Clinical Engineering

Dr. Ahmed Abdelhamid Torki

Ph.D. Biomedical Engineering & System

Consultant Assessment & Development of Healthcare Facilities

Board Member of the Egyptian Biomedical Engineering Society

https://www.linkedin.com/in/dr-ahmed-abdelhamid-torki-a3518a95

https://www.linkedin.com/groups/9312944

https://www.facebook.com/dr.atorki?mibextid=

https://ebmes.com/

https://www.linkedin.com/company/ebmes/

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2024

Competency = Knowledge/Skills/Abilities

Knowledge	Skills	Ability
Knowledge is the theoretical or practical understanding of a subject	Skills are the proficiencies you develop through training or experience	Ability is the quality of being able to do something
Acquired through learning or experience	Practiced or learned behavior	Natural or inbuilt
Ex: knowing how to bake a cake (theory)	Ex: having baking and cooking skills or practice in baking	Ex: having natural abilities like attention to detail
Knowledge increases with experience	Skills can be developed with practice	Ability can be improved to a certain extent

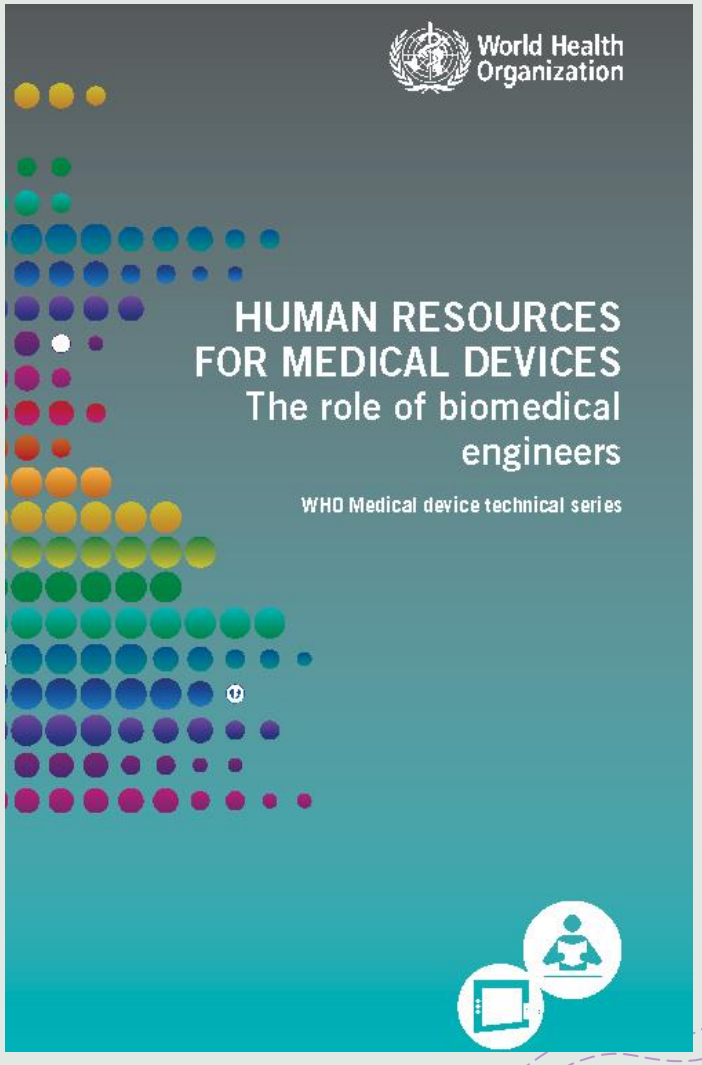
Pediaa.com

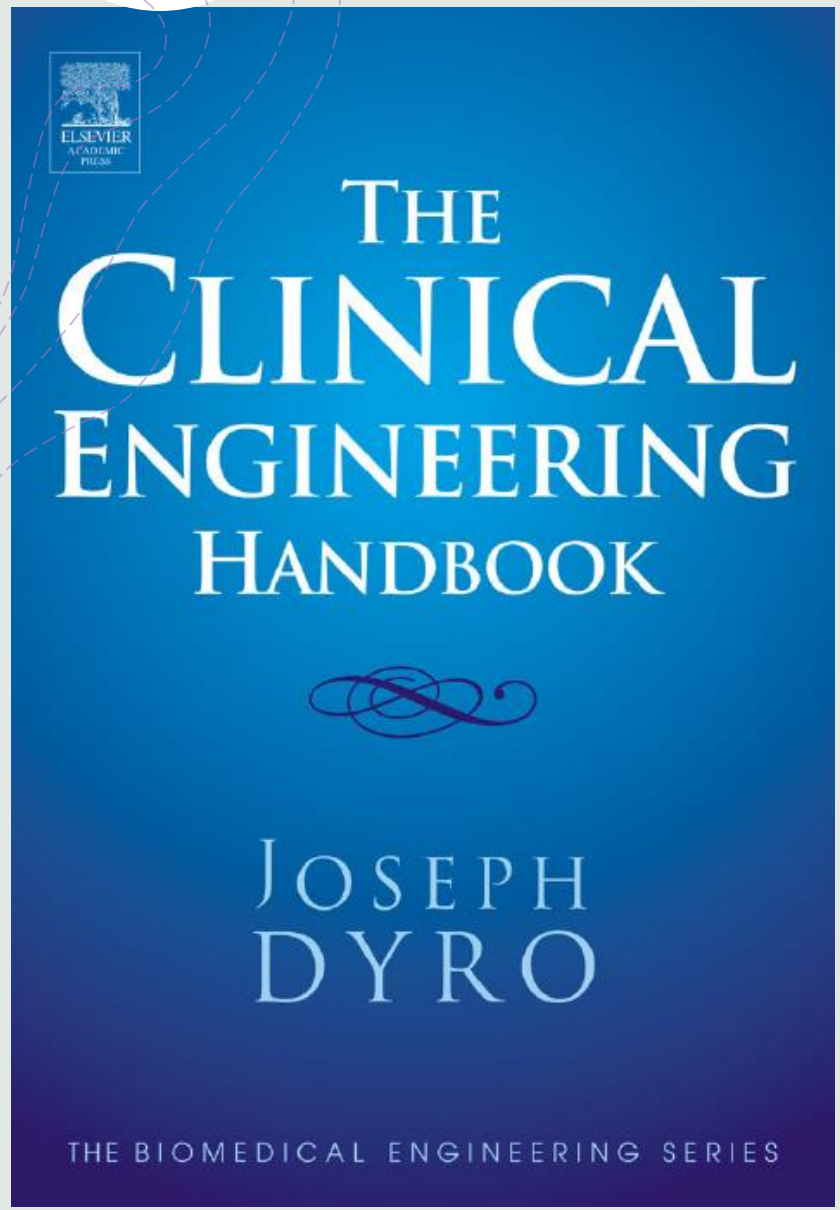
How to Choose Career and excel in it??

What is Clinical Engineering??

During the 2015 Global Clinical Engineering Summit

"Applying knowledge of engineering and technology to health-care systems to optimize and promote safer, higher quality, effective, affordable, accessible, appropriate, available, and socially acceptable technology to populations



