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Alternative Equipment Maintenance Using RCM-based Risk Assessment & Survivability Analysis

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Session Objectives

- AEM EPs
- Reliability Centered Maintenance (RCM) history and methodology
- Standard RCM Calculations-MTBF
- AEM using RCM Based Risk Assessment and Survival Analysis

HAP EC.02.04.01 EP 4

The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting and testing all medical equipment on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

HAP EC.02.04.01 EP 5

The hospital's activities and frequencies for inspecting and testing, and maintaining the following items must be in accordance with manufacturer's recommendations:

- Equipment subject to federal and state law
- Medical Laser devices
- Imaging and radiologic equipment
- New medical equipment with insufficient maintenance history

HAP EC.02.04.01 EP 6

- A qualified individual(s) uses written criteria to support the determination whether it is safe to permit medical equipment to be maintained in an alternate manner that includes the following:
  - How the equipment is used, including the seriousness and prevalence of had during normal use
  - Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of hard
  - Availability of alternative or backup equipment in the event that the equipment fails or malfunctions
  - Incident history of identical or similar equipment
  - Maintenance requirements of the equipment

HAP EC.02.04.01 EP 7

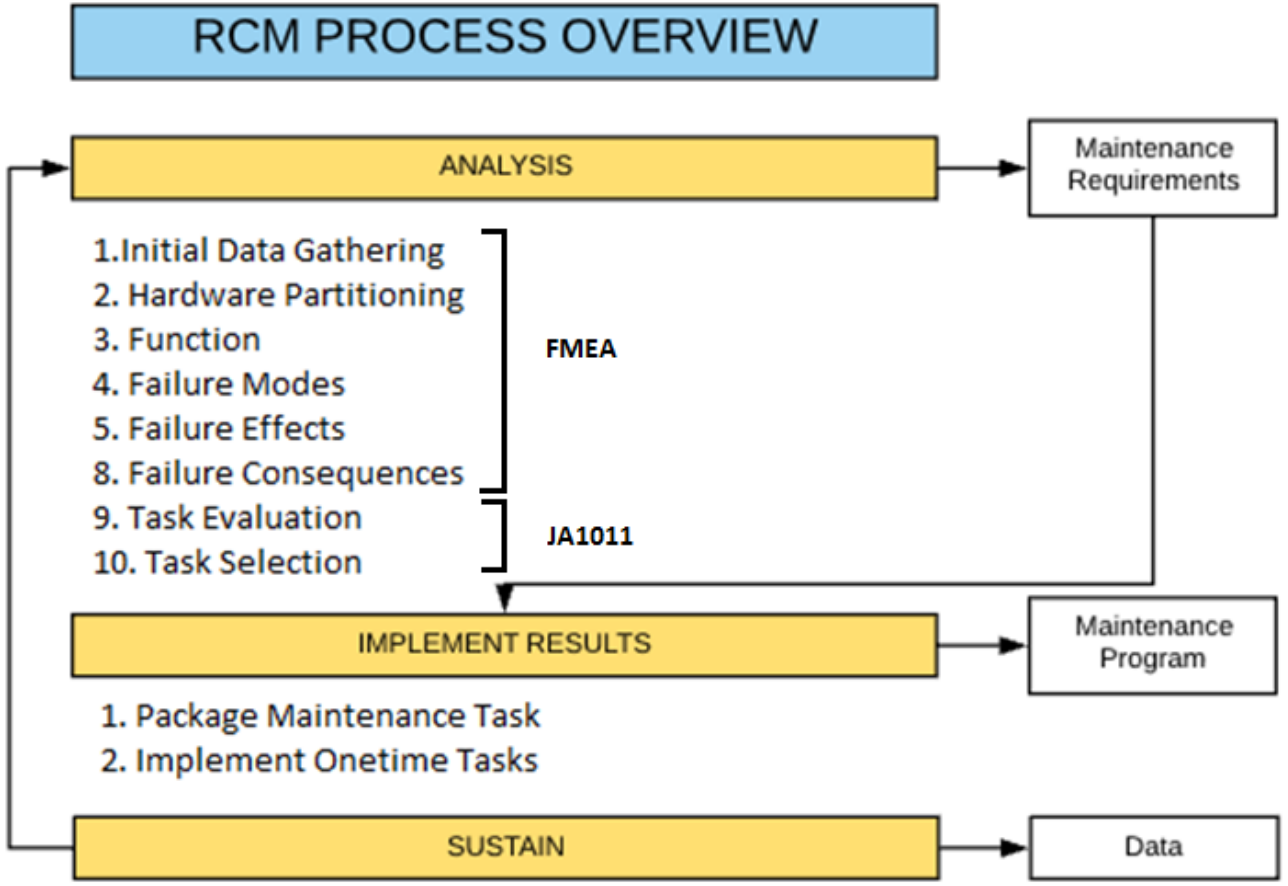
- The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

