The Clinical Establishments (Central Government) Rules, 2012

CONTENTS

The Clinical Establishments (Central Government) Rules, 2012[1]

In exercise of the powers conferred by Section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010), the Central Government hereby makes the following rules, namely—

1. Short title and commencement.—(1) These rules may be called the Clinical Establishments (Central Government) Rules, 2012.

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

2. Definitions.—In these rules, unless the context otherwise requires,—

(*a*) "Act" means the Clinical Establishments (Registration and Regulation) Act, 2010;

(*b*) "Secretary" means the Secretary of the National Council for clinical establishments;

[2][(*bb*) "Schedule" means the Schedule appended to these rules.

(*c*) Words and expressions used and not defined in these rules, but defined in the Act, shall have the same meanings respectively assigned to them in the Act.

3. Appointment of Secretary of the National Council by the Central Government.—(1) The officer of the rank of Joint Secretary dealing with the subject of Clinical Establishments in the Ministry of Health and Family Welfare, Government of India shall be the ex-officio Secretary of the National Council for clinical establishments established under sub-section (1) of Section 3 of the Act.

(2) The Secretary of the National Council shall be responsible for the control and management of the secretariat of the National Council and supervision of the other staff of the National Council Secretariat and perform such other duties as may be required of him by the National Council for the purposes of the Act.

(3) He shall attend the meetings of the National Council for clinical establishments.

(4) The duties and responsibilities of the staff of the National Council shall be such as may be laid down from time to time by the Secretary of the National Council.

4. National Council and its sub-committees.—(1) The National Council shall classify and categories the clinical establishments of recognised systems of medicine and submit the same to the Central Government for its approval.

---

1. Ministry of Health and Family Welfare (Deptt. of Health and Family Welfare), Noti. No. G.S.R. 387(E), dated May 23, 2012, published in the Gazette of India, Extra., Part II, Section 3(*i*), dated 25th May, 2012.
2. *Ins.* by GSR 468(E), dated 18-5-2018 (w.e.f. 21-5-2018).

(2) For the appointment of each sub-committee the National Council shall define the functions of the sub-committee, number and nature of members to be appointed thereon and timeline for completion of tasks. At the time of formation of each sub-committee, effort should be made to ensure that there is adequate representation from across the country in each committee from experts in the relevant fields across the private sector, public sector and its organisations, non-governmental sector, professional bodies, academia or research institutions amongst others.

(3) The Chairperson of every such sub-committee shall be appointed by the National Council at the time of the appointment of the sub-committee.

(4) The proceedings of the meetings of the sub-committees shall be preserved in the form of minutes.

(5) Any recommendations made by the sub-committees shall be placed before the National Council for its consideration and further necessary action.

(6) The National Council of clinical establishments may request the State Councils or Union territory Councils to provide inputs for its consideration on particular matters. If required, the State Council or Union territory Council shall at the request of the National Council or the Central Government, as the case may be, constitute sub-committee consisting of members of the State and Union territory Council and field experts for such period not exceeding one year, for deliberations and making recommendations on a particular matter or issue.

5. Allowances for the members of the National Council and sub-committees.—The official members of the National Council for clinical establishments shall draw their travel and daily allowances as per the Government of India rules from the same source from which their salary is drawn. The non-official members of the Council shall be paid travel allowance and daily allowances in accordance with the Government of India rules as applicable, from time to time for the Group 'A' officers of Junior Administrative Grade.

6. State Council or Union Territory Council representation in the National Council meeting.—The National Council may invite representative(s) from one or more State Councils or Union territory councils to participate in its meetings, as may be considered appropriate and the expenses on account of participation by such representatives will be met by the National Council.

7. Common registration form for compilation of the State and National Register.—In order to ensure uniformity in collection of information by the State Governments or Union territory's administration and data flow in connection with the compilation and maintenance of the State Registers and the National Register in digital format for the purpose of Sections 38 and 39 of the Act, the National Council shall also develop the standard application form for registration of clinical establishments.

