Accreditation of Biomedical Engineering Department in Hospitals

By Dr Ibrahim Andijani

Medical Equipment Standards

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How safe is healthcare?

Healthcare

Driving

Regular air transport

Mountain climbing

Chemical industry

European railways

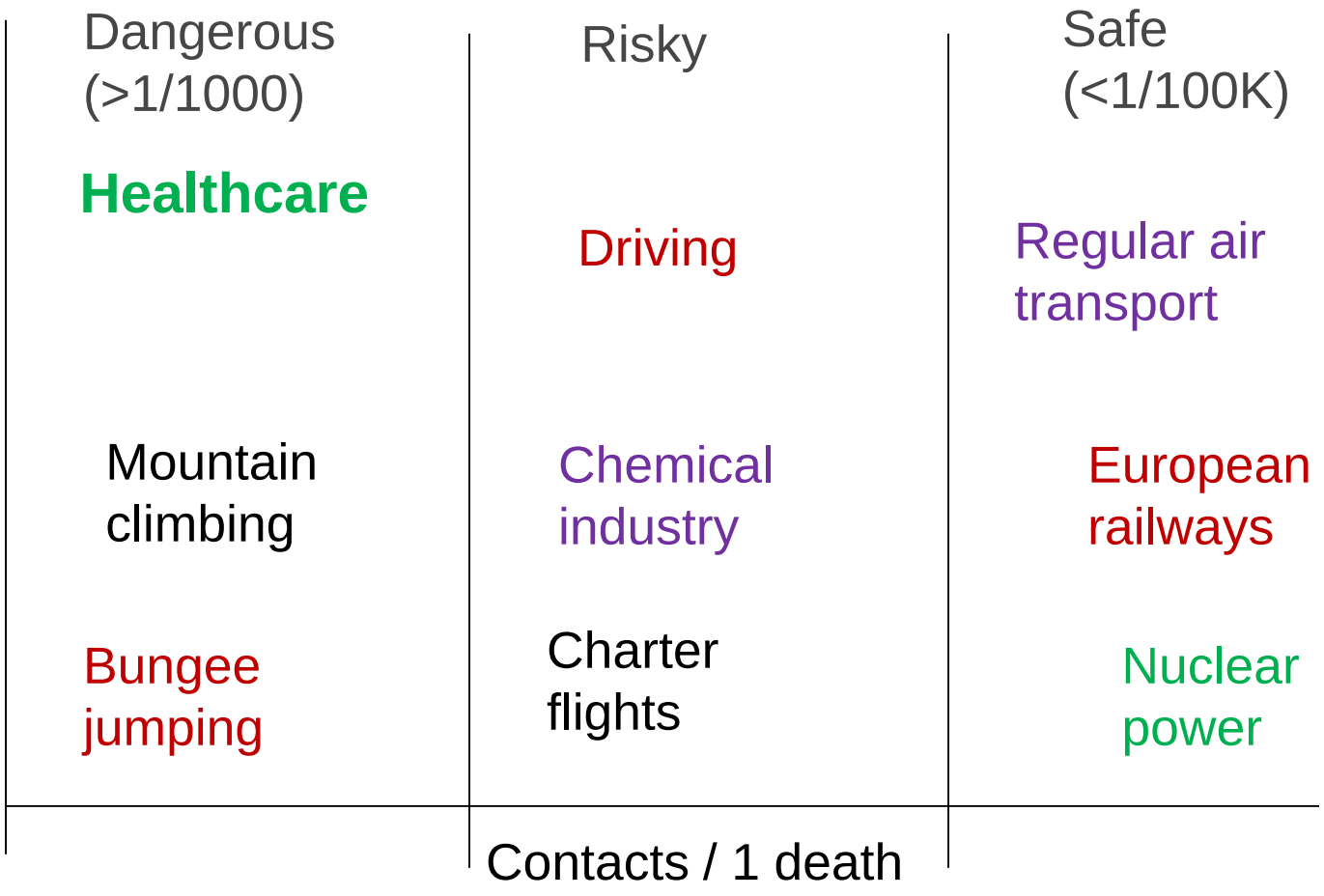
Bungee jumping

Charter flights

Nuclear power

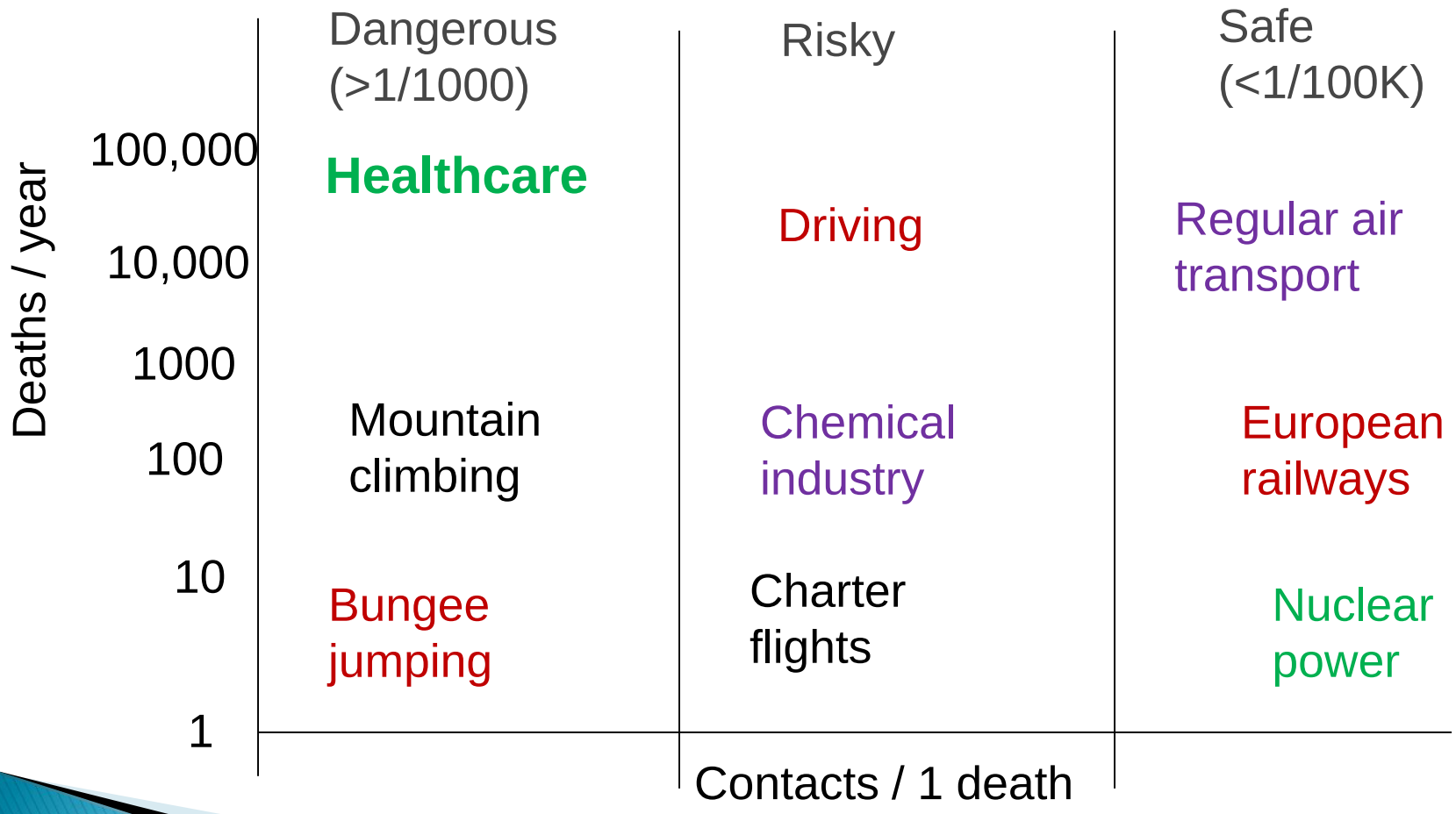
(Chang, JCI)

How safe is healthcare?



