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QUALITY OF LIFE SERVICES

How to use ISO 14971 to plan AEM

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ABSTRACT

Despite the fact that AEM has been allowed by the Centers for the Medicare & Medicaid Services (CMS) for almost a decade, confusion still persists how it should be planned, executed and evaluated. Many CE/HTM professionals still believe they can continue to use the traditional “risk-based criteria” for AEM planning. We will demonstrate why this is inadequate and present an alternative approach that takes into consideration not only potential harm severity but also the probably of harm to patients, as recommended by the ISO 14971 risk management standard. Some guidelines and specific examples of applying this approach to AEM planning will be presented. Also will be covered is the process to continually improve the AEM using data collected from workorders to update the risk probability.

CONTENTS

Presentation Objectives

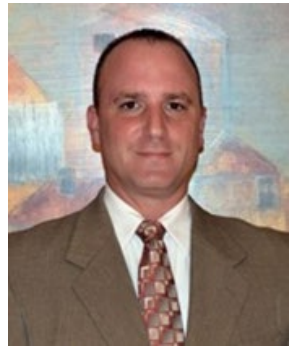
- Demonstrate why the risk-based criteria is inadequate for AEM planning
- Explain what is ISO 14971 standard and how it can be applied to AEM planning
- Provide guidelines and examples on how to use ISO 14971 to plan AEM

About the Speakers – Binseng Wang

- Binseng Wang is vice-president with SODEXO HTM, an independent medical equipment service organization.
- Previously, Dr. Wang was Director, Quality & Regulatory Affairs for Greenwood Marketing LLC, Vice President, Quality & Regulatory Affairs, for Sundance Enterprises, Aramark Healthcare Technologies, and MEDIQ/PRN. He also worked as a Visiting Scientist at NIH, Adjunct Professor at the Milwaukee School of Engineering, and Associate Professor at Univ. of Campinas, Brazil.
- He is a fellow of ACCE and AIMBE. He received the 2010 AAMI CE Achievement Award, the 2015 ACCE Lifetime Achievement Award and the 2019 AAMI-TRIMEDX Iconoclast award. He was inducted into the Clinical Engineering Hall of Fame by ACCE in 2017.
- He earned a Doctor of Science degree from MIT and is a Certified Clinical Engineer (CCE).

Opinions provided here are solely of the author and does not represent those of his employer or any entity with which he is associated.

About the Speakers – Jason Gibson



- Jason is the Director of Quality & Compliance with Sodexo Healthcare Technology Management. He is responsible for ensuring the quality and regulatory of the program provided
  by Sodexo CTM to numerous healthcare delivery organizations ensuring compliance with all federal, state, and local requirements. Additionally, he serves as the corporate Safety Officer, Medical Laser Safety Officer, Radiation Safety Officer, and is the EBRG Chair for HONOR – Atlanta Metro Chapter.
- Prior to taking his role with Sodexo, Jason served in different leadership roles from managing multi-state in-house programs to directing an ISO's field service group. Jason got his start in the HTM profession when he enlisted in the U.S. Army where he honorably served eight years.
- While in the U.S. Army, Jason attended the Army Medical Equipment and Optical School in Aurora, Colorado. Jason received his Bachelor of Science in Business Administration from Bryan College in Dayton, Tennessee. He is certified as a Laser Safety Officer – Medical and has completed the OSHA 10 General Industry and the Radiation Safety Officer training.

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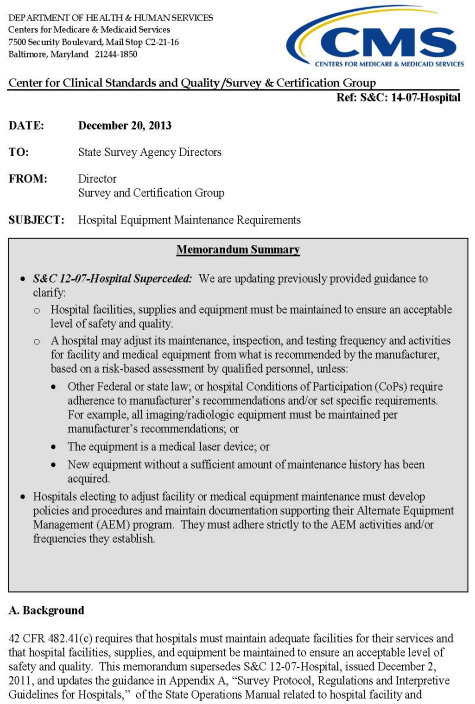
HISTORICAL PERSPECTIVE

- Originally issued by CMS on Dec 20, 2013, through S&C 14-07, revising the S&C 12-07 memorandum issued in 2011, it stated:

  - ***S&C 12-07-Hospital Superceded*** [sic]: We are updating previously provided guidance to clarify:
    - Hospital facilities, supplies and equipment must be maintained to ensure an acceptable level of safety and quality.
    - A hospital may adjust its maintenance, inspection, and testing frequency and activities for facility and medical equipment from what is recommended by the manufacturer, based on a risk-based assessment by qualified personnel, unless:
      - Other Federal or state law; or hospital Conditions of Participation (CoPs) require adherence to manufacturer's recommendations and/or set specific requirements. For example, all imaging/radiologic equipment must be maintained per manufacturer's recommendations; or
      - The equipment is a medical laser device; or
      - New equipment without a sufficient amount of maintenance history has been acquired.
  - Hospitals electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their Alternate Equipment Management (AEM) program. They must adhere strictly to the AEM activities and/or frequencies they establish.



DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 14-07-Hospital

DATE: December 20, 2013

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Hospital Equipment Maintenance Requirements

Memorandum Summary

- ***S&C 12-07-Hospital Superceded:*** We are updating previously provided guidance to clarify:
  - Hospital facilities, supplies and equipment must be maintained to ensure an acceptable level of safety and quality.
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- Hospitals electing to adjust facility or medical equipment maintenance must develop policies and procedures and maintain documentation supporting their Alternate Equipment Management (AEM) program. They must adhere strictly to the AEM activities and/or frequencies they establish.

A. Background

42 CFR 482.41(c) requires that hospitals must maintain adequate facilities for their services and that hospital facilities, supplies, and equipment be maintained to ensure an acceptable level of safety and quality. This memorandum supersedes S&C 12-07-Hospital, issued December 2, 2011, and updates the guidance in Appendix A, "Survey Protocol, Regulations and Interpretive Guidelines for Hospitals," of the State Operations Manual related to hospital facility and

HISTORICAL PERSPECTIVE (cont)

The S&C 14-07 memorandum actually reflects a long history of maintenance requirements by the US government

- The Social Security Amendments (SSA) of 1965 (that created Medicare & Medicaid programs) established the minimum requirements for healthcare organizations to participate in those programs, known as "Conditions of Participation" (CoP), which states (42 CFR 482.41(c)(2)):

> *Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.*

- The 1965 SSA also recognized The Joint Commission and American Osteopathic Association (AOA)'s HFAP as "deemed" accreditation organizations (AOs) for Medicare & Medicaid
- Until 2008, when Congress put all AOs under CMS through the Medicare Improvements for Patients and Providers Act (MIPPA), each AO developed its own standards with diverging requirements for equipment maintenance.
- Around 2009-2010, someone called CMS to complain about different standards being applied by AOs and state agencies surveying on behalf of CMS => CMS issued S&C 12-07 in 2011 requiring all equipment to be maintained per OEM recommendations
- Many organizations and persons lobbied CMS against S&C 12-07 by providing proof that there is no evidence of safety issues when OEM recommendations are not followed => thus the 2013 revision

CONTENTS

The AEM Program (S&C 14-07-Hosp & S&C 14-41-CAH)

- An Alternate Equipment Management (AEM) Program can be established to maintain medical (and facility) equipment at frequencies and using work instructions (aka “activities”) different from those recommended by the manufacturer unless other Federal or state law; or hospital Conditions of Participation (CoPs) require adherence to manufacturer’s recommendations and/or set specific requirements, with the exception of:
  - Imaging/radiology equipment
  - Medical laser device
  - “New equipment without a sufficient amount of maintenance history has been acquired”
- Hospital must develop policies and procedures and maintain documentation supporting their AEM program. They must adhere strictly to the AEM activities and/or frequencies they establish.

AEM Program Requirements

- Hospital must have AEM policies & procedures
- AEM program must be based on "*generally accepted standards of practice*"
- Decision made by *qualified personnel*
- Factors to be considered in AEM inclusion:
  - Consequences of equipment failure or malfunction: severity and scope (mission criticality)
  - OEM recommendation rationale
  - Intrinsic maintenance needs
  - Availability of alternate or backups
  - Incident history
- "*Critical equipment*" must be identified in the AEM Program
- Safety and effectiveness of the AEM must be evaluated periodically and, if needed, revisions made to the AEM Program => It is not enough to just use risk to plan AEM, the outcomes must be evaluated to support continual use of AEM.

Additional CMS Requirements

- Incoming Inspection (aka Equipment Acceptance)
  - All equipment must be inspected and tested for performance and safety before initial use and after major repairs or upgrades
- Oversight
  - Hospital leadership assign responsibility for equipment maintenance to someone who is responsible for equipment maintenance policies, procedures and programs, as well as specific equipment maintenance inventories, activities and schedules
- Maintenance Personnel Qualification(s)
  - Individual(s) responsible for overseeing the development, implementation, and management of equipment maintenance programs and activities must be qualified
  - Records of hospital and contracted personnel are maintained

Additional CMS Requirements (cont)

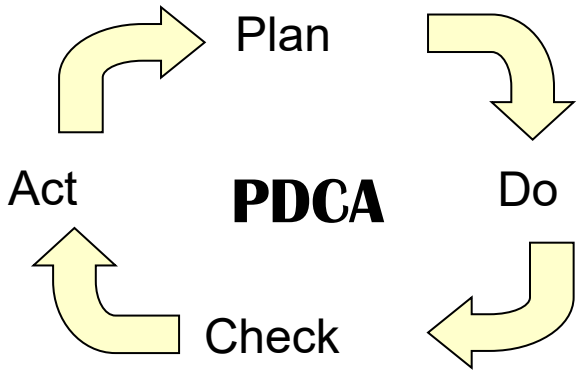
- Maintenance per manufacturer-recommended maintenance activities and schedule ("OEM Program")
  - Maintain documentation of those recommendations
  - Maintain documentation of the maintenance activities
- AEM Program (in addition to prior slides)
  - Documentation: risks, PM frequency, PM work instructions
  - Service records
  - Equipment failures (but not necessarily the causes, especially use errors)
- Inventory Management
  - Equipment Inventory with identification for:
    - AEM inclusion
    - Critical equipment (regardless whether in AEM or not ("OEM"))