8. District Registering Authority.—(1) *Qualifications and the terms and conditions for appointment of the members of the authority.*—The district registering authority established by way of notification by the State Government

under clause (*c*) of sub-section (1) of Section 10 of the Act shall consist of three other members who shall be nominated by the District Collector or District Magistrate and they shall include the City Police Commissioner or Senior Superintendent of Police or Superintendent of Police, or his nominee, as the case may be, a senior level officer of the Local Self Government at the district level, one representative from a professional medical association or body having presence preferably in the district or within the State, as the case may be, for a tenure of two years.

(2) *Filling up of casual vacancy.*—if a casual vacancy occurs whether by reason of death, resignation or inability to discharge functions owing to illness or any other incapacity of a nominated member, such vacancy shall be filled by the District Collector or District Magistrate by making a fresh appointment and the member so appointed shall hold office only for the remaining tenure of the person in whose place he is so appointed.

(3) *Powers of the District Health Officer or Chief Medical Officer for the purposes of provisional registration of clinical establishments.*—The District Health Officer or the Chief Medical Officer (by whatever name called) shall exercise the following powers for the purposes of provisional registration of clinical establishments under sub-section (2) of Section 10 of the Act, namely—

(*a*) for the purposes of provisional registration of the clinical establishment, an application in the prescribed pro forma as adopted by the State Government with the requisite fee as the State Government may by rules determine;

(*b*) the application shall be filed in person or by post or online;

(*c*) the District Health Officer or Chief Medical Officer shall, within a period of ten days from the date of receipt of such application, grant to the applicant a certificate of provisional registration in such form, particulars and information, as the State Government may by rules determine;

(*d*) the District Health Officer or Chief Medical Officer shall riot conduct any inquiry prior to the grant of provisional registration;

(*e*) notwithstanding the grant of the provisional certificate of registration, the District Health Officer or Chief Medical Officer shall, within a period of forty-five days from the grant of provisional registration, cause to be published in such manner, as the State Government may by rules determine, all particulars of the clinical establishment so registered provisionally;

(*f*) where the clinical establishments in respect of which standards have been notified by the Central Government, provisional registration shall not be granted or renewed beyond.

(*i*) the period of two years from the date of notification of the standards in case of clinical establishments which came into existence before the commencement of this Act;

(*ii*) the period of two years from the date of notification of the standards for clinical establishments which came into existence after the commencement of this Act but before the notification of the standards; and

(*iii*) the period of six months from the date of notification of standards for clinical establishments which come into existence after standards have been notified;

subject to the conditions as mentioned above, every provisional registration shall be valid till the last day of the twelfth month from the date of issue of the certificate of registration and such registration shall be renewable;

(*g*) the application for renewal of registration shall be made to the District Health Officer or Chief Medical Officer within thirty days before the expiry of the validity of the certificate of provisional registration and, in case the application for renewal is made after the expiry of the provisional registration, the authority shall allow renewal of registration on payment of such enhanced fees, as the State Government may be rules determine;

(*h*) in case the certificate is lost, destroyed, mutilated or damaged, the authority shall issue a duplicate certificate on the request of the clinical establishment and on the payment of fees as the State Government may by rules determine.

[3][**8-A. Minimum Standards for Medical Diagnostic Laboratories (or Pathological Laboratories).**—Every clinical establishment relating to diagnosis or treatment of diseases, where pathological, bacteriological, genetic, radiological, chemical, biological investigations or other diagnostic or investigative services, are usually carried on with the aid of laboratory or other medical equipment, shall comply with the minimum standards of facilities and services as specified in the Schedule.]

9. Other conditions for registration and continuation of clinical establishments.—For registration and continuation, every clinical establishment shall fulfil the following conditions, namely—

(*i*) every clinical establishment shall display the rates charged for each type of service provided and facilities available, for the benefit of the patients at a conspicuous place in the local as well as in English language;

(*ii*) the clinical establishments shall charge the rates for each type of procedures and services within the range of rates determined and issued by the Central Government from time to time, in consultation with the State Governments;

(*iii*) the clinical establishments shall ensure compliance of the Standard Treatment Guidelines as may be determined and issued by the Central

3. *Ins.* by GSR 468(E), dated 18-5-2018 (w.e.f. 21-5-2018).