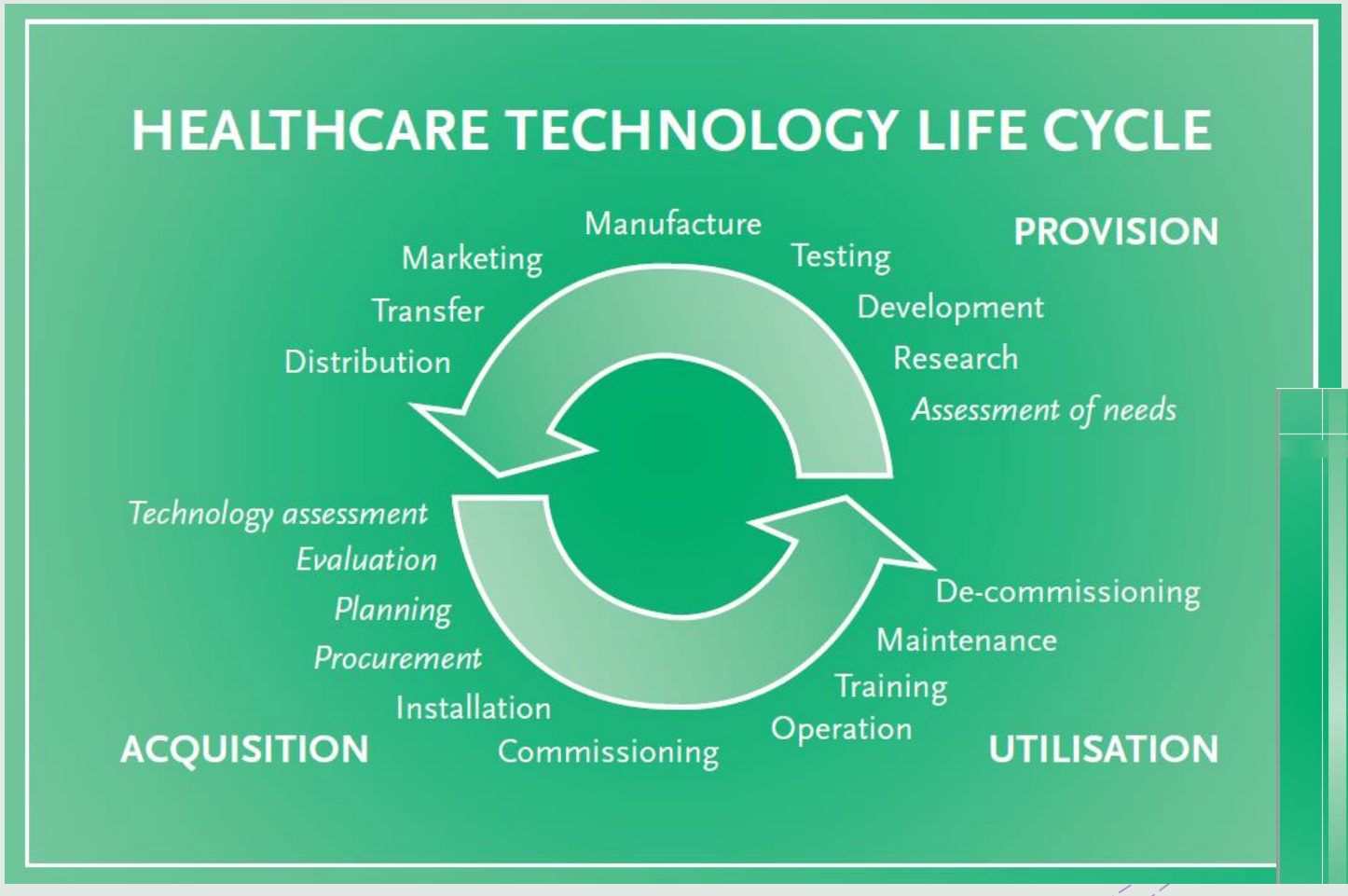


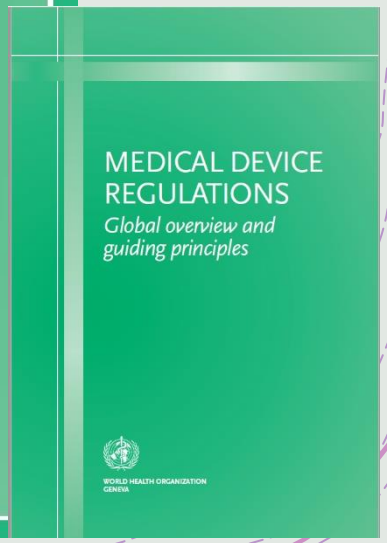
The American College of Clinical Engineering defines a clinical engineer (CE) as:

"A professional who supports and advances patient care by applying engineering and managerial skills to health care technology."

Clinical engineering is a subset of biomedical engineering. Whereas biomedical engineering is practiced primarily in academic institutions, the research laboratory, and manufacturing, clinical engineering is practiced in hospitals and other environments where medical device technologies are utilized.