Caution! (from CMS)

- “Other Federal law (for example, regulations promulgated by another Federal agency) or State law may require that facility or medical equipment maintenance, inspection and testing be performed strictly in accordance with the manufacturer’s recommendations, or may establish other, more stringent maintenance requirements. In these instances, the hospital must comply with these other Federal or State requirements, but State Surveyors conducting Federal surveys assess compliance only with the federal hospital CoPs.” => state/local regulations and codes may be more stringent and must be followed, although federal (CMS/AO) surveys will only check CMS requirements. Examples:
  - More recent NFPA 99 standard
  - CLIA
  - Radiation protection

The AEM Process

- Planning [Plan]
  - Planned maintenance (PM)
  - Unscheduled, corrective maintenance
- Execution [Do]
  - PM completion (completed versus performed)
- Evaluation [Check]
  - Safety evaluation
  - Effectiveness evaluation
- Improvement [Act]
  - Revision of the AEM program



CONTENTS

ISO 14971:2019 Medical devices— Application of risk management to medical devices

- Within ISO 14971, risk is defined as

Combination of the probability of occurrence of harm and the severity of that harm

- In other words,

risk = probability & severity [of harm]

where & represents combination, not multiplication

ISO 14971:2019 – The Risk Concept

- Why risk is a combination of two factors: probability and severity?
  - Severity only indicates consequence of failure
  - Probability complements the risk estimation by including the likelihood of occurrence
- Example
  - Which means of transportation presents higher risk of harm to you due to poor/lack of maintenance:
    a) driving or riding in a car
    b) flying in a commercial aircraft?

TRANSPORTATION	SEVERITY	PROBABILITY	RISK
Car travel	Minor/Serious	Likely	HIGH
Air travel	Serious/Death	Unlikely (very low)	VERY LOW

ISO 14971:2019 – Risk Concept Applied to Medical Equipment

- Medical equipment example
  - Which type of equipment presents higher risk to patients in case of failure due to poor/lack of maintenance: :
    a) ICU patient monitor
    b) Continuous passive motion machine (CPM)
    c) portable pulse oximeter

TRANSPORTATION	SEVERITY	PROBABILITY	RISK
ICU monitor	Serious/Death	Unlikely	MEDIUM
CPM machine	Medium/Serious	Likely	HIGH
Portable pulse ox	Minor	Unlikely	LOW

Risk-Based Criteria (Fennigkoh & Smith model - 1989)

- Originally (1960's and 70's), equipment was required to be tested for electrical safety (EST) and, later, "PM'd" semi-annually regardless of its potential safety risks and PM needs, due to the electrical shock myth propagated by Ralph Nader and others.
- To alleviate unnecessary PMs, Fennigkoh & Smith proposed to classify equipment according to a set of criteria, aka Equipment Management (EM) number

EM = Function + Physical Risk + Maintenance Requirements

- With the association maintenance strategy
  - If EM ≥ 12, included equipment into inventory and "preventive" (scheduled) maintenance performed monthly, quarterly, semi-annually or annually, according to the EM value.
  - If EM < 12, excluded from inventory and repaired as needed ("run to failure").
- This appeared in a TJC publication and, thus, considered "sanctioned" by TJC

Fennigkoh L & Smith B (1989), Clinical equipment management JCAHO PTSM Series, 2:5-14

Fennigkoh & Smith's Approach

CRITERIA	CATEGORY	SUBGROUP	NUMERICAL VALUE
Function	Therapeutic	Life support	10
		Surgical and intensive care	9
		Physical therapy and treatment	8
	Diagnostic	Surgical and intensive care monitoring	7
		Additional Physiological monitoring and diagnostic	6
	Analytical	Analytical laboratory	5
		Laboratory accessories	4
		Computer and related	3
	Miscellaneous	Patient related and other	2
Physical Risk		Patient death	5
		Patient or operator injury	4
		Inappropriate therapy or misdiagnosis	3
		No significant risks	1
Maintenance Requirements		Extensive	5
		Average	3
		Minimal	1

Why the Risk-Based Criteria is Not Appropriate for AEM?

- Both “Function” and “Physical Risk” are estimates of “risk severity” without considering “risk probability”
- So the Fennigkoh & Smith model should be called “severity-based criteria” or, at least, “severity and maintenance requirement criteria”
- Actually, Dr. Fennigkoh never called his method a “risk-based criteria.” Unclear who proposed this term but it became widely accepted.
- This fact was also publicly recognized by the former TJC Director of Engineering, George Mills, who said

