Mission, Function & Organizational Structure of Clinical Engineering Services

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Organization’s (Hospital’s) Mission

• To improve the health of the communities we serve by delivering a broad range of high quality services with sensitivity to the needs of our patients and their families
  – Hospital’s Goal: **To improve the health of the communities we serve**
  – What hospital does: **delivers a broad range of high quality services**
  – How hospital does it: **with sensitivity to the needs of our patients and their families**
• Program Mission
  – Should be simple
  – Should support & be consistent with organization’s mission statement
Healthcare Technology Program Mission

- To support the delivery of healthcare by insuring the availability of safe and effective medical technology in a cooperative effort with other members of the healthcare team
  - Our Goal: **To support delivery of healthcare**
  - What we do: **Provide safe & effective medical technology**
  - How we do it: **In a cooperative effort with other members of the healthcare team**
Mission Statement

• The Office of Engineering Services will apply engineering, technical, and managerial expertise to provide safe, effective, and economical facilities and equipment as needed by University Hospital for patient care, teaching, research, and community service. †

† Slide 10 of Roles of Supervisors & Managers (Miller ~ Peru 2002)
Requirements of a Technology Management Program†

• Program to control & monitor equipment performance
  – Routine performance testing
  – Initial inspection
  – Preventive maintenance
  – Repair
  – Action reports on device hazards & recalls

† ECRI
Requirements of a Technology Management Program†

• That accurately and consistently computes and monitors total equipment maintenance costs, including:
  – In-house costs
  – Manufacturer costs
  – 3rd party service costs

† ECRI
Requirements of a Technology Management Program†

• Involvement in all aspects of equipment acquisition and replacement decisions, development of new services and planning of new construction and major renovations:
Requirements of a Technology Management Program†

- Development of training program for all equipment users of patient care equipment and for biomedical technicians

† ECRI
Requirements of a Technology Management Program†

• A quality assurance program relating to technology use
Requirements of a Technology Management Program†

• Risk management as it relates to technology
Traditional Roles & Responsibilities

• **Technical services**
  – Inspection & testing (functional, safety, performance)
  – Calibration
  – Preventive maintenance
  – Repair

• **Technology management services**
  – Equipment management program (risk analyses, control elements)
  – Evaluation of new technologies prior to acquisition, including life cycle cost analyses
  – Service vendor management
  – Compliance (government, accrediting standards)
  – Education services (equipment users & biomedical equipment technicians)
  – Device tracking (hazards & recalls)
  – Incident reporting & investigation

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Policies & Procedures

• **Policies**
  Statements of principles and values that guide organizational activities … Effective policies are flexible, coordinated, comprehensive, ethical, and clear

• **Procedures**
  Defined courses of established methods used to achieve an objective
Policies & Procedures

1. Equipment Classification System ~ *Criteria for including equipment categories in program*
2. Biomedical equipment inventory management ~ *Process for adding, deleting*
3. Inspection & PM ~ *Determining protocols & frequencies*
4. Obtaining Equipment Service/Repair
5. Incoming inspection of all medical devices & systems ~ *Installation & acceptance testing of all purchased, leased, loaned devices*
6. Storing & Retiring medical equipment
7. Medical Device Tracking ~ *Dealing with hazards and recalls*
8. Education/Training ~ *Regarding proper use, testing & troubleshooting*
10. Incident reporting & investigation
11. Reporting to Safety Committee
## Equipment Inventory

**INVENTORY**

- **ID or Control #**
- **Description**
- **Manufacturer**
- **Model #**
- **Serial #**
- **Location/Cost Center**
- **Acquisition Date/Cost**
- **Maintenance requirements** (frequency/schedule)

[Diagram of equipment inventory process]

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Centralized Documentation System
Incoming Inspection of Biomedical Equipment

Purchased, Leased Demo or Loaner Equipment

Clinical Engineer

Equipment Inventory & EM Classification

Centralized Biomedical Equipment Documentation

Biomedical Equipment Technician (BMET)

Inspection Form

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Equipment Management Program
“Risk-based Classifications”

Equipment Categories

Equipment Management (EM) Category Classification Policy/Procedure

- Application
  + Risk
  + Maintenance Requirements
  + History

= Total EM Rating/Score

High EM Rating/Score

Included in program

Low EM Rating/Score

Exempt from program

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**Inventory Tag**

**Inspection Tag**

**Exempt Tag**

**Storage Tag**

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**NOTICE**

This piece of equipment has recently been serviced by a qualified service technician. During the service procedures, settings of the controls, patient circuit components, and other auxiliary devices may have been changed. Check the equipment for proper settings prior to clinical use. Remove this label following the preoperational check.

