

Preface

Foreword

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Part A:

POLICY AND PROCEDURE MANUAL
STATE EQUIPMENT MANAGEMENT UNIT
For inhouse implementation of Biomedical
Equipment and Maintenance Program (BMMP)

1. Background

There was no proper facility in the public sector for maintenance of health care equipment in the states till a couple of years ago. Hon'ble Prime Minister had observed that many equipment in hospitals and other health facilities are either unused or there is no maintenance resulting wastage of resources. He directed that Ministry may consider either maintenance or management contract along with purchases or outsource maintenance after the guarantee period.

- To address this, MoHFW organized consultations with officials from states to devise appropriate mechanisms to ensure that medical equipment already purchased are properly maintained. An extensive exercise was undertaken to map the inventory of all Bio-medical equipment including their functionality status. **The mapping was undertaken in 29 States under the guidance of NHSRC. 7,56,750 no. of equipment in 29,115 health facilities costing approximately Rs 4564 Crores were identified. The mapping data State wise is available on NHSRC website**
- **Equipment in range of 13% to 34% were found dysfunctional across states.**
- Comprehensive guidelines were designed on Biomedical Equipment Management and Maintenance Program (BMMP), linked with uptime of equipment (95% in District Hospitals, 90% in Community Health Centres, and 80% in Primary Health Centres). The guidelines along with the model tender document were developed in 2014.

Under BMMP, support is being provided to state governments to outsource medical equipment maintenance comprehensively for all its machinery across all the facilities.

- Subsequent to inventory mapping, RFPs/tenders were rolled out to award maintenance contract for the respective states.
- **20 States in PPP mode in the state of Andhra Pradesh, Arunachal Pradesh, Assam, Chhattisgarh, Jharkhand, Kerala, Madhya Pradesh, Maharashtra, Meghalaya, Mizoram, Nagaland, Puducherry, Punjab, Sikkim, Telangana, Tripura, Rajasthan, Uttar Pradesh, West Bengal, Jammu and Kashmir.**

Presently, an asset base of approx. Rs 2416 Crores worth of equipment (as per initial mapping) is being served under the program in 16 states in PPP mode and four more states have outsourced the services. In short time of less than 6 months of award of contract, dysfunctional equipment worth nearly Rs 555 Cr was made functional, with an investment of 119 Crore only in the first year. It is expected that with more states joining the BMMP program this year, a total of 900 Crores worth of dysfunctional equipment is expected to be made functional by the end of this financial year.

The implementation of Biomedical Equipment Management and Maintenance Program (BMMP) has helped in providing assured quality diagnostics services in public health facilities, thereby reducing cost of care and improving the quality of care for poor patients

6 States/UT have implemented the program in inhouse mode. However, as there is no guidelines on implementation in in-house mode. The filed review of ongoing BMMP program highlighted that there is lack of implementation guideline for Medical Equipment Maintenance and Management program at State level. The draft a revised guidance document for inhouse as well as PPP Model of implementation of BMMP Program has been developed to support State for smooth implementation and monitoring of services.

With this mandate the HCT Division has drafted the guidelines for implementation and formation of State Equipment Management Unit for inhouse management of BMMP as well as monitors the program in PPP Mode also. With the formation of SEMU (State Equipment Management Unit) a beginning will be made towards addressing the maintenance issues of Medical Equipment. Costly & valuable medical equipment are imported with hard earned foreign exchange and used for some time before being discarded for want of maintenance. It is intended to start the unit with a mandate to be an independent unit to undertake entire equipment maintenance issues independently. The mandate of SEMU will be to oversee the Medical Equipment Maintenance and Management including Preventive Maintenance and calibration of all the Medical Equipment.

2. Operations Summary:

The SEMU will have the following functions:

- a. Follow the policy outlined in Annexure I for Inspection of new equipment. Devices used within the Public Health System in the entire state will be inspected prior to patient use to ensure safe and effective operation.
- b. Maintenance of Medical Equipment and proper usage of new equipment.

Many medical equipment can be maintained in- house. Some of the specialized equipment viz. CT scanner, MRI, Blood Gas Analyzer, Auto analyzer, Laparoscopes etc. will need company maintenance for which AMC/CAMC will need to be signed. Unit will maintain the basic medical equipment for repair and Calibration at the central workshop at the head office, the divisional workshops at four divisions and in the District hospital Workshops and appropriately will also maintain the equipment at hospital by sending repair team. Medical equipment of different District hospital and hospital which the unit cannot repair due to non-availability of spare parts, maintenance manual & circuit diagram and technical skill will be repaired through private companies/vendors under the supervision of Biomedical Engineer at the head office and other divisional offices.

Problem has multiplied due to procurement of medical equipment from different countries of different makes and brands without supply of spare parts, operation manual and circuit diagram from the supplier and manufacturing companies.

In District hospital & other institution, only technician and instrument care taker (ICT) are responsible to maintain all medical equipment. But actually ICT play a role as a custodian of medical equipment. There is lack of basic medical equipment repair toolkits, spare parts and workshop facility at division and district level. Secondly, spare parts, calibration and troubleshooting tools for repair of medical equipment are also not available. So in most of the cases, ICT become helpless to repair simple types of equipment due to want of spare parts and workshop facilities. The SEMU will appoint Certified Technicians and Engineers for maintenance and calibration.

3. Objective of SEMU:

1. To do acceptance and inspection tests for new equipment prior to the equipment being used on any patient.
2. To function as Asset Management Centre for all Medical Equipment with their functional status.

- 3.To assist in the repair and maintenance of hospital/electro-medical equipment used for diagnostic, therapeutic and patient care in hospital and medical institutions.
- 4.To train technical personnel to undertake the repair/maintenance job by imparting regular training to different categories and fields.
- 5.To train user of the medical equipment in its proper care and for preventive maintenance.
- 6.To assist in calibration and installation of medical equipment.
- 7.To collaborate and assist in repair activities of medical equipment at different District hospital etc.
- 8.To assist procurement agencies in the field of repair, maintenance services and giving technical support for procurement of general and sophisticated medical equipment.
- 9.To assist for detection and declaration of medical equipment which is not feasible for repair and the unit will gives further technical assistance to declare condemnation of the medical equipment.
10. The SEMU will function by establishing Equipment Cells at various levels of healthcare facilities.

4. Equipment Cell Structure, Facility etc:

4.1 Introduction:

SEMU will be an in-house system for medical technologies management equipped with experienced engineers and technicians trained in multi-modality. It will provide hands-on experience of supporting technical activities per annum comprises preventive, breakdown, performance verification services equipment of various types. Continuous professional training programs, e-training modules for the technical staff across from the level of Sub center up to the level of District hospital. It will store technical and operation manuals of various equipment. The key priorities will be to ensure the best supplies of cost effective spares, tools etc. for the better life cycle of equipment. The unit will establish IT based dashboard for medical technologies asset management. It will include Breakdown call management, Preventive and Predictive maintenance, Calibration schedule record etc. It will ensure effective user training modules and programs covering a wide array of life support equipment. The unit will have in-house specialized workshops for calibration, PCB repair, Flexible Endoscope, Dental Hand piece, Pipette calibration etc. The briefed structure is as below:

S.no.	Designation	Number
1	State Equipment Cell - At capital headquarter	1
2	Divisional Equipment Cell – At all the divisions of the state located in District Hospitals of the Divisional Head Quarter/Govt. District hospital	01 each per division
3	District Equipment Cell- In all the district hospital	01 each per district

4.2 Maintenance Load under Equipment Centre

There are about <INSTERT NUMBERS> Medical Institutions in Public Health Sector in <insert name of the State> as below:

- | | |
|--|----|
| 1. District Headquarter Hospitals. ----- | DD |
| 2. Sub Divisional Hospitals ----- | SS |
| 3. Community Health Centers ----- | CC |
| 4. Primary Healthcare Centers----- | PP |

TOTAL

This center will provide maintenance services to these institutions as and when asked for. The center will be able to provide maintenance services for basic health care equipment like X-ray machine, ECG, Autoclave, Portable Sterilizers, Distill Water Plant, Suction Apparatus, Anesthesia equipment, O.T. Light, O.T. Table, Dental Chair, Microscope, B.P. Instruments etc. This center will coordinate but not handle directly sophisticated and specialized equipment like Nuclear Medicare equipment, Gamma Camera, Auto Analyzer, Angiogram, Scanner, Laser equipment, CT Scanner, MRI etc.

State Equipment Management Unit - Will be headed by Chief Biomedical Engineer with an experience of 15 years or more and will be located in Capital City in the Central Workshop which will be located preferably in Head quarter. He will be assisted by a Biomedical Engineer having 05 years of experience and a team of Certified Technicians.

State Equipment Cell will be the administrative head of State Equipment Management Unit and will be responsible for entire equipment management including the following:

- i. Assisting in Drafting of Technical Specifications.
- ii. CMC/AMC Management.
- iii. Monitoring of the functional status of all the equipment in the state health facilities. Will submit fortnightly report on Functional and Calibration status of all the equipment in the state. Shall also be responsible for pending maintenance of all the equipment in the state.
- iv. Shall submit acceptance report of all the new equipment installation and will facilitate the installation support requirement including the site readiness and other pre installment requirements.
- v. A Centralized Dash board for Equipment Maintenance and Management will be available in the SEMU. SEMU shall be responsible for maintaining the Dash Board containing the inventory of all the equipment, with warranty, calibration, preventive maintenance and functional status of all the equipment in the state. CDAC has made such a dashboard for the state of Madhya Pradesh and Rajasthan and the same may be customized for in-house maintenance for all the equipment.