Why consider implementing an AEM program?

- We can reduce costs while achieving the same level of safety
- EP 4 also sets requirements for the “on-schedule completion of PM” metric. An appropriate AEM PM procedures will streamline PM operations and make it easier to meet 100% metric requirement.

What is RCM?

- Reliability-Centered Maintenance (RCM): a process used to determine the maintenance requirements of any physical asset in its operating context



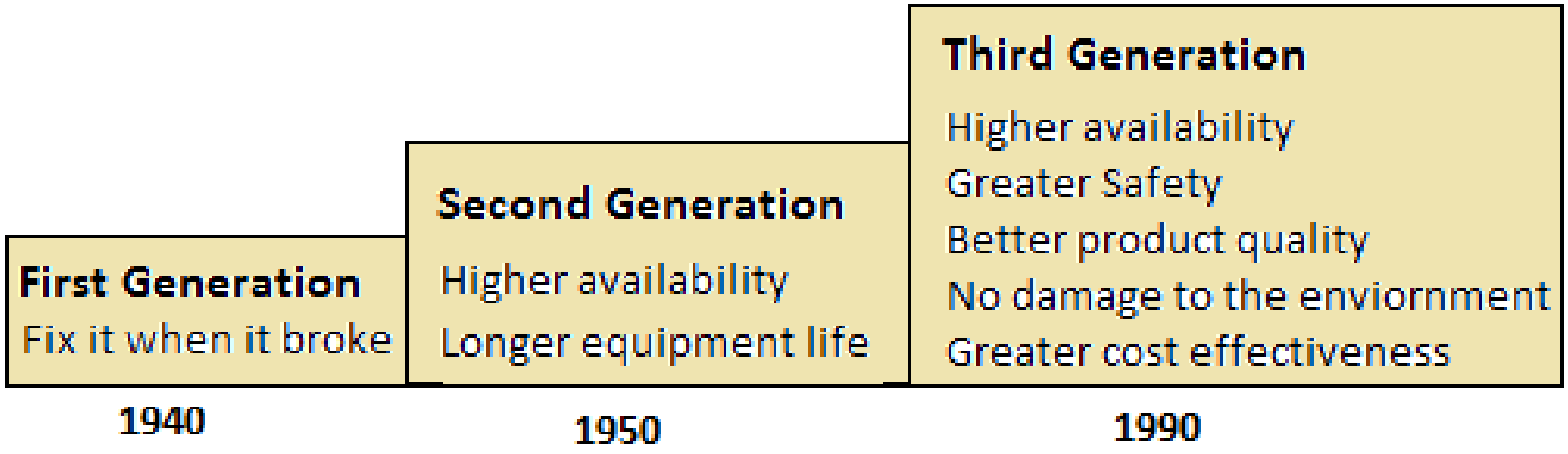
Pre-RCM

- 1960s in aviation industry
- “traditional approach”
  - Federal Aviation Administration (FAA) formed a task force which determined that scheduled overhauls did very little to improve the overall reliability of a complex device