**DATE:** __________ **BY:** __________

Clinical Engineering

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**DEFECTIVE**

Do Not Use

Comments: __________

____________________

____________________

____________________

**DATE:** __________ **BY:** __________

Clinical Engineering

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**Operator Warning Tag**

**Red (Remove from Service) Tag**

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Clinical Engineering

This equipment has been placed in storage. Contact Biomedica/Clinical Engineering before using.

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Biomedical Equipment Storage/Retirement

This equipment has been placed in storage. Contact Biomedical/Clinical Engineering before using.

- Temporarily removed from service
- Obsolete or
- Repair not cost-effective

Clinical Engineering

DETECTIVE
Do Not Use

Comments:
________________________
________________________
________________________
DATE: __________ BY: ______

Clinical Engineering
Acquisition of Biomedical Equipment

1. Assess Need ~ Determine Specifications
2. Compare available manufacturers & models. Assess ease of use, ease of maintenance, operating & life cycle costs
3. Make selection & prepare purchase order with specifications including operator & service manuals, user & service training, warranty, etc.
4. Acceptance/payment conditional on passing incoming technical inspection, inclusion of manuals, provision of user & service training, adequate warranty
Equipment Hazard/Recall Program

- Manufacturer Recalls & Alerts
- FDA Enforcement Reports
- ECRI/Health Devices Alerts
- Centralized Biomedical Equipment Documentation

Clinical Engineer

Biomedical Equipment Inventory

Action Reports

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Equipment Program Education

• Clinical Staff
  – Basic operation & proper use
  – Basic Troubleshooting
  – Potential hazards
  – Equipment management (dealing with obtaining equipment service, equipment related incidents)

• Clinical engineering staff
  – Professional (mission, ethics, conduct)
  – Codes & standards
  – Technical (troubleshooting & use of equipment)
  – Clinical equipment operation & inspection procedures
  – Policies, procedures & documentation
Equipment Related Incident Investigation

1. Minimize further injury to patients & personnel
2. Minimize any damage to equipment & facilities
3. Impound all equipment, supplies, disposables, wrappers, etc.
4. Identify witnesses
5. Notify Risk manager, clinical engineering
6. Complete incident report
7. Notify authorities
Equipment Management Program Benchmarking

- **Safety Committee**
  
  How to measure program performance & effectiveness?

- **Establish Goal & Compare with Actual**
  
  For example:
  - User related equipment problems
  - Scheduled vs Actual inspections
  - Percent of inspections with problems found

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Typical Organization Chart
Healthcare Technology Program

- Technology Consultation
- Pre-purchase evaluation, life cycle cost analysis
- Education of users, technicians
- Compliance (government, accrediting authorities)
- Device Tracking (Hazards, Recalls)
- Incident Investigation
- Contract/vendor management

- Inspection
- Preventive Maintenance
- Calibration
- Repair

- Bookkeeping
  - Accounts Payable & Receivable
  - Payroll & Benefits Management
- Correspondence
- Filing
- Data entry
- Reporting

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Organizational Reporting

• **Reports directly to**
  – Director of Engineering (a “traditional” approach)
  – Director of Information Technology (the “trend”)
  – Other (e.g., Administrator of Support Services)

• **Also reports indirectly to**
  – Safety Committee (interdisciplinary group responsible for hospital safety … including technology management elements)
Safety Committee

• **Purpose**
  To bring members of the healthcare team together in an non-adversarial environment to:
  ♦ identify issues affecting patient & staff safety and formulate an effective approach toward the resolution of those issues
  ♦ reviews and approves elements of technology management program that impact on safety of patients & staff

• **Membership must be interdisciplinary to be effective**
  Typically includes representatives of
  • administration
  • nursing/clinical staffs
  • personnel
  • engineering
  • risk management
  • medical staff
  • education
  • purchasing
  • security
  • clinical engineering
Staff Qualifications