Divisional Equipment Cell - Will be available in Divisional Workshop and will cater to average of six districts each. This will be located in the District Hospital located in Divisional Headquarters.

These workshops will be having commonly used necessary spare parts and technical support manuals.

The Divisional Workshop will be headed by Divisional Workshop Superintendent /Divisional Biomedical Engineer (with 10 years of experience) and 02 Biomedical Engineers and 2 nos. of technicians each (Certified Medical Equipment Technician).

District Equipment Cell- Will be available in the Electro-Medical workshops in districts and will be headed by District Workshop Superintendent (Certified Biomedical Engineer with certification in any one advanced equipment skill with 07 years of experience) with 5 nos. of technical manpower each (Certified Medical Equipment Technician). These workshops will be engaged to look after the maintenance, repair and services of medical equipment in the District Hospital as well as provide assistance to all the public healthcare facilities in the district.

The District Equipment Cell will be providing the support to the technicians at the CHC and PHC Level.

The deployment at the CHC and PHC Level will be as below:

Certified Medical Equipment Technician at CHC and PHC as per the requirement

Certified Medical Equipment Technician at PHC- 01 per PHC. The technicians at PHC will be responsible for equipment at Sub Centre also.

4.3 Facilities to be planned at all the Divisional /District Equipment Cell:

1. Main Building, floor area: 15,000 Sq. ft. with provisions as below:
 - a.) Workshop and Store area for large equipment.
 - b.) Office, Stores of accessories and spares & Lecture room.
2. Office Building- 1500 Sq. ft.
3. Transport Vehicles: A mobile van will be placed at all the locations of Workshops (preferably on rented basis)- Total of <insert numbers> vans will be required. The Equipment Van will carry out the following functions:
 - a.) These vehicles will carry the Technicians/Engineers to the maintenance/ installation site.
 - b.) Will be used as mobile repair workshop as well as preventive maintenance of the equipment.
 - c.) Will pick up any equipment that will be required to be carried at the workshop for repairs.

4.4 Tools & Equipment:

The Mechanical Section will be equipped with lathe and grinding machine, mechanical hand tools, power tools and electronic testing and calibration equipment, Instruments. Besides a good number of technical books on different engineering fields will also be made available.

Workshop Facilities: Workshops will be planned as below:

- i) Central Workshop- This will have all the repair, maintenance and calibration facilities. All the equipment that can't be repaired at the divisional level will be sent to Central Workshop for the same. This will also be the administrative head quarter for all the equipment related issues.
- ii) Divisional Workshop- Each Divisional Workshop will cater to 5-6 districts on an average. This will have all the facilities except calibration facilities for specialized equipment.
- iii) District Workshop- Each District Hospital will have an Equipment Repair Workshop and will cater to all the healthcare facilities in the district viz. DH, CHC and PHC. The equipment which can't be repaired at the district Workshop will be transferred to Divisional Workshop for repairs.

All the workshops will have the following sections-

- a) Mechanical Section.
- b) Electrical Section.
- c) Electronics Section.
- d) Air Condition & Refrigeration Section.
- e) X-Ray Section

f) Optical Section.

5. Human Resources:

Recommended Technical Manpower:

a.) The Technical Human Resources for State Equipment Cell will be as below:

GM (Equipment)/Chief Biomedical Engineer/State Biomedical Engineer-01 each

Essential Qualification - B.E.

Minimum Experience of 15 years and preferably having Management/ Hospital Administration qualification.

Biomedical Engineers-02 each

Essential Qualification-B.E.-Biomedical Engineering - Minimum 10 Years of experience.

Certified Medical Equipment Technicians - 05

Should be certified by Health Sector Skill Council in Basic Clinical Equipment Maintenance Skills or Certified by the OEM/Manufacturer for common basic medical equipment.

b.) The Human Resources for Divisional Equipment Cell will be as below:

Divisional Biomedical Engineer—01 each per division

Essential Qualification- B.E. - Biomedical Engineering

Minimum Experience of 10 years

Biomedical Engineer-02 each per division

Essential Qualification- B.E. - Biomedical Engineering with Minimum 07 Years of experience.

Certified Medical Equipment Technicians- 2

c.) The Human Resources for District Equipment Cell will be as below:

District Biomedical Engineer - 01 each per district

Essential Qualification- B.E. - Biomedical Engineering

Minimum Experience of 10 years

Biomedical Engineer- 02 each per district

Essential Qualification- B.E.-Biomedical Engineering with Minimum 05 Years of experience.

Certified Medical Equipment Technicians- 05

District Equipment Cell will also support and supervise the deployment of the Medical Equipment Technicians at CHC and PHC level as below:

d.) Certified Medical Equipment Technicians- 01 each in all the CHC.

e.) Certified Medical Equipment Technicians- 01 each in all the PHC. The Technicians at the PHC will support all the SC attached to it. The Electricians may be trained and Certified as Medical Equipment Technicians for the Medical Equipment Technicians positions at the SC and PHC level

6. Activities of the Cell:

6.1 Maintenance Activities:

The flow of the activities for maintenance will be as below:

Initiating a service request- The Service Request by the facility will be raised as below:

- a.) For District Hospital- CMO/ Hospital Manager (HM)/End user
- b.) For Sub District Hospital- CMO/ Program Manager (PM)/Hospital Manager/End user.
- c.) For Community Health Centers- MOIC/Block Program Manager (BPM)/End user.
- d.) ADMO/SDMO & MOIC will be the accountable entities and HM, PM and BPM will be their authorized representatives for communicating to the Equipment Cell.
- e.) For PHC and SC- Facility in-charge will be the accounting as well as Communicating entities.

A. Breakdown Maintenance

1. The facility raises a request through a tollfree number. The request is forwarded to the Divisional/District Biomedical Engineer of the division or the Biomedical Engineer i/c of the District hospital and the job is allocated to appropriate Biomedical Engineer with SMS acknowledged to all concerned.
2. The respective Biomedical Engineers raises a job number and allocates the job to the technician with an intimation to Head Office.
3. Technician attends to the request and submits a closure report to the respective Biomedical Engineer. If he is unable to solve the problem Biomedical Engineer will assist him further. The closure report will be submitted to the facility as well as to the Head Office. In case the problem is not resolved by the divisional office the same will need to be highlighted to the Head Office to the General Manager Equipment/State Biomedical Engineer/Chief Biomedical Engineer. The Technician attaches a tag with date of repair or if it needs to carry to workshop the tag indicates-Not working with date.
4. General Manager Equipment/State Biomedical Engineer/Chief Biomedical Engineer submits a monthly report on the status of the equipment to the top management classifying: Functional Equipment, Non-Functional Equipment needing replacement, Equipment under repairs.

B. Preventive Maintenance- PM

1. The Divisional Biomedical Engineer submits a Planned Preventive Maintenance Programme and schedules dates and then allocates District BME/Facility Technician for the job and sends the copy of the schedules to the health facilities under his jurisdiction as well as to the General Manager- equipment at HO and the schedule is uploaded on the Dashboard so that all the stakeholders are aware about the PM and time planning is done accordingly. PM includes appropriate calibration of the equipment.
2. The facility intimates all the technicians and staffs to co-operate with the preventive maintenance.
3. The technician undertaking the preventive maintenance tags the equipment with date of PM and also indicates the date when next PM is due.
4. During PM the technicians also carries out breakdown maintenance if the same is advised to him by the facility.

5. The functional status of all the equipment is submitted by the Divisional Biomedical Engineer to the GM- Equipment.
6. GM-Equipment combines the status of Breakdown as well as the Preventive Maintenance and submits the functional status to the top management every month.

6.2 AMC and CMC Management-

1. The specialized and lifesaving critical equipment will require AMC- Annual Maintenance Contract without spares and CMC- Comprehensive Maintenance Contract with all the spares included.
2. The AMC and CMC will be monitored centrally. It will be initiated by the Divisional Biomedical Engineer based on the assessment as to whether to go in for CMC or for AMC. The Divisional Biomedical Engineer will initiate the process at least 30 days in advance of the date of expiry of the warranty period.
3. The procurement division will procure the equipment with either 2 years warranty and five years CMC (For equipment costing less than 1 Crore) OR with 5 Years warranty and 5 years CMC (for equipment costing more than one crore). In both the cases the post warranty AMC/CMC rates are approved and the supplier will have to sign contract based on approved rates only. Post warranty the rates can't be modified by the vendor unless there is a clause to do so.
4. The Divisional Biomedical Engineer will examine the AMC/ CMC rates with respect to the approved rates and will send the contract for formal approval to the GM-Equipment.
5. GM- Equipment will examine the same and will sign the contract and send the same back to the Divisional Engineer.
6. The Divisional Biomedical Engineer can also go in for per call basis of maintenance.

