Medical Equipment Quality Assurance and Safety Systems in the USA
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Definitions

- Quality assurance
  - Planned and systematic actions that can be demonstrated to provide confidence that a product of services will fulfill the requirements for quality (American Society for Quality)
- Safety
  - Freedom from danger (Webster’s dictionary)

The Need for Quality Assurance (QA) in the 21st Century: Trends

- Recognition that medical equipment is a major contributor to the quality of care (Joint Commission)
- Reliability of newer devices
- Move to higher electronics content in medical devices
- Large increase in the number of medical devices
- Pressure on funding in health care
- Growing realization that rigid PM schedule does not always yield high reliability
- Safe and effective devices need to be available for patient care
- Regulations, accreditation requirements and standards

The Need for Quality Assurance (QA) in the 21st Century: Economic Benefits

- QA increases the availability of medical equipment for patient use
  - Patient care is not delayed; Quality is improved; Staff is better utilized
- QA reduces the potential for high cost major failures
- Preventative maintenance required for medical devices

The Need for Quality Assurance (QA) in the 21st Century: Economic Benefits

- QA increases the life of medical equipment
  - Medical devices can be used for a longer time and are not replaced prematurely
- QA increases the availability of medical equipment for patient use
  - Patient care is not delayed; Quality is improved; Staff is better utilized
Ten Steps for Quality Improvement

1. Assign responsibility
2. Delineate scope
3. Identify most important aspects
4. Identify quality indicators
5. Establish thresholds for evaluation
6. Collect and organize data
7. Evaluate function
8. Take actions to solve problems
9. Assess actions and document improvement
10. Communicate relevant information

Medical Device Regulations in the United States

Affecting Hospitals:
- Food & Drug Administration (FDA)
  - Safe Medical Device Act of 1990.
- Nuclear Regulatory Commission
  - Patient and worker safety related to radiation producing devices
- Federal Communications Commission
  - Regulates medical telemetry, telemedicine and wireless systems

Hospital medical device QA affected by regulations
- Lasers, ultrasound therapy, and radiation emitting devices
- Electrical safety if regulatory agency adopts NFPA 99
- The hospital defines the QA for other devices/tests

Joint Commission

Accreditation
- If passed, healthcare facility will be paid by the government for services to patients covered
- “Deemed Status” & Medicare regulations
- Survey of healthcare facility
  - Environment of Care Standards
  - Sentinel Events
  - National Patient Safety Goals

Joint Commission

Medical Equipment Management
- Selection process for purchasing medical devices
- Routine safety and performance testing for all devices using preventive maintenance, test and inspection procedures
- Management of equipment problems and hazards
- Education of staff on safe operation and use of medical devices.
- Records on each device
Elements of a Medical Equipment Management Program

- **Purpose**
  - Reduce time when equipment is not available
  - Improve clinical effectiveness
  - Reduce total cost of device ownership
  - Improve staff morale & professionalism
  - Improve patient confidence
  - Comply with regulations

Computerized Medical Equipment Management System (CMMS)

- Inventory, parts, work orders and lists
  - Staff, departments, locations, etc.
  - Equipment history
  - Regulatory related
    - E.g. Preventative maintenance completion
  - Maintenance, Asset, Safety and Internal management
  - Equipment replacement and acquisition

Maintenance and Service Management

- **Proper maintenance can improve patient care!**
  - Equipment reliability > Equipment availability > *Quality patient care*
  - Proper equipment function aids caregivers ability to serve patients
  - Proper maintenance reduces risk
  - Reduce the risk of adverse patient events

Maintenance and Service Management

- Setting up a program
  - Determine scope of services
  - Measure inventory
  - Match inventory to maintenance needed
  - Develop schedules and procedures
  - Determine workload and skills
  - Hire staff
  - Purchase test equipment
    - General and specialized
  - Monitor results and change as needed

Scheduled device testing, maintenance and quality assurance

*What devices are included and how much testing and maintenance is required?*

- Quality Assurance requirements
  - Manufacturer recommendations
  - Regulations
  - Device history
  - Maintenance "Sensitivity"
  - Environment of use
  - Device function & utilization
  - Device risk
  - Device incidents/recalls
  - Resources available to do the work

Benchmark Study

(from T. Cohen, AAMI 1987)

- Commonly accepted benchmark

\[
\text{Annual Service Cost} \div \text{Acquisition Cost} = X \%
\]

- Acquisition Cost
  - This averages about <5% for U.S. hospitals for large U.S. hospitals with CE departments (T. Cohen 1986)
Benchmark Study
(from B. Wang, JCE 2008)

New Study
(employee is Biomedical Technician)
- 2.5 employees per 100 staffed beds
- 1 employee per 4000 adjusted discharges
- 1 employee per 600 devices
- 1 employee per $9 million in equipment assets (USD)
- Clinical engineering budget
  - 20% cost is labor, >50% is service contracts
  - 0.5% Hospital budget is clinical engineering

Quality Assurance:
Indicators

- Scheduled work
- Inspections and preventative maintenance completion
  - Equipment not tested and why
  - Devices failing inspections
  - Unscheduled failures due to improper maintenance
- Documentation
  - Date missing, in error, illegible...