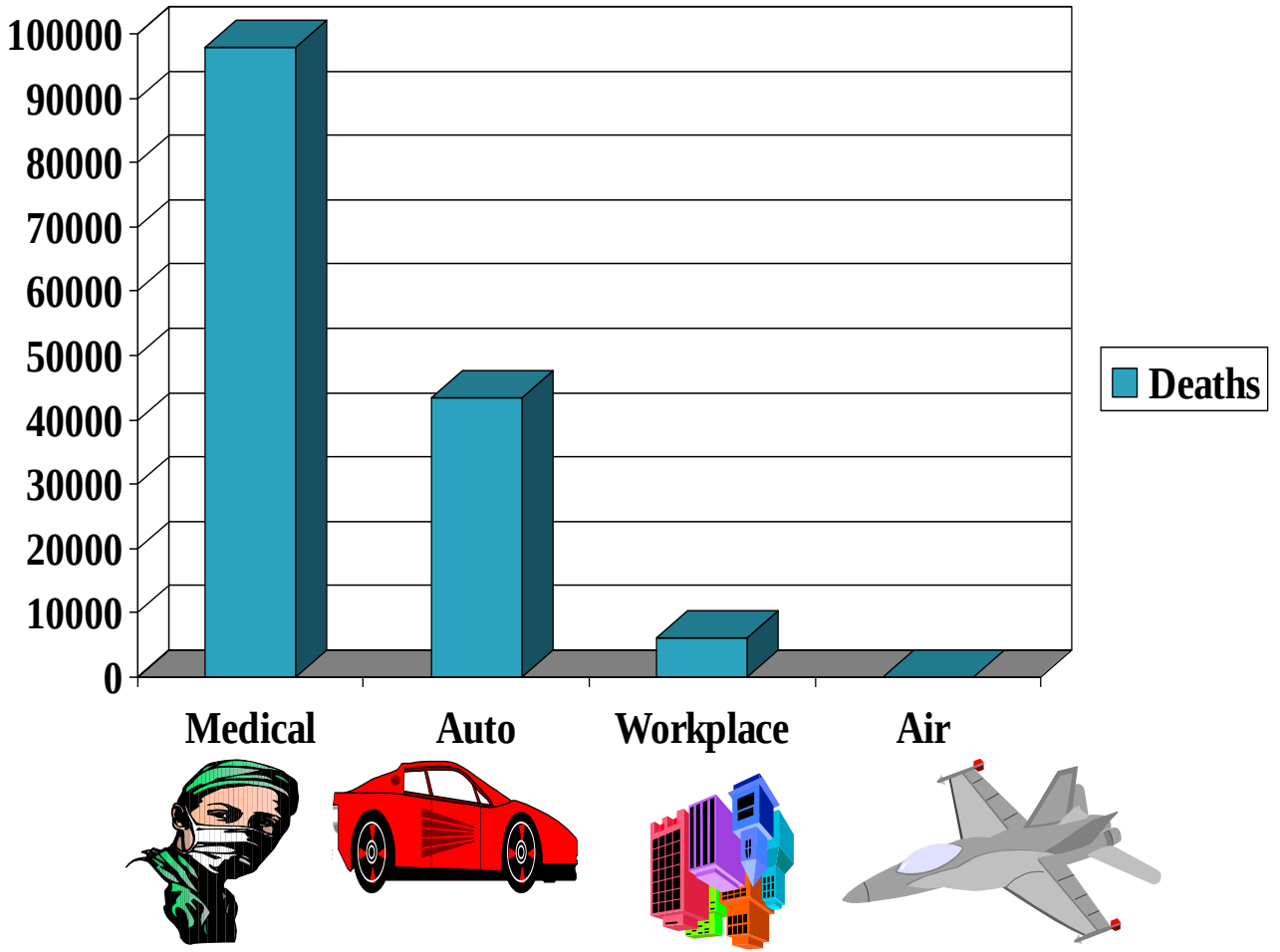
(Chang, JCI)

How safe is healthcare?



(Chang, JCI)

Annual Accidental Deaths (USA)



A fire started in a patient room. What the staff did ?