6.3 Warranty management-

1. The Divisional Engineer will update the arrival of any new equipment into the Equipment Asset Register on the Dashboard which will be maintained at the HO.
2. After entry into the Asset Register he will make Preventive Maintenance schedules for the vendor and send an intimation of the schedules.
3. If the vendor fails to respond to the PM schedules he may be issued a show cause notice and on repeated violations of three times the HO may initiate actions to forfeit his performance security and initiate a show cause notice for blacklisting him for two years. If he fails to respond he may be issued a blacklisting notice and be barred for participation in the future procurements.
4. The same applies for breakdown maintenance if the vendor fails to attend to the service breakdown requests his performance security may be forfeited if the equipment is lying unrepaired for days provided in the contract. He may be subsequently issued a show cause notice for blacklisting followed by barring him for further procurements.

6.4 Training Activities:

Biomedical Engineers of the unit will be simultaneously engaged in developing health care manpower to fulfill needs of the public healthcare facilities.

The following regular Training Modules (3 months each) will be available at this center. There will be certification provided jointly by GM-Equipment and Health Sector Skill Council.

- Training modules for Laboratory Technicians
- Training modules for end users- Junior Doctors/Nursing staffs.
- Training modules for Store Personnel for Inventory Management.

- Training Modules for Medical Equipment Technicians- Basic
- Training Modules for Medical Equipment Experts- Advanced Skills

Objective of Training:

1. To develop skill and competency among users of medical equipment.
2. To acquire knowledge in detection of trouble shooting.
3. To carry out preventive maintenance.
4. To apprise communication method among user of medical equipment for carrying out maintenance work.
5. To carry out survey, inspection and preparation of inventory for medical equipment.
6. To impart skills by on the job training for technicians and engineers and be certified for the acquired skills.

Training Curriculum for orientation of engineers and technicians:

All the Technicians joining the cell will have to complete the orientation program.

The following are included in the curriculum:

1. Basics of Electrical / Mechanical Engineering.
2. Workshop practice and Mechanical maintenance.
3. Biomedical Electronics and Applied Physics.
4. Basics of Cold Chain Equipment
5. On job training in operation and maintenance of basic medical equipment.
6. On job training for repair and maintenance of SNCU Equipment.
7. On the job training for repair and maintenance of Basic Clinical Equipment-
8. Medical Equipment Technician- Certification by Health Sector Skill Council.

The centre will be equipped with modern training aids like projectors (Slide and Overhead), Audio-Visual Equipment and these will be used during training programme. In addition, occasional field trips to medical institutions will be conducted for the trainees.

Acceptance Test and Inspection of new equipment prior to use on patient or in a clinical lab.

The cell will follow the policy and procedures for any new/ demo/ clinical research equipment being put to use as per safe practices of usage.

7. Equipment requirement for each Workshop: (Each center will be equipped with five work benches)

The following equipment will be required for the each workshop at the Divisional and District level workshops in Phase-1

S/N	DESCRIPTION	Unit Price INR	QTY	Amount INR
01	Digital Multimeter- Bench-top	5000	05	25,000
02	DC Power Supply	2500	05	12,500
03	Variac	1500	05	7,500
04	Oscilloscope	50,000	01	50,000
04-01	Scope meter (OPTIONAL)	2,50,000	01	250,000
05	Electrical Safety Analyzer (OPTONAL)	1,50,000	01	150,000
06	Multipara Patient Simulator (OPTIONAL)	2,00,000	01	2,00,000
07	ECG Simulators	10,000	01	10,000
08	BP Simulator	10,000	01	10,000
09	Tachometer	5,000	01	5,000
10	Humidity and Temperature meter	1,000	01	1,000
11	Lux Meter & Irradiance Meter	30,000	01	30,000
12	Precision Weight Set	5,000	01	5,000
13	Multipurpose Tool Kit with Drill Machine with 10 piece Hex Wrench Set	5,000	01	5,000
14	Electro Mechanical Tool Kit	1500	05	7500
15	Table Lathe Machine	5000	01	5000
16	Grinder / sharpener	5250	01	5250
17	Power Drill	1000	01	1000
18	Extension Boards	250	05	1250
	SPARES & CONSUMABLES			
19	Halogen Bulbs	500	10	10,000
20	Universal Coaxial Adaptor Kit	400	10	4000
21	Coaxial Adaptor Connector Set	200	10	2000
22	Antistatic Wrist strap	200	10	2000
23	Complete Grounding Kit	500	10	5000
24	Basic Audio Video Tool Kit	500	05	2500
25	Compression Termination Kit	2500	01	2500
26	Assorted Fuses	500	10	5000
27	Assorted Resistor	500	10	5000
28	Assorted Capacitors	500	10	5000
29	Assorted Transistors, ICS etc	20000	01	20000
30	Miscellaneous	20000	01	20000
31	Technical Books and Manuals	20000	01	20000
32	Biomedical Equipment Field Tool Kit with portable multimeter	5000	01	5000
33	Healthcare Product Management System Database Annual Membership		01	2,50,000

TOTAL INR per center

Rs 3,37,000/-

OPTIONAL FOR CENTRAL WORKSHOP AT HEAD QUARTER – Rs 6,00,000

Field Kit for each technical staff

Total budget required for equipment:

For Divisional/District workshops @ 3,37,000/- each x no. of Workshops- XXXXXX

Additional for Central Workshop ----- 6,00,000

(This will be extended for other workshops during next financial years)

Field Engineers Toolkit – 5,000 x no. of BME/Technicians----- YYYYYY

Healthcare Product Management System Database ----- 2,50,000

Equipment requirement Phase-2: It is proposed to upgrade the workshops during next five years with additional facilities as given below:

EQUIPMENT REQUIREMENT PHASE-2

The following equipment will be required for the up-gradation of workshops during next 5 years for eight identified Divisional Workshops for States having 40 districts. For districts having more than 40 or less than 40 the numbers may be reduced on pro rata basis.

S/N	DESCRIPTION	Unit Price- INR	QTY	Amount-INR
01	Scope meter	2,50,000	08	20,00,000
02	Electrical Safety Analyzer	1,50,000	08	12,00,000
03	220 V , 1A Source Current	2,000	08	16,000
04	Ultrasound Safety Tester with all accessories[At HO]	1,80,000	01	1,80,000
05(A)	Universal Patient Simulator	1,80,000	08	14,40,000
05(B)	Calibrated Fingers set for SPO2	30,000	08	2,40,000
06	Defibrillator Analyzer[At HO]	2,40,000	01	2,40,000
07	ESU Analyzer[At HO]	2,40,000	01	2,40,000
08	Infusion Pump Analyzers[At HO]	1,20,00	01	1,20,000
09	Ultrasound Wattmeter[HO]	75,000	01	75,000
10	Digital Pressure Meters	50,000	08	4,00,000
11	Gas Supply Fitting Kit	3,000	08	24,000
12	Medical Gas Outlet Kit	3,000	08	24,000
13	Ventilator Analyzer[At HO]	6,00,000	01	6,00,000
14	Gas Calibration Flow meter	60,000	08	4,80,000
15	Adult Lungs Simulator	60,000	08	4,80,000
16	Pediatric Lungs Simulator	60,000	08	4,80,000
17	Oxygen Analyzers	40,000	08	3,20,000
18	Ultrasound Phantom[At HO]	2,50,000	01	2,50,000
19	X-Ray meters with all accessories [At HO]	3,00,000	01	3,00,000

TOTAL INR

Rs 91,09,000/-

8. Disposal of obsolete and condemned equipment

The disposal of condemned and obsolete equipment will be made as per the attached guidelines in Annexure- II.

Part B:

Biomedical Equipment Management & Maintenance Program: Technical Manual for implementation in PPP mode

Introduction

Medical device availability and upkeep is one of the key interventions for mass access to diagnostic, preventive, assistive and therapeutic services. Inventory mapping of medical device is the first key step in situational analysis and formulation of next stride for medical device management. On completing inventory mapping in approximately 29 States/UTs which have done the inventory mapping, it was found that Government Hospitals have around 13-34% of medical device dysfunctional. This amounts to INR 4,500-6,000 Crores worth of medical inventory lying idle, large proportion of it due to small problems.

A Medical Device may vary from a simple instrument to complex implants, as defined by WHO and IMDRF. However, engaging trained engineering human resources, adequate to provide asset management and maintenance for the entire medical devices in the state both in terms of availability and feasibility is a challenge.

To address this, MOHFW organized consultations with officials from states to devise appropriate mechanisms to ensure that medical device remain functional. Based on best practices, it was felt that outsourcing of this activity with payment linked to service delivery would improve time bound maintenance service which was named as Biomedical Equipment Management and Maintenance Program (BMMP). BMMP is an initiative by the Ministry of Health Family Welfare, Govt. of India under which support is being provided to state governments to outsource medical equipment maintenance comprehensively for all facilities. The guideline with model RFP document was disseminated to states on 16th February 2015. The extent of financial support is based on actual tendering process subsequent to state wide inventory mapping and is largely dependent upon Equipment Density, Current Dysfunctional rate and geographical constraints in a state. The inventory mapping exercise is also supported by the central government and is completed in majority of states.