Required Test Medical Device Test Equipment

- Electrical Safety Analyzer
- Physiological Simulator
- Defibrillator Analyzer
- Pacemaker Analyzer
- Electrosurgery Analyzer
- Ventilator and air flow test system
- Test lung
- Tachometer
- Oxygen Analyzer
- Non-invasive blood pressure monitor tester
- Digital volt Meter
- Oscilloscope
- Infusion pump analyzer
- Pulse Oximeter Analyzer
- Laser Power meter
- Ultrasound Imaging Phantoms
- Radiographic measurement system
- Radiological and MRI phantoms
- Dialysis test equipment
  - including conductivity meter
  - Electronic balance and weights for scale testing
  - Test jigs, fixtures, cables
  - Hand tools

Scheduled device testing, maintenance and quality assurance

- Interval
  - Manufacturer Recommendations
  - Professional Guidelines
  - Maintenance History
- Procedures
  - Manufacturer Recommendations
  - Professional Guidelines
  - Generic procedures
    - ECRI
    - U. of Vermont/Fluke Biomedical

Scheduled device testing, maintenance and quality assurance

- Focus your limited resources on the most important equipment
  - High risk & dangerous
  - Most important for patient care and flow of patients
    - MISSION CRITICAL!
  - Strict manufacturer or regulatory need
  - High maintenance sensitivity

Quality Assurance:
Clinical & Risk Factors

1. Device Function
   - What function does the equipment perform in a clinical environment? The highest risks are with life-support devices, lower risks with non-invasive, diagnostic devices

2. Risk of Misuse or Failure
   - What are the possible consequences to the patient of a device malfunction or misapplication? The range is from "death" to "no significant risk"

3. Mission Criticality
   - What is the impact on overall hospital patient care or patient flow? Critical, important, non-critical.
Quality Assurance: Maintenance Factors

4. Manufacturer Maintenance Requirements
   - This is a function of manufacturer’s recommendations and the nature of the device, its design, and the types of components used in it.

5. Equipment Maintenance History
   - How prone to failure is this particular device, or group of devices? For devices that fail more often, we may wish to increase the number of preventive, or scheduled, services, to reduce the overall failure rate. High Maintenance Sensitivity: Expected not to function properly in the absence of scheduled maintenance and testing.

Medical Equipment Quality Assurance

Table of Contents
- Definitions
- Risk-Based Assessment Inspection Program
- General Procedures
  - Electrical Safety
  - Specific Procedures
- Appendix – Device Standards
  - IEC 60601-1 & 62353, NFPA 99 and Joint Commission

Medical Equipment Quality Assurance

- General procedures
- Inventory control
- Computerized medical equipment management system
- Which devices will be managed
- Risk based Assessment
- Goals
- Intervals
- Maintenance strategy worksheet
- Evaluating program effectiveness

Medical Equipment Quality Assurance

- Device Inclusion - what will be inspected?
  - MEDICAL EQUIPMENT
  - An answer of “YES” to any of the above three questions indicates that the device should be included in the medical equipment management program and be inventoried under those provisions.
  - Is the powered device used for direct patient treatment or care?
  - Yes No
  - Does the powered device provide diagnostic/monitoring information used in treatment?
  - Yes No
  - Does this powered device come in contact with the patient?
  - Yes No

Medical Equipment Quality Assurance

Risk Scoring System - Part 1

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Choose 1 rating from each category</th>
<th>Weight</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Function</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No patient contact</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Device may make contact with patient but function is non-critical</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Device is used for patient diagnosis, or direct monitoring</td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Device is used to deliver direct treatment to the patient</td>
<td></td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Device is used for a life support</td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Physical Risk</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device poses no appreciable risk due to failure</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Device failure will result in low risk</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Device failure will result in inappropriate therapy, misdiagnosis or loss of monitoring</td>
<td></td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Device failure could result in severe injury to, or death of, patient or user</td>
<td></td>
<td>4</td>
<td></td>
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</tbody>
</table>
Problem Avoidance Probability

<table>
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<tr>
<th>Maintenance or inspection would not impact reliability of the device</th>
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<tbody>
<tr>
<td>Common device failure modes are unpredictable or not very predictable</td>
<td>2</td>
</tr>
<tr>
<td>While common device failure modes are not very predictable, device history indicates that TSP testing frequently detects problems</td>
<td>3</td>
</tr>
<tr>
<td>Common device failure is predictable and can be avoided by preventive maintenance</td>
<td>4</td>
</tr>
<tr>
<td>Specific regulatory or manufacturer requirements dictate preventive maintenance or testing</td>
<td>5</td>
</tr>
</tbody>
</table>

Incident History

<table>
<thead>
<tr>
<th>No significant history</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>A significant history of incidents exists</td>
<td>2</td>
</tr>
</tbody>
</table>

Manufacturers / Regulatory Requirements For Specific Schedules

<table>
<thead>
<tr>
<th>No requirements.</th>
<th>1</th>
</tr>
</thead>
<tbody>
<tr>
<td>There are requirements for testing independent of a numerical rating system</td>
<td>2</td>
</tr>
</tbody>
</table>

Scoring System

- Greater than 13 = 2 x per year
- Between 9-12 = 1 x per year
- Less than 9 = 1 x 2 years

Exception: Certain devices such as life support equipment have more frequent inspections by regulation or manufacturer requirements

Incoming inspections

- Documentation
- Missing equipment
- Safety
  - Electrical, Mechanical, Infection control, and Cleaning equipment
- Electrical safety
  - Principles
  - Standards - Focus on IEC 62353

Electrical safety testing to IEC 62353

Twenty-five (25) Common Devices

- Patient monitoring
- Surgery
- Fetal/neonatal Care
- Life support
  - Pacemakers and ventilators
- Therapy
  - Infusion
  - Physical therapy
Medical Equipment Quality Assurance

Form and procedures

Summary

- QA requirements for medical devices have changed over time
- QA specific requirements for tests and intervals generally not specified by regulations in the US
- QA is an important part of an equipment control program
- Risk, mission, maintenance sensitivity, history, and requirements
- Resources available to guide medical device QA

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Thank you

Questions?