⇑Severity ≠> ⇑PM

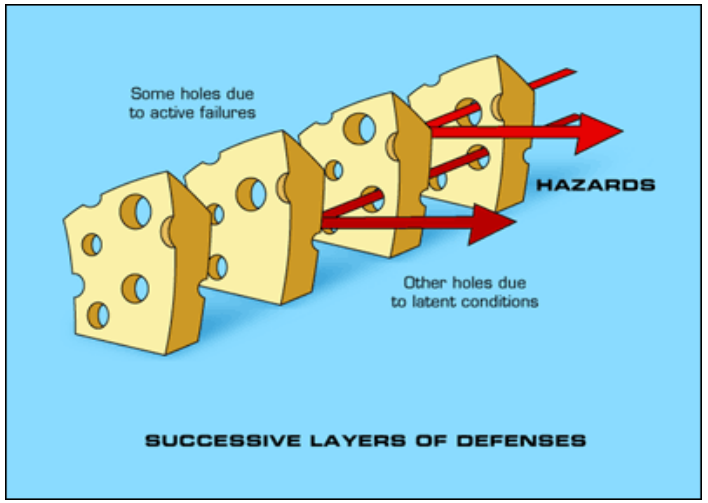
The Role of Maintenance in Risk Management

- Professor James Reason's Swiss cheese model shows an accident only happens when multiple layers of protection ("cheese slices"), each with failure probabilities (number and sizes of holes"), are penetrated by a hazard, i.e.,

$$\text{risk}=(\prod_i P_i) \;\&\; \text{severity}$$

where Pi denotes individual probability.

- Risk can be reduced by having multiple layers of protection ("cheese slices") and reducing the failure probabilities (number and sizes of holes") in each layer
- For medical equipment, typical layers are
  - Medical device design
  - User training and care
  - **Maintenance** => **our job is to reduce holes and keep them small!**



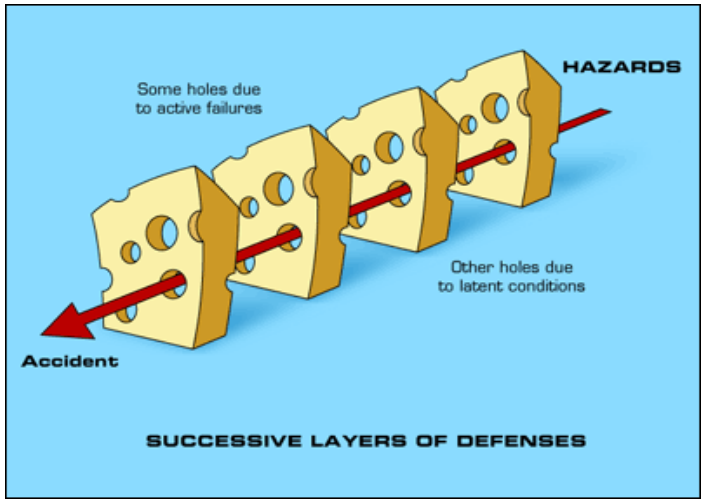


Figure adapted from Reason (2000), Duke Univ. MC patientsafetyed.duhs.duke.edu/module_e/swiss_cheese.html

CONTENTS

APPLICATION OF ISO 14971 TO AEM PLANNING

- Since risk is the combination of severity and probability, let's see how each can be characterized
- Harm severity

Severity Level	Impact on Patient or Clinical User
Serious/Death	Results in permanent impairment or life-threatening injury or death
Significant	Results in temporary injury or impairment without professional medical intervention
None or minor	Results in inconvenience or temporary discomfort

- Harm probability

Probability Level	Annual failure rate (not including failures due to accessories, batteries, use, accident, and network)	MTBF (y) (not including failures due to accessories, batteries, use, accident, and network)
Likely	≥ 10	< 0.1
Probable	< 10 and ≥ 0.5	< 2 and ≥ 0.1
Unlikely	< 0.5	≥ 2

APPLICATION OF ISO 14971 TO AEM PLANNING (cont)

- Equipment risk levels

		HARM PROBABILITY		
		Unlikely	Probable	Likely
HARM SEVERITY	None or minor	LOW	LOW	MEDIUM
	Significant	LOW	MEDIUM	HIGH
	Serious/Death	MEDIUM	HIGH	HIGH

- How equipment risk levels are used in PM planning
  - REMEMBER: High risk ≠> high maintenance
  - AEM exclusions
    - Those required by CMS
    - Lab equipment (CLIA 1998)
    - Blood bank equipment
    - True preventive maintenance – TPM (replacement of wearable parts)
    - Others based on experience and liability risk considerations (e.g., surgical robots, radiation therapy, hyperbaric chambers, NucMed, neonatal ICU, etc.)

APPLICATION OF ISO 14971 TO AEM PLANNING (cont)

- Equipment risk levels

		HARM PROBABILITY		
		Unlikely	Probable	Likely
HARM SEVERITY	None or minor	LOW	LOW	MEDIUM
	Significant	LOW	MEDIUM	HIGH
	Serious/Death	MEDIUM	HIGH	HIGH

- How equipment risk levels are used in PM planning (i.e., safety & performance inspections (SPIs) and not TPM)
  - SPI frequencies

EQUIPMENT RISK LEVEL	MININUM AEM PROGRAM PM FREQUENCY (with respect to OEM recommended frequency)
HIGH	1/3 of OEM recommended frequency, if available
MEDIUM	1/4 of OEM recommended frequency, if available or run to failure (RTF)
LOW	RTF

  - SPI activities
    - EST only needed for incoming/returned equipment and after repairs affecting electrical safety
    - Follow OEM recommended tasks unless evidence exist otherwise

