सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

BIOMEDICAL
EQUIPMENT MANAGEMENT AND MAINTENANCE PROGRAM:
Technical guidance document for in-house support and monitoring of public private partnerships

Ministry of Health & Family Welfare
Government of India, New Delhi

सत्यमेव जयते

NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

BIOMEDICAL

EQUIPMENT MANAGEMENT AND MAINTENANCE PROGRAM:

Technical guidance document for in-house support and monitoring of public private partnerships.

Ministry of Health & Family Welfare
Government of India, New Delhi

सबका साथ, सबका विकास, सबका विश्वास
Sabka Saath, Sabka Vikas, Sabka Vishwas

सत्यमेव जयते

डॉ हर्ष वर्धन
Dr Harsh Vardhan

स्वास्थ्य एवं परिवार कल्याण, विज्ञान और प्रौद्योगिकी
व पृथ्वी विज्ञान मंत्री, भारत सरकार
Union Minister for Health & Family Welfare,
Science & Technology and Earth Sciences
Government of India

Message

Medical devices are crucial for efficiency and sustainability of health systems as they aid in prevention, diagnosis and treatment of illness and disease. The Ministry of Health and Family Welfare, Government of India, has observed during various assessments that at any point of time, 13%-34% of the equipment have been lying dysfunctional across the public health facilities in the country. Needless to say that appropriate utilisation of technologies as well as maintenance/upkeep protocols maximize the service life of medical equipment and also enable the Government to provide healthcare at an affordable cost while at the same time preventing irrational use.

2. To ensure the timely availability and proper functioning of medical equipment, Biomedical Equipment Management and Maintenance Programme (BMMP) was launched in the year 2015. The Programme, which is being implemented in 28 States/UTs, has evidently been successful in reducing healthcare delivery costs.

3. Further, with a view to supplement the programme, Ministry of Health and Family Welfare, Government of India, has prepared a technical manual for use by the concerned stakeholders. This technical manual would facilitate the States/UTs to strengthen in-house Equipment Management Units as well as manage their maintenance contracts.

4. I urge the States/UTs to regularly refer and utilise this technical manual with an aim to deliver quality health services in public health facilities and efficient leveraging of resources.

(Dr. Harsh Vardhan)

New Delhi,
August 19, 2019.

कार्यालय: 348, ए–स्कंध, निर्माण भवन, नई दिल्ली–110011 • **Office:** 348, A-Wing, Nirman Bhawan, New Delhi - 110011
Tele: (O) : +91-11-23061661, 23063513 • **Telefax:** 23062358 • **E-mail:** hfwminister@gov.in
निवास: 8, तीस जनवरी मार्ग, नई दिल्ली–110011 • **Residence:** 8, Tees January Marg, New Delhi - 110011
Tele: (R) : +91-11-23794649 • **Telefax:** 23794640

अश्विनी कुमार चौबे
Ashwini Kumar Choubey

सत्यमेव जयते

सर्वेसन्तु निरामया

एक कदम स्वच्छता की ओर

स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

संदेश

सार्थक और प्रभावी स्वास्थ्य सेवाएं प्रदान करने के लिए बेहतर चिकित्सा उपकरण होने अनिवार्य हैं। चिकित्सा उपकरणों का प्रबंधन और रख-रखाव न होने पर संसाधनों की बर्बादी के साथ-साथ स्वास्थ्य सेवाओं की प्रदायगी की लागत भी बढ़ती है। कम से कम डाउन-टाइम के साथ उपकरण को कार्यात्मक बनाए रखना, विशेषकर दूर-दराज के क्षेत्रों में, एक चुनौती रहा है। इसका निराकरण करने के लिए स्वास्थ्य एवं परिवार कल्याण मंत्रालय ने वर्ष 2015 में "बायो मेडिकल इक्विपमेंट मैनेजमेंट एन्ड मेन्टेनेन्स प्रोग्राम (बीएमएमपी)" शुरू किया। अधिकतर राज्य/संघ-राज्य क्षेत्र पब्लिक-प्राइवेट पार्टनरशिप में यह कार्यक्रम चला रहे हैं।