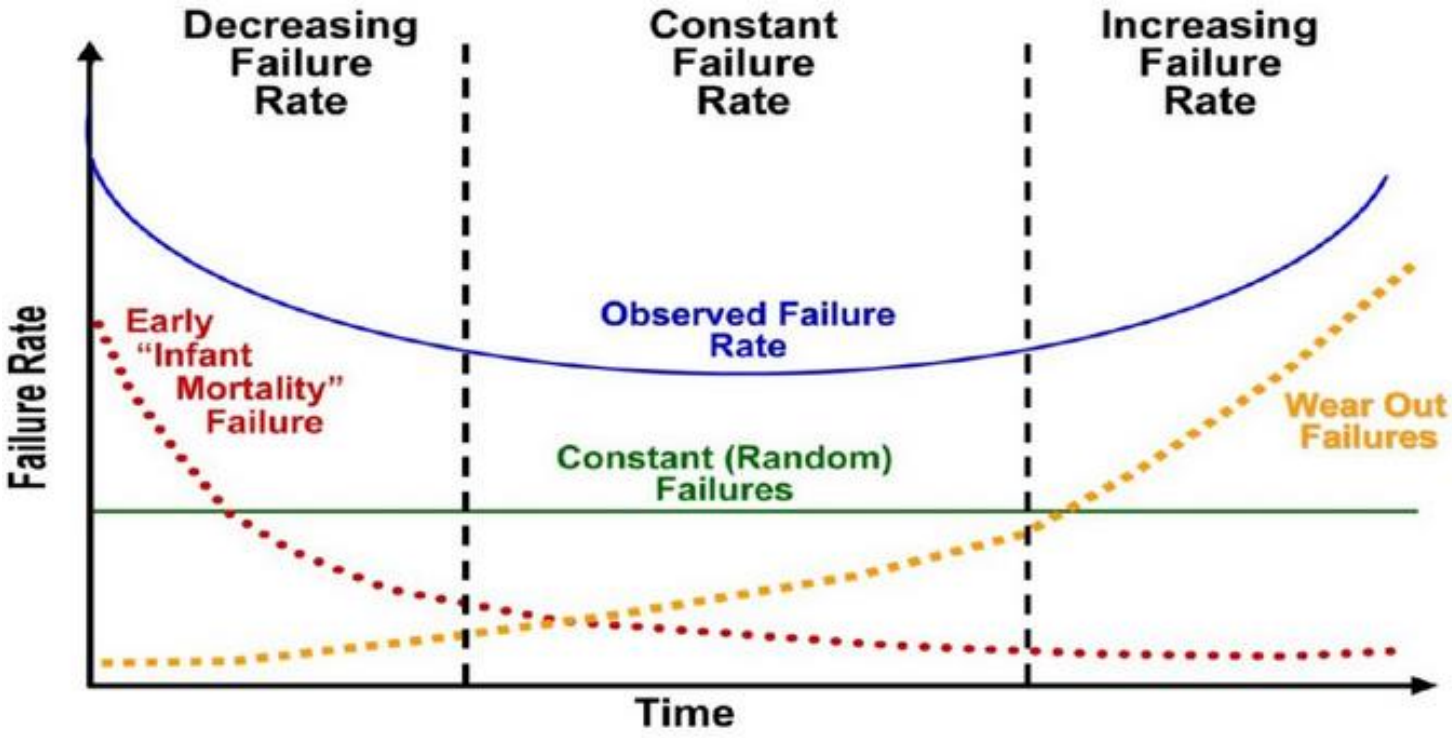
RCM History

- ‘Reliability Centered Maintenance’ authored by F. Stanley Nowlan and Howard F. Heap
- Military adopted the approach for both its ships and its aircraft
- NASA also adopted the RCM approach for its shuttle program
- As of October 2018, the term *reliability-centered maintenance* returned over 8 million results and *reliability-centered maintenance in medicine returned* 11.5 million results.

