



## Rajasthan Medical Services Corporation Limited, Jaipur

D-Block, Swasthya Bhawan, C-Scheme, Jaipur-302005

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Website: <http://rmisc.health.rajasthan.gov.in>

F.8 () RMSCL/QA/EPM/2018/2513


Date: 10.07.18

### Order

Guidelines for Quality Assurance of Hospital Supplies and Equipment are hereby issued to ensure the quality of equipments supplied to Health Facilities. These guidelines include the norms for quality inspection of Hospital Supplies and Equipments only. These guidelines do not include drugs, medicines, surgical items, sutures and other consumables. The Guidelines have been duly approved from Medical & Health Department, Government of Rajasthan (copy enclosed).

These Guidelines shall come into force with immediate effect:

Enclosed: Guidelines


  
Mahavir Prasad Sharma (IAS)  
Managing Director, RMSCL, Jaipur

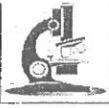
F.8 () RMSCL/QA/EPM/2018/2513

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Copy to the following for information/necessary action:

1. PS to Additional Chief Secretary M&H
2. Secretary, Medical & Health and Family Welfare cum Mission Director, NHM, Jaipur
3. Special Secretary, Medical & Health cum Mission Director NUHM, Jaipur
4. Director, Public Health/ RCH/ESI/AIDS/FW, Swasthya Bhawan, Jaipur
5. Director Finance, NHM, Jaipur/Financial Advisor, PH, Swasthya Bhawan, Jaipur
6. Additional Director (HA)/ PD, MNJY, Swasthya Bhawan, Jaipur
7. ED(EPM)/Sr. Manager-I and II, RMSCL, Jaipur
8. All Bio-Medical Engineer (HQ and Zonal)
9. Guard File.

  
Mahavir Prasad Sharma (IAS)  
Managing Director, RMSCL



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### Guidelines for Quality Assurance of Hospital Supplies and Equipment

#### 1. Basic Principle:

The quality of hospital supplies/equipment should conform to the specifications specified in Bid Document/ Contract/Purchase Order.

These guidelines do not include drugs, medicines, surgical items, sutures and other consumables.

#### 2. Standard Operating Procedure (SOP)/ Protocol for Quality Assurance :

2.1 The **hospital supplies and equipment** should conform to the specification, nomenclature and description as mentioned in the Purchase Order. A copy of purchase order is always endorsed to the concerned health facility incharge for this purpose.

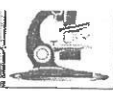
2.2 Zonal Bio-Medical Engineer shall inspect hospital supplies and equipment. In case of Quality Assurance (QA) of supply at CD Store, Zonal BME Jaipur shall comply with the guidelines of Quality Assurance.

Note:- In case of motor vehicles, inspection shall be done by Mechanical Engineer. If mechanical engineer is not available in the Department then such member may be invited from District Magistrate Office (District Pool)/ Public Works Department (PWD)/Rajasthan State Motor Garage/RSRTC Depot/ Transport Department etc.

2.3 **Role and responsibilities of Zonal BME's, Health Facility Incharge, Health Managers and District Nodal Officers for quality assurance of Hospital Supplies and Equipment :**

2.3.1. The Health Facility Incharge should inform immediately (through e-mail or any other electronic media) to the Zonal BME about the receipt of hospital supplies and equipment in health facility.

2.3.2. The Health Manager/ Urban Health Consultants and District Nodal Officers shall be actively involved by Zonal Biomedical Engineers and Health Facility



incharge, in ensuring quality of Hospital Supplies and equipment at the Health facility Level. The Health Manager/ Urban Health Consultant should accompany the Zonal BME at the time of inspection. District Nodal Officers of NHM will coordinate with Health Facility Incharge and support the zonal BME at the time of inspection in the district. The Zonal BME shall communicate the inspection date immediately (through e-mail or any other electronic media) to Health Facility Incharge for inspection of hospital supplies and equipment in health facility premises. The inspection report shall be signed by at least two members, in which Zonal BME should sign compulsorily.