Two years since the first state launched the program of Biomedical Equipment Management & maintenance Program, it is about time that we strengthen our monitoring mechanism. With this objective, the technical manual is intended to streamline the implementation plan across states.

I Implementation Plan

The implementation plan of Biomedical Equipment Maintenance Program intends to break each strategy into identifiable step and suggest when each step would be completed. A maintenance strategy includes procedure for corrective and preventive maintenance and its technical inspection on completeness. Such inspections shall ensure that equipment are operating correctly and is safe for user, patient, public in general and the environment.

This section is important for review of service provider's performance at the implementation stage.

1. Technical Infrastructure

The infrastructure required for Biomedical Equipment Maintenance Program has number of requirements including workshop, tools, test equipment, spare parts and operation & service manual.

i. Repair Workshop

When service provider plans for implementing the program, the location for maintenance workshop is to be considered critically. There would be mainly two kinds of equipment, firstly like X-Ray, laboratory analysers, etc. where maintenance would be only possible on site. Secondly smaller equipment which would be transported to the workshop for maintenance. While there is a need for transporting of medical devices, the service provider must also ensure that no equipment is transferred across health facilities to meet requirements at random as this could disturb patient care and planning. On need basis service provider is also expected to setup satellite workshop at remote location to meet frequent failures.

A good workshop should be clean, well-lit and organised. It should have proper availability required for equipment maintenance like electricity, work stations, store for spare parts and test equipment. Workshop is also expected to have provision like electrostatic workbench/testbench, pneumatic outlets etc.

The workshop is also expected for demarcated areas like:

A: Receipt and despatch area should be suitably equipped for the handling and storage of components and materials.

B: Storage rooms and/or areas should be furnished as required for the storage of items such as:

- working spare parts
- consumable items (such as gaskets, bolts and nuts, etc.)
- Chemical products (for analyser testing, etc.).

C: Standards equipment room (Cold room) should house all special tests, measuring equipment/analysers and calibration standards. The workshop can also function as an office for documentation, record keeping, operation and service manuals, etc.

ii. Tools and test equipment

Human resource employed by the service provider are of limited use, if they are not equipped and trained to use proper tools and test equipment. Proper usage of the equipment will ensure reliability, accuracy and safety for the user and all the stakeholders.

The basic set of such tool will include voltmeter, weight & temperature measuring devices, resistance and capacitance substitution box and electrical safety meter. Middle ranged tool kit may include physiological simulator, electrosurgical unit and safety analyser. These test equipment needs to be stored in good condition, calibrated regularly and repaired as required.

Some of the test equipment which are expensive to maintain and procure may be used on sharing/renting basis for the services or as and when required. Without which, it's not appropriate to take responsibility of maintaining that equipment.

iii. Spare parts

In order to ensure a good medical equipment maintenance program, an inventory of spare parts and supplies should be in place. A proper forecast should be made on items like batteries, filters, valves, tubings etc. and should be procured in advance to save time. Cleaning and lubricating material should also be procured in advance with bigger quantity. The service provider is expected to make contacts with medical equipment manufactures with proper need anticipation to ensure availability of spare parts for equipment. The service provider is expected to change worn out parts at a time frame specified by manufacture during preventive maintenance.

iv. Operation and Service Manuals

The service provider should maintain a library with operating and service manual for every model of equipment under his/her maintenance contract. These manuals shall help support in inspection, preventive maintenance, repair and calibration.

2. Tagging of medical Equipment

It is very important that the service provider label each and every medical equipment under his service contract with a unique identification number or a bar code for an easy access/breakdown call via Toll free number. This number shall act as a reference for registering and complaint medical equipment breakdown.

Similar type of stickers or online QR code may be used for signifying the preventive maintenance and calibration status of medical equipment. Every sticker should clearly highlight the NHM logo. Samples of various sticker designs are attached in Annexure III for reference.

3. Call Centre

Call centre is a backbone of any maintenance service and like any other service, the Biomedical Equipment Maintenance Service provider has to setup a centralised call centre with a toll-free number. Call centre is expected to handle state/ regional language in addition to other languages. These call centres would receive phone calls directly from clinical staff, public healthcare professional having equipment issues/breakdowns/request for training/calibration, available 24 hours a day 7 days a week. When a medical device is having issues/breakdowns/request for training/calibration the hospital staff calls the call centre giving the operator their name, phone number, asset ID number, and a brief description of the problem. This could be using an automated Interactive Voice Response System (IVRS) mechanism as well.

The call centre has access to the Medical Equipment Maintenance Software system and generates a work order to the assigned technician. The work order is then e-mailed to the concerned technician. The call is kept open in the software database until the work is complete and the call is closed. This system enables complainant to receive status of the repair. Keeping the complainant informed of their equipment status helps build relationships and trust between the clinical staff and the service provider. Closing of complaint calls shall be done only by nodal officer of concerned PHC/CHC/DH. Every public health facility is expected to have three nodal officers, anyone could be called from call centre to convey rectification of opened call and make record of call closure. Call closure via response through SMS/Email/IVRS from registered nodal officer of concerned facility is also allowed.

4. Software/Dashboard

The Biomedical Equipment Maintenance and management services under NHM are usually outsourced to a service provider, selected via tender process at the state level. Hence it is very important to monitor the program at the state level. One of the important tools to monitor this program at the state (and even below) level is through a dashboard (online real-time monitoring web page) provided by the service provider. Some of the important features a dashboard should have are:

- i. **Work Order management:** The moment a complaint is registered on the toll-free number, the system software in the call centre should be able to generate a work order, depute a person for the job and reflect the same on the dashboard. The software should be capable of tracking the equipment and also inform if the equipment is under any service agreement with the OEM or elsewhere. The system should be capable of generating emails and SMSs to customer as well as the technical team on various notifications. The dashboard and all the reports generated should clearly highlight the NHM log.
- ii. **Equipment Tagging:** Once all the equipment are tagged, the data should be available on the software/dashboard. This data should contain the serial number, model number, and all other requisite details for tracking. The tracking mechanism should also allow tracking the maintenance history and maintenance schedule (preventive maintenance, calibration etc.) of the equipment. Every field of individual should also allow uploading relevant photographs, manuals, etc.
- iii. **Invoicing:** The software shall allow generation of invoice and also have the feature of import/export bills. These invoices should be linked to uptime, material (spare parts, tools, etc.) and other expenses.
- iv. **Dashboard:** Like majority of the states, the dashboard can be shared on a public domain, however certain states may like to secure it with a login password. In case service provider wants to ensure secure access by user name and password, keep a “Guest login access” for public information. The dashboard should be easily customisable as per the requirements of the state. The dashboard should give a summary of all medical equipment maintenance in the state including but not limited to total number of equipment, total number of call received, total number of call resolved, total function/non-functional equipment, summary of user training conducted, information on asset value and periodic revision, details of equipment under beyond economical repair category, information on organisation structure, location of workshop and expertise of human resources hired for maintenance . These details should also allow to be traced down to district as well as facility level with percentage functionality. The dashboard should display Preventive Maintenance and Calibration schedule for all the equipment. Maintenance details of all the critical equipment with uptime should be separately displayed. It is also pertinent to note that the dashboard should also display the NHM logo.
- v. **Mobile:** The dashboard should preferably be accessible from mobile phone as well. This allows flexibility. These features allows capturing the signature of the user on electronic service reports and then email them directly, saving paper and environment. This feature also allows capturing photographs and uploading with relevant documents. Mobile based applications further enhances the user experience from both the customer as well as the technician’s side.

5. Training

Proper training is crucial for both technical staff and users to ensure safety and appropriate use of medical equipment. Service providers are expected to provide continued training on every equipment under maintenance contract to own technical staff and end user (healthcare professional). Training should be an ongoing activity to ensure that users are trained and informed of their particular responsibility. The service provider needs to ensure that he setups a system in place all the necessary training.

Such trainings can be given by following methods:

- i. Through knowledge on equipment service and training manuals or any other additional training material provided by the Original Equipment Manufacturer (OEM).
- ii. By sourcing specialised training expert to teach staff about particular medical equipment maintenance and usage.
- iii. Training given by the OEM on operations and maintenance of a particular equipment.
- iv. Third party training program

The service provider shall submit a Gantt chart at the time of signing contract and the authority shall ensure compliance to the same.