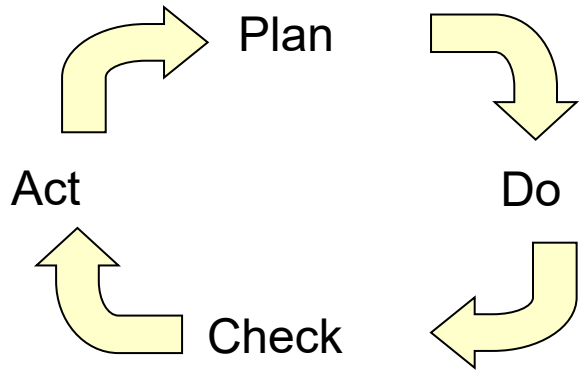
Examples

EQUIPMENT	AEM FREQUENCY	AEM TASKS	OEM RECOMMENDATIONS
SpO2 (Nellcor BPMS)	RTF	On demand SPI	Biannual
PCA Pump (CADD Solis)	Annual	Condensed versions of OEM-recommended PM activities	Annual with complex procedure
Defibrillator (LIFEPAK 20e)	Annual	Performance tests using standard test & measurement equipment (output test, AED function check, pacer check, and sync test)	Annual using its proprietary “performance inspection procedure” (PIP) software

CONTENTS

DISCUSSION & CONCLUSIONS

- AEM is not only planning and execution (Plan & Do) but also requires evaluation and continual improvement (Check & Act)
  - AEM evaluation is not simply measuring MTBF => use FCC to analyze failure causes
  - The AEM plan is only a starting point. Realities and needs change => periodic updates and revisions are inevitable using data (evidence-based maintenance – EBM)
- ISO 14971 is still imperfect: does not consider pt population, only individuals => collective risk model
  - Large quantity of medium risk devices (e.g., infusion pumps) can present HIGH risk to a hospital due to the high number of patients potentially affected



Correspondence Between PDCA and ISO 14971

- ISO 14971 was originally created for device manufacturers, so it has to be interpreted in a slightly different way for device servicing

PDCA	ISO 14971 FOR MFG	SERVICING
Planning	Risk Analysis Risk Evaluation Risk Control	Service planning (e.g., AEM)
Execution	Production	Service delivery
Evaluation	Post-Production	Safety and effectiveness evaluation
Improvement	Continual improvement	Service plan revision

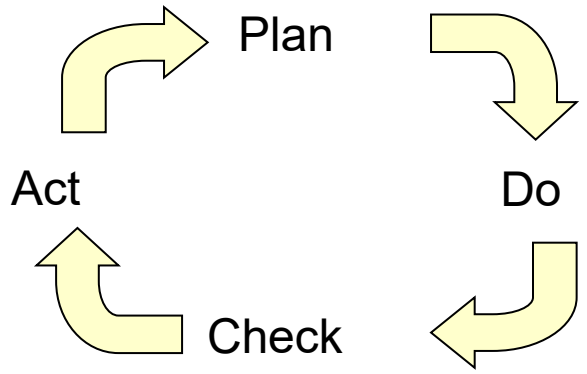
PM Completion Illusion

- CMS and its accrediting organization require 100% PM completion BUT does this ensure low risk to patients (and clinical users)?

QUESTION: Does perfect school attendance guarantee student learning?

- Shouldn't we (CE/HTM professionals and healthcare delivery organizations) worry more about the actual outcomes of our maintenance and management efforts than reaching a numerical target, much like clinicians focus on pt outcomes and not on drugs, devices or procedures?
  - Process measure: PM completion
  - Outcome measure: equipment safety incidents and maintenance-related reliability (failure causes)

DO: Collect data using Root Cause Analysis (RCA) of Failures => Failure Cause Codes (FCC)



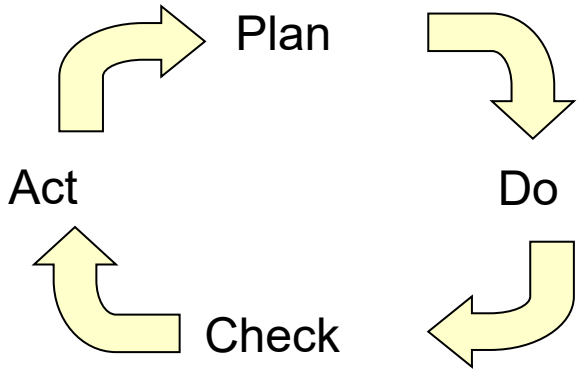
- Data must be collected to allow analyses (evaluation) later
- RCA is needed to understand why a piece of equipment failed, so one can determine what can be done about it.
- Full RCA is time consuming and not needed in most cases (except when a patient injury occurred).
- Simplified RCA => **Failure Cause Codes (FCC)**: a limited set of failure causes easy to be assigned and analyzed.