- Faisal escaped .....
- Sami Called civil defense
- Ali is trying to extinguish the fire with his Shomagh..
- Adel called the hospital switch board
- Mary is trying to evacuate patients
- Hasan closed oxygen valve of the ward and patient died in room 212

Everyone took action in his own way.!!!

Solution

Standards

Preparation of plans, policies, regulations and programs

Staff training

Coordinated team work effort

PPPP

POLICIES & PROCEDURES, PLANS, PROGRAMS

- Policies & Procedures

  Removal of equipment from service. Tagging medical equipment. Eliminate the use of extension cords. Inspection on all new equipment before put into operation.

- Plans

  Medical Equipment Management Plan.

- Programs

  Biomedical Engineering Training Program, PPM Program

FMS

Facility Management & Safety

- Building Safety
- Security
- Hazardous Materials & Waste Disposal
- Emergencies
- Fire Safety
- Medical Equipment
- Utility Systems

Hospital Standards

Saudi

Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI).

CBAHI Medical Equipment Standards

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.1 The hospital has adequate number of qualified biomedical staff.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.2 There is a written biomedical equipment plan that covers the following:
  - FMS.25.2.1 A comprehensive inventory of medical equipment with their corresponding locations.
  - FMS.25.2.2 Preventive maintenance program that conforms with the manufacturer's instructions.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.2.3 The program specifies, for each equipment, the frequency of checks, methods of checks, acceptance criteria, and actions to be taken in the event of unsatisfactory results.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.2.4 The program includes the process for investigation and follow-up of equipment failure that addresses reporting of failure, immediate remedial actions, assessment of the failure effect on reported results and services (needs alignment), and requalification of the equipment.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.2.5 Electrical safety testing for patient related equipment.
- FMS.25.2.6 History record for the maintenance schedule, failure incidence, and repairs done.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.3 Technical service manuals for all equipment are available at the biomedical workshops.
- FMS.25.4 Operator manuals are available at all departments using the equipment.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.5 The hospital ensures that all maintenance works are conducted by qualified and trained staff.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.6 Equipment maintenance and repairs are documented to help in the decision making for replacement.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.7 Investigation procedures conform to manufacturer's instructions.
- FMS.25.8 There is an equipment recall system that is implemented.

Medical equipment

FMS.25 The hospital has a biomedical equipment plan to ensure that the medical equipment are regularly monitored, maintained, and ready for use.

- FMS.25.9 Each department has a back-up or alternative for each critical equipment to cover for prolonged downtime.
- FMS.25.10 Preventative Maintenance data are used for upgrading/replacing of equipment.

Medical equipment

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

- FMS.26.1 There is a policy to perform inspection on all new equipment for conformity before commissioning including those brought for "demos".

Medical equipment

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

- FMS.26.2 There is a written policy for tagging medical equipment as follows:
  - FMS.26.2.1 Preventive maintenance with testing date and due date.
  - FMS.26.2.2 Inventory number.
  - FMS.26.2.3 Removal from service.
  - FMS.26.2.4 Electrical safety check.

Medical equipment

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

- FMS.26.3 There is a policy for removal of equipment from service.
- FMS.26.4 There is a policy to address agent or contractor repairs.

Medical equipment

FMS.26 The hospital has policies and procedures that support the medical equipment management program.

- FMS.26.5 There is a policy to eliminate the use of extension cords.
- FMS.26.6 There is a policy to restrict the use of cellular phones in the intensive care units, operating room, and cardiology units, as needed.

Medical equipment

FMS.27 Hospital staff are trained on safe operation of medical equipment.

- FMS.27.1 Hospital staff are trained to operate safely all medical equipment.
- FMS.27.2 The training includes physicians, nurses, and paramedics.

Medical equipment

FMS.27 Hospital staff are trained on safe operation of medical equipment.

- FMS.27.3 The training considers the following:
  - FMS.27.3.1 New equipment.
  - FMS.27.3.2 Staff transferred from a department to another.
  - FMS.27.3.3 New staff hired.
  - FMS.27.3.4 Recurrent misuse of equipment.