Gantt chart

	1 st Month	2 nd Month	3 rd Month	4 th Month	5 th Month
Technical Infrastructure					
Equipment Tagging					
Call center					
Software/Dashboard					
Training					

II Standard Operating Procedure (SOP)

About the program:

Scope of services: Comprehensive maintenance (including spares, user training, real-time monitoring etc.) of all medical equipment in public health facilities from (PHC, CHC, and DH)

- (i) To maintain Biomedical Equipment in all public healthcare facilities up to the PHC level supported by 24 X 7 call center ;
- (ii) To provide 24x7, 365 days uptime of 95% for all medical equipment in District Hospitals, 90% for CHCs and 80% for PHCs. At no point of time in a single breakdown the breakdown should not be more than 7 days from the date and time of registration of fault.
- (iii) Medical Equipment that are already in AMC or CMC. The service provider shall administer the contract on behalf of state health department. For this purpose, the service provider shall take authorization from services providers for the respective equipment for which AMC/CMC may be in existence.
- (iv) For Medical Equipment that is currently under warranty. The service provider shall administer all maintenance activities on behalf of the state health department for the entire duration.
- (v) For all medical equipment that is under any form of AMC/CMC/Spares agreement or under warranty, the state health department shall not be renewing the equipment specific maintenance contracts
- (vi) The maintenance service provider shall not be including cost of maintaining any equipment which is under any kind of AMC/CMC/warranty in its first proposal and cost of such equipment shall not be included till the time existing contract(s) with other service provider(s) is valid for the respective equipment. The maintenance service provider may choose to take authorization for doing maintenance such equipment from existing AMC/CMC contract holder(s).
- (vii) Maintenance costs for equipment that are currently in any AMC/CMC/warranty contract shall be added by the service provider only after the expiry of contracts for the respective equipment.
- (viii) The sole service provider shall however be liable to ensure upkeep time declared in the bid for all equipment irrespective of any AMC/CMC/warranty status for any equipment.
- (ix) The maintenance service provider shall be identifying and responding to requests seeking maintenance of all requests seeking maintenance of all Biomedical Equipments available on the district/sub district/state up to the level of primary health centre through the maintenance process tracking identification number (MPT-IDs)
- (x) Maintenance service provider shall establish and operate an exclusive 24x7-customer care center for accepting calls and managing the maintenance services.

For purposes of clarity, operationalization will be regarded as:

- (a) Setting up of maintenance workshop for maintenance of medical equipment, and
- (b) Setting up Customer Care Centre to accept user calls
- (c) Appointment and recruitment of trained engineering and administrative human resource and
- (d) To provide Equipment Management Information System and
- (e) To provide categorization of all equipment, clearly identifying critical equipment along with their

clinical functions

- (f) To maintain biomedical equipment in all public healthcare facilities in an entire district/ region/ state; and
- (g) To furnish the format of equipment identification code system

The Contracting Authority (Usually a government body/agency) shall have the right to increase the number of equipment beyond the present number from the date of execution of the Agreement. In the event of any such increase in the number and density of equipment by the Authority, the Operator shall operate and maintain the additional equipment till the remaining term/duration of the Agreement in the given year and the monetary value for the maintenance of the added equipment shall be included in the subsequent years; as part of the existing scope of work and upon the same terms and condition specified in the Agreement.

Equipment are being classified based on their criticality as below:

1. Ventilator- ICU & Transport
2. Defibrillator
3. Dialysis Machines
5. Baby Incubators.
8. Electrosurgical Units- Surgical Cautery
18. ICU Monitors
19. Blood Gas Analyser
24. ICU Nebulizers

Any other equipment as deemed appropriate by the state authority.

Organogram:

The service provider is expected to develop an organogram suiting State Specific terms and condition of Biomedical maintenance and management agreement, considering State health authority/State National health mission and State Medical service corporation.

1 Equipment tagging:

- **Objective:** To carry out Tagging and Registration of Biomedical Equipment
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** Service provider, dept. in charge of health facility, district medical officers

Procedure:

S.No	Activity	Responsibility	Record
1	Service Provider visits the hospital	Service Provider	-
2	Tagging Sticker is pasted by the SP	Service Provider	Tagging sticker
3	Service provider records this info in registration form	Service Provider	Registration form
4	SP keeps the record of registration form and updates the dashboard	Service Provider	Dashboard
5	Facility in charge provides the details of year of installation, warranty and etc.	Facility In charge	-
6	Facility in charge verifies the registration and approves it	Facility In charge	Copy of registration form

2 Complaint log:

- **Objective:** To register a Medical Equipment maintenance complaint
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** user of Medical Equipment, Facility In charge, Deputy In charge

Procedure:

S.No.	Activity	Responsibility	Record
1	User calls the toll-free no. to register equipment problem	End user	Call log
2	User provides the mandatory info to register the complaint Equipment Identification number Location User name and contact Nature of complaints	Users	Call log
3	Call centre register the request with work order no	Call centre	Work order no. via email and SMS
4	Call centre forwards the work order to respective technical staff and regional In charge	Call centre	email and SMS
5	Technical Staff resolves the problem and gets it acknowledged on a service report	Service provider	Service report
6	Closure of work order is followed by a SMS to respective user In charge	Facility incharge or Nodal officer through Call centre	SMS and work order

3 Breakdown Maintenance

- **Objective:** To ensure Breakdown Maintenance Activity is carried out for All Biomedical Equipment within specific time frame as per the contract agreement
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** Service report, Facility In charge, Deputy *In charge*, *end users*

Procedure:

S. No	Activity	Responsibility	Record
1	Service provider visits the facility after call registration	Service provider	-
2	Service provider performs necessary repairs	Service provider	-
3	Feedback is provided to the user if machine is not repaired in the 1 st instance	Service provider	Email & SMS
4	Service report is signed and updated on the dashboard	Service provider	Dashboard
5	In charge verifies the functionality through Deputy In charge, end user	Facility In charge	Service report
6	Service provider prepares the Service report and submits to the In charge	Service provider	Service report
7	Call Closure	Facility In charge /Nodal Officer	Call Record and SMS

4. Preventive Maintenance & Calibration

- **Objective:** To provide Preventive Maintenance & Calibration on all Biomedical equipment
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** *Service provider, Facility In charge*

Procedure:

S. No	Activity	Responsibility	Record
1	Annual Schedule of Preventive Maintenance and Calibration is submitted to the state	Service provider	Preventive Maintenance and Calibration & Dashboard
2	Checklist for Preventive Maintenance & Calibrations is also submitted by the Service provider initially	Service provider	Preventive Maintenance and Calibration & checklist, report
3	Preventive Maintenance is performed as by facility In charge per schedule and verified by the checklist	Service provider & end users	Preventive Maintenance and Calibration & Dashboard
4	Preventive Maintenance of under maintenance equipment is rescheduled	Service provider	Preventive Maintenance and Calibration & Dashboard
5	Details are updated on the dashboard	Service provider	Preventive Maintenance and Calibration & Dashboard
6	Sticker is affixed stating the date of PM&C and next due date	Service provider	Preventive Maintenance and Calibration & sticker

5. User Training

- **Objective:** To provide Periodic User training of all types of medical equipment
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** Service provider and Mission Director

Procedure:

S. No	Activity	Responsibility	Record
1	Prepare annual user training schedule	Service provider	Training schedule & dashboard
2	Schedule is approved by the authority	Mission Director	Training schedule & dashboard
3	User training is conducted (at least once a year per equipment)	Service provider	Training report
4	Attendance and feedback of the training is collected	Service provider	Attendance & feedback report

6. New Equipment Installation

- **Objective:** To ensure that newly installed Equipment are smoothly brought into the system of Biomedical Equipment maintenance program and supported by their respective suppliers' during the warranty period.
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** Service provider, Facility In charge, supplier

Procedure:

S. No	Activity	Responsibility	Record
1	Information to the Service provider for new equipment through toll free no.	Facility In charge	Call log
2	Service Provider asks for a copy of records from the supplier/manufacturer with the support of the facility in charge	Service provider, Supplier & facility In charge	Purchase order, warranty duration, operating manual, maintenance manual
3	Service provider coordinates with supplier for installation	Service provider, Supplier & facility In charge	-
4	Dash Board is updated	Service provider	-
5	Service provider ensures training provided to the end user by the supplier	Service provider, Supplier & facility In charge	Installation report
6	If any of the point 2, 3 or 5 is complied partially or fully, the service provider informs the facility in charge to withhold the payment	Service provider, Supplier & facility In charge	Email, letter
7	Service provider registers the equipment, affix the tag and informs the supplier/manufacturer	Service provider	Equipment tag

7. Biomedical Equipment Not Found during Preventive/Corrective Maintenance

- **Objective:** To notify the user for Biomedical Equipment Not Found during Preventive Maintenance
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** Service Provider, Dept. In charge of Health Facility, facility In charge

Procedure:

S. No	Activity	Responsibility	Record
1	Service Provider technical staffs visit the Healthcare facility for preventive Maintenance as scheduled.	Service provider	-
2	Any equipment not found in its registered location, the technical staff record in Service report.	Service provider	Service report
3	Submit the form to Respective Health facility Nodal officer/ Dept In Charge	Service provider	-
4	Health facility Nodal officer acknowledges the Service report	Service provider & Facility In charge	Service report
5	Technical staff to submit the Service report to DMO	Service provider	Service report
6	Service Provider to follow up with respective nodal officer to provide the equipment not found during technical staff visit	Service provider & facility In charge	-
7	Service provider shall send follow up letter to DMO after one month if no feedback from Nodal officer	Service provider & dept. health officer	Email & letters
8	Preventive Maintenance work order is completed with remarks	Service provider	Service report
9	The equipment is removed from the asset base of inventory	Service Provider	Dash Board

8. Warranty / AMC Management:

- **Objective:** To ensure that biomedical equipment under warranty are maintained and supported by their respective suppliers in accordance with the provisions of the warranty terms of supply.
- **Scope:** All biomedical equipment under warranty.
- **Responsibility:** Service Provider, Dept. In charge of Health Facility, Equipment In charge, facility In charge

Procedure:

S. No	Activity	Responsibility	Record
1	Health facility In charge / end users to report any Equipment under Warranty / AMC requires repair	Facility In charge & End users	Call log
2	Service provider to notify respective Vendor for any repair / service	Service provider	Call centre/call log/letter/email
3	The copy of such letter and email will be submitted to Health facility In Charge	Service provider	Call log/letter/email
4	Service provider to notify respective vendor one month prior to expiry of warranty	Service provider	Call log/letter/email
5	Medical equipment under AMC will be added to service provider contract after the expiry of such AMC to the inventory asset base	Service provider	Dash board
6	Service provider updates all service done in Dashboard	Service provider	Dash board

9. Condemnation of Biomedical Equipment

- **Objective:** To formally condemn equipment for reason defined below
- **Scope:** All Biomedical Equipment under Contract
- **Responsibility:** Service provider, Facility In charge, Mission Director, Condemnation committee

Procedure

S.No.	Activity	Responsibility	Record
1	Service Provider to indicate a list of equipment to be condemned	Service provider	Condemnation
2	State government to form a committee to declare the condemnation of equipment	Mission director	Condemnation order
3	To recommend for condemnation of Biomedical Equipment shall satisfy one or more following conditions: <ul style="list-style-type: none"> • Beyond Economic repair • Obsolescence • Reliability • Worn Out 	Mission Director & Service provider	Dashboard
4	The condemnation committee to issue a list of biomedical equipment approved for condemnation	Condemnation Committee	Letter
5	Approved equipment for condemnation shall be removed from the asset inventory asset base and billing henceforth	Service provider	Condemnation
6	For radiology equipment, approval from AERB to be taken and condemnation to be done as per the guidelines	Condemnation committee	Government order

Recommended Member of Condemnation Committee:

1. Mission Director or his representative
2. BMMP Nodal Officer
3. Facility In charge
4. Biomedical Engineer of the state
5. Store In charge
6. Purchase officer/ Finance Officer
7. Service Provider as an invitee

10. Process the Bills for Payment and Documentation

- **Objective:** Document requirement and verification for processing the service providers Invoice
- **Scope:** Biomedical Equipment Maintenance Bills
- **Responsibility:** Service provider, Facility In charge, BMMP state Nodal Officer
- **Procedure:** Service Provider to prepare following reports (Facility Wise) for processing the Bills

No	REPORTS	Record
1	Breakdown Report	Service Report duly signed by respective MO
2	Preventive Maintenance / Calibration Report	PM report with Check List and calibration report
3	Penalty Report	Service Report
4	User Training Report	Attendance record & Feedback Form
5	Lists of Equipment Proposed for Condemnation	Condemnation Reports (Equipment wise)
6	Lists of Out of Warranty Equipment	Installation Reports / Copy of Department Register
7	Lists of Out of AMC / CAMC Equipment	AMC / CAMC Agreement
8	Lists of newly Registered Equipment	Equipment Registration form

- Service Provider to prepare Facility wise all above reports, duly approved by the facility in charge and submit to accounts department with copy of Support Document.
- Service Provider Prepare the State Wise Summary as per the Monthly Reports.
- Service Provider Shall submit all the reports on or before 5th of every month.
- Nodal Officer shall verify the reports within 7 days of submission and forward the same to the accounts department for payment. In case of objection the invoice may be sent back to the service provider stating the reasons thereof.
- Accounts to clear the payment within 30 days of receipt of invoice by the facility incharge/ Nodal officer

11. Adverse Event Reporting (Materiovigilance)

Materiovigilance Programme of India was launched by DCG (I) on 6th July 2015 at Indian Pharmacopoeia Commission (IPC) Ghaziabad. Following organisation plays below key roles for this program, Indian Pharmacopoeia Commission functions as a National Coordination Centre (NCC) for MvPI. Sree Chitra Tirunal Institute for Medical Sciences & Technology (SCTIMST), Thiruvananthapuram, shall act as National Collaboration Centre, National Health System Resource Centre (NHSRC), New Delhi shall act as Technical Support & Resource Centre and Central Drugs Standard Control Organisation (CDSCO), New Delhi shall act as regulator.

Materiovigilance Programme of India aims to monitor medical devices in health system and weed out substandard or unreliable medical devices from marketing or selling in India. Even though Materiovigilance is not in the scope of services of service provider, any activity like informing National Coordination Centre on spurious or unreliable medical devices will be appreciated. Toll free number for reporting is **18001803024** and technical support can be sought from NHSRC.

III Training Manuals

Training is a key element in the Biomedical Equipment Maintenance Program. This requires ensuring adequate training programs are in place for safety and reliability of equipment. The below thematic areas may be converted into PowerPoint slides and used for in-house personnel for giving an overview of the program.

1. Objectives of the Program

The objective of this program are as below.

- Exact assessment of all equipment available in DHs, SDHs, CHCs & PHCs.
- Make all the equipment in working condition to deliver uninterrupted patient service.
- Provide periodic user training to all the users to improve the patient care.
- Manage the equipment under AMC/CAMC/Warranty in coordination with service providers and to ensure the suppliers provide services as per purchase terms.
- Carry out Preventive maintenance of all equipment to meet the manufacturer's specifications to ensure availability of equipment at all times for patient care
- Calibration of all the equipment to ensure performance and standards.
- Submission of monthly/ quarterly report on functional status of equipment
- Assist in site-preparation, installation and commissioning and arrange the user-training with suppliers.

Scope of services

- Break down Maintenance
- Preventive Maintenance & Calibration Services
- User Training
- Installation and Commissioning support
- Acceptance testing
- AMC/CAMC/ Warranty Management
- Condemnation (Beyond Economic Repair)

2. Installation and Commissioning

a. Service provider/Supplier responsibilities

- To help the authorities to ensure the new equipment are installed in a location to ensure the proper functioning of the equipment.
- To advise the authorities to arrange a proper electrical supply, air conditioning, environmental requirements and other installation requirements
- To support the Authorities to ensure proper delivery of the equipment as per the purchase order and its installation.
- The Service provider's engineer need to ensure the functionality and performance of the supplied new equipment in support with the user.

b. User responsibilities

- To inform the service provider about the new purchase and expected installation period and its location.
- To arrange a proper electrical supply, air conditioning, and other installation requirements.
- To allow the service provider engineer to coordinate with the supplier to ensure all the equipment delivery as per the purchase order.

3. AMC/CAMC/Warranty Management

- The service provider need to coordinate with the supplier for Preventive Maintenance Service and Calibration of the equipment.
- It is the responsibility of the service provider need to decide whether the equipment is necessary to get AMC/CAMC from the supplier.
- The user can discuss with the service provider to get the supplier's support if necessary for future service and criticality of the equipment for patient service.

However it is the responsibility of the service provider to keep the equipment functioning either by engaging supplier or by appointing in-house engineer to ensure the equipment meet the uninterrupted patient service. In case the supplier is not responding to any of the request the service provider should escalate the matter with higher authorities which may lead to penalising the supplier.

4. User Training

- The user training need to be conducted across all the DH/SDH/CHC/PHC
- A schedule to be given to the respective Nodal officer / Facility In-charge
- Upon acceptance of the user training schedule the training to be given to the users to ensure the equipment is used properly for patient care safely.

5. Break down Maintenance

- It is the user responsibility to call the customer care (Call Centre) toll free number to make a complaint about the non-functioning of the equipment.
- The user need to note down the following information to register a complaint with the customer care about the non-functioning of the equipment
- Equipment ID Number, Equipment name, User's Name, User's mobile contact number, E mail ID and the nature of the problem.

An E mail & SMS notification sent to the caller upon registration of the complaint in the maintenance management system and another notification of completion of the repair. The caller need to verify the equipment function with this E mail or SMS information. If not satisfied with the repair again the caller can reregister the complaint to the customer care (Call centre)

- The service provider need to ensure to repair the equipment at the earliest without affecting the patient services.
- If necessary based on the criticality of the equipment, the user may have to provide the standby equipment to ensure the patient services are not affected.
- Upon completion of the repair the service provider need to prepare a service report and get the acknowledgement from the facility In-charge or Nodal officer. In case the user wants to observe the function of the equipment then the user needs to write a note in the service report and acknowledge the report.

6. Preventive Maintenance (PM Service)

The Preventive Maintenance is to ensure the reliability during use usage, user safety & patient safety. This is done in order to:

- To prevent breakdowns and ensure the machine is available for patient services.
- To make the equipment functioning at all times to its specified performance and safe to the user and the patient.
- To increase the expected lifespan of equipment

- To increase the effective utilisation
- The service provider should ensure the PM is carried out as per the accepted scheduled and as per the standards with use of approved check list.

7. Calibration Services

- Calibration/ Performance verifications need to carry out by using the proper test equipment as per the manufacturer's recommendations or NABL/as per the Regulatory authorities like AERB.
- The equipment which do not require calibrations need to mentioned clearly and submit a list to the user and the Nodal officer.
- Upon calibration a certificate need to be submitted to the user or the facility In-charge/ Nodal officer.
- If any equipment failed during the calibration, a corrective action need to carried out by registering a complaint through call centre and after the corrective action, the calibration need to be again carried out for that particular equipment.