Like EB Medicine, EB Maintenance tries to find ways to address the failure root causes and uses the outcomes to determine which one works best

DO: Failure Cause Codes (FCC)

Code	Failure Cause Description	PM/CM
NPF	No problem found (or the reported problem was not duplicated).	both
UPF	Unpreventable failure, typically caused by normal wear and tear but is unpredictable.	CM
ACC	Accessory failure, excluding batteries, typically caused by normal wear and tear.	both
BATT	Battery failure, i.e., battery(ies) failed before the scheduled replacement time. Does not include scheduled replacement of batteries.	both
NET	Failure in or caused by network, while the equipment itself is working without problems. Applicable only to networked equipment.	both
USE	Failures induced by use, e.g., abuse, abnormal wear & tear, accident, or environment issues.	CM
EF	Evident failure, i.e., a problem that can be detected, but was not reported by the user, without running any special tests or using specialized tester.	PM
SIF	Service-induced failure, i.e., caused by CM or PM that was not properly completed or a part that was replaced and failed prematurely ("infant mortality").	CM
HF	Hidden failure, i.e., a problem that could not be detected by the user under normal circumstances, unless running a special test or using specialized tester.	PM
PF	Potential failure, i.e., failure is either about to occur or in the process of occurring but has not yet caused equipment to stop working or problems to patients or users.	PM
PPF	Preventable and predictable failure, typically caused by wear and tear that can be predicted or detected.	CM

CHECK: Maintenance Evaluation



- Primary goals of equipment maintenance (including PM)
  - Safety: equipment is safe for patients and clinical users
  - Reliability: equipment is available for use whenever needed
- Therefore:
  - **Safety Evaluation**: determine if the maintenance strategy is enhancing the safety of patients and clinical users (i.e., reduce equipment malfunctions that negatively affect patients and clinical users).
  - **Reliability (Effectiveness) Evaluation**: determine if the maintenance strategy is enhancing the reliability of equipment and, thus, the care of patients (i.e., making equipment more available for use when needed).

Safety

Effectiveness = Reliability

CHECK: An Example of Safety Evaluation

	YEAR										Decade Total	%
Data Type	**2004**	**2005**	**2006**	**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**		
# incidents reports received	31	28	47	46	48	49	62	88	58	61	**518**	NA
# incidents investigated	28	26	39	36	41	48	61	84	53	60	**476**	**91.9%**
# investigated incidents with harm, including deaths (to patient or user)	12	11	16	21	11	21	23	38	17	27	**197**	**41.4%**
# investigated incidents with deaths	6	5	4	8	7	9	9	12	7	7	**74**	**15.5%**
# investigated incidents with deaths but no equipment or accessory failures	5	4	2	4	4	7	9	8	3	5	**51**	**10.7%**
# investigated incidents traced to equipment or accessory failures	14	8	14	19	19	24	22	31	21	30	**202**	**42.4%**
# investigated incidents potentially related to maintenance omission	1	0	0	1	0	2	0	0	1	1	**6**	**1.3%**
# equipment managed	694,148	827,503	944,449	942,006	920,109	895,064	905,747	1,195,054	1,176,401	1,182,936	9,683,417	
# PM performed	555,318	662,002	755,559	753,605	744,209	726,933	768,669	935,020	885,629	905,955	7,692,900	
# repairs performed	277,659	331,001	377,780	376,802	358,546	359,177	364,629	455,046	474,211	473,016	3,847,868	

Data collected by Aramark Healthcare Technologies and presented at MD-Expo Oct. 2014

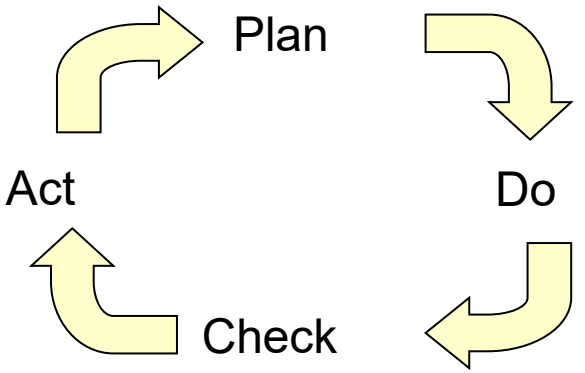
CHECK: An Example of Reliability Evaluation

- Data Analyzed
  - Single hospital group (3 sites)
  - 3 years: 2012-2014
  - Inventory: ~7,900 units
- FCC Analysis
  - Few SIF, HF, PF and PPF
  - However, one equipment group had several HF (9 out of 65 units) => further review needed
    - Most due to premature component wear out not subject to OEM-recommended PM
- Conclusion: Revise PM strategy by increasing frequency higher than the recommended by OEM.

