

MEDICAL EQUIPMENT MAINTENANCE POLICY (2012)



EMPLOYEES' STATE INSURANCE CORPORATION
Panchdeep Bhawan, C.I.G. Road,
New Delhi-110 002



FOREWARD

The Medical Equipment Maintenance Policy 2012 is a self-contained guidelines document for MSs/SMCs/SSMCs of ESIC/ESIS Hospitals, diagnostic centers, dispensaries & teaching institutions. This Policy will strive for effective and efficient maintenance of medical equipments used for diagnosis, treatment and prognosis of IPs, beneficiaries, staff & pensioners and also for educational purpose in ESI teaching institutions. This is for the first time that ESIC is bringing out a comprehensive manual for the maintenance of medical equipments.

I congratulate Dr. Surinder Kumar, Medical Commissioner and the dedicated band of officers and staff involved in preparation of this document. I believe this would go a long way in keeping the medical equipments used in ESIC/ESIS Hospitals in top working condition for long time.

Dr. C.S. Kedar
Director General

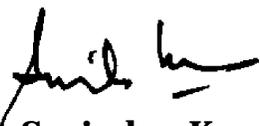


PREFACE

The ESI Corporation has been providing comprehensive social security to the workers and their families in the contingencies of sickness, disablement and death for over six decades. The Corporation has been continuously striving to improve and upgrade the facilities for delivery of benefits as well as the quality of services. For providing the best available healthcare to IPs, Beneficiaries, Staff and Pensioners, costly equipments of latest technology are being used in ESIC/ESIS Hospitals.

In order to maintain the costly medical equipments being used for the diagnosis, prognosis and treatment of IPs, Beneficiaries, Staff and Pensioners, the corporation has established its own Medical Equipment Maintenance Policy 2012. As the process of Medical Equipment Maintenance involves various procedures, need was felt to have a Medical Equipment Maintenance Policy incorporating Life cycle of the equipment, Inventory & Documentation, Commissioning & Acceptance of equipment, Breakdown maintenance, Planned preventive maintenance, Equipment Audit to provide self-contained guidelines for MSs/SMCs/SSMCs for effective and efficient maintenance of Medical Equipments in all ESIC/ESIS hospitals, diagnostic centers, dispensaries & teaching institutions.

I congratulate the team comprising of Dr. S.K. Jain (Dy. Medical Commissioner), Dr. N.K. Arora (Dy. Medical Commissioner), Dr. R.K. Sharma (Dy. Medical Commissioner), Dr. A.K. Vaid (Medical Superintendent), Sh. Manish Agarwal (Assistant Director), Sh. Nitin Juneja (Bio-Medical Engineer), Ms. Khushabu Paliwal (Bio-Medical Engineer) - Headquarters and all other MSs of various ESIC/ESIS Hospitals and SSMCs/SMCs for bringing out this comprehensive Medical Equipment Maintenance Policy. I hope this document will serve the purpose it is meant for.


Dr. Surinder Kumar
Medical Commissioner



INDEX

1. Terminology	1
2. Introduction	2
3. Mission	2
4. Objective	2
5. Life Cycle of the Equipment	3
6. Equipment Maintenance Guidelines	3
I. At ESIS/ESIC Hospital Level	4
1. Inventory & Documentation	4
2. Commissioning & Acceptance of equipment	6
3. Monitoring of use and performance	6
4. Maintenance of equipment	7
5. Equipment Audit	16
6. Training & Development	17
II. At ESIC Hqrs. (Procurement Cell) Level	18
7. Organizational Structure	19
8. Summary	21
Appendices:-	
Annexure - I	22
Annexure - II	23



2. INTRODUCTION

Employees' State Insurance Corporation has a number of hospitals (149), dispensaries (1402), few Medical/Dental/Post Graduate health institutes (PGIMSR) and some new Medical Institutions are in pipeline too. There is a need of large number of medical equipments for providing the best health care services to our IPs, staff & beneficiaries. In addition, we need medical equipment for teaching as well as research purpose.

There is a necessity of certain guidelines to be followed by the users of medical equipment so as to have maximum life of the equipment with minimum downtime and let these equipments give the accurate results during their life.

This policy has been developed to ensure that medical equipment is stored, deployed and maintained in such a way that the risks inherent in its use i.e. safety, radiation effect etc. are minimised and accurate & reliable results are provided by these equipments.

The Policy aims to ensure that whenever medical equipment is used, it is:

- Suitable for its intended purpose
- Properly understood by appropriately trained users
- Maintained in a safe and reliable condition.