यह तकनीकी नियम पुस्तिका राज्यों/संघ-राज्य क्षेत्रों को बीएमएमपी कार्यक्रम के आंतरिक प्रबंधन पर मार्गदर्शन प्रदान करने तथा राज्य उपकरण प्रबंधन इकाई की कार्य प्रणाली पर ब्यौरा प्रदान करने के लिए तैयार की गई है। इससे बढ़िया डायग्नोस्टिक देखभाल प्रदान कराने तथा बेहतर रोगी देखभाल प्रबंधन की दिशा में प्रगति के लिए मार्ग प्रशस्त होगा। मुझे आशा है कि राज्य/संघ राज्य क्षेत्र इस तकनीकी नियम पुस्तिका का उपयोग समयबद्ध ढंग से चिकित्सा उपकरणों के बेहतर प्रबंधन और अनुरक्षण के प्रयासों को संपूरित करने हेतु करेंगे।

(अश्विनी कुमार चौबे)

दिनांक : 19/8/2019
स्थान : नई दिल्ली.

Office : 250, 'A' Wing,
Nirman Bhavan, New Delhi-110 011
Tel. : 011-23061016, 011-23061551
Telefax : 011-23062828
E-mail : moshealth.akc@gov.in

Residence :
30, Dr. APJ Abdul Kalam Road,
New Delhi - 110003
Tel. : 011-23794971, 23017049

प्रीति सूदन
सचिव
PREETI SUDAN
Secretary

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

Dated : 6th August, 2019

Message

Medical equipments play an indispensable role in improving health service delivery and meeting the needs of people. Its availability and upkeep is one of the key interventions for ensuring access to diagnostic, preventive, assistive and therapeutic services in public health facilities. The successful implementation of Biomedical Equipment Management and Maintenance Program (BMMP) has assured minimal down-time and timely preventive maintenance, thereby, assuring quality diagnostic services and reducing the cost of care.

This technical manual has been developed specifically to aid the State/UTs in effective planning and execution of Biomedical Equipment Management and Maintenance Program. The manual has incorporated guidelines on Standard Operating Procedures, Training manuals, Reporting formats, State Equipment Management Unit policy and other important components required for effective implementation of the program. I am certain that this technical manual would be resourceful for all the States/UTs and contribute to health systems strengthening.

(Preeti Sudan)

Tele : (O) 011-23061863, Fax : 011-23061252, E-mail : secyhfw@nic.in
Room No. 156, A-Wing, Nirman Bhavan, New Delhi-110011

मनोज झालानी
Manoj Jhalani
अपर सचिव एवं मिशन निदेशक (रा.स्वा.मि.)
Additional Secretary & Mission Director (NHM)

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
निर्माण भवन, नई दिल्ली - 110011
GOVERNMENT OF INDIA
MINISTRY OF HEALTH & FAMILY WELFARE
NIRMAN BHAVAN, NEW DELHI - 110011

05th August, 2019

FOREWORD

The Ministry of Health and Family Welfare launched the Biomedical Equipment Management and Maintenance program in the year 2015 for comprehensive maintenance of medical equipment in public health facilities from Primary Health Centre level to District Hospital level. So far, the program has been implemented in 28 States/UTs through In-house and Public Private Partnership mode.

An effective medical equipment maintenance program entails proper planning, management and implementation. Therefore, in order to strengthen the State/UT capacities on program implementation, a comprehensive technical manual has been developed to ensure service delivery in an assured manner. The objective of this technical manual is to strengthen State/UTs monitoring mechanism for BMMP and to streamline the implementation process, The manual includes a set of quantifiable deliverables developed for each stage of the implementation, along with Standard Operating Protocols for inventory management, breakdown call management and protocols for condemnation of equipment. I expect all the States/UTs to form State Equipment Management Units on priority and contextualize this manual based on their local requirements to ensure quality equipment maintenance services.