Expectations of Maintenance

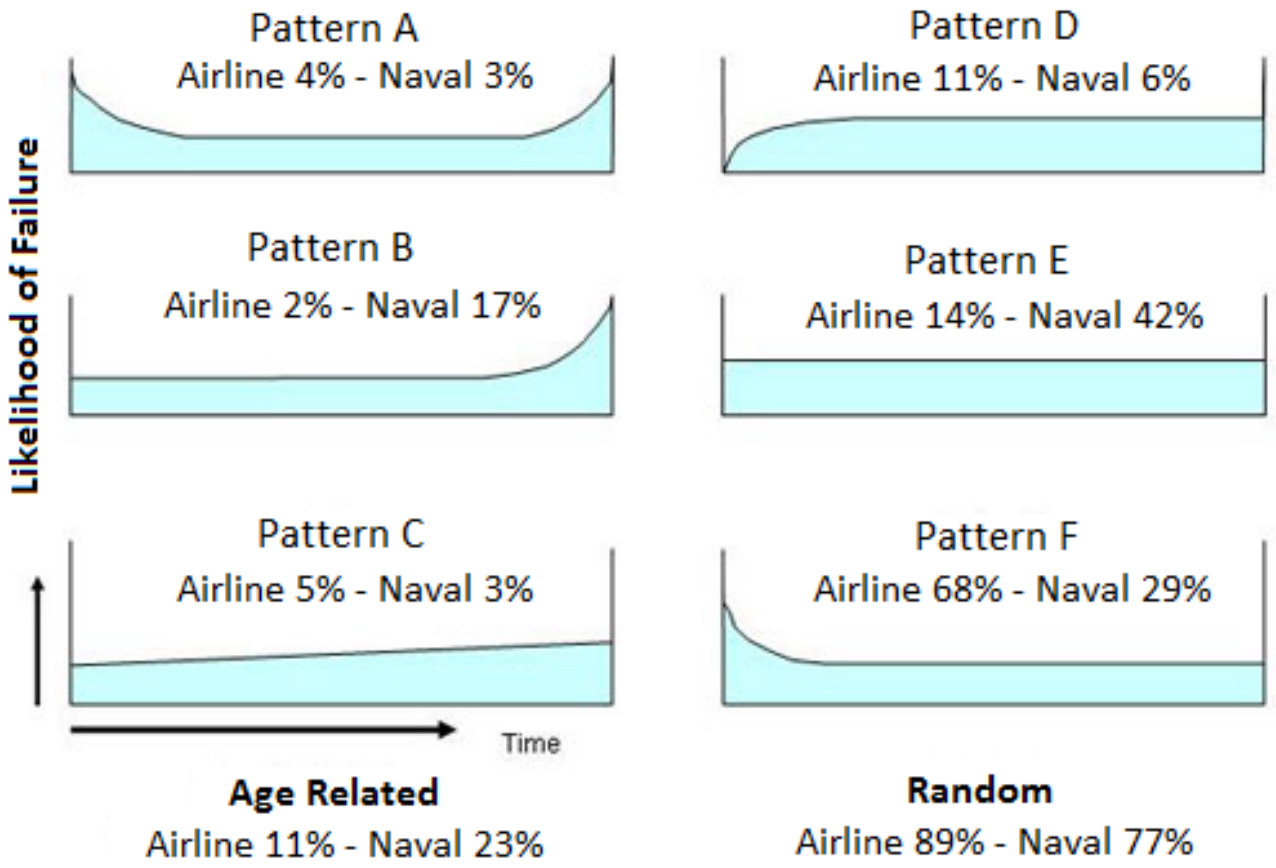


Failure Pattern: “Bathtub Curve”