Keeping Medical device safe and effective will require planned preventive maintenance and breakdown maintenance services carried out by competent people.

3. MISSION OF THE POLICY

To maintain all medical equipments to the appropriate standards as prescribed by equipment manufacturer, so as to ensure that all medical equipments to be used to provide the best health care services to patients (IPs, staff, pensioners & beneficiaries) should be safe, efficient, effective, reliable and long lasting.

4. OBJECTIVES OF THE POLICY

This Policy is intended for the maintenance of medical equipment that ensures:

- a. Maximum availability and reliability of equipments
- b. Minimum downtime and Maximum Uptime

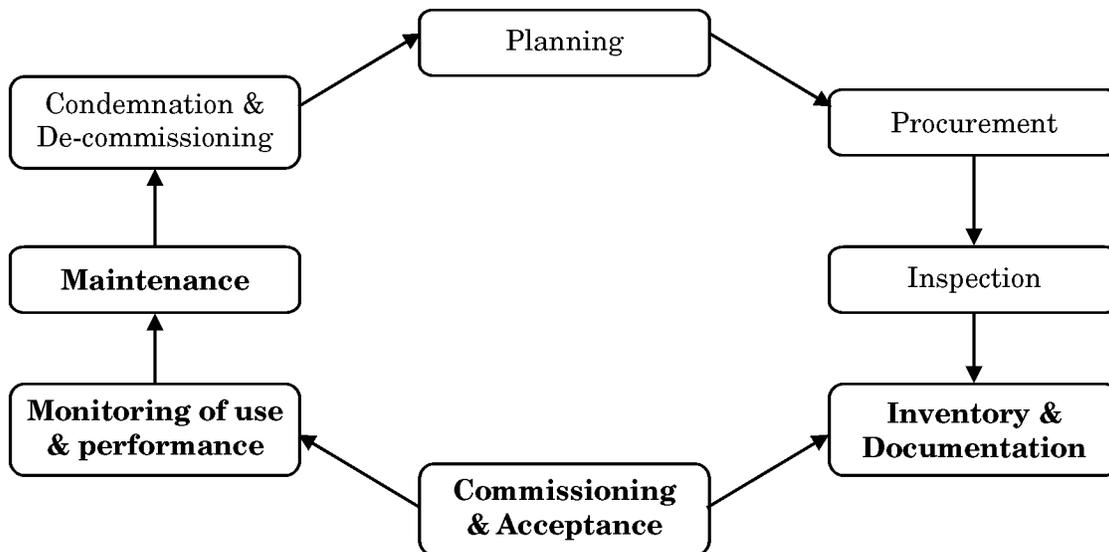


- c. Maximum return on investment
- d. Prevention of wastage of consumables and spares
- e. Extended useful life of equipments
- f. Readiness of the equipment for emergency use whenever required

5. LIFE CYCLE OF MEDICAL EQUIPMENT

The delivery of the best healthcare services depends heavily on medical equipment, whether for life support, for diagnosis, for patient monitoring, or for the delivery of therapies or teaching and research purpose. The risks associated with the use of medical equipment can only be controlled by managing the whole life-cycle of the equipment.

Life cycle of Medical Equipment



The bolded phases of the lifecycle of the equipment have been covered in this document.

6. STRATEGY: EQUIPMENT MAINTENANCE GUIDELINES to be followed at:

- I. ESIS/ESIC Hospital Level**
- II. ESIC Hqrs. (Procurement Cell) Level**

Details are given below:



6(I). GUIDELINES TO BE FOLLOWED AT ESI HOSPITAL LEVEL

The tasks to be performed at hospital level are related to:

- (i) inventory & documentation
- (ii) commissioning & acceptance
- (iii) monitoring of use & performance
- (iv) maintenance of the equipment.

6I(1). Inventory and Documentation

*** It should be mentioned in the Tender Enquiry Document while floating the tender that manufacturer/supplier has to provide CMC (for all the major equipment(s)) for atleast three to five years after expiry of warranty period.**

Inventory provides information to support different aspects of medical equipment management.

The inventory of Medical Equipments should be maintained department wise at store level for the equipments:

- Purchased at MS/SMC/SSMC Level and
- Purchased through Procurement Agency (if any)

The inventory record includes the following details:

1. Reference ID
2. Equipment Name
3. Company/Make (with contact details)
4. Serial no.
5. Date of Indent
6. Tender No. /Local Purchase
7. NOA no. (With date)
8. Cost per unit
9. Date of issue of CRC (Consignee receipt certificate)



- **Insurance** - If the Costly Equipments are not covered under AMC/CMC, then they should be got insured so that if any breakdown occurs the expenditure incurred for the same can be claimed from the Insurance Provider.

