

# 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





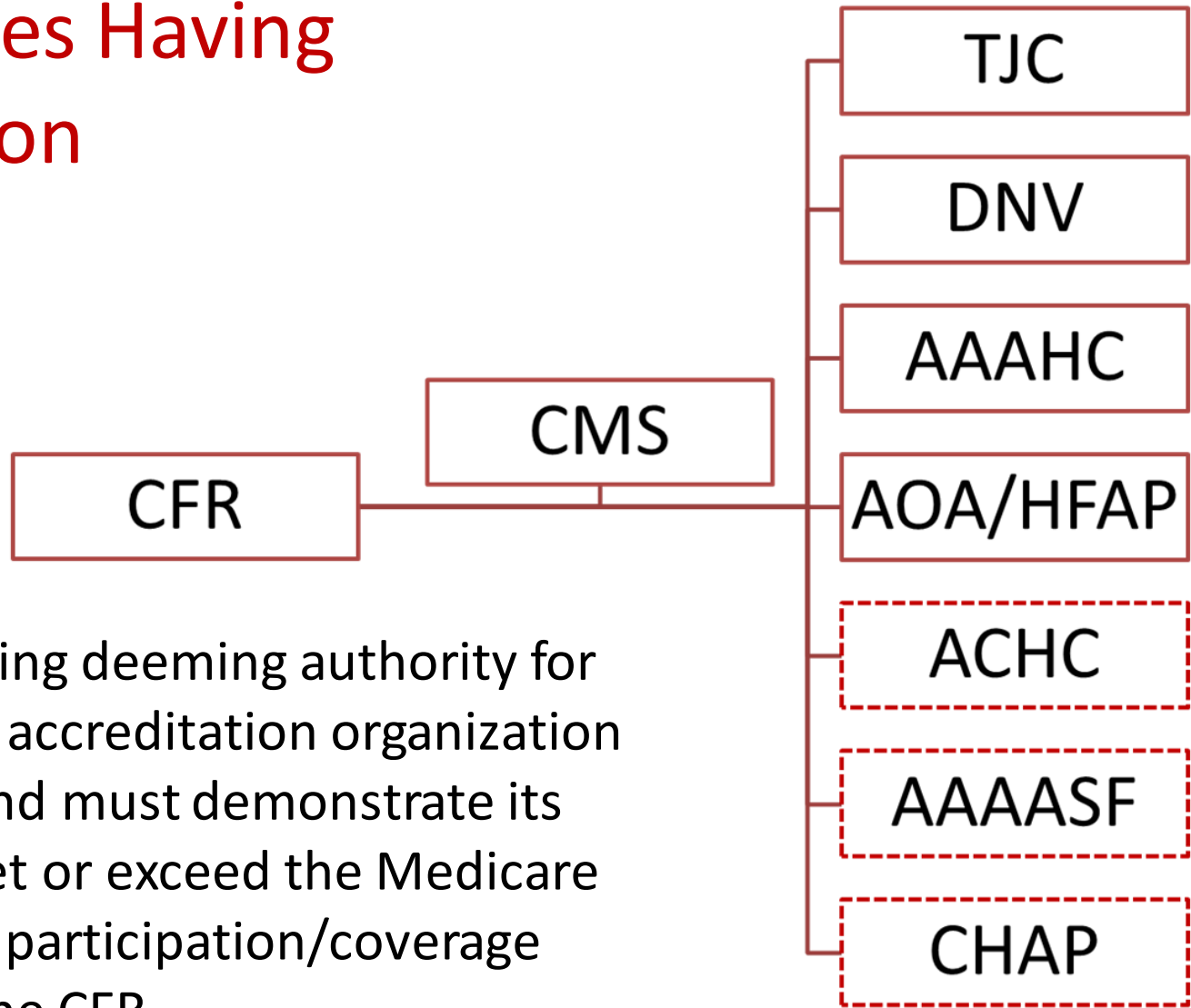
# Why Make New Purchases?

- 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

# Authorities Having Jurisdiction



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*

## *Processes*

## *Personnel*

- Volume going up or down?
- Integration with existing peripherals and processes?
- Unique containers
- Storage
- Unique equipment and supplies for cleaning
- Time and man power to clean
- Space and utilities
- Sustainability
- Durability