2.3.3. Zonal Bio-Medical Engineer shall ensure to submit their report to the incharge of health facility within 15 days of the receipt of hospital supplies and equipment.

2.3.4. The inspection note shall contain complete details of inspection, sample drawn and discrepancies etc. In case of MNJY equipment (**Annexure-1**), results of Laboratory test are found varying in values/ incorrect etc.; it should be mentioned in the inspection report and submitted to RMSCL.

2.3.5. The health facility incharge shall keep the report in his office file for record purpose. A copy of the report will be kept by Zonal BME who will communicate the above report (through e-mail to edepmrmsc-rj@nic.in or any other electronic media) to inventory management cell (IMC) of RMSCL Headquarter within a week after inspection.

2.3.6. This arrangement will facilitate and ensure early payment of hospital supplies and equipment at RMSCL.

2.3.7. In case of any difference of opinion in Quality inspection report among members of inspection committee, the same may be reported to MD, RMSCL. The decision of MD, RMSCL in such cases shall be treated as final.

### **3. Detailed inspection with Samples and Procedure for drawl of Samples :**

3.1 The hospital supplies and equipment will be checked to conform to the specification and/or drawings given in the purchase order and in case of approved samples the supply shall conform also to the approved samples. In all such cases, the sample will be supplementary to and will not supersede the specifications and/or drawings; and

3.2 The hospital supplies and equipment will be received subject to tests in cases where laboratory tests are to be carried out.

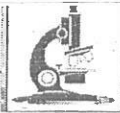


- 3.3 In any case, the number of articles picked for inspection shall not be less than 10% of the hospital supplies and equipment unless this is impracticable.
- 3.4 Zonal Bio-Medical Engineer inspecting the hospital supplies and equipment shall pick up articles from the hospital supplies and equipment and compare these articles with the sample and the specifications, with a critical eye, to ascertain whether the articles supplies conform in all respects, with the sample and specification.
- 3.5 If required, request for sample kept as control (approved sample) at RMSCL Head Quarter may be asked for comparison with relation to the supplied items.
- 3.6 Where necessary or prescribed or practicable, tests shall be carried out for random samples to adjudge the suitability of the hospital supplies and equipment. These random samples shall be sent to such inspecting agencies like Council of Industrial and Scientific Research (CISR)/ Rail India Technical and Economic Service (RITES) or prescribed by RMSCL.
- 3.7 It would be pertinent to mention here that the inspection of 10% of the hospital supplies & equipment is indicative. The purpose is to ensure quality of the hospital supplies and equipment and if possible inspect the maximum number of items supplied. If the number of hospital supplies & equipment is in permissible limits then whole lot of supply should be inspected.
- 3.8 All equipment shall be inspected which cost above Rs. 5.0 lacs.

#### 4. Quality Inspection

The hospital supplies and equipment shall be inspected for quality on the following points:-

- 4.1 The quality of hospital supplies/equipment should conform to the specifications in Bid Document/ Contract/Purchase Order.
- 4.2 In case of proprietary items, the manufacturer's mark, trade mark, part number, etc., on the hospital supplies and equipment and/or cartons/label shall be verified, with description given in the purchase order.
- 4.3 The size and/or type required from the documents and/or nameplates and other identification details marked on the stores will be checked.
- 4.4 Dimensional details like length, width, height, thickness, diameter, bore, etc., will be verified.



- 4.5 In any circumstance where Zonal Bio-Medical Engineer makes recommendation for outsourcing of inspection of hospital supplies and equipment, it shall contain a separate justification note signed by Zonal Bio-Medical Engineer duly verified by Health Facility incharge.
- 4.6 Zonal Bio-Medical Engineer shall send such recommendation for suitable decision to MD RMSCL. After approval of MD, RMSCL, the inspection of hospital supplies and equipment may be outsourced to such inspecting agencies like Council of Industrial and Scientific Research (CISR)/ Rail India Technical and Economic Service (RITES) or prescribed by RMSCL.