(Manoj Jhalani)

Telefax : 23063687, 23063693 E-mail : manoj.jhalani@nic.in

TABLE OF CONTENTS

ABBREVIATION

SEMU	State Equipment Management Unit
PM	Preventive Maintenance
AMC	Annual Maintenance Contract
CMC	Comprehensive Maintenance Contract
SOP	Standard Operating Procedure
CAMC	Comprehensive Annual Maintenance Contract
RFP	Request for Proposal
BER	Beyond Economical Repair
BMMP	Biomedical Equipment Management & Maintenance Program
MoHFW	Ministry of Health and Family Welfare
NHSRC	National Health Systems Resource Centre
PPP	Public Private Partnership
HCT	Healthcare Technology
ICT	Instrument Care Taker
DGHS	Director General of Health Service
NOHP	National Oral Health Programme
RNTCP	Revised National Tuberculosis Control Programme
NHM	National Health Mission
NABH	National Accreditation Board for Hospital
NABL	National Accreditation Board for Testing and Calibration Laboratories
NQAS	National Quality Assurance Standard
IT	Information Technology
PCB	Printed Circuit Board
ECG	Electro-Cardiogram
OT	Operation Theatre
BP	Blood Pressure
CT	Computed Tomography
MRI	Magnetic Resonance Imagining
CDAC	Centre for Development for Advance Computing
CHC	Community Health Centre
PHC	Primary Health Centre
DH	District Hospital
GH	General Hospital
OEM	Original Equipment Manufacturer
SC	Sub-Centre
CMO	Chief Medical Officer
HM	Hospital Manager
MOIC	Medical Officer in-charge
BPM	Block Programme Manager
ADMO	Additional District Medical Officer
SDMO	Sub Divisional Medical Officer
SMS	Short Message Service
BME	Biomedical Engineer
HO	Head Office
GM	General Manager
SNCU	Special Newborn Care Units
DC	Direct Current
IC	Integrated Circuit
ESU	Electrosurgical Unit
WHO	World Health Organization

IMDRF	International Medical Device Regulators Forum
IVRS	Interactive Voice Response System
AC	Alternative Current
RRCNE	Regional Resource Centre for North-East
DMO	District Medical Officer
AERB	Atomic Energy Regulatory Board
MO	Medical Officer
DCG(I)	Drug Controller General (INDIA)
IPC	Indian Pharmacopoeia Commission
NCC	National Coordination Centre
SCTIMST	Sree Chitra Tirunal Institute for Medical Sciences and Technology
CDSCO	Central Drugs Standard Control Organisation
SDH	Sub District Hospital
SatCom	State Committee
MC	Medical College
GH	General Hospital
SOP	Standard Operating Procedure
ICU	Intensive Care Unit
SP	Service Provider
MPT-IDs	Maintenance Process Tracking Identification Number
PM&C	Preventive Maintenance & Calibration
MvPI	Materiovigilance Programme of India
ME	Medical Equipment

PART–A

"POLICY AND PROCEDURE MANUAL, STATE EQUIPMENT MANAGEMENT UNIT (SEMU) FOR IN-HOUSE IMPLEMENTATION OF BIOMEDICAL EQUIPMENT MANAGEMENT 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. Devices used within the Public Health System in the entire state will be inspected prior installation.

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 (internal components), 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 (internal components), 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 (internal components) and workshop facility at division and district level. Secondly, spare parts (internal components), 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 (internal components) and workshop facilities. The SEMU will appoint Certified Technicians and Engineers for maintenance and calibration.

3. Objectives 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 medical devices used for diagnostic, therapeutic and patient care in hospital and medical institutions. All medical devices including those purchased by government for National disease specific program (eg: DGHS/MoHFW-TB program, NOHP, RNCTP etc) and labs at district level supported under NHM. Medical devices commissioned in government hospital under rental basis with third part agency would not be considered as it may cause duplication of government expense. SEMU will also need to support in condemnation of medical equipment.
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. SEMU will also Support in accreditation activities: NABH, NABL, NQAS related to medical devices and in attaining regulatory compliances.
7. To collaborate and assist in repair activities of medical equipment at different District hospital etc and assessment for optimal utilization (Under/Over utilization) of medical devices under each department and specaility.
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 give 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 Unit

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 (The table mention below is only indicative in nature):

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 (internal components) 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/B.Tech.