• **Biomedical Equipment Technicians (BMET)**
  – Associate Degree in Technology (AA) or higher, Military or Manufacturer Training
  – Certified Biomedical Equipment Technician (CBET)
  – Specialties: General Biomedical, Laboratory, Medical Imaging
  – Rankings: Level I, II, III ... higher level reflects more experience, education and/or specialization

• **Clinical Engineers (CE)**
  – Batchelor or Masters of Science Degree in Engineering
  – Certified Clinical Engineer (CCE)

• **Manager**
  – Clinical Engineer
  – Master’s in Business Administration ... or business education
Organization Chart for Small Clinical Engineering Program

Typical
- 300-500 bed hospital
- 1500 device inventory

✓ Capable of providing basic service on majority of general biomedical devices
✓ 3rd parties provide most sophisticated technical services
✓ 3rd party provides clinical engineering consultation & related services

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Organization Chart for Medium Clinical Engineering Program

Typical
- 500-700 bed hospital
- 2000 device inventory

✓ Capable of providing basic to mid-level services on all but most sophisticated medical devices (e.g., lab, imaging) in inventory
✓ Capable of providing basic clinical engineering services
✓ 3rd party provides most sophisticated technical services (e.g., lab, imaging)
✓ 3rd party provides high-level clinical engineer services

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Typical
- 1000-1500 bed hospital
- 4000 device inventory

Capable of providing basic to high-level services on almost all medical devices on inventory (including imaging, lab)
Capable of providing basic to high-level clinical engineering services
3rd party provides sophisticated technical services on few devices
3rd party provides audit of clinical engineer services

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Equipment & Other Resources

- **Test & Repair equipment**
  - Oscilloscope
  - Digital multimeter
  - Electronic thermometer
  - Electronic pressure/vacuum gauge
  - Spirometer
  - Flowmeters
  - ECG analyzer
  - Defibrillator analyzer
  - Electrosurgical unit analyzer
  - Gas analyzer
  - Electrical safety analyzer
  - Pacemaker analyzer
  - Hand tools

- **Library**
  - reference books
  - equipment manuals,
  - reference guides,
  - subscriptions to journals, services

- **Office furnishings**
  - Workbenches
  - Desks
  - Chairs
  - Stools
  - Tables
  - File cabinets
  - Shelving units
  - Storage cabinets

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Logistic Models for Service Delivery

- **Service Delivery Models**
  - Centralized (dispatch or depot)
    - less duplication, easier management
  - Distributed
    - Better response time (therefore less downtime)
    - Generally less efficient use of resources (more costly)

- **Issues affecting decision on which model is best for situation**
  - Nature (method) & quality of communications
  - Geography of service area (i.e., travel distances)
  - Nature (method) & quality of transportation available
  - Response time necessary
Mixed Approach toward Service Delivery

- Use resident or *in-house* services for “basics”
- Use centralized or *ISO* services for more technically specialized needs
Centralized Model for Service Delivery

Central Technology Management Office and Service Center

Client Hospitals

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Central Dispatch Model for Service Delivery

In this scenario
Cost = 3 hours labor
Downtime = 3 hours

Necessary if
- equipment is not portable
- speed to restore is critical

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Central Depot Model for Service Delivery

In this scenario:
Cost = 1 hour labor plus shipping
Equipment Downtime = 2-3 days

OK if
• there is redundant capacity &
• equipment is portable
Distributed (Resident) Model for Service Delivery

Central Office for Technology Management

Hospital-based Resident Programs
## Centralized Technician Schedule

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<th>Location</th>
<th>Beds</th>
<th>Mon</th>
<th>Tues</th>
<th>Wed</th>
<th>Thu</th>
<th>Fri</th>
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Important that clients can rely on a firm schedule … there will be fewer “emergencies”
Advantages/Disadvantages of Sourcing Options

• **In-house (e.g., hospital owned & based)**
  – Less expensive in organizations with larger workload
  – Hospital can exercise more control over process

• **Independent Service Organization (ISO)**
  – Less expensive in organizations with smaller workloads
  – Usually a more efficient use of resources
  – Shared resources with other clients (program development, management, specialized technical expertise & equipment)

  Access to resources *(specialized expertise, equipment)* that couldn’t be afforded on own
Questions?

Thank You!

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