

MINISTRY OF HEALTH AND FAMILY WELFARE
(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 5th May, 2017

G.S.R. 441(E).—The following draft of certain rules further to amend the Clinical Establishments (Central Government) Rules, 2012, which the Central Government proposes to make in exercise of the powers conferred by section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010), after consultation with the National Council for Clinical Establishments, is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which copies of the Gazette of India containing these draft rules are made available to the public;

Objections and suggestions, if any, may be addressed to the Under Secretary (Medical Services), Ministry of Health and Family Welfare, Government of India, Room No. 508, D Wing, Nirman Bhavan, New Delhi – 110011 or sent on email to sunil.kumar20@gov.in;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government.

DRAFT RULES

1. (1) These rules may be called the Clinical Establishments (Central Government) Amendment Rules, 2017.
(2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the Clinical Establishments (Central Government) Rules, 2012, (hereinafter referred to as the said rules), in rule 2 after clause (b), the following clause shall be inserted, namely.-
'(bb) "Schedule" means the Schedule appended to these rules'.
3. In the said rules, after rule 8, the following rules shall be inserted, namely:-
"8A. Minimum Standards for diagnosis or treatment of diseases. - 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".
4. In the said rules, after rule 9, the following Schedule shall be inserted, namely:-

"SCHEDULE

Sl. No.	Type of laboratory	Basic Composite	Medium	Advanced
I	Definition	Laboratories processing upto 30 samples.	Laboratories processing between 30 and 100 samples	Laboratories processing more than 100 samples
II	Scope of services	These tests can be performed in mobile laboratory at field centres also.	Apart from the tests performed in basic composite laboratory, additional tests mentioned as under.	Apart from the 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 dry chemistry based rapid test.	(a) Routine Biochemistry, (b) Hormone Bioassay, Tumor markers, plasma protein electrophoresis	(a) Routine Biochemistry, (b) Hormone Bioassay, Tumor markers, plasma protein electrophoresis, coagulation profile, Drug monitoring and toxicology assay, (c) Molecular genetics, Inborn errors of metabolism

	(b) Haematology	Haemogram, Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping	Haemogram, Bleeding Time, Clotting Time, Prothrombin Time, Activated Partial Thromboplastin Time, Blood grouping, Coagulation Assay	All other Haematology tests also.
	(c) Histopathology	Not applicable	May or may not do (optional)	Histopathology Examination
	(d) Molecular Genetics	Not applicable	May or may not do (optional)	Molecular genetics
	(e) Cytopathology	Not applicable	PAP smear, Fine Needle Aspiration Cytology(FNAC), sputum and CSF cytology	PAP smear, FNAC, sputum cytology and other biological fluid cytology; Desirable: Ultrasound and CT guided FNAC.
	(f) Immuno-histopathology	Not applicable	Not applicable	Immuno histopathology: As per scope of laboratory
	(g) Medical Microbiology and Immunology	Basic tests like Rapid Test (Point of Care) 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) Basic tests as in basic composite laboratory. (b) Serological tests for viruses, bacteria, fungi, parasites (c) Culture sensitivity tests: Bacterial or fungal (d) Other special stains besides Gram's.	(a) Basic test as in composite laboratory. (b) Serological tests for viruses, bacteria, fungi, parasites. (c) Culture sensitivity tests, bacterial or fungal or viruses. (d) Gene based tests (Nucleic acid tests for infections like Real time Polymerase Chain Reaction (PCR) tests). Histopathology of infectious diseases. Desirable: Immunocytochemistry
III	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 Genetics- whichever is applicable	Essential	Essential	Essential

	(d) Timings of the different consultants	Essential	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 Signages (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, infected biological material.	Essential	Essential	Essential
	(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 , Enzyme-linked immune sorbent assay(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 tests of Immuno-fluorescence	Not applicable	Not applicable	Essential
	(n) Frozen Section facilities	Not applicable	Essential as per scope of services	Essential as per scope of services
	4. Furniture and fixtures	Essential	Essential	Essential
	5. Communication system - Telephone and mobile number for appointment	Desirable	Desirable	Desirable
	6. Wash Basins	Essential	Essential	Essential
IV	HUMAN RESOURCE			
	(a) Designation, minimum qualification of Technical Head of Laboratory or Specialist or Signatories.	Essential: Bachelor of Medicine and Bachelor of Surgery (MBBS)from a recognised institution (with at least one year experience in laboratory work-Desirable)	Essential: In-charge may be 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) with one year post diploma experience or Bachelor of Medicine and Bachelor of Surgery (MBBS) with Doctor of Philosophy (PhD) in any of the 3 subjects or apart from incharge, if	Essential: In-charge can be Doctor of Medicine (MD) or Diplomate of National Board (DNB) Pathology or Laboratory Medicine or Biochemistry or Medical Microbiology or Diploma in Clinical Pathology (DCP) with one year post diploma experience or Bachelor of Medicine and Bachelor of Surgery (MBBS) with Doctor of Philosophy (PhD) in any of the 3 subjects or apart from in-charge, if any special test of other speciality is done, it is desirable that specialist of that subject need be there on full time or part time or outsourced

			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 (Special tests means any other apart from routine basic biochemistry, haematology, or medical microbiology tests as listed in basic composite laboratory)	(Special tests means any other apart from routine basic biochemistry, haematology, or microbiology tests as listed above)
	(b) Number of laboratory technicians with Diploma in Medical Laboratory Technology (DMLT) or Medical Laboratory Technology (MLT) or Bachelor of Science (B.Sc.) in laboratory sciences or Master of Science (M.Sc) in laboratory sciences or Doctor of Philosophy (Ph.D) in laboratory sciences qualification from University or recognized institution.	Essential: 1	Essential: 2	Essential: 4
	(c) Support staff (Laboratory Assistant or Laboratory Attendant) Roster of salary of staff, Periodic health check- ups and vaccination of staff	Essential: 1	Essential: 1	Essential: 2
V	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
VI	LEGAL OR STATUTORY REQUIREMENTS			
	Legal or statutory requirements such as registration under the provisions of the Biomedical Waste Management Act with State or Union territories' Pollution Control Board with registration number and date of expiry, site, space, location and environmental requirements to be as per local bye- laws	Essential	Essential	Essential
VII	RECORD MAINTENANCE 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	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	Desirable	Desirable	Desirable

	e-journals or Compact Discs(CDs)			
	(e) Duration of preservation of record (as applicable from time to time)	Essential	Essential	Essential
VIII	STANDARDS ON BASIC PROCESSES			
	(a) Infection Control practices - as per Bio- Medical Waste Management Rules , 2016	Essential	Essential	Essential
	(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”.

[F. No. Z. 28013/40/2017-MS]

K. L. SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i) *vide* G.S.R. No. 387(E), dated the 23rd May, 2012.