Government or the State Government as the case may be, from time to time;

(*iv*) the clinical establishments shall maintain and provide Electronic Medical Records or Electronic Health Records of every patient as may be determined and issued by the Central Government or the State Government as the case may be, from time to time;

(*v*) every clinical establishment shall maintain information and statistics in accordance with all other applicable laws for the time being in force and the rules made thereunder.

[4][SCHEDULE

Sl. No.	Type of Laboratory	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 bio chemistry based rapid test.	Hormone Bioassay, Tumor markers, plasma protein electrophoresis	(*a*) coagulation profile, Drug monitoring and toxicology assay, (*b*) Molecular genetics, tests for detection of inborn errors of metabolism
	(*b*) Haematology	Haemogram, Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood	Coagulation Assay	All other Haematology tests also.

4. *Ins.* by GSR 468(E), dated 18-5-2018 (w.e.f. 21-5-2018).

		grouping and matching.		
	(*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	Immunohisto-chemistry:
	(*g*) Medical Microbiology & Immunology	Basic tests like Rapid Test (Point of Care tests) for infection, urine routine examination and microscopy, Hanging drop for Vibrio cholerae, Stool for ova, cyst. All HIV positive rapid assays need to be confirmed from the next level diagnostic laboratory.	(*a*) Serological tests for viruses, bacteria, fungi, parasites (*b*) Cultural Sensitivity tests: Bacterial or fungal (*c*) Other special stains besides Gram's stain.	(*a*) Culture sensitivity tests for viruses. (*b*) Real Time Polymerase Chain Reaction (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 radioactive materials, toxic chemicals, microbial agents,	Essential	Essential	Essential

	infected biological material.			
	(*b*) Appropriate Fire exit signages - Minimum one fire extinguisher	Desirable	Desirable	Essential
	3. Space requirement			
	(*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 equipment like flow cytometry and chemiluminescence equipment, ELISA test equipment etc.	Essential	Essential	Essential
	(*k*) Counselling room for HIV	Essential, if HIV test is done	Essential, if HIV test is done	Essential, if HIV test is done
	(*l*) FNAC room for all patients for sample collection	Desirable	Desirable	Desirable

	(*m*) Dark room for Immuno-fluorescence	Not required	Not required	Essential
	(*n*) Frozen Section facilities	Not applicable	Essential	Essential
	4. Furniture and fixtures	Essential	Essential as per scope of services	Essential as per scope of services
	5. Communication system— Telephone and mobile number for appointment	Desirable	Desirable	Desirable
	6. Wash Basins	Essential	Essential	Essential
[5][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 the advice of a registered medical practitioner.	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 training or experience or 2. M.Sc in Pathology or Medical Microbiology or Medical Biochemistry from a recognised university 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 with Ph.D qualification in the field of Pathology or Microbiology or Biochemistry or Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years	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 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

5. *Subs.* by GSR 115(E), dated 14-2-2020 (w.e.f. 14-2-2020).

		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. 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. *Note*: Laboratory technician with qualification as mentioned in Part III(*b*) of this Notification working in a Medical Diagnostic Laboratory registered under a Central or State Clinical Establishments	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. Or 3. M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.	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. Or 3. M.Sc. with Ph.D qualification in the field of Pathology or Medical Microbiology or Medical Biochemistry or Medical Genetics or Biotechnology or Immunology or Molecular Biology or Applied Biology from a recognised university or institution and having experience of at least three years post Ph.D in a Laboratory of same or higher level in a Government or Recognised medical college or hospital or institution or organisation shall be entitled to conduct the tests, generate and sign test reports in respect of tests of their respective specialty, without recording any opinion or interpretation of lab results.

