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Using RCM to Create a Practical AEM Program

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AAMI's RCM Task Force

AAMI announced in October 2015 its support for a new project …

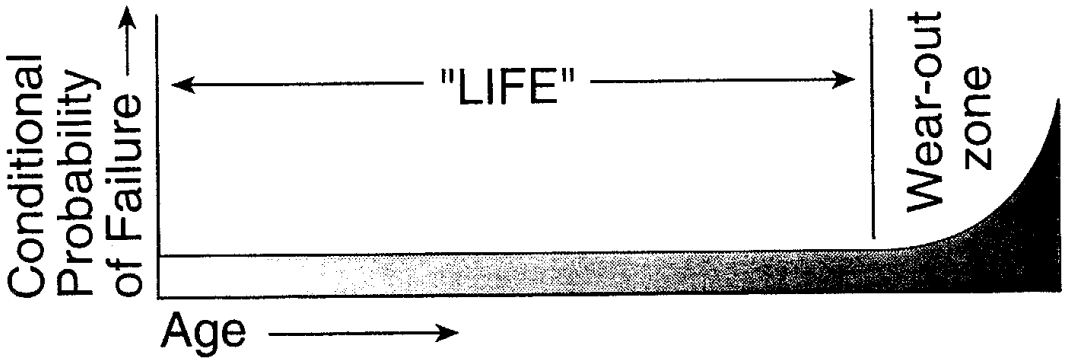
> "***to begin exploring whether an approach known as reliability-centered maintenance (RCM) should be adopted on a wider scale throughout the field of healthcare technology management".***

Objective #1. "… Develop … … a scientifically sound … RCM methodology for determining which types of medical devices are actually made safer by periodic PM… … …"

What is “the RCM approach”?

- The traditional approach to maintenance used for relatively simple machines (locomotives, autos) has been periodic scheduled overhauls
- This was much too costly for the new Jumbo jets that were introduced by the airlines in the 1970s
- In the mid-1960s an FAA Task Force investigated how more complex machines actually fail - and this lead to a more systematic and less costly way of maintaining these more complex devices – known as reliability-centered maintenance (RCM)

The traditional (pre-1960) idea of how a machine fails (by wearing out)



Basics - Planned Maintenance (PM)

There is absolutely nothing magical about PM

PM = { Device restoration (DR) tasks + Safety verification (SV) tasks }

- **DR** tasks restore parts that might need attention
- **SV** tasks check to confirm that the device's performance and safety are still within the specified limits (No hidden failures)

Basics - RCM

The basic analytical approach used in RCM is the **5-part Failure Modes and Effects Analysis (FMEA)**

- Map (describe) the process.

1. Identify the device's failure modes & causes.
2. Project the severity of the adverse outcomes of the device failing.
3. Project the probability of the device failing.

- List possible failure prevention strategies.

Three basic causes of device failures

1. Inherent causes (circuit boards failing, poor construction, poor design, etc.)

2. Process-related causes (device being dropped, incorrect operation by the user, etc.)

3. Maintenance-related causes (inadequate PM, etc.)

PM-preventable failure modes and PM-critical devices

A full FMEA analysis of a medical device can be quite overwhelming because there are (usually) very many ways for devices to fail, besides receiving insufficient or untimely PM

- So the Task Force is using the legitimate shortcut of looking at only PM-preventable failure modes
- And using the term PM-critical to label those devices that have PM-preventable failure modes

PM-focused Risk Assessment

Examines the PM tasks listed in the manufacturer's recommended PM procedure to see whether or not there are PM tasks listed that could prevent the device from having a failure that …….

a) Could result in an adverse outcome …at some (non-trivial) Level of Severity (LOS 1, 2 or 3) … and

b) Could be prevented by either:
- timely restoration of a non-durable part
- or timely detection of a serious performance or safety degradation

If the device has such tasks – it is a PM-critical device

Severity of the potential adverse outcome …

… if the device suddenly stops working while in use, because a non-durable part (NDP) was not restored properly, or in a timely manner …. and/or … if the device falls out of spec and fails one or more of the safety verification tests.

Level of severity (LOS) of the outcome of the failure	
LOS 3	Serious, life-threatening situation
LOS 2	Less serious, non life-threatening injury
LOS 1	No injury but possible disruption of patient care
LOS 0	Consequence of adverse outcome is negligible

Failure severity analysis of PM-critical devices

The analyses showing which devices are judged to be PM-critical are summarized in Table 2 and Table 3 on the Task Force's website

http://htmcommunitydb.org/wiki/index.php?title=Table_2.

http://htmcommunitydb.org/wiki/index.php?title=Table_3.