Health care Technology Life cycle





Medical Equipment Management

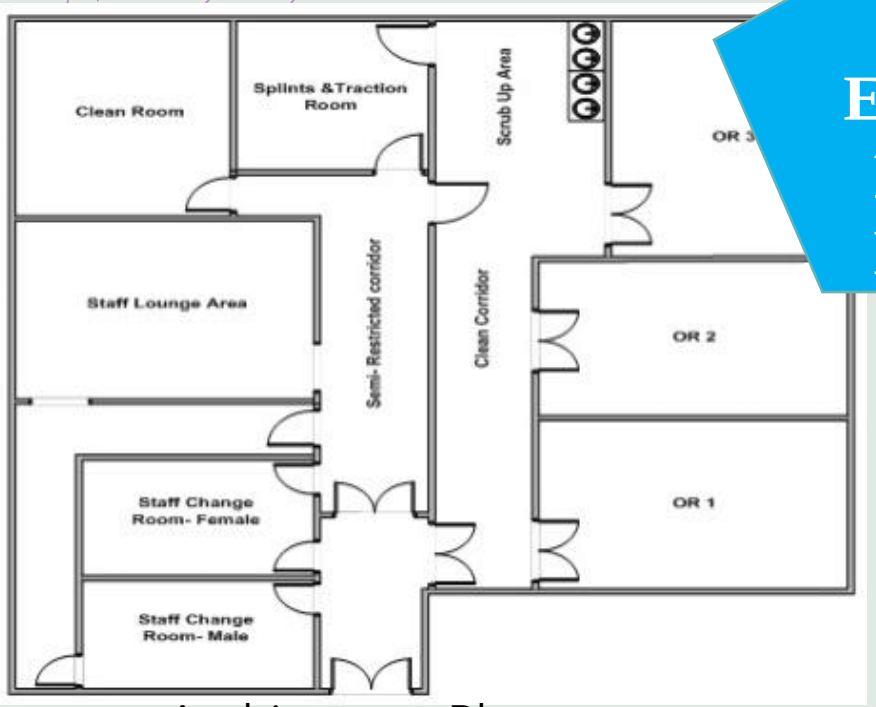
Quality of Patient Care

Return on Investment

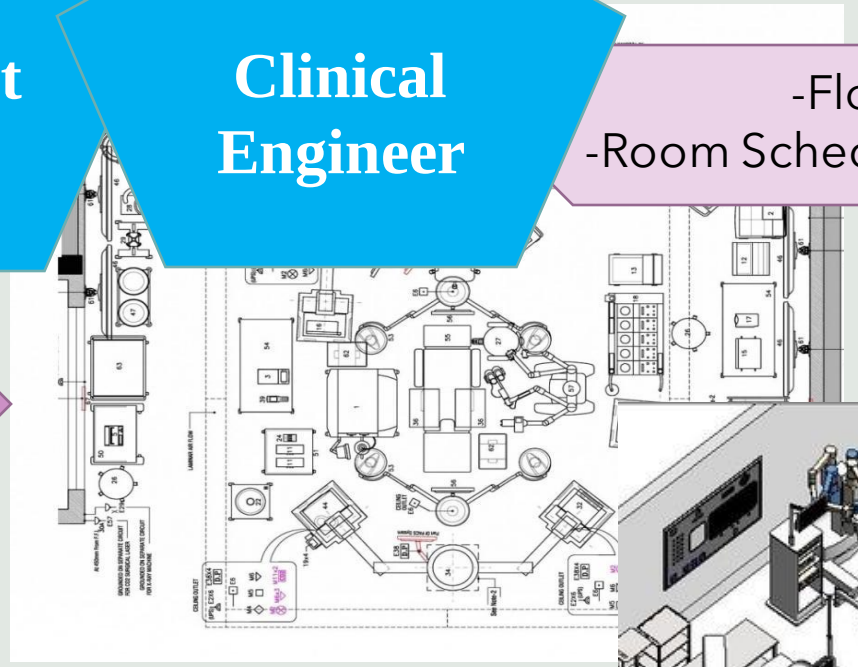
Hospital Planning & Construction Phase

Medical Equipment Planning Engineer

Clinical Engineer



Architecture Plans



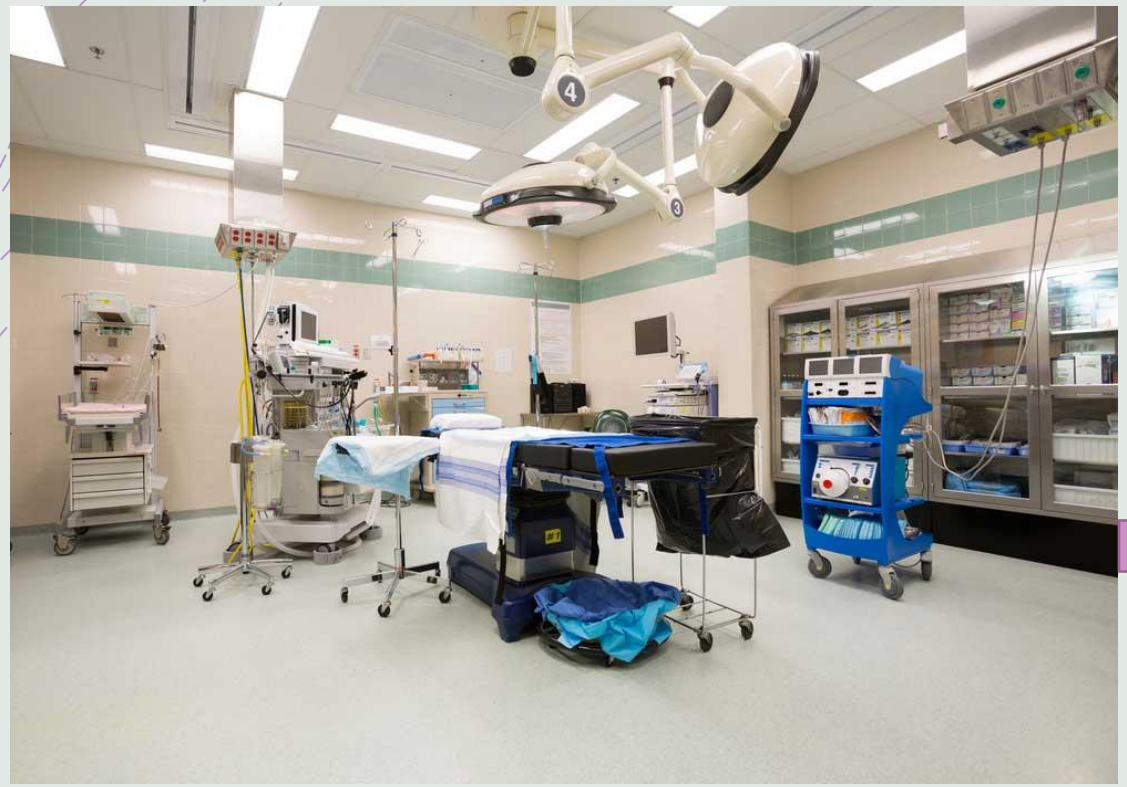
-Floor Plans
-Room Schedules (Datasheets)

-Medical and Functional Needs
-Medical Equipment (datasheet) Cutsheet
-Room by Room

Building Information Modeling (BIM)

https://www.researchgate.net/figure/First-case-modified-OT-layout-plan_fig2_256457508
https://www.omnia-health.com/product/room-data-requirement-drawings-uhs-hospital-designers-medical-equipment-planners?Bibblio_source=footer
https://shoptly.com/bim1modeler

Acquisition Phase



Medical Equipment Planning Engineer

Clinical Engineer

-Bill of Quantities
-Technical Specifications and Mandatory Conditions
-Procurement (Selection & Negotiation)
-Receiving & Installation & Testing & Training

Operation Phase

Clinical Engineer

- Risk Management including
  - Risk Assessment
  - Troubleshooting & Repairs & Corrective Maintenance
  - Planned Preventive Maintenance & Related Output Verification and Calibration
  - Daily Inspection Round
  - Incident Investigation
  - Hazard Alerts/Recalls
  - Decommissioning
- Cost Optimization including
  - Service Agreements
  - Spare Parts Management
  - Cost Analysis
  - Maintenance Budget Planning
- Quality Management including
  - Policies & Procedures
  - Key performance Indicators
  - Inventory & Work Order Management
  - Staff Continuous Education

Knowledge in Clinical Engineering

- Hospital departments, their purpose and workflow and rooms relations and spaces
- Knowledge about Various Medical equipment:
  - *Locations (Rooms & Departments and Floors)*
  - *Purpose, basic functions including related Anatomy and Physiology*
  - *Block diagram including related electro-mechanical fundamentals*
  - *Environmental and MEP requirement for medical equipment*
  - *Installation & Site Preparation basic procedures*
  - *Commissioning basic Procedures*
  - *Periodic Inspection & Preventive Maintenance basic procedures*
  - *Testing &Verification & Calibration Concepts and basic procedures*
  - *Troubleshooting and Corrective Maintenance techniques*
  - *Incident Analysis & Corrective Actions*

