

UNIT – II MEDICAL TECHNOLOGY MANAGEMENT PRACTICES 9

Strategic Medical Technology Planning, Scope , Clinical necessity operational support, strategic planning process - Technology assessment: Technology audit, Budget strategies, Pre requisite for medical technology assessment - Management Practice for Medical Equipment - Device evaluation, Risk reduction, Asset management, ESHTA

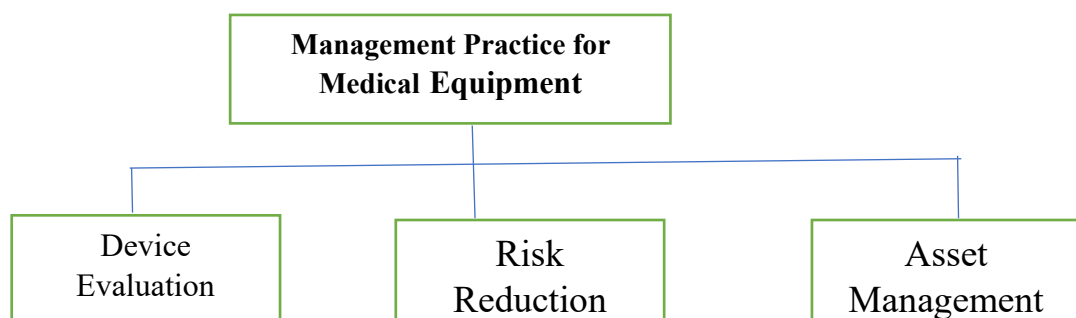
this.)

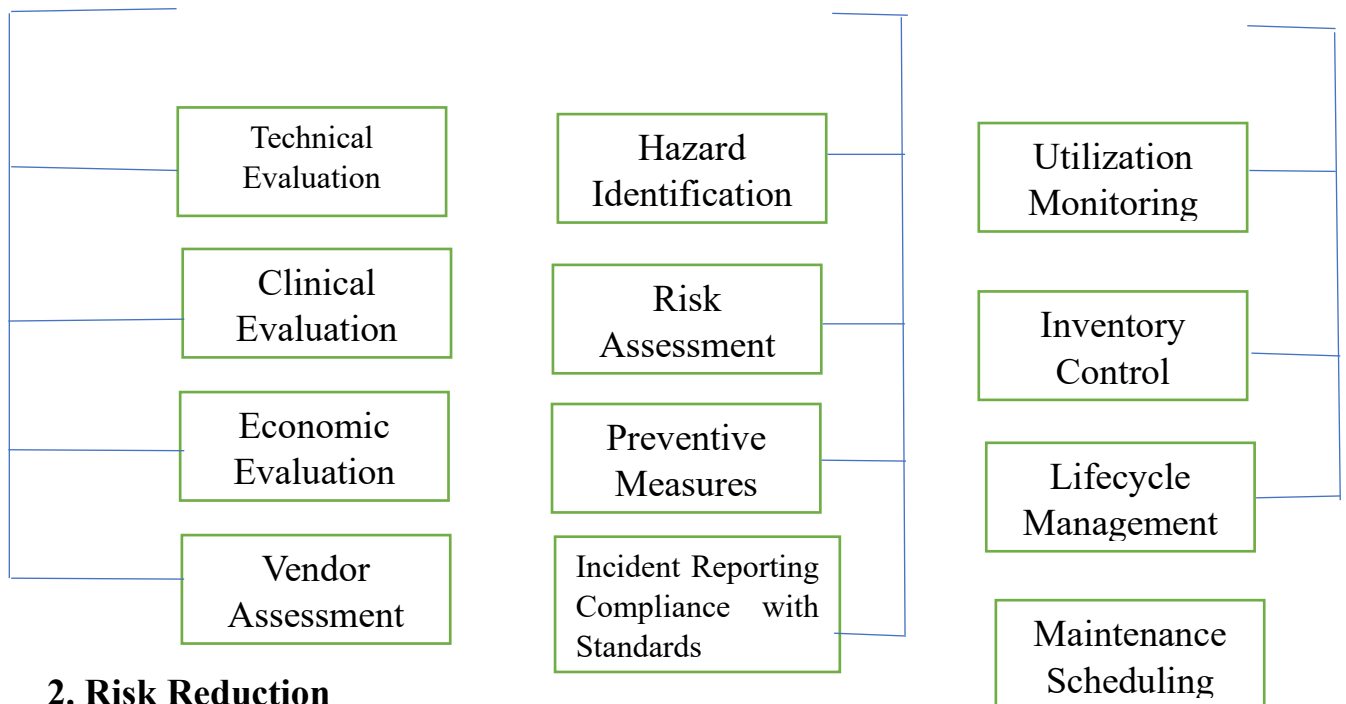
5.Management Practice for Medical Equipment

The overall objective of the Medical Device Equipment Management Policy is to provide an organisation wide framework for the management of Medical Device Equipment and to make sure that the highest standards of device safety, risk management and financial efficiency are obtained in the management of the device

1. Device Evaluation

- **Technical Evaluation:**
 - Evaluate the functionality, performance, and durability of medical equipment.
 - Compare specifications with clinical requirements and standards.
- **Clinical Evaluation:**
 - Evaluate how effectively the device supports for patient care.
 - Evaluate ease of use, patient safety, and outcomes.
- **Economic Evaluation:**
 - Conduct cost-benefit analysis (purchase, maintenance, operation).
 - Consider lifecycle costs (purchase + maintenance + disposal).
- **Vendor Assessment:**
 - Review after-sales service, training, and support capabilities.





2. Risk Reduction

- **Hazard Identification:**
 - Analyze potential risks (e.g., electrical hazards, mechanical failure, software bugs).
- **Risk Assessment:**
 - Use methods like Failure Modes and Effects Analysis (FMEA) or Hazard Analysis and Critical Control Points (HACCP).
- **Preventive Measures:**
 - Implement preventive maintenance, user training, and safety checks.
 - Regular calibration and performance testing.
- **Incident Reporting:**
 - Maintain a system for reporting adverse events and device malfunctions.
 - Conduct root cause analysis for incidents.
- **Compliance with Standards:**
 - Follow IEC 60601, ISO 13485, and local regulatory guidelines.

3. Asset Management

- **Inventory Control:**

- Maintain detailed records (model, serial number, location, purchase date).
- Use Computerized Maintenance Management Systems (CMMS) for tracking.

- **Lifecycle Management:**

- Monitor acquisition → usage → maintenance . How long could it be used.
- Plan for timely upgrades or replacement.

- **Utilization Monitoring:**

- Evaluate usage rates to optimize availability and avoid downtime.
- Reduce idle equipment and ensure resource optimization.

- **Maintenance Scheduling:**

- Create PM (Preventive Maintenance) and CM (Corrective Maintenance) plans.

Preventive maintenance (PM) involves activities that are carried out in the routine maintenance and servicing of software and systems to avoid future problems

Corrective Maintenance (CM) is used to restore a system, machine, or software to its optimal working condition after a failure

- Track downtime and repair history.