health Statistics under Deputy Chief Medical Officer of Health –II in case of district as a part of health intelligence of the state.
- (x) Every person keeping or charring on a clinical establishment, **shall submit an immediate report to the Authority for receiving such report**, as mentioned below under intimation to the licensing authority as soon as it comes to the notice, that any person who has been attended as an outdoor patient or been admitted as an indoor patient in the establishment is suffering from any **notifiable disease**, and the establishment shall be placed under quarantine immediately, and the premises of the establishment shall be disinfected in a proper manner.

AUTHORITY FOR RECEIVING THE REPORTS NOTIFIABLE DISEASES FROM THE CLINICAL ESTABLISHMENTS

- (a) **Within Kolkata**—Chief Municipal Health Officer, Kolkata Municipal Corporation.
- (b) **Outside Kolkata**—Where Municipal exist –Municipal Health Officer, Chairman Administration or Executive Officer of the municipality as the case may be.
- (c) **In other areas**—the Chief Medical Officer of Health or The Deputy Chief Medical Officer of Health-II of the district.

23. Every license shall :-

- a) Cause any child born therein **to be vaccinated within 3 days** from the date of birth or the discharge which ever is earlier unless the medical superintend, medical officer or the medical authority in-charge of the clinical establishment is of opine that the child is **not in a fit state** of health to be vaccinated which shall be mentioned clearly in the discharge certificate;
- b) Cause every admitted patient **to be vaccinated** therein or re-vaccinated unless such patient has been vaccinated or re-vaccinated as required under the West Bengal Vaccination Act, 1973.

24. The number of acceptable technical and non-technical **staff to provide round the clock care to the admitted patients** of clinical establishment having in-door facility must be appointed as per table below:-

**TABLE
FOR MINIMUM NUMBER OF STAFF TO BE APPOINTED FOR IN-DOOR TO PROVIDE
ROUND THE CLOCK CARE TO THE ADMITTED PATIENTS**

Sl. No.	Category of Staff	For How many patients	Number to be provided
1.	Residential Medical Officer	20 patients or its part	1
2.	Registered Nurse or Midwife	5 patients or its part	1
3.	General Duty Attendant	3 patients or its part	1
4.	Sweeper	5 patients or its part	1

Explanation –Registered Midwives may be appointed for maternity homes or for maternity cases.

Nothing in this rules will be applicable to the establishments having license under the Indian Lunacy Act 1912 and under the Lepers Act 1898.