	total	per year	CM/PM rate
CMs	5381	1794	23%
PMs	11012	3671	46%

Code	#WO	Equip Groups
SIF	6	6
HF	16	7
PF	4	4
PPF	7	5

ACT: Use of EBM Evaluations



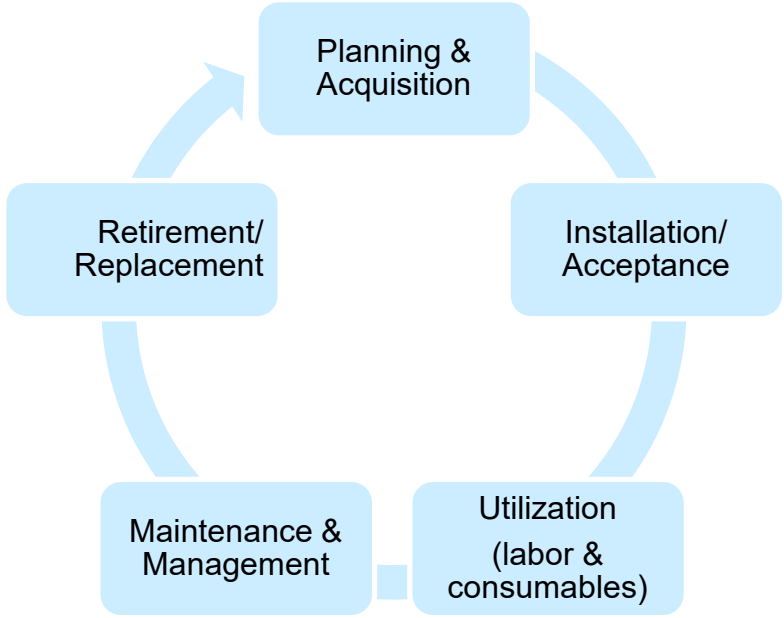
- Results of Safety and Reliability Evaluations should be used to revise and refine PM and CM strategies, i.e., to determine corrective & preventive actions (CAPA):
  - CAPA for "unsafe acts" (or "active failures") committed by individual staff:
    - Training
    - Revision of work instructions
    - Disciplinary actions
  - CAPA for "latent conditions" created by the organization
    - **Revision of PM/CM strategies** (procedures, frequencies, work instructions, etc.)
    - Supervision of in-house and external service staff

Plan=>Do=>Check=>Act **aka Scientific Method**

Why Evidence-Based Maintenance (EBM)?

Classical Approach

- Maintain equipment as recommended by the manufacturer to ensure safety
- Reduce maintenance costs
- Minimize Capital Investment (CapEx)



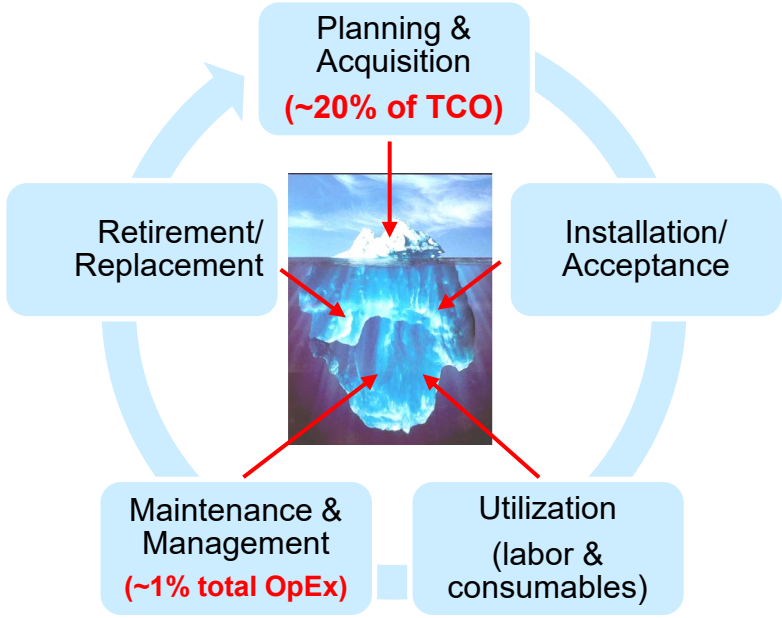
Why Evidence-Based Maintenance (EBM)?

Classical Approach

- Maintain equipment as recommended by the manufacturer to ensure safety
- Reduce maintenance costs
- Minimize Capital Investment (CapEx)

HOWEVER

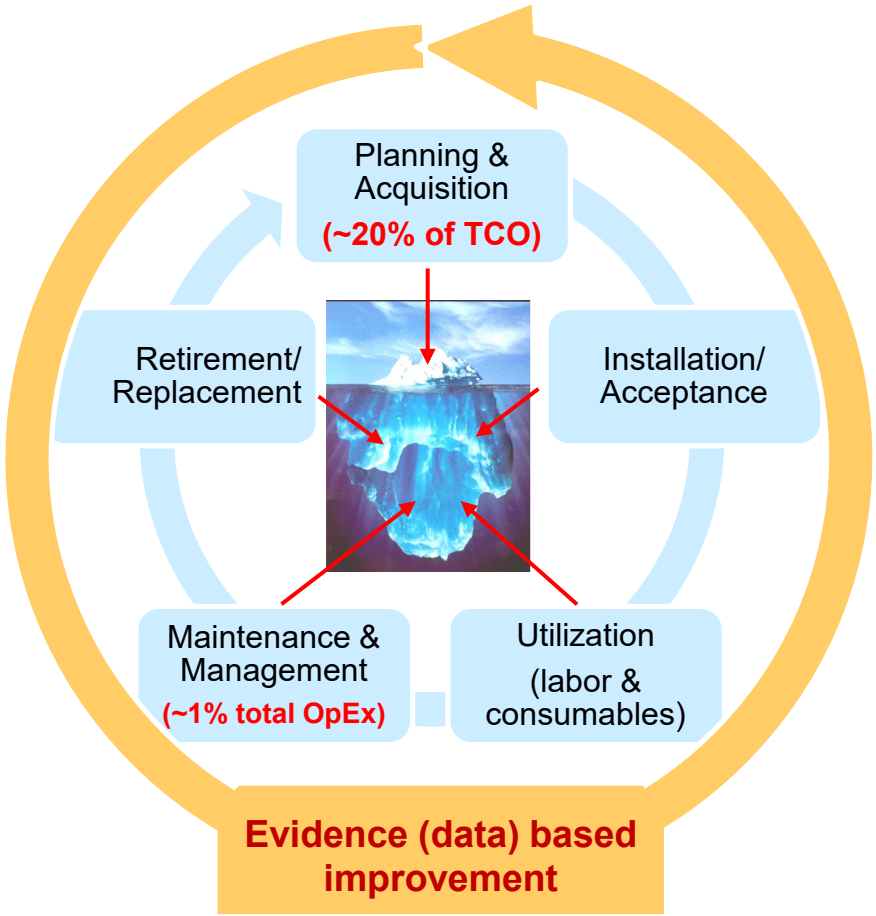
- CapEx is only ~20% of total cost of ownership (TCO)
- Maintenance cost is only ~1% of total hospital operating expense (OpEx)