5. **Quality Check Parameters :**

In case of hospital supplies and equipment where precision tests, Calibration test and validation test are necessary at the receiving points, Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) etc parameters shall be followed by the committee:-

- 5.1 **Installation Qualification (IQ):** The supplied equipment should be installed as per requirement of equipment including layout, power supply and other necessary parameters required for quality output of that equipment.
- 5.2 **Operational Qualification (OQ):** Once each protocol of the IQ phase has been met, Operational qualification (OQ) is performed to check that the equipment's performance is consistent with the user requirement specification, within the manufacturer-specified operating ranges.
- 5.3 **Performance Qualification (PQ):** PQ is the final step in qualification processes for equipment, and this step involves verifying and documenting that the equipment is working productively within a specified working range. Rather than testing each instrument individually, they are all tested together for overall process. Before the qualification begins, a detailed test plan is created, based on the process description.

6. **Defective hospital supplies and equipment :**

On receipt of report from Zonal Bio-Medical Engineer about defective items, Health facility incharge shall take a decision regarding acceptance/ rejection/ replacement of items in consultation with RMSCL.

Essential Equipments commonly used in MNJY	
Laboratory	
1	Binocular Microscope
2	Monocular Microscope
3	Centrifuge Machine 8T 16T 32T
4	Three part haematology blood cell counter
5	Five part differential heamatology blood cell counter
6	Semiauto biochemistry Analyzer
7	Fully Automated bicochemisrty Analyzere
8	Automated ESR analyser
9	Glucometer
10	Semiautomated coagulation analyzer
11	Bacteriological Incubators
12	Electrolyte Analyser
13	Semiautomated urine test strip analyzer
14	Digital haemoglobinometer
15	Adhm key for cell count digital
16	Horizontal laminar flow
17	Dry bath incubators
18	Serological incubators
19	Hot air Oven
20	Portâble Autoclave
21	Autoclave vertical
22	VDRL rotator
23	Water deionizer for laboratory grade water
24	Microprocessor controlled micro typing centrifuge machine & incubator
25	Blood bank refrigerator
26	Refrigerator 240 ,280,340 lt
27	Syringe and neddle destroyer
28	Dielectric tube sealer
29	Blood collection monitor
30	Blood mixer
31	Fully Automated Elisa reader
32	Elisa reader witer washer multiscan
33	Fully automated deluxe donner couch
34	haemoglobin scale book
35	Neaubars chambers
36	Dissposable ESR pipettes
37	Test tube stand autoclavabe plastic
38	Various ranges Micropipettes
39	RBC Pipettes
40	WBC pipettes
41	Digital stop watch
42	Spirit Lamp
43	Biowaste management items
44	Haematocytometer
45	ESR stand metal
46	ESR stand plastic

	Radiology
47	100 mA xray machine digital & non didgital
48	300 ma xray machine digital & non didgital
49	500 ma xray machine digital & non didgital
50	Mobile Xray machines
51	CR Machine
52	Sonography colour doppler machine with 4 probe
53	Ultrasonography with 3 probe
54	Flat pannel detection system for digital radiography
55	Digital radiography Machines
56	Automatic Film Processors
57	DEXA Machines
58	Lead Rubber Gloves
59	X-ray protective apron coat type
60	Chest Stand wall mount and mobile
61	Florosent elluminator to view x-ray films
62	Lead Rubber sheet
63	Noramal x-ray cassettes and digital x-ray cassettes various sizes
64	Blue and Green base x-ray films various size
65	x-ray cassettes various sizes
66	Digital x-ray cassettes
67	Lead letter
68	Film Processing Equipments: Hanger and clips
69	X- Ray protection mobile screen with lead glass window
	<b>ECG</b>
70	ECG Machine (3 Channel)
71	ECG Machine (6 Channel)
72	ECG Machine (12 Channel)
73	ECG Paper Roll As per machine (50mmx30 mtr.)
74	ECG Gel
75	Disposable ECG solid Gel Electrode