# Due Diligence by Value Analysis Team

Option #1



Option #2



Option #3



Risks

Benefits

Alternatives

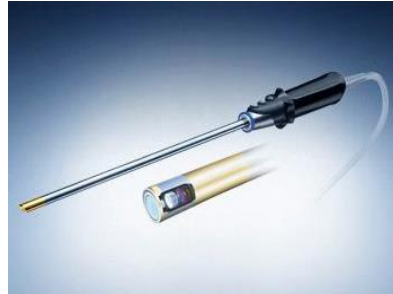
Consequences

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

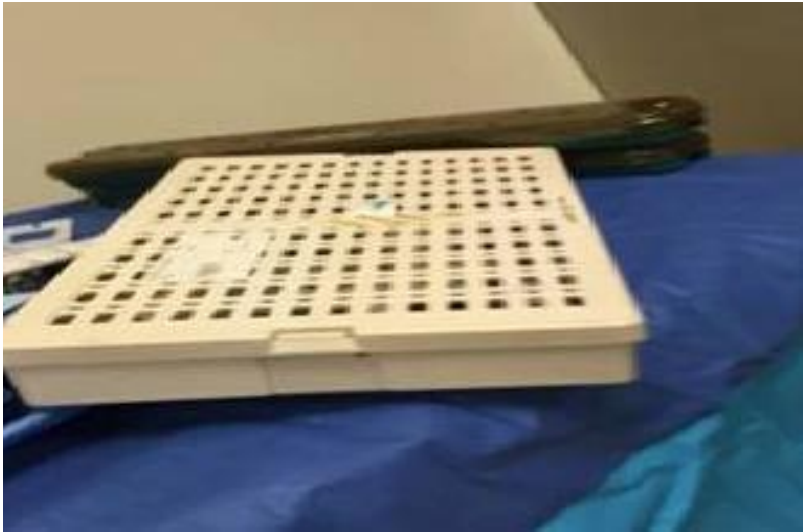
# Sophisticated Devices



# How Is Cost of Ownership Controlled?



# Room Prep



# Room Turn

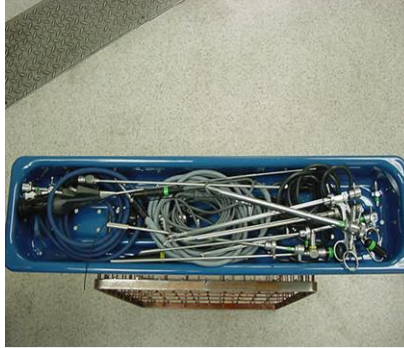




# Habits That Increase Costs



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



Check distal tip for shaves or burns



Check shaft for dents, metal burs



Check illumination at distal tip

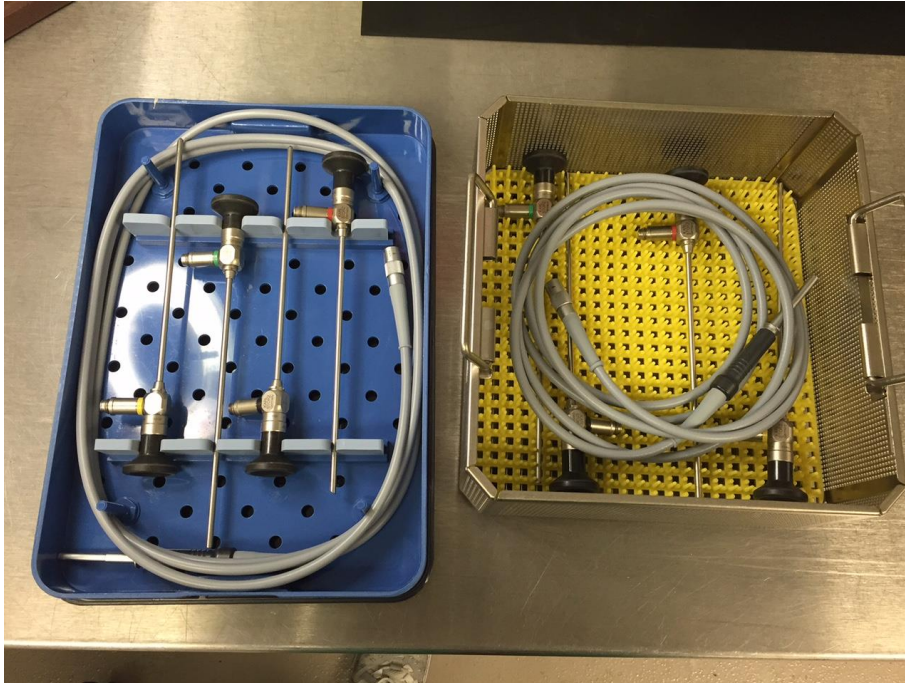


Check straightness of shaft



Check for clear image

# Container Safety



# Review Processes for Cause, Effect and Prevention of Controllable Repair or Replacement Needs

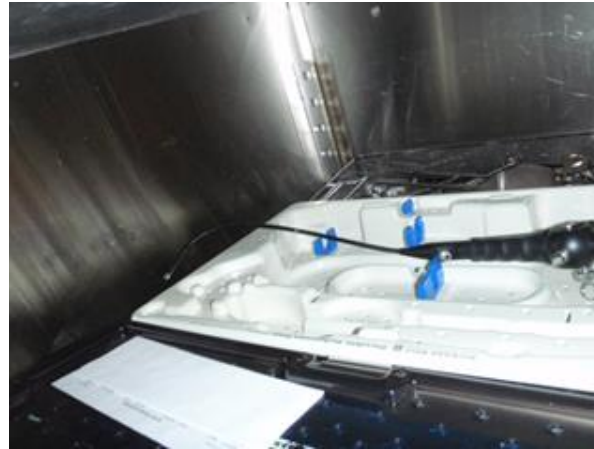


# Cause, Effect and Prevention of Damages

- 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