6I(2). COMMISSIONING AND ACCEPTANCE OF THE EQUIPMENT:

The competent authority should ensure installation and commissioning of the equipment by manufacturer/supplier. The process should be monitored by in-house technical staff so that any technical matters can be noted and recorded in the Maintenance Register (*Annexure- II*). This occasion also provides an excellent opportunity for in-house technical staff to gain familiarity with the new item and its operation. Ideally, in-house technical staff should also attend the operator's training session.

It is particularly important to bear in mind that normally the manufacturer/supplier's warranty starts the day equipment is installed in the hospital. If equipment is not going to be used for some time after delivery, special arrangements must be made with the supplier to define the warranty period. Such an agreement should preferably be made in the purchase order. Final Acceptance Certificate (FAC) to the supplier should not be issued before the satisfactory performance has been confirmed by the in-house technical staff.

Regarding equipment with Turnkey project like CT/MRI Scanner, CSSD etc., the details will be handed over by the agency to the store manager or Medical Superintendent or authorized person in the presence of Head of the Department and in-house staff.

6I(3). MONITORING OF USE AND PERFORMANCE:

It is important that user should make a safe use of the equipment and also continuously monitor the performance of the equipment. User should also keep a direct link with manufacture/supplier/service provider and observe any supplier's technical services. Such services should be recorded in the Maintenance Register (*Annexure- II*). This will also provide a good learning opportunity for the in-house user.

Many equipment will require daily/weekly inspection and simple maintenance. This type of maintenance is vital for the continuous, safe, effective and reliable operation of medical equipment so as to get accurate and reliable results.



Daily/Weekly Inspection and Maintenance includes:

- a. Visual Inspection
- b. Performance Tests
- c. Calibration
- d. Checkout etc.

These tasks can and must be carried out by the users as per the manufacturer's instructions and suitable documentation should also be maintained for the same. Any discrepancies if found, should be brought into the notice of the controlling authority for necessary corrective action.

6I(4). MAINTENANCE OF THE EQUIPMENT :

Proper maintenance of medical equipment is essential to obtain sustained benefits and to preserve capital investment. Medical equipment must be maintained in working order and periodically calibrated for effectiveness and accuracy of the results.

The Maintenance consists of:

- a. Planned Preventive Maintenance**
- b. Breakdown Maintenance**

a. Planned Preventive Maintenance (PPM)

Planned Preventive Maintenance involves maintenance performed to extend the life of the equipment and prevent its failure. Planned Preventive Maintenance is usually scheduled at specific intervals and includes specific maintenance activities such as lubrication, calibration, 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.

Planned Preventive maintenance will be a statutory requirement for most of the medical equipments. It will enhance the efficiency, effectiveness and reliability of medical equipment and must be carried out at appropriate frequency as suggested by the manufacturer/service provider.



Each equipment on the inventory will show whether it is

- a. maintained in-house
- b. maintained by external agency or manufacturer.

The conditions for preventive maintenance required for medical equipment can vary due to factor such as type of equipment, age of the equipment, frequency of use of the equipment, etc.

The record of Planned Preventive Maintenance should be maintained department wise and must include following details:-

1. Reference ID as per inventory
2. Equipment Name
3. Company/Make
4. Serial No.
5. Date of Installation
6. Warranty Period
7. Under AMC/CMC
8. Frequency of Preventive Maintenance/Calibration
 - a. as per manufacturer guidelines
 - b. presently being followed
9. Preventive Maintenance/Calibration Done On
10. Preventive Maintenance/Calibration Due On
11. Expenditure with cost and details
12. Remarks with Functional Status

The record should be maintained in table form as given in *Annexure-II*.

Here is given the frequency of Planned Preventive Maintenance (PPM) of some of the medical equipment as a guideline.