Experiences in Clinical Engineering

- All Types of Maintenance on all types of equipment
- Extraction data from operational and service manuals
- Work Order Management
- Contracting Management
- Safety in hospitals
- Healthcare Information Technology

Skills in Clinical Engineering

- Troubleshooting, Reasoning & problem-solving skills
- Hand skills of repair and utilization of tools and testers
- Oral and written communication skills
- Teamwork and collaboration skills
- Management and Decision-making skills
- Negotiation skills

Medical Equipment Management in National and International Quality & Safety standards

Facility Management and Safety (FMS)

Standards

Leadership and Planning

FMS.1 The hospital complies with relevant laws, regulations, building and fire safety codes, and facility inspection requirements.

FMS.2 A qualified individual oversees the facility management and safety structure to reduce and control risks in the care environment.

FMS.8.2 The fire safety program includes measures to ensure safe exit from the facility when fire and non-fire emergencies occur. Ⓟ

FMS.8.3 All fire safety equipment and systems, including devices related to early detection, alarm notification, and suppression, are inspected, tested, and maintained. Ⓟ

FMS.8.4 The hospital involves staff in regular exercises to evaluate the fire safety program. Ⓟ

FMS.8.5 The fire safety program includes limiting smoking by staff and patients to designated non–patient care areas of the facility. Ⓟ

Medical Equipment

FMS.9 The hospital develops and implements a program for the management of medical equipment throughout the organization. Ⓟ

FMS.9.1 The medical equipment program includes inspection, testing, preventive maintenance, and documenting the results. Ⓟ

FMS.9.2 The hospital has a process for monitoring and acting on medical equipment hazard notices, recalls, reportable incidents, problems, and failures. Ⓟ

Safe medical equipment

EFS.10 NSR.27 **Medical equipment plan ensures safe selection, inspection, testing, maintenance, and safe use of medical equipment.**

Safety

Keywords:
Medical Equipment Plan

Intent:
Medical equipment is critical to the diagnosis and treatment of patients.
In most hospitals, a trained biomedical and engineering team manages the entire medical inventory, and is responsible for dealing with medical equipment hazards. Being responsible for such an extensive array of devices can be cumbersome, especially when the stakes are so high. Not only does lazy monitoring and management lead to inefficiency, but it can also seriously harm patient outcomes. As an example, poor maintenance increases the chances of downtime, and inadequate servicing and sterilization can be harmful to both doctors and patients.
This is why it is crucial to establish some basic equipment safety and service guidelines.
The hospital develops a plan for medical equipment management that address at least the following:

a) Developing criteria for selecting new medical equipment.

Medical Equipment in FMS Chapter in JCI standards

- **FMS.9 The hospital develops and implements a program for the management of medical equipment throughout the organization**
  - **FMS.9.1 The medical equipment programs includes inspection, testing, preventive maintenance and documenting the results**
  - **FMS.9.2 The hospital has a process for monitoring and acting on medical equipment hazard notices, recall reportable incidents, problems and failures**

Medical Equipment in EFS Chapter in GAHAR standards

+ Safe medical equipment

+EFS.10 NSR .27 Medical equipment plan ensures safe selection, inspection, testing, maintenance, and safe use of medical equipment.

Intent:

+ Medical equipment is critical to the diagnosis and treatment of patients.
+In most hospitals, a trained biomedical and engineering team manages the entire medical inventory and is responsible for dealing with medical equipment hazards.
+Being responsible for such an extensive array of devices can be cumbersome, especially when the stakes are so high.
+Not only does lazy monitoring and management lead to inefficiency, but it can also seriously harm patient outcomes.
+As an example, poor maintenance increases the chances of downtime, and inadequate servicing and sterilization can be harmful to both doctors and patients.
+ This is why it is crucial to establish some basic equipment safety and service guidelines.

Medical Equipment in EFS Chapter in GAHAR standards

+The hospital develops a plan for medical equipment management that address at least the following:

a) Developing criteria for selecting new medical equipment.
b) Inspection and testing of new medical equipment upon procurement and on a predefined interval basis.
c) Training of staff on safe usage of medical equipment upon hiring upon installation of new equipment, and on a predefined regular basis by a qualified person.
d) Inventory of medical equipment including availability, criticality, and functionality.
e) Identification of critical medical equipment that should be available for the operator even through provision of back-up such as life-saving equipment, ventilator, DC shock.
f) Specialized and critical equipment(s) lists are identified.
g) Periodic preventive maintenance according to the manufacturer's recommendations which usually recommends using tagging systems by tagging dates and due dates of periodic preventive maintenance or labelling malfunctioned equipment.
h) Calibration of medical equipment according to the manufacturer's recommendations and/or its usage.
i) Malfunction and repair of medical equipment.
j) Dealing with equipment adverse incidents, including actions taken, backup system, and reporting.
k) Updating, retiring and/or replacing for medical equipment in a planned and systematic way.