Why Evidence-Based Maintenance (EBM)?

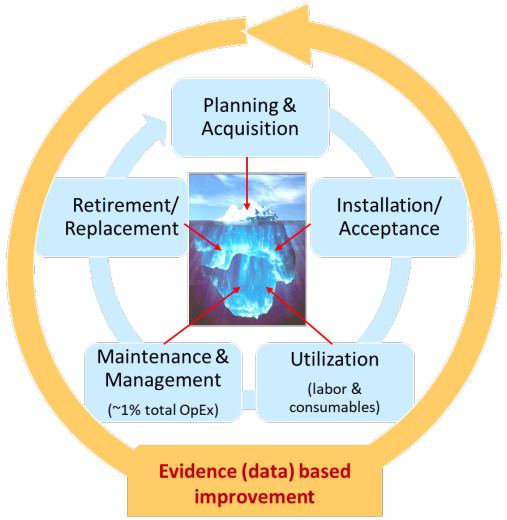
EBM Approach

- Use data collected (not only from your hospital but also hundreds others) to:
  - Improve capital planning
  - Increase utilization
  - Reduce unnecessary maintenance
  - Delay premature replacement
  - Enhance safety and protect against cyberattacks
- Thus increase productivity & revenue



How can EBM improve equipment management?

- Why perform schedule maintenance if it does not reduce failure or increase safety? Example: routine electrical safety test eliminated by NFPA
- Shouldn't I use my limited resources (time, material, money, etc.) to focus on other clinical engineering duties, e.g.
  - Help plan and select better equipment before purchase
  - Help users to understand and use better the equipment
  - Help users to understand and take better care of the equipment
  - Help to determine when equipment needs to be replaced
  - Help to investigate patient incidents related to medical equipment
  - Address recalls promptly to reduce risks to patients and users
  - Address cybersecurity issues presented by equipment



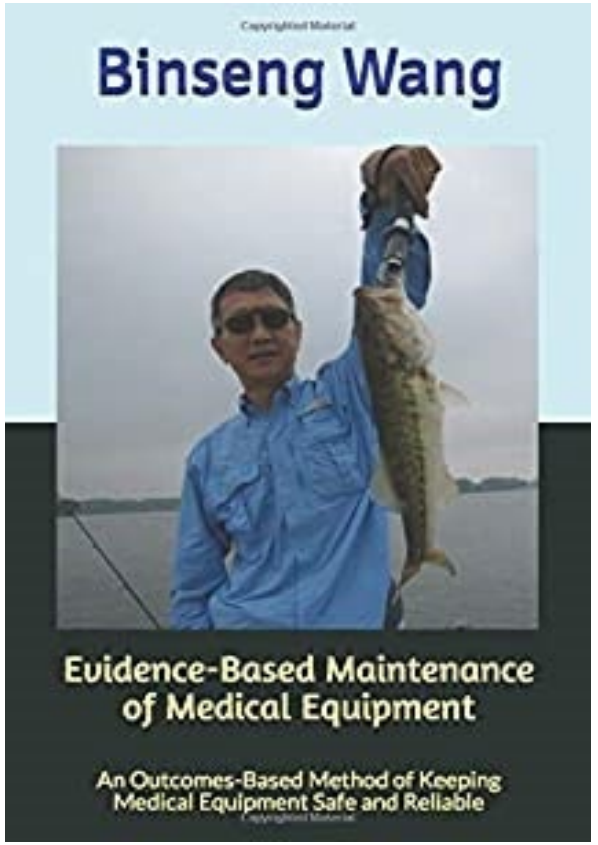
CE = maintenance + management

A Reference

- ***Evidence-Based Maintenance of Medical Equipment***

  An Outcome-Based Method of Keeping Medical Equipment Safe and Reliable

- BSI, Cornelius NC, 2019
  (available through amazon.com)



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- Hundreds of my former colleagues at Aramark Healthcare Technologies, current colleagues at Sodexo HTM, and friends from other healthcare organizations provided the data presented here. Jared Koslosky, Jim Fedele, Salil Balar and many others contributed to the concepts presented here. Torgeir Rui was responsible for most of the data analyses.
- Several other healthcare organizations and independent service organizations have started also to implement EBM, including some in Italy and Brazil.
- However, we are solely responsible for all the mistakes and confusion in this presentation.

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QUALITY OF LIFE SERVICES

Thank you!

Questions & suggestions are most welcome!