Table showing broad based basic frequency of Planned Preventive Maintenance of some of the equipments is as given below:

S.No.	Equipment Name	Frequency*
1	X-Ray (Complete System)	Quarterly
2	CT Scanner (Complete System)	Quarterly
3	MRI Scanner (Complete System)	Quarterly
4	Mammography (Complete System)	Quarterly
5	Cath Lab System	Quarterly
6	C-Arm Machine	Quarterly
7	Heart & Lung Machine	Quarterly
8	Arterial Blood Gas analyzer	Quarterly
9	Electrosurgical Unit	Quarterly
10	Autoclave	Quarterly
11	Ultrasonic Washer	Quarterly
12	Dental X-Ray Machine	Quarterly
13	Ultrasound Machine	Half Yearly
14	IABP (Intra aortic balloon pump)	Half Yearly
15	Echocardiography Machine	Half Yearly
16	TMT Machine	Half Yearly
17	PFT Machine	Half Yearly
18	Patient Monitor	Half Yearly
19	Cardiac Monitor	Half Yearly
20	ECG Machine	Half Yearly
21	Defibrillator	Half Yearly
22	Anesthesia Machine	Half Yearly
23	Ventilator	Half Yearly

** These are broad guidelines. However, frequency can be altered depending upon manufacturer's guidelines*



S.No.	Equipment Name	Frequency
24	OT Table	Half Yearly
25	OT Light	Half Yearly
26	Suction Machine	Half Yearly
27	Insufflators	Half Yearly
28	Endoscope/Laparoscope	Half Yearly
29	Syringe & Infusion Pump	Half Yearly
30	Infant Warmer	Half Yearly
31	Phototherapy Unit	Half Yearly
32	Fetal Doppler	Half Yearly
33	Patient Bed	Half Yearly
34	Pulse Oximeter	Half Yearly
35	ACT Machine	Half Yearly
36	Tourniquet System	Half Yearly
37	Blood and Fluid Warmer	Half Yearly
38	Electromyogram Machine	Half Yearly
39	Electroencephalogram Machine	Half Yearly
40	Bi-Pap Machine	Half Yearly
41	Humidifier	Half Yearly
42	Holter System	Half Yearly
43	Pace Maker	Half Yearly
44	Bubble CPAP (Continuous positive airway pressure) System	Half Yearly
45	Infant Resuscitator	Half Yearly
46	Microwave Diathermy	Half Yearly
47	Hot Pack Unit	Half Yearly
48	Traction Unit	Half Yearly
49	Continuous Passive Motion System	Half Yearly



S.No.	Equipment Name	Frequency
50	Cold Pack unit	Half Yearly
51	Ultrasonic Tens System	Half Yearly
52	Hemodialysis Machine	Half Yearly
53	Continuous renal replacement therapy (CRRT) Machine	Half Yearly
54	Donor Couches	Half Yearly
55	Microscopes	Half Yearly
56	Centrifuge/Cryofuge	Half Yearly
57	Hot Plate	Half Yearly
58	Cell Counter	Half Yearly
59	Cell Separator	Half Yearly
60	PH Meter	Half Yearly
61	Refrigerator	Half Yearly
62	Deep Freezer	Half Yearly
63	Bio-safety Cabinet	Half Yearly
64	Water Bath	Half Yearly
65	Laminar Flow	Half Yearly
66	Incubator	Half Yearly
67	Urine Analyzer	Half Yearly
68	Micropipettes	Half Yearly
69	Weighing Balance	Half Yearly
70	Plasma Thawing Bath	Half Yearly
71	Platelet Agitator	Half Yearly
72	Tube Sealer	Half Yearly
73	ELISA Reader	Half Yearly
74	Immuno Assay System	Half Yearly
75	Microtome	Half Yearly



S.No.	Equipment Name	Frequency
76	Refractometer	Half Yearly
77	Ophthalmoscope	Half Yearly
78	Slit Lamp	Half Yearly
79	Keratometer	Half Yearly
80	Auto Perimeter	Half Yearly
81	Image Capturing system	Half Yearly
82	Dental Chair	Half Yearly
83	Dental Sterilizer	Half Yearly
85	Lithotripsy Machine	Half Yearly
86	Lithotripsy Table	Half Yearly
87	Uroflowmeter	Half Yearly
88	ENT Examination Unit	Half Yearly
89	Harmonic Scalpel System	Half Yearly
90	Chest Vibrator	Half Yearly
91	Fibrillator	Half Yearly
92	VDRL Rotator	Half Yearly
93	Hormone Analyzer	Half Yearly
94	Air Sampler	Half Yearly
95	Wax Bath	Half Yearly
96	Surgical/Operating Microscope	Half Yearly
97	Phaco-emulsification Machine	Half Yearly
98	Tissue Flotation Bath	Half Yearly
99	Vortex Mixer	Half Yearly
100	Transport Incubator	Half Yearly

This is not the end of the list; other equipments may also be added in the list as per the requirement of the ESIC Health Institution(s).