Medical Equipment in EFS Chapter in GAHAR standards

- Evidence of compliance:

1. The hospital has an approved medical equipment management plan that addresses all elements from a) through k) in the intent.
2. **The hospital have qualified individuals to oversee medical equipment management.**
3. Staff are educated on the medical equipment plan at least annually.
4. Records are maintained for medical equipment inventory, user training, equipment identification cards, company emergency contact, testing on installation, periodic preventive maintenance, calibration and malfunction history.
5. The hospital ensures that only trained and competent people handles the specialized equipment(s) .
6. The plan is evaluated and updated annually with aggregation and analysis of necessary data

Risk Management
Hazard Identification And Risk Analysis (HIRA)

Critical equipment failure brings unexpected costs and the possible loss of revenue-generating services. It can significantly impact patient care/satisfaction and employee safety, while increasing exposure to litigation and negative public relations.

The failure mode and effect analysis (FMEA) is one of the tools that can be used for performing hazard identification and risk analysis (HIRA) on processes involving medical equipment. The FMEA like any other process improvement methodology is a team activity wherein relevant members from different department will be involved.

The goals of FMEA are as follows:
- To identify the failure modes in the process involving medical equipment
- Establish the risks and the consequences of these failure modes
- Identify and implement mitigation strategies for the effects
- Assess the success of the mitigation strategies
- Implement modifications to hospital procedures as appropriate

Hazard Identification & Risk analysis concerning to Medical Equipment in Hospital
By DEEPAK AGARKHED SEPTEMBER 27, 2013
https://hospitalspeak.wordpress.com/2013/09/27/hazard-identification-risk-analysis-concerning-to-medical-equipment-in-hospital/

Failure Mode And Effect Analysis (FMEA)

Worksheet for Defibrillator using external paddle

Steps of usage of Defib	Potential failure mode	Effects of failure: Description	Effects of failure: Severity	Effects of failure:Probability of occurrence	Effects of failure: Detectability	RPN number	Significance of failure	Causes of failure	Mitigating strategies
1.Switch on defibrillator	Unit not working	Can't use unit	Major(3)	Occasional(2)	Medium (2)	12	Yes	(a)Batteries not charged due to	
								1) power chord of unit was disconnected	Nursing: Adopt shift wise visual inspection of defib as part of crash cart checklist & weekly testing unit on test load
								2)Defective power chord	Clinical Engineer: Regular preventive maintenance &
								3)Forgot to switch on power outlet.	Nursing: Adopt shift wise visual inspection of defib as part of crash cart checklist& weekly testing unit on test load
								4)Non functional power outlet	Nursing & Engineering Team
								b) Unit malfunctioning	Clinical Engineering: Regular preventive maintenance & calibration

- Estimate the Severity number (S) i.e. a numerical measure of how serious is the effect of the failure to the patient.
- List potential causes or mechanism of failure.
- Estimate the occurrences number (O) i.e. a numerical measure of probability that a particular failure mode will actually happen.
- Estimate the detection number (D) i.e. a numerical measure of probability that particular failure mode would be detected by process members.
- RPN = S X O X D

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Medical Equipment Selection

- Assess Needs
- Specify Specifications
  - Basic Mandatory Condition as per required category

    (e.g. CE/FDA, Country of Origin, Sales and after Sales Reputation)
  - Basic Mandatory Specs
  - Competing Specs
    - Technology
    - Material Grade
    - Ergonomic Design
    - Unique features
    - Level of Integration with HIS
    - User Friendly Application
    - Sustainability of the Manufacturer
    - Stability of the Supplier

Service Contracting

- Scope of Work (Labor only, Labor & Spare Parts…)
- Specify Service Level Agreement (SLA)
- Penalties
- Pricing & Payment Terms

Workbench, Tools, Testers / Simulators

Computerized Maintenance Management System (CMMS)

- In most modern health-care facilities, the number of pieces of medical equipment and the number of service events are **so large that keeping and organizing this information can only be done by a computer system.**

- A computerized maintenance management system **(CMMS**), a software tool that is able to run on a stand-alone computer, can be very useful in managing the medical equipment maintenance program.