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

Biomedical Engineers – 02 each

Essential Qualification – B.E./B.Tech. – 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./B.Tech. – Biomedical Engineering

Minimum Experience of 10 years

Biomedical Engineer – 02 each per division

Essential Qualification – B.E./B.Tech. – 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./B.Tech. – Biomedical Engineering

Minimum Experience of 10 years

Biomedical Engineer – **02 each per district**

Essential Qualification – B.E/B.Tech. – 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

Objectives 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 medicalequipment.
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

The following equipment will be required for each workshop at the Divisional and District level workshops in Phase–1. The table mention below is only indicative in nature.

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. The table mention below is only indicative in nature.

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/-**

PART–B

BIOMEDICAL EQUIPMENT MANAGEMENT & MAINTENANCE PROGRAM: TECHNICAL MANUAL FOR IMPLEMENTATION IN PPP MODE

1. 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.

2. 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. All medical devices including those purchased by government for National disease specific program (eg: DGHS/ MoHFW-TB program, NOHP, RNCTP etc) and those labs at district level supported under NHM, would come under the purview of program. Medical devices commissioned in government hospital under rental basis with third part agency would not be considered as it may cause duplication of government expense.

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

2.1. 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.

2.1.1. 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.

2.1.2. 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 al 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.

2.1.3. Spare Parts

In order to ensure a good medical equipment maintenance program, an inventory of spare parts (internal components) 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 (internal components) for equipment. The service provider is expected to change worn out parts at a time frame specified by manufacture during preventive maintenance.

2.1.4. 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.

2.2. 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 I for reference.

2.3. 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.

2.4. 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:

2.4.1. 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.

2.4.2. Equipment Tagging

Once all the equip-ment 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.

2.4.3. 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.

2.4.4. 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.

2.4.5. 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.

2.5. 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.

2.6. Gantt chart

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

3. 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	4. Baby Incubators.
5. Electrosurgical Units – Surgical Cautery	6. ICU Monitors
7. Blood Gas Analyser	8. ICU Nebulizers

The table indicated above is only indicative in nature. Any other equipment as deemed appropriate may be added by the state authority

3.1. 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.

3.2. 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

3.3. 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

3.4. Breakdown Maintenance:

- **Objective:** To ensure Breakdown Maintenance Activity is carried out for All Biomedical Equipment within specific time frame as per the contract agreement and replace number of spare parts (internal components) to be undertaken as per manufacturer recommendations. Wherever possible, PPP service provider shell use PM kit of manufacturer.
- **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 1st 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

3.5. Preventive Maintenance & Calibration:

- **Objective:** To provide Preventive Maintenance & Calibration on all Biomedical equipment as per OEM (Original Equipment Manufacturer) recommendations (including but not restricted to) frequency of PM and spare-parts (internal components) to be replaced.
- **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 Checklist for Preventive Maintenance & Calibration on all Biomedical equipment as per OEM recommendations (including but not restricted to) frequency of PM and internal components to be replaced.	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. Checklist for Preventive Maintenance & Calibration on all Biomedical equipment as per OEM recommendations (including but not restricted to) frequency of PM and internal components to be replaced.	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

3.6. 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

3.7. 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

3.8. 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

3.9. Warranty / AMC/CMC 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

3.10. 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: • 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

3.11. 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

3.12. 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.

4. 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.

4.1. Objectives of the Program

The objectives 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.

4.1.1. 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)

4.2. 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.

4.3. AMC/CMC/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.

4.4. 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.

4.5. Breakdown 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.

4.6. Preventive Maintenance (PM Service)

The Preventive Maintenance is to ensure the reliability during use usage, user safety & patient safety.

