Total Cost of Ownership

Optimizing the Lifecycle of Your Medical Devices and Equipment

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Cradle to Grave Accountability for Surgical Equipment
Objectives

• Discuss regulations that impact an equipment management program
• Determine how the elements of product selection are impacted by supply chain, OR and Sterile Processing and Distribution members
• Recognize stewardship responsibilities toward equipment management after the purchases
Why Make New Purchases?

- Need additional inventory
- New technological advancements
- Current inventory is old and breaking
- Surgeon demand
CFR §482.41 (c)(2)

• “The hospital must ensure that supplies are maintained to produce an acceptable level of safety and quality for patients.”
• Required for day-to-day need
• Likely to be needed in an emergency
• Adequate provisions to support and maintain
• Stored to ensure safety
  • Theft
  • Damage
  • Contamination
  • Deterioration
Before receiving deeming authority for Medicare, an accreditation organization must apply and must demonstrate its ability to meet or exceed the Medicare conditions of participation/coverage specified in the CFR.
CMS Requirements & National Standards

• Maintenance, inspection and testing frequency and activities for facility and medical equipment is recommended by a risk-based assessment
• Must develop policies and procedures and maintain documentation supporting practice
• ANSI/AMMI EQ56:2013 – Recommended practice for a medical equipment management program
• ANSI/AAMI EQ 89:2015 – Guidance for the use of medical equipment maintenance strategies and procedures
Medical Equipment Management Plan

• ANSI/AMMI EQ56 Create and maintain a medical equipment management plan that describes the functions and activities of the medical equipment management program
• TJC Minimize risk in facility: written plan for managing medical equipment
• DNV Establish a medical equipment management system
• AOA/HFAP Establish scheduled preventive maintenance programs for all biomedical equipment in accordance with manufacturer’s recommendations
Equipment Selection & Acquisition

• ANSI/AAMI EQ56 Document selection process; demonstrate that organization’s experience is utilized

• TJC  Input from users and servicers

• DNV  Employ processes for acquisition and selection of equipment
AORN: 2015 Guidelines for Product Selection

I. A mechanism for product selection should be developed

II. The multi-disciplinary committee should develop a process to guide product selection

III. Perioperative RNs should demonstrate competency related to product evaluation and selection

IV. The product selection process and any product-specific information should be documented

V. Policies and procedures for evaluating and selecting products should be developed, reviewed periodically, revised as necessary and readily available in the practice setting

VI. A quality assurance/performance improvement process should be established to measure product performance to include post-purchase cost effectiveness and user satisfaction
Economics of Selection Process Standardization

• Selection review considerations
• Integration of systems
• Processes to maintain
  • My work group
  • Other work groups
• Training, learning curve
• Competencies to verify
• Accountability
Purchases

Capital
• Surgeon > OR > Supply Chain
• SPD
• Clinical Engineering
• Facilities Management

Operating
• SPD
• Supply Chain
More Than the Purchase Price

**Equipment**
- Volume going up or down?
- Integration with existing peripherals and processes?
- Unique containers
- Storage

**Processes**
- Unique equipment and supplies for cleaning

**Personnel**
- Time and man power to clean
- Space and utilities
- Sustainability
- Durability
Due Diligence by Value Analysis Team

Option #1 | Option #2 | Option #3
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Risks | Benefits | Alternatives | Consequences

Find out what the pros and cons are on each to help make a more sound business decision, plan for the future, and remain standardized.
Due Diligence by Value Analysis Team

Less expensive to purchase.
More expensive to maintain.
Cannot be leak tested.

Average repair - $6,000
15 repairs a year – $75,000
6 year lifespan of maintenance - $450,000

More expensive to purchase.
Less expensive to maintain.
Can be leak tested.

Average repair - $3,000
5 repairs a year - $45,000
6-year lifespan of maintenance - $270,000
Evaluation of Variable Benefits

HD Camera
Accommodates Both

HD
SD
Sophisticated Devices
How Is Cost of Ownership Controlled?
Room Prep
Room Turn
Habits That Increase Costs

- Scope Placed Back in Dedicated Tray for Transport
- Stacking Items on Scope During Transportation
- Basin Placed on Scope Shaft
Decontamination and Sterile Processing
QC Inspection and Proactive Maintenance

1. Check distal tip for shaves or burns
2. Check shaft for dents, metal burs
3. Check illumination at distal tip
4. Check straightness of shaft
5. Check for clear image
Container Safety
Review Processes for Cause, Effect and Prevention of Controllable Repair or Replacement Needs
Cause, Effect and Prevention of Damages

• Unique to each service line
• Correlate to QMS
  • Source of business metrics
  • Priority for training
  • Process validation
  • Employee competence verification
  • Audit preparedness
Peripheral Expenses

- Containers
- Cleaning supplies
- Reprocessors
- Sterilizers
- Storage
- Proactive and ongoing maintenance
- Environmental impact
Economic Considerations of Reprocessing

- Supplies
- Space
- Human Resources
- Standardization
- Centralization/Decentralization
- Certification
Review

- Regulatory
  - CFR § 482.41 (c)(2)
  - ANSI/AAMI EQ56:2013
  - ANSI/AAMI EQ89:2015
  - AORN Guideline for Product Selection (2015)
- Equipment management program controlled by
  - My work group
  - In collaboration with others
Questions