JCI standards for medical Equipment

Standard FMS 8

- **The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results**

Measurable Elements:

- 1. Medical equipment is managed throughout the organization according to a plan.

Standard FMS 8

- **The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results**

Measurable Elements:

- 2. There is an inventory of all medical equipment

Standard FMS 8

- **The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results**

Measurable Elements:

- 3. Medical equipment is regularly inspected.

Standard FMS 8

- **The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results**

Measurable Elements:

- 4.Medical equipment is tested when new and according to age, use, and manufacturers' recommendations thereafter.

Standard FMS 8

- **The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results**

Measurable Elements:

- 5. There is a preventive maintenance program.

Standard FMS 8

- **The organization plans and implements a program for inspecting, testing, and maintaining medical equipment and documenting the results**

Measurable Elements:

- 6. Qualified individuals provide these services.

Standard FMS 8.1

- **The organization collects monitoring data for the medical equipment management program.**

Measurable Elements:

- 1. Monitoring data are collected and documented for the medical equipment management program

Standard FMS 8.1

- **The organization collects monitoring data for the medical equipment management program.**

Measurable Elements:

- 2. Monitoring data are used for purposes of planning and improvement.

Standard FMS 8.2

- **The organization has a product/equipment recall system.**

Measurable Elements:

- 1. There is a product/equipment recall system in place.

Standard FMS 8.2

- **The organization has a product/equipment recall system.**

Measurable Elements:

- 2. Policy or procedure addresses any use of any product or equipment under recall.

Standard FMS 8.2

- **The organization has a product/equipment recall system.**

Measurable Elements:

- 3. The policy or procedure is implemented.

THANK YOU


Thank You!

BIOMEDICAL ENGINEERING DEPARTMENT

ACCREDITATION & CERTIFICATION

By Dr. Ibrahim Andijani

FMS Surveyor

ECRI Institute

The Discipline of Science. The Integrity of Independence.

Accreditation – What? Why? Who? When? How?

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What is Accreditation?

- ECRI – which is the original provider of all Biomedical Standards and processes related to Medical Equipment Management has introduced Accreditation with an objective to

- Measure and Evaluate the performance of Hospital Biomedical Departments vis a vis international benchmarks
- Guide Biomedical Departments to support hospital clinical staff in providing high quality services
- Intended to focus only on Medical Equipment and Systems Management only
- Supports Hospital accreditation to JCI/CBAHI

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Why Accreditation?

- Medical Equipment and Technology Management is the most sizable investment in the Hospital (> 30-35%)
- Failure or Errors in Medical Technology Management can have disastrous consequences.
- The performance in this area impacts hospital performance – both in terms of quality as well as financial operations
- With new technology, there are possibilities of Hazards, Recalls and Management of Healthcare Technology is a major safety and risk management requirement for a hospital

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Who should get accreditated?

- Accreditation will benefit
  - Tertiary/Quaternary Care Hospitals that have a large installed base of Medical Equipment
  - Hospitals that have a generic ISO 9001 – 2008 program, with quality manuals. Accreditation can become part of the Quality Improvement Process and the same manuals can be enhanced, so that no new documentation is required
  - Hospitals with JCI, that would like to focus and improve Medical Equipment Management and reduce costs while improving quality
  - Hospitals that are part of a network of hospitals
  - It is planning to introduce this for both service providers and healthcare providers

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When should you plan for Accreditation

- When hospitals have a mature Biomedical Engineering process
- When hospitals would like to improve their internal quality and handling of equipment.
- They have ISO 9001 but would like to improve their management and cost effectiveness of medical equipment
- Bring global best practices into the management of Medical Equipment and Technologies.

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How does this Accreditation Process Work?

