

	अपशिष्ट प्रबंधन नियम 2016 के अनुसार			
	(ख) सुरक्षा विचार - त्याज्य सुदृगों आदि का उपयोग	आवश्यक	आवश्यक	आवश्यक
	(ग) रोगी सूचना और शिक्षा	आवश्यक	आवश्यक	आवश्यक
	(घ) उपस्करों और संकर्मकों के अंशांकन(कैलिब्रेशन) की प्रक्रिया	आवश्यक	आवश्यक	आवश्यक
	(ङ.) उपलब्ध सभी प्रक्रियाओं के मानक संचालन प्रक्रियाओं की पुस्तिका	आवश्यक	आवश्यक	आवश्यक
	(च) शिक्षात्मक रजिस्ट्रीकरण और निपटान की क्रियाविधि	आवश्यक	आवश्यक	आवश्यक
	(छ) बाह्य गुणवत्ता- आश्वासन योजना या अंतर्प्रयोगशाला तुलना यथा स्थिति रूप में गुणवत्ता नियंत्रण	वांछनीय	वांछनीय	वांछनीय
	(ज) किए गए परीक्षणों की प्रवीणता परीक्षण संबंधी नीति।	वांछनीय	वांछनीय	वांछनीय

[फा. सं. जेड. 28013/40/2017-एमएस]

मुधीर कुमार, संयुक्त सचिव

नोट : मूल नियम तारीख 23 मई, 2012 की अधिसूचना संख्या सा.का.नि 387(अ) के तहत भारत के राजपत्र, असाधारण, भाग-II, धारा 3, उप धारा (i) में प्रकाशित किए गए हैं।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 18th May, 2018

G.S.R. 468(E).—Whereas the draft of certain rules to amend the Clinical Establishments (Central Government) Rules, 2012 was published, as required under section 52 of the Clinical Establishments (Registration and Regulation) Act, 2010 (23 of 2010), in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) vide notification of the Government of India in the Ministry of Health and Family Welfare, Department of Health and Family Welfare, number G.S.R. 441(E), dated the 5th May, 2017 inviting objections and suggestions from all persons likely to be affected thereby;

And whereas objections and suggestions received from the public have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 52 of the said Act, the Central Government hereby makes the following rules further to amend the Clinical Establishments (Central Government) Rules, 2012, namely:—

RULES

- (1) These rules may be called the Clinical Establishments (Central Government) Amendment Rules, 2018.
- (2) They shall come into force on the date of their publication in the Official Gazette.
- 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”.
- In the said rules, after rule 8, the following rule shall be inserted, namely:—
“8A. 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."

4. In the said rules, after rule 9, the following Schedule shall be inserted, namely:-

SCHEDULE

S. 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. ⁷	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 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	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	(a) Serological tests for viruses, bacteria, fungi, parasites (b) Cultural Sensitivity tests: Bacterial or fungal (c) Other special stains besides Gram's stain.	(a) Culture sensitivity tests for viruses. (b) Real Time Polymerase Chain Reaction (RT-PCR) tests. (c) Tissue diagnosis test for infectious diseases.

		assays need to be confirmed from the next level diagnostic laboratory.		
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, 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	Desirable	Essential	Essential

	water etc.			
	(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
III	HUMAN RESOURCE			
	(a) Minimum qualification of Technical Head of Laboratory or Specialist or *Authorised Signatories.	Desirable: Bachelor of Medicine and Bachelor of Surgery (MBBS) from a recognised university institution. **Where ever interpretation of lab results or opinion there on are required, registered Bachelor of Medicine and Bachelor of Surgery (MBBS) medical practitioner is	Essential: 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) or Bachelor of Medicine and Bachelor of Surgery (MBBS) with Doctor of Philosophy (PhD) in any	Essential: 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) or Bachelor of Medicine and Bachelor of Surgery (MBBS) with Doctor of Philosophy (PhD) in
	*The authorised signatory will be liable for authenticity of the laboratory test report.			

		essential.	of the subjects above. 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 tests means any other apart from routine basic biochemistry, haematology, or medical microbiology tests as listed in basic composite laboratory. <i>Illustration:</i> <i>(i) Special Tests pertaining to Bio-Chemistry and Micro-biology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) Micro-biology respectively.</i> <i>(ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) Pathology.</i>	any of the subjects above. 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 tests means any other apart from routine basic biochemistry, haematology, or medical microbiology tests as listed in basic composite laboratory. <i>Illustration:</i> <i>(i) Special Tests pertaining to Bio-Chemistry and Micro-biology shall be reported by Doctor of Medicine (MD) or Diplomate of National Board (DNB) Bio-Chemistry and Doctor of Medicine (MD) or Diplomate of National Board (DNB) Micro-biology respectively.</i> <i>(ii) Biopsies or Cytology specimens has to be reported by a person possessing Doctor of Medicine (MD) or Diplomate of National Board (DNB) Pathology.</i>
	(b) Number of laboratory technicians with Diploma in Medical Laboratory Technology (DMLT) or Bachelor of Science (BSc.) Medical Laboratory Technology (MLT) or Master of Science (M.Sc.) Bio-chemistry or Micro-biology qualification from a recognised university or institution.	Essential: 1	Essential: 2	Essential: 4
	(c) Support staff (Laboratory Assistant or Laboratory Attendant) Roster of salary of staff, Periodic health check-ups and vaccination of	Essential: 1	Essential: 1	Essential: 2

	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 registration number and date of expiry, site, space, location and environmental requirements to be as per local bye-laws	Essential	Essential	Essential
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 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

[P. No. Z. 2801340/2017-MS]

SUDHIR KUMAR, Jr. Secy.

Note: The principal rules were published in the Gazette of India, Extraordinary, Part II, Section 3, sub-section (i) vide notification number G.S.R. 387(E), dated the 23rd May, 2012.