8. Condemnation

- If any equipment cannot be repaired due to obsolete or discontinued or very high cost, to be informed to the user and the nodal officer.
- A technical report is to be submitted with the reasons for proposing the Condemnation and get it approved by the user / Nodal officer/ Committee.
- Upon Condemnation (BER) approval a quarterly report need to be submitted for the removal of the equipment from the list/ Dash board.

9. SMS & email Feedback at the time of Registering Breakdown Call

SMS Format:

Service Call <Insert automatic call generation number > on <date > < Equipment Name > Not Working > Engineer :< Name > <Phone Number > will attend shortly

Email Format:

Subject: Repair / Service Call XY-ZA-2018-00042 is created

Dear Sir / Madam

The below mentioned service call is created.

Service call No:

Customer name:DH/CHC/PHC

Equipment Identification No:

Equipment Name:

Call logged on date:

Problem Reported:

Pl. call, if any queries

This email is system automatically generated. Please do not reply

10. Documents Required to Process the Quarterly Invoice

Reports	Service Provider	Hospital Authority/ Nodal Officer
Equipment List	Prepare Hospital wise Equipment list – Quarterly Once	Respective MO to Acknowledge in Verified column of List
2.Equipment List – Out of Warranty_Out of AMC / CMC	Prepare Hospital wise Equipment list – Quarterly Once	Respective MO to Acknowledge in Verified column of List
3.Equipment List proposed for Condemnation & Summary	Prepare Hospital wise Equipment list – Quarterly Once	Respective MO to Acknowledge in Verified column of List
4.Equipment List – Newly Tagged & Summary	Prepare Hospital wise Equipment list – Quarterly Once	Respective MO to Acknowledge in Verified column of List
5.Breakdown Calls Report	Prepare Hospital wise – Monthly	Respective MO to Acknowledge in Verified column of List
6.Preventive maintenance / Calibration Report	Prepare Hospital wise – Monthly	Respective MO to Acknowledge in Verified column of List
7.User Training Report	Prepare Hospital wise – Monthly	Respective MO to Acknowledge in Verified column of List
8.Penalty report	Prepare Hospital wise – Monthly	Acknowledge Summary along with Reports and Invoice
9.Summary of Variation to Service	Prepare Hospital wise Equipment list – Quarterly Once	Acknowledge Summary along with Reports and Invoice

Other Reports to be submitted

Reports		
1. Walkthrough Report i. DH – Monthly (Dept. Wise) ii. SDH – Monthly (Dept. Wise) iii. CHC / PHC – Quarterly (As per Equipment List)	Prepare Hospital wise critical and major important equipment list and submit to respective MO, CMO,DMO and NHM (Equipment functionality is checked and recorded during walk through report)	Respective MO, CMO,DMO to acknowledge the List
2. Breakdown Feedback Report – Hospital wise (every fortnight)	Prepare Breakdown Feedback report with Expected Date of Completion to Respective MO, CMO , DMO	Respective MO, CMO,DMO to acknowledge the List

Reports to be kept in the each Health Facility

- Equipment List – While Taking over
- Equipment list – Out of Warranty , AMC , CMC
- Equipment List – New tagging List
- Breakdown Service Report Copy
- Preventive Maintenance report
- User Training report
- Walkthrough Report
- Breakdown Feedback Report

IV. Oversight Committee

A national programme has the responsibility of creating support systems that would ensure that the goals of the program are achieved in a time-bound manner, are replicable in the and can be continually improved, both upstream and downstream.

A State Oversight Committee (SatCom) would be set up as the overall owner of the Biomedical Equipment Maintenance Programme. The SatCom shall establish an overall policy-framework, assess progress, identify areas of improvement and guide StateCom in implementation of policy. SatCom will also formulate the standards of professional conduct and maintain an oversight on the overall conduct of the participating Service Providers.

The SatCom would support and promote human resource and academic development of Service Providers and coordinate with Bidders to organize and deliver such activities. In addition, the SatCom would commission committees or working groups, conduct meetings and seminars for disseminating knowledge.

The SatCom would meet every quater where districts would present the progress of the program in their area. The structure of the SatCom would be as follows:

1. Mission Director, Chair
2. Chief Medical Officer(s)
3. State Biomedical Engineers
4. External Biomedical Engineering experts
5. State Program Manager (BMMP) , Member secretary
6. Any other member as deemed appropriate by the state

V Reporting Formats

Equipment Registration Form

1. Hospital /Clinic Details				2. Equipment Details			
Hospital /Clinic Name*				Equipment No.*			
Hospital /Clinic Category		MC() DH() CHC() PHC()		ME General name*			
Hospital /Clinic Address				Manufacturer*			
Department				Model*			
District Name				Supplier/Service Agent.			
Zone				Supplier Contact info			
State				ME functional Status			
Contact Details		Name*		Contract Start Date			
		Mobile		Type Of Equipment			
		Email		Date of Installation			
				Equipment Value		AMC/CAMC Value	
				3. Remarks			
4. Standard Components /Accessories							
S.No	Part Description	Part No.	Qty.	Registration Done by(Engineer/Technician) Signature:		Verified &Approved by User Signature:	
				Name:		Name:	
				Date:		Date:	
						Stamp:	

Note: In the status field, except for the condition “function Good” for all other condition should carry detailed explanation in the remarks field.

FG: Functional Good /NW: Not Working/ AMC: Annual Maintenance Contract/CAMC: Comprehensive Annual Maintenance Contract

DH: District Hospital/CHC: Community Health Centre/PHC: Primary Health Centre/MCH: Medical College Hospital

*Mandatory Fields to be filled

Certificate of Medical Equipment Tagging Status

District	
Health Facility	
Category of Health Facility	MC() DH() CHC() PHC()
Total Number Of Equipment Tagged	
Number of Equipment Functioning	
Number of Equipment Not Functioning	

I hereby certify that all the Medical Equipment available in the Hospital/Clinic has been tagged by (name of service provider). There is no more Medical Equipment available in the Hospital/Clinic pending for Tagging. There are no equipment mentioned in the list which do not physically exist.

For Hospital /Clinic		Service Provider	
Name		Name	
Designation		Designation	
Sign		Sign	
Date		Date	

STATE: LIST OF EQUIPMENT – TAGGED AS PER RFP

No	District	Hospital name	Me number	Medical Equipment name	Manufacture	Model	Serial number	Functional status	Department
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

Recommendation For Beyond Economical Repair (BER)

BER Ref No:

ME NO		Hospital Code	
ME Name		Hospital Name	
Manufacturer		District	
Model		State	
Serial No.		Hospital Type	GH() CHC() PHC()

Purchase Cost		Date Of Purchase	
---------------	--	------------------	--

Estimated Repair Cost exceeds Depreciated Cost or it is more than 50% of market value of new equipment	Accumulated Maintenance Cost(1 Year)	Rs
	Estimated Cost of Present Repair	Rs
	Total Cost	Rs
	Depreciated Cost	Rs 0.00

Condition Appraisal & Recommendation for Beyond Economic Repair Certification

Obsolescence	
Reliability	
Statutory Requirement	
Worn Out	

Prepared By	Verified By	Approved By
Engineer/Technician	State In-Charge	Nodal Officer
Name	Name	Name
Date	Date	Date

Format for Equipment Not found during “Preventive Maintenance”

Date:

Dr.....

Hospital:

Dear Dr,

The below equipment scheduled for Preventive Maintenance inMonth is not able to locate in its registered location. Kindly provide the Equipment to perform the Preventive Maintenance.

NO	District	Hospital Name	Department	ME Number	ME Name	Manufacturer	Model	Serial no.	Functional status

Prepared By

Acknowledged By

Service Report

Hospital Type	DH		CH		PH	Work Order Number	
Hospital Name					WO Date &Time		
ME No					WO Respond Date &Time		
					WO Respond Date &Time		
Contract Equipment() BER ()	Under Warranty() Reimbursed Work()			Under AMC() Standby Provided()			
Problem Reported							
Action Taken							
Material Used					Stand By Equipment Details		
No	Item Description			Qty	Equipment No :		
					Equipment Provided Date:		
					Equipment Condition : Good () Damaged()		
					Equipment Returned Date:		
					Customer Acceptance for Stand By Equipment		
Breakdown Execution details							
Engineer/Technician Name	Date	Start Time	End Time				
Customer Remarks							
Engineer/Technician Signature					Customer Signature for WO Completion		
Name:					Name: Designation Stamp		

Verification
In charge

Training Feedback Form

Name: _____ Designation _____
 Program Title _____ Date _____
 Trainer Name _____ Venue _____

The purpose of this evaluation form is to assess the effectiveness of the course that you have just attended. Please refer to the ratings below to assist us in your evaluation .We thank you for your participation