User department should:

1. Record details of the defect(s).
2. Attach label to the faulty equipment(s).
3. Contact Service engineer of manufacturer/supplier/hired agency by telephone number/fax/email supplied and keep a record of the same.
4. Ensure that information regarding breakdown is passed to all staff, including any shift changes and head of the institution.

All the breakdowns occurring in the department should be maintained on record and must include following details:-

1. Reference ID as per inventory
2. Equipment Name
3. Company/Make
4. Serial No.
5. Date of Installation
6. Warranty period
7. Under AMC/CMC
8. Breakdown Date and Time
9. Breakdown Details (Technical fault or other reasons)
10. Date and Time of Rectification
11. Total Time Taken (Rectification Time – Breakdown Time)
12. Rectification Details with expenditure including cost (if any)
13. Remarks with functional status

The record should be maintained in the table form as given in *Annexure-II*

Note: - The replacement of the defective part(s) should be done at the earliest feasible after taking the necessary concurrence from the finance department and sanction from the Competent Authority. The reason(s) for the delay if any, should be recorded.



Information regarding Planned Preventive Maintenance and Breakdown Maintenance can be kept on a single sheet. The desired information recorded and analyzed are as given below (also given in Annexure – II)

S.No.	Information	
1.	Reference ID	} "Information about the equipment"
2.	Equipment Name	
3.	Company/Make	
4.	Serial No.	
5.	Date of Installation	
6.	Warranty Period	
7.	Under AMC/CMC (with cost)	
8.	Average Life (as per manufacturer)	
9.	Contact details of the company (manufacturer/supplier)	
10.	Location of the equipment	
11.	Contact details of External contractor (if any)	
12.	Frequency of Preventive Maintenance/Calibration	} "Information about PPM of the equipment"
a.	as per manufacturer guidelines	
b.	presently being followed	
13.	Preventive Maintenance/Calibration Done On	
14.	Preventive Maintenance/Calibration Due On	
15.	Expenditure with cost and details	
16.	Remarks of Service Engineer	
17.	Remarks of HOD/User	
18.	Breakdown Date and Time	} "Information about Breakdown of the equipment"
19.	Breakdown Details (Technical fault or other reasons)	
20.	Date and Time of Rectification	
21.	Total Time Taken (Rectification Time – Breakdown Time)	
22.	Rectification Details with expenditure including cost (if any)	
23.	Remarks of Service Engineer	
24.	Remarks of HOD/User	

Note: - Due care should be given for the safety and security of the equipment so as to prolong its active life.



6I(5). Equipment Audit

Equipment audit is a periodic evaluation system to measure the quality of performance of the medical equipments.

At any given point of time, a substantial number of equipment in the hospital may be non-functional. The reasons for the same could be:

1. Want of Minor repairs
2. Lack of Preventive Maintenance
3. Lack of corrective Maintenance
4. Lack of essential Spares
5. Electrical Faults
6. Unfavorable environmental conditions
7. Mishandling of equipment by untrained and unskilled manpower
8. Purchase of equipment without justifiable demand etc.
9. False Reporting, Willful Damage and Overuse than rated

For this, there is a need for periodic evaluation of the quality of performance of the equipment in a hospital. If such an audit is performed, it will be an advantage to all ESI Hospitals so that not only better utilization of medical equipment is ensured but also it contributes to the improvement in the quality of health care to beneficiaries and judicious use of resources.

The Equipment Audit should be done by a committee (Equipment Audit Committee) at Hospital Level on half yearly basis.

The Equipment Audit Committee should consist of:

1. The Medical Superintendent/designated medical officer of the hospital
2. The head of the concerned department
3. Head of maintenance (If Posted)
4. Representative from Administration
5. Representative from Finance Department
6. Hospital Store In-charge
7. Nursing Superintendent



Focus of the Audit is to:

1. Check the current status of the medical equipment
2. Analysis of the records such as Breakdown Register, Preventive maintenance Register
3. Questioning the user about the usage and performance of the equipment.
4. Suggesting measures to optimally utilize the equipment for quality health services.

Advantages of the equipment audit are to:

- Evaluate the performance and utilization of the equipment
- Provide an objective method for planning of equipment procurement in future
- Analyze various inadequacies (including downtime) in the utilization of an equipment and recommendation of remedial measures (including training to the users) so as to maximize the efficiency and effectiveness of the equipment.