Preventive maintenance involves maintenance performed to extend the life of the device and prevent failure. Preventive maintenance is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. In special cases the user may change the frequency to accommodate local environmental conditions.

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.

4.7 Calibration Services

Calibration of a medical device is carried out to minimize the uncertainty in measurements. It helps in reducing the errors and brings the measurement to an acceptable level for clinical diagnosis or therapy. With repeated use and over a period of time, all equipment tends to degrade and that affects its accuracy and precision. Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analysers, etc.) also require periodic calibration to ensure accuracy compared to known standards.

- 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.

4.8. 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.

4.9. 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

4.10. Documents Required to Process the Quarterly Invoice

Reports	Service Provider	Hospital Authority/ Nodal Officer
1. 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

Reports	Service Provider	Hospital Authority/ Nodal Officer
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

4.11. 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

4.12. 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

5. 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

6. Reporting Formats

6.1 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: Name: Date:	Verified & Approved by User Signature: Name: 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

6.2 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	

6.3 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									

6.4 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 Name Date	State In-Charge Name Date	Nodal Officer Name Date

6.5 Format for Equipment Not Found During "Preventive Maintenance"

Date:.....

Dr.....

Hospital:.....

Dear Dr,

The below equipment scheduled for Preventive Maintenance in …….Month 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

6.6 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 ()	Under Warranty ( )					Under AMC ()	
BER ()	Reimbursed Work ()					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

6.7. Preventive Maintenance (PM Service)

A sample design of report is given below. The report on Planned Preventive Maintenance should be submitted by service provider to institution and it should capture following isto be maintained hospital wise:-

<table>
<tr><td colspan="3">Name of organisation undertaking preventive maintenance</td><td>Report identification

No. .....</td></tr>
<tr><td>Reference ID as per inventory:</td><td></td><td>Hospital category:
Hospital Name:</td><td>PHC ( ) CHC ( ) SDH ( ) DH ( )
.....</td></tr>
<tr><td colspan="2">Equipment Name (as per UMDN/GMDN nomenclature/local name):</td><td colspan="2"></td></tr>
<tr><td colspan="2">Manufacturer details</td><td colspan="2">Name: .....
Year of Manufacturing:.....
Model Number:.....
Serial Number: .....
Date of Installation: .....</td></tr>
<tr><td colspan="2">Manufactures warranty period</td><td colspan="2">Start date: DD/MM/YYYY
End Date: DD/MM/YYYY</td></tr>
<tr><td colspan="2">Frequency of Preventive Maintenance</td><td colspan="2">(a) As per manufacturer guidelines/user manual/service manual:
.....
(b) In absence (a), bi-annual preventive maintenance:
Scheduled: MM/YYYY MM/YYYY</td></tr>
<tr><td colspan="2" rowspan="2">Preventive maintenance checklist</td><td colspan="2">a. Issued by Manufacturer in user manual/service manual (needs to be attached with report):
Yes, attached[ ]No [ ]……. (refer below point)</td></tr>
<tr><td colspan="2">b. In absence of (a), service provider may prepare checklist and attach same with this report.</td></tr>
<tr><td colspan="2" rowspan="2">List of spares replaced or used in preventive maintenance:</td><td colspan="2">a. Spare parts indicated by manufacture to replace (manufacture instructs spares which have finite life in user manual/service manual that needs to be replaced after certain cycles of operation or duration of working hours):
Yes, details of replacement attached[ ]No [ ]……. (refer below point)</td></tr>
<tr><td colspan="2">b. In absence of (a), service provider shall list parts to be replaced in preventive maintenance.</td></tr>
<tr><td colspan="3">Preventive Maintenance followed by calibration</td><td>Yes ( ) No ( )</td></tr>
<tr><td colspan="2">Credential of Engineer:</td><td colspan="2">Name: .....
Designation: .....
Signature: .....
Date: .....</td></tr>
<tr><td colspan="2">Credential of hospital nodal officer:</td><td colspan="2">Name: .....
Designation: .....
Signature: .....
Date: .....</td></tr>
<tr><td colspan="4">Any remarks on the functional Status of medical devices:</td></tr>
<tr><td colspan="4">Self-Declaration of Service provider: Staff conducting preventive maintenance behalf of this organisation is trained and qualified enough to conduct preventive maintenance on above mentioned medical device.</td></tr>
</table>