- 1. Course Objectives:** Rating System 1=Very Poor, 10 =Very Good
- How well has this course met its stated objectives? 1 2 3 4 5 6 7 8 9 10
- Have the objectives met your personal needs? 1 2 3 4 5 6 7 8 9 10
- 2. Course Contents:**
- The subject content/skills applicable to your job 1 2 3 4 5 6 7 8 9 10
- New ideas /skills knowledge gained by attending this1 2 3 4 5 6 7 8 9 10
 program?
- The quality of Contents 1 2 3 4 5 6 7 8 9 10
- 3. Facilitator /Trainer**
- Knowledge of subject matter 1 2 3 4 5 6 7 8 9 10
- Ability to Present views and ideas clearly 1 2 3 4 5 6 7 8 9 10
- Communication skill 1 2 3 4 5 6 7 8 9 10
- 4. Overall Rating**
- How do you rate this course /program 1 2 3 4 5 6 7 8 9 10
- 5. Miscellaneous**
- Training Venue 1 2 3 4 5 6 7 8 9 10
- Course /Program coordination 1 2 3 4 5 6 7 8 9 10
- Any Other comments/suggestions 1 2 3 4 5 6 7 8 9 10

User Signature

Trainer Signature

SUMMARY – USER TRAINING CONDUCTED

District	Hospital	Equipment	Trainer Name	No. of Staffs Attended

WALKTHROUGH REPORT

District			Hospital				
No	ME Number	Medical Equipment Name	Manufacture	Model	department	Functional Status	User Signature
1							
2							
3							
4							
5							
6							
7							
8							
9							
10							
11							
12							
13							
14							
15							
16							
17							
18							
19							

STATE:

LIST OF EQUIPMENT NEWLY TAGGED

No	District	Hospital name	Department	ME number	ME Name	Manufacturer	Model	Serial	Functional status
1									
2									
3									
4									
5									
6									
7									
8									

State: **Breakdown Feedback Report**

No	District	Hospital	Me number	M.E. name	Make	Model	Work order no	Call date	Spare requirement	Action taken	Expected date of completion
1											
2											
3											
4											
5											
6											
7											
8											
9											
10											
11											
12											
13											
14											

LIST OF EQUIPMENT OUT OF WARRANTY

No	District	Hospital	M.E. number	M.E. name	Manufacture	Model	Serial no	Functional Status	Dept. /location	Warranty	Warranty end
1											
2											
3											
4											
5											
6											
7											

State: **List of Preventive Maintenance**

No	District	Work order no	Work order date	Hospital	M.E name	M.E. number	Completed date & time	status	Remarks
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									

**STATE: LIST OF EQUIPMENT – TAGGED AS PER
RFP**

No	District	Hospital name	Me number	Medical Equipment name	Manufacture	Model	Serial number	Functional status	Department
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									

ANNEXURE-1

Form GFR-10

(See rule 217(iii) of the General Finance Rules 2017)

Report of surplus, Obsolete and Unserviceable Stores for Disposal

Item No.	Particulars of Stores	Quantity/Weight	Book Value/Original Purchase Price	Condition and year of purchase	Mode of Disposal (Sale, open auction, advertised tender etc.)	Remarks
1	2	3	4	5	6	7

Date

Signature of Indenter
Designation of Indenter

Annexure-II

FORM GFR 11
 [See Rule 222 of GFR 2017]
Sale Account

Item No . 1	Particulars of Stores 2	Quantity / Weight 3	Name and full address of purchaser 4	Highest bid accepted 5	Highest bid rejected 6	Earnest money realized on the spot 7	Date on which the complete amount is realized and credited into treasury 8	Whether the articles were actually handed over on the spot. If not, the actual date of handing over of the articles with quantities 9	Auctioneer's Commission and acknowledgment for its payment 10

Date

Signature of Indenter
 Designation of Indenter

Annexure III

**CAUTION
OUT OF
ORDER**

Problem-----
Signed-----
Date-----

DANGER!
Do Not Use with
AC Power Source

INSPECTED

Date	By
_____	_____
Due	

BIOMEDICAL ENGINEERING SERVICES

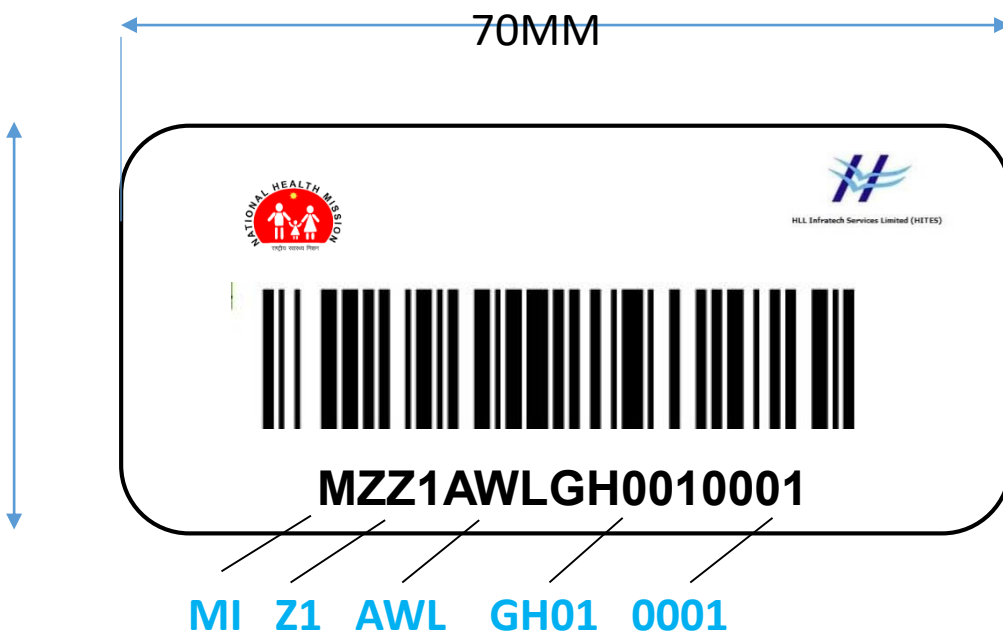
SAFETY CHECKED

BY-----
DATE -----

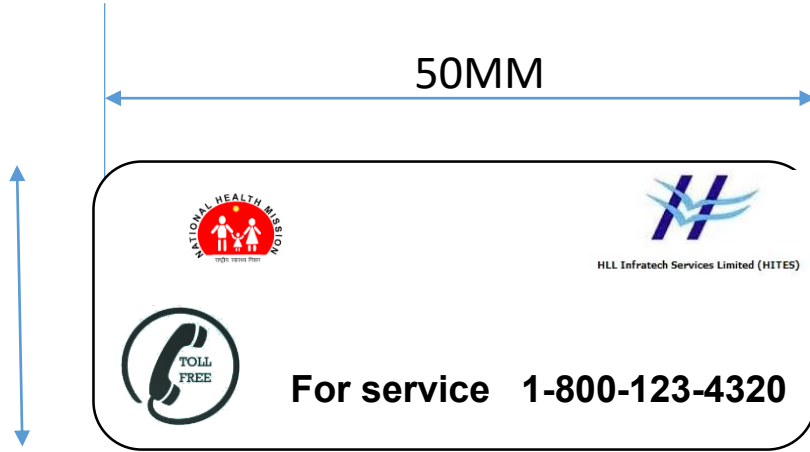
SERVICED

Date----- By _____
Due-----

	CAL	PM
Service Performed	<input type="checkbox"/>	<input type="checkbox"/>



State
Zone
District
Facility
S. No.



List of Contributors

State Representatives:

1. Mr Narendranath K.R, Kerala Medical Services Corporation Ltd.
2. Mr Bryan Don, NHM Meghalaya
3. Dr Aruna Kumar, NHM Telangana
4. Mr Shivakumar, NHM Karnataka
5. Dr Ved Prakash, NHM Uttar Pradesh
6. Mr Neel Ranjan, NHM Jharkhand
7. Mr Praveen Singh, NHM Jharkhand
8. Mr Amit Karwal, NHM Rajasthan
9. Mr K Dhineshkumar, NHM Puducherry

Industry representatives

1. Mr Rajesh Jain, Instromedix (India) Ltd.
2. Mr Selvakumar, Medici Healthcare Services Pvt. Ltd
3. Mr AL Biren Chandar, HLL Lifecare Ltd
4. Mr Padmanaban, Faber Sindoori Management
5. Mr PR Srinivas, Faber Sindoori Management
6. Mr Vijay , Faber Sindoori Management
7. Mr Mahadeo, Faber Sindoori Management
8. Mr Chelvadorai, TBS India Pvt Ltd
9. Mr Ajai Dang, AOV International
10. Mr Vishwas, Kirlosakar Technologies

Secretariat

1. Dr Manohar Aghnani, Joint Secretary (Policy), MoHFW
2. Ms Sunita Sharma, Director NHM – III, MoHFW
3. Dr Yuvaraj, Director, NHM – I , MoHFW
4. Mr SD Nayak, Deputy Secretary, NHM – IV, MoHFW
5. Mr Niranjan Khamabate, External Biomedical Engineering expert
6. Dr SB Sinha, Ex- Advisor HCT , NHSRC
7. Mr Bhaswat Kumar Das, Sr Consultant, RRCNE Guwahati
8. Mr Anjaney, Consultant NHSRC
9. Mr Ajai Basil , Consultant NHSRC
10. Mr Vigneshwaran, Consultant NHSRC
11. Ms Akriti Chahar, Consultant NHSRC
12. Mr Mohd. Zoheb, NHSRC
13. Ms Kesari Thukran, NHSRC
14. Mohammad Ameen, Sr. Consultant, NHSRC