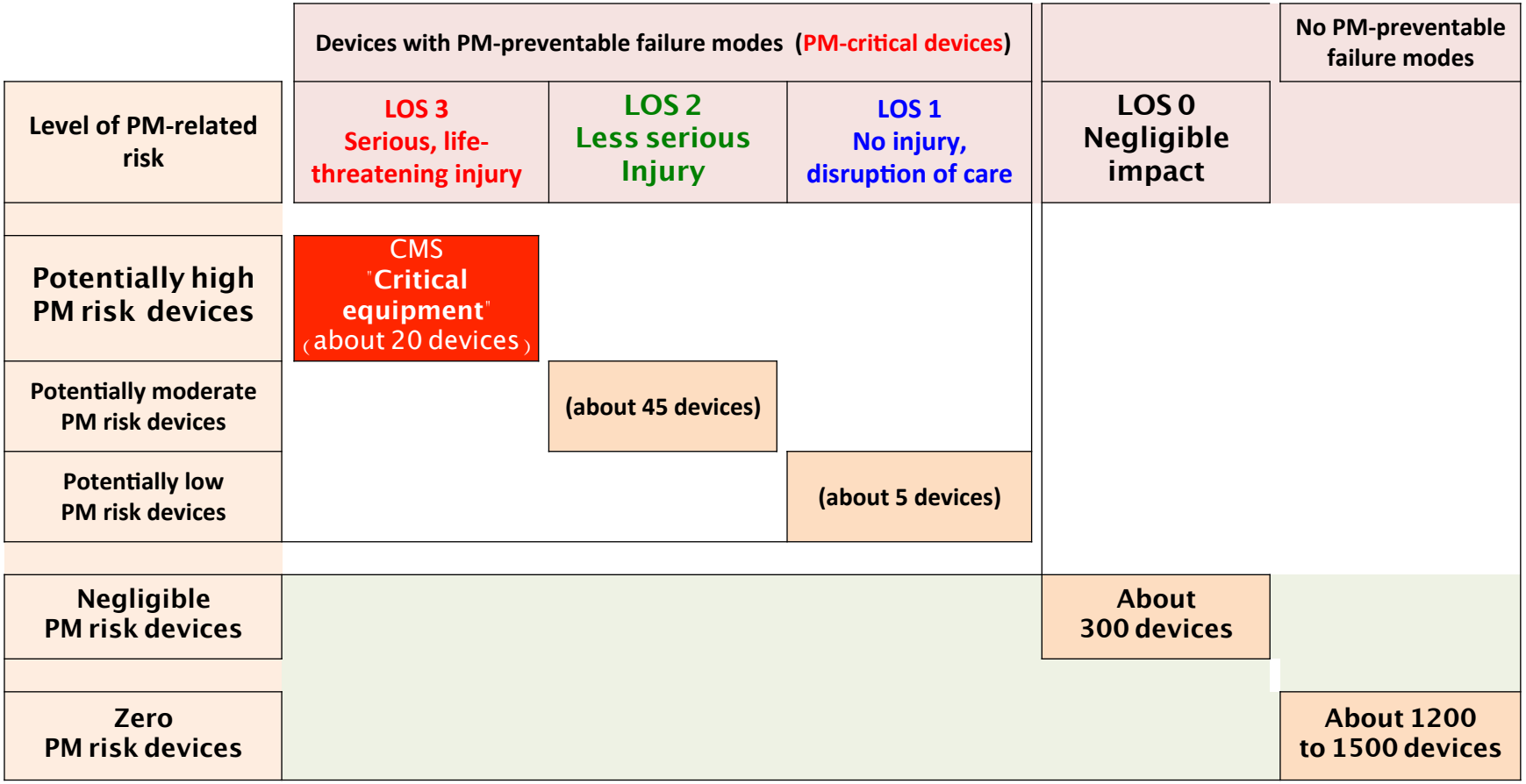
The result of combining these two analyses is a list of twenty devices that are PM-critical at the highest level of severity (potentially high PM risk devices - also called "critical equipment" by CMS)

http://htmcommunitydb.org/wiki/index.php?title=Table_4.