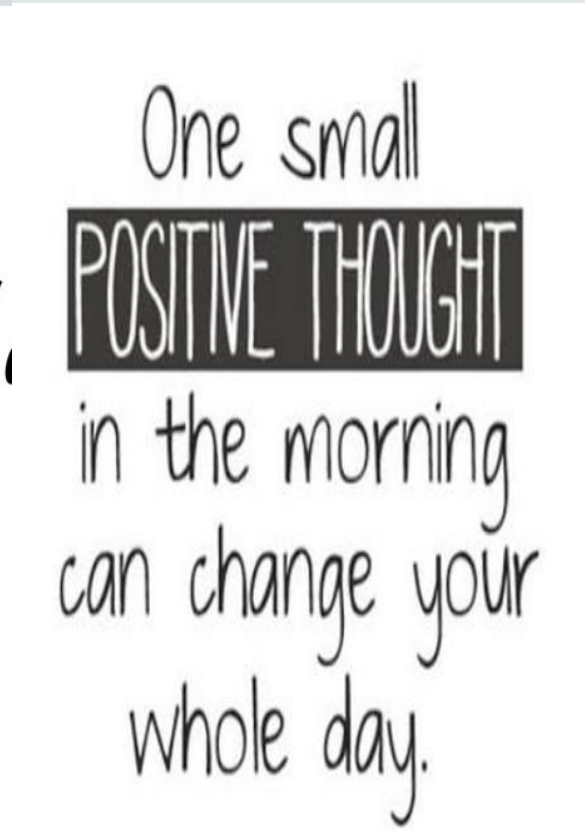
Facilitates Measurement of Departmental & Individual Key Performance Indicators

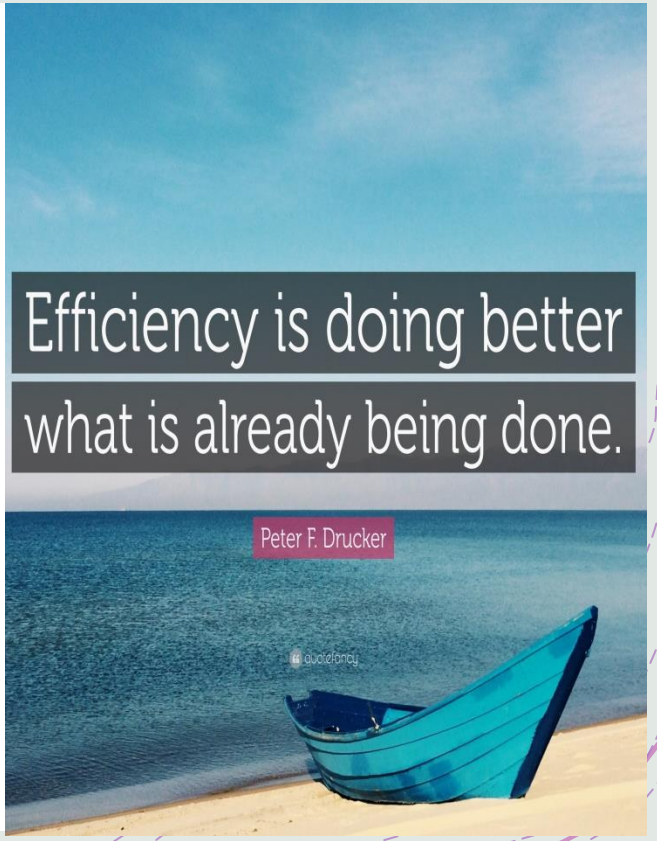
Hard-work

Opportunity

Positive Thoughts

Efficiency






WHICH STEP HAVE YOU REACHED TODAY?
YES I DID IT!
I WILL DO IT
I CAN DO IT
I'LL TRY TO DO IT
HOW DO I DO IT?
I WANT TO DO IT
I CAN'T DO IT
I WON'T DO IT

LinkedIn Profile

Clinical Eng- Facebook Page

Thank You....