- 1 : Preliminary Questionnaire
- 2 : On Site Evaluation
- 3 : Report of findings
- 4 : Gap Evaluation
- 5 : Suggestions for Improvement
- 6 : Modification of Manuals
- 7 : Accreditation Audit
- 8 : Accreditation

ALL DATA COLLECTION THROUGH STRUCTURED QUESTIONNAIRES

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Accreditation – Step 1
Preliminary Questionnaire

- Hospital Data
- Operational parameters
- Current processes
- Operational Manuals for Biomedical Engineering Services

Objective : Analyse " As Is "
Processes

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Preliminary Evaluation (off site) based on CE Questionnaire (Baseline Evaluation)

- Is the hospital certified to an existing Quality program – ISO 9001-2008/JCI etc. The objective is to understand if a Quality Manual is available, which can be easily modified as a Quality Improvement Program. This will ensure that no new manuals need to be written
- Is there a Medical Equipment Management Plan developed for the hospital? This would consist of a series of procedures that are typically part of a process based management system.
- Based on the questionnaire, we might be able to assess where the hospital stands currently and how long it would take for the accreditation

Medical Equipment Management

Typical Policy/Program Components

- Scope, responsibilities and procedures
- Credentialing
- Asset Management
- Management of Equipment Repair and Calibration Services
- Planned Preventive Maintenance Program including Safety and Performance Testing
- Acceptance Testing
- Avoiding failure during use (Disaster Planning/Contingency Planning)
- Management Information Systems and Reports
- Warranty Management

Medical Equipment Management

Typical Policy/Program Components

- Project Management (Coordination of engineering work performed in the Hospital by external vendors)
- Risk and Safety Management
- Spare Parts Management
- Handling hazardous or contaminated equipment
- Decommissioning of Medical Equipment
- Development and Implementation of documentation protocols required by external and internal accreditation and licensing agencies
- User Training
- Advice on procurement of replacement equipment
- Incident Reporting and Management (Sentinel Events)

Accreditation : Step 2 : Site Visit 1 :
On site Evaluation based on Preliminary Questionnaire

- On Site team visits to evaluate operations. Key Areas of evaluation which will include walkthroughs:
  - Availability of Medical Equipment Management Plan components. Key Areas
    - Availability of Computerized Maintenance Management System(CMMS)
    - Asset Register (check for accuracy, consistent descriptions, fields captured).
    - Service Call handling (Help Desk/On line etc)
    - Planned Preventive Maintenance (Protocols, Scheduling, Performance, Test Equipment availability)
    - Breakdown/Emergency/Predictive Maintenance

Accreditation : Step 2 : Site Visit 1 :
On site Evaluation based on Preliminary Questionnaire

- On Site team visits to evaluate operations. Key Areas of evaluation which will include walkthroughs:
  - Availability of Medical Equipment Management Plan components. Key Areas
    - Hospital Risk management program
    - Training and Credentialing of Staff to handle equipment
    - Service Contracts and scope of contracts
    - Supply Chain Management process for contracts and spare parts
    - Customer feedback

Accreditation : Step 3 – Gap Analysis

- Identification of specific areas of improvement
- If Hospital has an ISO 9001 manual or Biomedical Manual, amendments to the manual
- Guidance to hospital on amendments required

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Accreditation : Step 4 – Hospital Action Plan based on Gap Analysis

- Remedial Plan
- Timelines for implementation of action plan
- Draft of new processes
- 3 months consistent implementation of new processes.

Accreditation : Step 5 : Site Visit 2 : Mock Audit

- This will take place approximately 2 month after the hospital introduces into operations, and based on the hospital remedial plan schedules.
- There will be a detailed evaluation of the Medical Equipment Management Plan with Key Performance Indicators, Biomedical Reporting, Risk and Safety Management etc.
- Based on the satisfactory completion, we can discuss dates for the final certification audits. This will typically be approximately 1 to 1.5 months after the mock audit.

Accreditation : Step 6: Certification Audit

- This will be done by an independent team.
- We shall be looking at all organization reports, meet the management staff. End users and review all processes and systems
- There will a detailed and systematic audit of medical equipment records
- Based on this the auditor will recommend to the ECRI Accreditation Management Team to accredit the hospital
- All copies of records will be retained by ECRI

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The Result

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Accreditation for Best Practices in Biomedical and Clinical Engineering

awarded to

CHARITÉ CFM FACILITY MANAGEMENT GMBH

AUGUSTENBURGER PLATZ 1

13353 BERLIN

2012


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Accreditation
for Best Practices in
Biomedical and Clinical Engineering

Thank You

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