Table 4 – PM-critical devices with the highest levels of outcome severity

	2. HTMC device type	3. Level of Severity of effects of device restoration failures	4. Level of Severity of effects of hidden safety failures	5. PM Failure Severity Level - based on potential severity of PM-preventable device failures	6. HTMC Procedure Code
1	AED	3	3	A. Highest severity	AED-01
2	anesthesia unit	3	3	A. Highest severity	ANES-01
3	critical care ventilator	3	3	A. Highest severity	C.VEN-01
4	defibrillator/ monitor	3	3	A. Highest severity	DEF-01
5	intra-aortic balloon pump	3	3	A. Highest severity	I.A.B.P-01
6	transport incubator	3	3	A. Highest severity	T.INC-01
7	transport ventilator	3	3	A. Highest severity	T.VEN-01
8	apnea monitor	2	3	B. High severity	APN.M-01
9	infant incubator	2	3	B. High severity	IN.IN-01
10	cardiac resuscitator	3	2	B. High severity	C.RES-01
11	external pacemaker	3	2	B. High severity	EX.PA-01
12	heart-lung bypass unit	3	2	B. High severity	H.L.BY-01
13	neonatal monitor	2	3	B. High severity	NEO.M-01
14	oxygen monitor	2	3	B. High severity	OXY.M-01
15	patient monitoring system	2	3	B. High severity	P.M.S-01
16	linear accelerator	1	3	C. Moderate-high severity	LN.AC-01
17	blood pump, extracorporeal	3	0	D. Moderate severity	BL.P.E-01
18	oxygen analyzer	0	3	D. Moderate severity	OXY.A-01
19	PCA pump	0	3	D. Moderate severity	INF.D-03
20	syringe pump	0	3	D. Moderate severity	INF.D-02

Mapping device eligibility for AEM program - **Phase One**



Based on the outcome severity ratings in Table 4 on website.
Devices with LOS 2,1,0 and Zero PM risk can be considered eligible for AEM
(Note that CMS has specifically excluded radiological imaging and medical lasers)

Setting up a “Phase 1” AEM program

- Consult the severity rating tables on the website to identify all of your devices that are either “zero PM risk” or “PM-critical” with adverse failure outcome severity levels of LOS 0, 1 or 2

- Then follow the 7-step implementation plan - in 16.9 http://www.htmcommunitydb.org/wiki/index.php?title=HTM_ComDoc_16#16.9_Creating_a_simple._2C_practical_AEM_program

- The Task Force has several works still in progress.

- In the meantime - enjoy an immediate boost in the efficiency of your PM program!

A device's level of PM-related risk

is determined by combining ….

The level of severity of the outcome of the PM-preventable failure
and
the probability that the failure will actually occur

Work still in progress

- Making credible determinations of PM-related failure rates (PM-related reliability) for all of the different make-model combinations of those devices considered to be CMS "critical equipment"

- Standardizing maintenance documentation (EQ 56?)

- Investigating what to set as an acceptable level of PM-related reliability ….