6.8. Calibration Services

Name of organisation undertaking Calibration					Certificate identification No. .....
Reference ID as per inventory:		Hospital category: Hospital Name:	PHC ( ) CHC ( ) SDH ( ) DH ( )		
Equipment Name (as per UMDN/GMDN nomenclature/local name):					
Calibration request via	Toll free number ( ) Corrective maintenance ( )	After scheduled Preventive maintenance ( )			
Manufacturer details	Name: ..... Year of Manufacturing:..... Model Number:..... Serial Number:				
Calibration Date	Date: DD/MM/YYYY ..... Next scheduled Date: DD/MM/YYYY				
Location at which Calibration is conducted	Hospital/Onsite ( ) Lab ( )				
Standard operating procedure or protocol followed for calibration as recommended by Manufacturer of medical devices. In case protocol/SOP are not available from manufacturer, service provider may develop own protocol,that shall ensure the function of medical device to satisfactory level for use in clinical diagnosis/treatment.					Manufacturer reference document No. ..... Self-developed SOP No. .....
External Environmental condition	Temp: ..... Humidity:				
Tools used for calibration	Name: ..... Serial Number: ..... Name: ..... Serial Number:				
Due date of calibration tool, Tracing number with NABL or other equivalent organisation or Manufacturer of tool.	Due date: ..... Tracing number:				
Test for electrical safety on medical device (only for electrical/electronic medical devices) *[Standard IEC 60601-1]*	Parameters	Measured Value	Reference range	Acceptable Tolerance	
Test on functional parameters of medical device used for clinical purpose.	Parameters	Measured Value	Reference range	Acceptable Tolerance	
Calibration Result	Corrective maintenance required ( ) Acceptable for clinical purpose ( )				
Credential of Engineer:	Name: ..... Designation: ..... Signature: ..... Date:				

Credential of hospital nodal officer:	Name: ..... Designation: ..... Signature: ..... Date: .....
Any remarks on the functional Status of medical devices:	
Self-Declaration of Service provider: Staff conducting preventive maintenance behalf of this organisation is trained and qualified enough to conduct calibration maintenance on above mentioned medical device. Also tools used for calibration are valid and calibrated with NABL or other equivalent national/international organisation or by Manufacturer of tool.	

6.9 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

		Rating System 1=Very Poor, 10 =Very Good									
1.	**Course Objectives:**										
	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 this program?	1	2	3	4	5	6	7	8	9	10
	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**

6.10 Training Attendance Record

Date		Event Type: Training ☐ Meeting ☐	
Venue		Trainer Name	
District		State	
Training Subject			

No	Employee Name	Dept.	Phone no/Email id	Signature

6.11. Summary – User Training Conducted

District	Hospital	Equipment	Trainer Name	No. of Staffs Attended

6.12. Summary – Equipment Newly Tagged

DISTRICT	HOSPITAL	QUANTITY	TOTAL PURCHASE COST
TOTAL			

6.13 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							

6.14. 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									

6.15. 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											

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

6.16. 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											

6.17. 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									

6.18. 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									

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

ANNEXURE

SAMPLES OF VARIOUS STICKER DESIGNS

CAUTION
OUT OF ORDER

Problem.....

Signed.....

Date.....

DANGER!

Do Not Use with AC Power Source

INSPECTED

Date
Due

By

BIOMEDICAL ENGINEERNG SERVICES

SAFETY CHECKED

BY.....