		Registration Act, as applicable, and a Health care worker in a Government National Health program trained for conducting identified specific tests, may conduct the tests and generate test results which shall be submitted to the signatory authority at Sl. Nos. 1 or 2 as applicable.	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. *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. 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. *Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory. Illustration: (*i*) Special Tests pertaining to Bio-	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. *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. 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. *Special test means any other apart from routine basic biochemistry, hematology, or medical microbiology tests as listed in basic composite laboratory. Illustration: (*i*) Special Tests pertaining to Bio-

			Chemistry and Microbiology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively. (*ii*) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology.	Chemistry and Microbiology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Micro-biology respectively. (*ii*) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) or Ph.D in Pathology.
	(*b*) Number of laboratory technicians with Diploma in Medical Laboratory Technology (DMLT) or Bachelor of Science (B.Sc.) Medical Laboratory Technology (MLT) or Master of Science (M.Sc) Bio-chemistry or Micro biology qualification from a recognised university or institution.	Essential: 1	Essential: 2	Essential: 4
	(*c*) Support staff (Laboratory Assistant or Laboratory Attendant) Roster of salary of staff.	Essential: 1	Essential: 1	Essential: 2]

	Periodic health check- ups and vaccination of staff.			
IV	INSTRUMENTS OR EQUIPMENT OR DRUGS			
	(*a*) List of minimum medical diagnostics laboratory equipment with quantity	Essential as per scope of services	Essential as per scope of services	Essential as per scope of services
	(*b*) List of minimum medical diagnostics laboratory instruments with quantity	Essential as per scope of services	Essential as per scope of services	Essential as per scope of services
	(*c*) Sterilisation such as hot air oven or autoclave	Essential	Essential	Essential
	(*d*) List of reagents and consumables required	Essential	Essential	Essential
	(*e*) List of Disposables	Essential	Essential	Essential
	(*f*) Policy of annual maintenance contract or comprehensive maintenance contract and records for equipment (Log books)	Desirable	Desirable	Desirable
V	LEGAL OR STATUTORY REQUIREMENTS			
	Legal or statutory requirements such as registration under the provisions of Biomedical Waste Management Rules, 2016 with State or Union territories' Pollution Control Board with	Essential	Essential	Essential

	registration number and date of expiry, site, space, location and environmental requirements to be as per local bye-laws			
VI	RECORD MAINTANENCE AND REPORTING			
	(*a*) Reports of all patients date wise and specialty wise for example: Histopathology, Cytology, Haematology and Laboratory Medicine.	Essential (Clinical Establishment to maintain information and statistics provided)	Essential (Clinical Establishment to maintain information and statistics provided)	Essential (Clinical Establishment to maintain information and statistics provided)
	(*b*) Medico legal records, if applicable (as per relevant law)	Essential	Essential	Essential
	(*c*) Record keeping of technicians working in laboratory indicating their details of qualification training and others	Essential	Essential	Essential
	(*d*) Availability of reference library including books or periodicals or e-journals or Compact Disc (CD)s	Desirable	Desirable	Desirable
	(*e*) Duration of preservation of record (as applicable from time to time)	Essential	Essential	Essential
VII	STANDARDS ON BASIC PROCESSES			
	(*a*) Infection Control practices - as per Bio Medical Waste	Essential	Essential	Essential

	Management Rules, 2016			
	(*b*) Safety considerations-use of disposable needles etc	Essential	Essential	Essential
	(*c*) Patient Information and Education	Essential	Essential	Essential
	(*d*) Process of calibration of equipment and reagents	Essential	Essential	Essential
	(*e*) Booklet of Standard operating procedures of all procedures available	Essential	Essential	Essential
	(*f*) Grievance registration and disposal mechanism	Essential	Essential	Essential
	(*g*) Quality Control in the form of external quality assurance scheme or inter-laboratory comparison, as the case may be	Desirable	Desirable	Desirable
	(*h*) Policy of proficiency testing of tests performed	Desirable	Desirable	Desirable