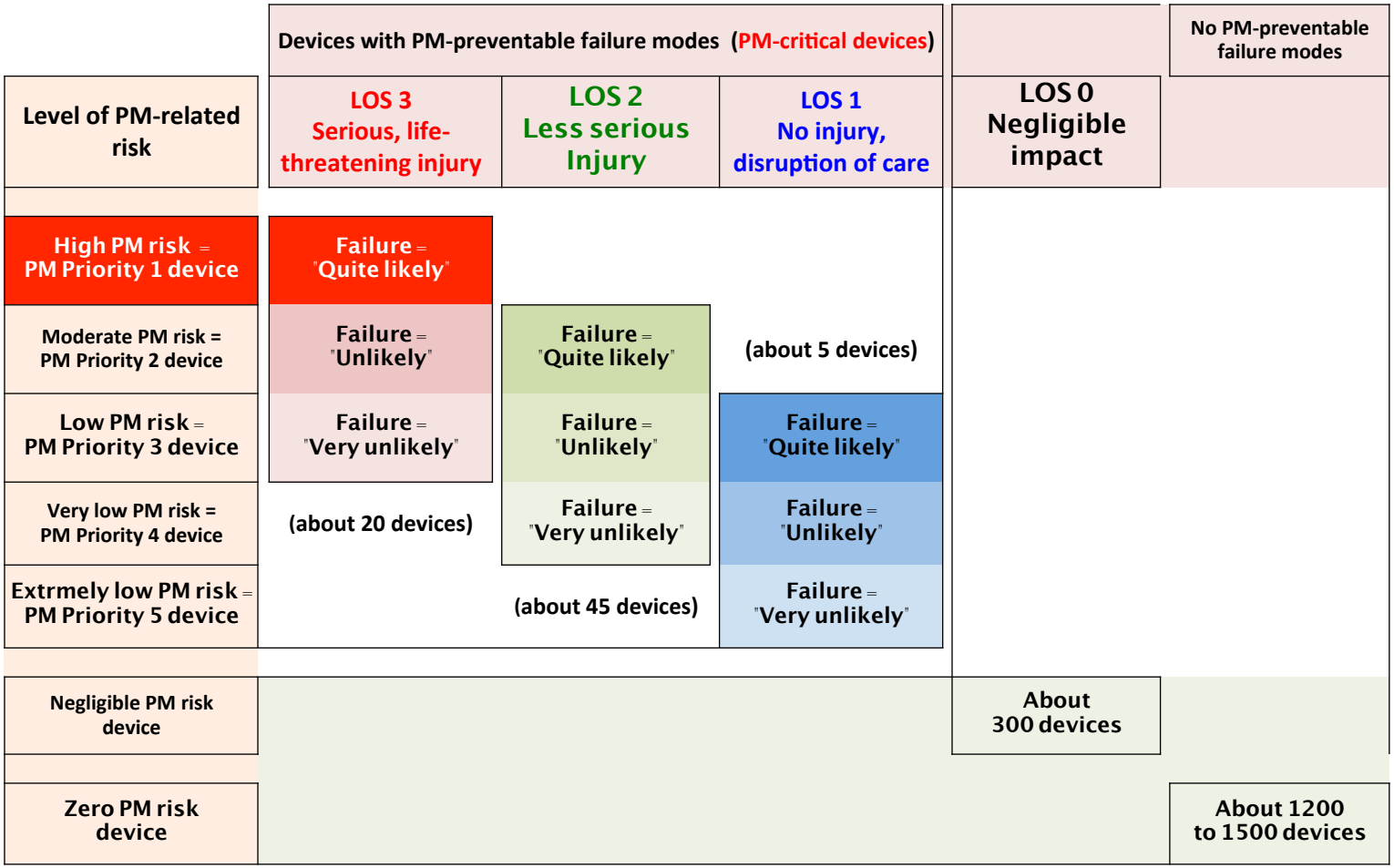
  …. and, therefore, PM-related patient safety)

Probability that the PM-related failure will occur (Level of PM-related reliability)	
Quite likely	**to fail** from a PM-preventable cause with a worst-case adverse outcome at some specified level of severity
Unlikely	**to fail** from …
Very unlikely	**to fail** from …

Devices with PM-preventable failures that have high severity adverse outcomes are potentially high PM risk devices
(aka CMS "critical equipment")

Devices with PM-preventable failures that have high severity adverse outcomes that are "quite likely" to occur are high PM risk devices
(aka "PM Priority 1 devices")

Mapping device eligibility for AEM program - **Phase Two**



Assembling credible data

- The Task Force has created a national database to aggregate relevant maintenance findings
- Data will be displayed by manufacturer-model
- Already have a number of organizations that have volunteered to contribute data
- "Welcome package" for volunteers requiring them to use:
  - Standardized metrics
  - Standardized names for device types, manufacturers, different models
  - Standardized data structures

For more details:
http://www.htmcommunitydb.org/wiki/images/d/d4/Welcome_package_rev_11-3-16.pdf

The Renovo experience – Challenges

- Data on old PM work orders does not provide helpful information on physical state of device
- It is primarily boilerplate such as:
  - PM Passed/Completed
  - PM Failed
  - Equipment “Could not locate”
  - Equipment “In Use”

- Huge amount of data but little or no information on the effectiveness of current PM strategies

The Renovo experience - Progress

- Changes to CMMS system to adopt RCM concepts
- Introduced standardized coding on PM work orders
- Ask two simple questions during PM - about the:
  - Device restoration (DR) tasks
  - Safety verification (SV) testing
- Training on the new codes
- Customized reports to monitor the PM documentation
- Spot checks to get engineer/ technician perspectives on ease of assigning the codes during the PM
- Develop and share the reports on PM-related reliability by make/model

A message from the Task Force

- Our immediate goal is to provide the HTM community with a simple and safe, but scientifically sound, blueprint for an initial AEM program that can be implemented quickly and easily.

- It is our hope that this blueprint will be considered acceptable to the CMS by the various accrediting organizations with deeming authority.

- Our longer term goal is to create a national database of maintenance findings to provide the **key evidence** needed to make all of the nation's biomedical maintenance programs as safe and as efficient as possible.

- **Please consider signing up and committing to contribute your maintenance findings to the project**.

Thank you

Questions?

www.HTMCommunitydB.org