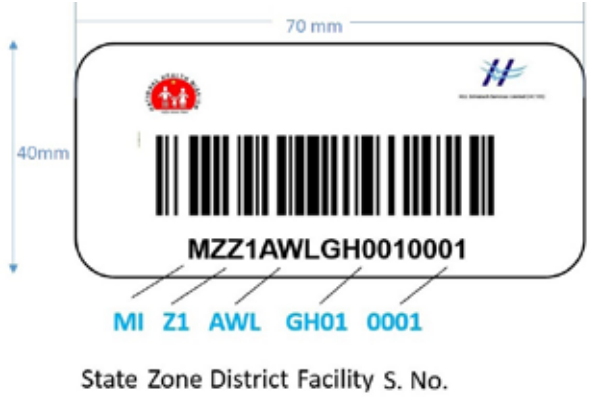
DATE.....

SERVICED

Date..... By

Due.....

	CAL	PM
Service Performed	☐	☐



GLOSSARY

Recognizing that there are multiple interpretations that exist for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of equipment, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life. It is used interchangeably with healthcare technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

Medical equipment: Medical equipment requiring calibration, maintenance, repair, user training, and decommissioning – activities usually managed by clinical engineers. Medical equipment is used for the specific purposes of diagnosis and treatment of disease or rehabilitation following disease or injury; it can be used either alone or in combination with any accessory, consumable, or other piece of medical equipment/ equipment. Medical equipment excludes implantable, disposable or single-use medical equipment.

Public private partnership: A long term contract whereby a public body associates a private sector enterprise in the financing, design, construction and operation of a public structure. The public structure could be provision of a service, maintenance of a system or creation of a new system and/or infrastructure.

Outsourcing: A form of contracting with pre-specified terms of financing, monitoring and supervision. Generally engaged over a longer time period, outsourcing is delegation of responsibility partially or wholly towards performance of a set of activities to achieve pre-specified results based on a mutually agreed form of reporting, monitoring, evaluation and performance.

Preventive maintenance: It is an action to eliminate the cause of a potential non-conformity. The care and servicing by personnel for the purpose of maintaining equipment and facilities in satisfactory operating condition by providing for systematic inspection, detection, and correction of incipient failures either before

they occur or before they develop into major defects, including tests, measurements, adjustments, and parts replacement, performed specifically to prevent faults from occurring.

Corrective maintenance: It is an action to eliminate the cause of a detected non-conformity. It is a maintenance task performed to identify, isolate, and rectify a fault so that the failed equipment, machine, or system can be restored to an operational condition within the tolerances or limits established for in-service operations.

Equipment breakdown rate: Also known as failure rate it is the frequency with which an engineered system or component fails. It is expressed in failure per equipment per hour /shift/day.

Upkeep time: It is the measure of the time a machine has been working or available.

Downtime: It is the period of time that a maintenance system fails to provide or perform its primary function in other words the time for which the dysfunctional equipment remains dysfunctional.

Maintenance contracts: It is the legal agreement normally conducted between two parties wherein the latter agrees to render the maintenance service annually to the formal in the exchange of a nominal amount. It ensures that the latter promises to provide maintenance services to the former all throughout the year on a regular basis. It includes service charges only. When charges include spare parts also it is termed as Comprehensive Maintenance Contract.

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, Mediciti 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 Agnani, Joint Secreatary (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 Mohammad Ameel, Sr. Consultant, NHSRC
8. Mr Bhaswat Kumar Das, Sr Consultant, RRCNE Guwahati
9. Mr Anjaney, Consultant NHSRC
10. Mr Ajai Basil, Consultant NHSRC
11. Mr Vigneshwaran, Consultant NHSRC
12. Mr Bharat Dahiya, Consultant NHSRC
13. Ms Akriti Chahar, Consultant NHSRC
14. Ms Sneha Mutreja, Consultant MoHFW
15. Mr Mohd. Zoheb, NHSRC
16. Ms Kesari Thukran, NHSRC
17. Mr. Pawan Kumar, NHSRC
18. Ms Purnima Dhamija, NHSRC

Notes

Notes

Ministry of Health & Family Welfare
Government of India, New Delhi