6I(6). Training and Development

For the safety of the patient and the user, proper training is critical for both the user and the technical staff. Training and education is not a one-time activity but a continuous process.

Training may be:

1. In-House
2. At recognized institutions

1. In-House Training

- a. For operating the equipment – to be given by Manufacturer/Supplier periodically and preferably to be mentioned in Tender Enquiry Document.
- b. To deal with routine maintenance and repairs
 - Use of tool kit
 - Knowledge about common and recurrent causes of failure of the equipment and how to rectify minor causes of failure
 - Calibration of the equipment



2. Training outside at recognized institutions – workshops etc.

- a. For operating the equipment (if required)
- b. To deal with routine maintenance

**6(II). GUIDELINES TO BE FOLLOWED AT ESIC HQRS.
(PROCUREMENTCELL) LEVEL**

The tasks to be performed at ESIC Hqrs. level:

1. To assist Head of the ESI Institutions in planning, managing and implementing the maintenance of medical equipment with the help of Bio-Medical Engineer(s) whenever request received.
2. Maintaining information obtained from all ESI Hospitals regarding Inventory, Planned Preventive Maintenance (PPM) and Breakdown.

The information received will be kept hospital-wise as well as equipment-wise in the format given in Annexure-I & II.

3. Analyzing the above information for Quality Management of Medical equipments being used at different ESI Health Institutions. This will be done through assessment and analysis of:
 - a. **Downtime of Major Equipments** such as in OT, ICU, Imaging, Dialysis and Laboratory etc. It needs to be compared quarterly.

Formula: -

$$\text{Downtime of equipment} = \frac{\text{Total Breakdown time}}{\text{Total Uptime}} \times 100$$

- b. **Maintenance Cost Index***

$$\text{Formula :-} \frac{\text{Maintenance Cost}}{\text{Capital Cost}} \times 100$$

* To check that maintenance cost should not increase 80% of the capital cost of equipment.

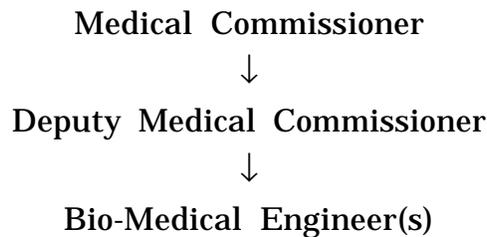
The above information will help in issuing necessary guidelines to ESI Health institutions (whenever required) in relation to maintenance of equipment.



Technician:

1. Safe & sound use of the equipment
2. Periodic (Daily/Weekly etc.) maintenance of the equipment.
3. Frequent communication with Sr. Technician and designated persons.

II. At ESIC Hqrs. Level



Medical Commissioner:

1. Guiding Deputy Medical Commissioner about the actions to be taken in relation to equipment maintenance at various hospitals.
2. Informing to Director General about the actions taken in relation to equipment maintenance policy.
3. Interference if problem is not solved at MS/ DMC level.

Deputy Medical Commissioner:

1. Supervision and monitoring the work of Bio-Medical Engineer(s)
2. Guiding Bio-Medical Engineer in maintaining records
3. Issuing necessary instructions to all ESI Hospitals whenever required.
4. Informing Medical Commissioner about the actions taken in relation to equipment maintenance policy.



Bio-Medical Engineer:

1. Guiding Head of the Institution(s) regarding maintenance and providing information to Deputy Medical Commissioner about the status of equipment and their functioning at various ESI Hospitals.
2. Maintaining the Inventory/PPM/Breakdown record hospital wise where the cost of the equipment is more than 10 Lakh rupees per unit and analyzing them. To suggest measures in appropriate situations.
3. Calculating Downtime of the equipments & maintenance cost index periodically, comparison with other ESI Health Institution(s) having the same equipment and suggesting measures.

There will be a frequent contact between functionaries at ESI hospitals and ESIC Head quarters through correspondence telephone/email/fax.

Note: - Once IT Roll out is fully operational, the data fed can be utilized at Head Quarters and periphery at the same time.

7. SUMMARY:

To provide the best healthcare services, there is a need of the best quality medical equipment which helps in diagnosis, treatment, monitoring of patients (IPs, Staff & beneficiaries). Some of the equipments are also to be used for teaching and research purpose. These guidelines have been framed to keep these equipments well maintained so as to get the accurate results in order to provide the best healthcare services to IPs, staff & beneficiaries. It is expected that these guidelines shall be followed by all in true spirit so to achieve our (ESIC) objectives and mission.