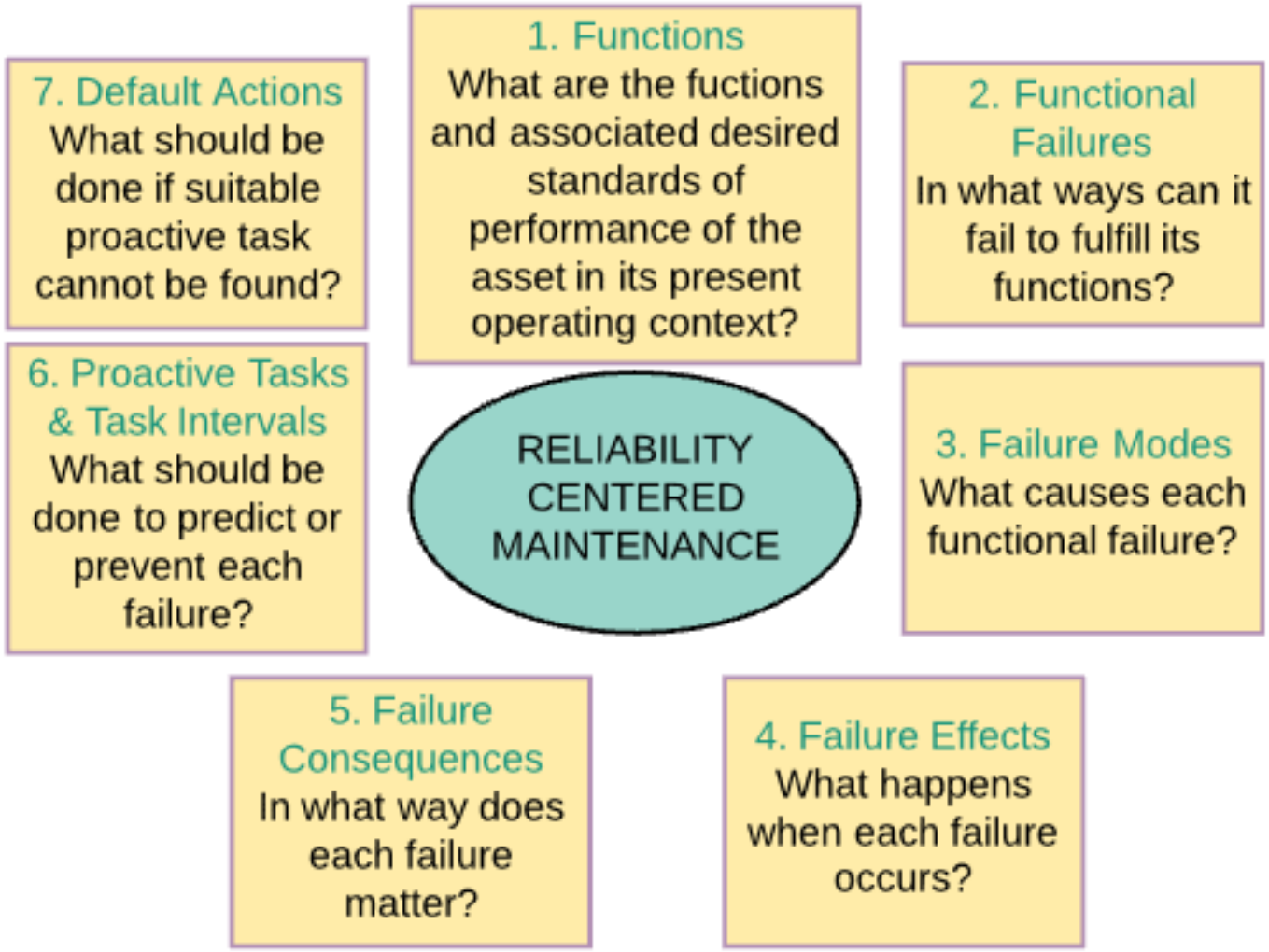
www.allthingsnuclear.org

Third Generation of Equipment Failure Models



http://reliabilitylink.com/how-to-use-condition-based-maintenance-strategy-for-equipment-failure-prevention/

The 7 Key Elements of RCM



Failure Modes

- Reliability related failures:
  - A random failure or malfunction of a component
  - Poor fabrication
- Process related failures:
  - Incorrect operation
  - Damage/abuse
  - Failure to recharge
  - Using wrong or defective accessory
  - Device output (interoperability)
- Maintenance related failures:
  - Inadequate periodic maintenance or calibration
  - Poor installation
  - Intrusive maintenance
- Hidden Failure

Failure Effects

Failure effect are described in terms of physical damage.

1. What evidence (if any) that the failure has occurred?
2. What does the failure result (if anything)?
3. What is the physical damage ?
4. What must be done to mitigate loss of function?

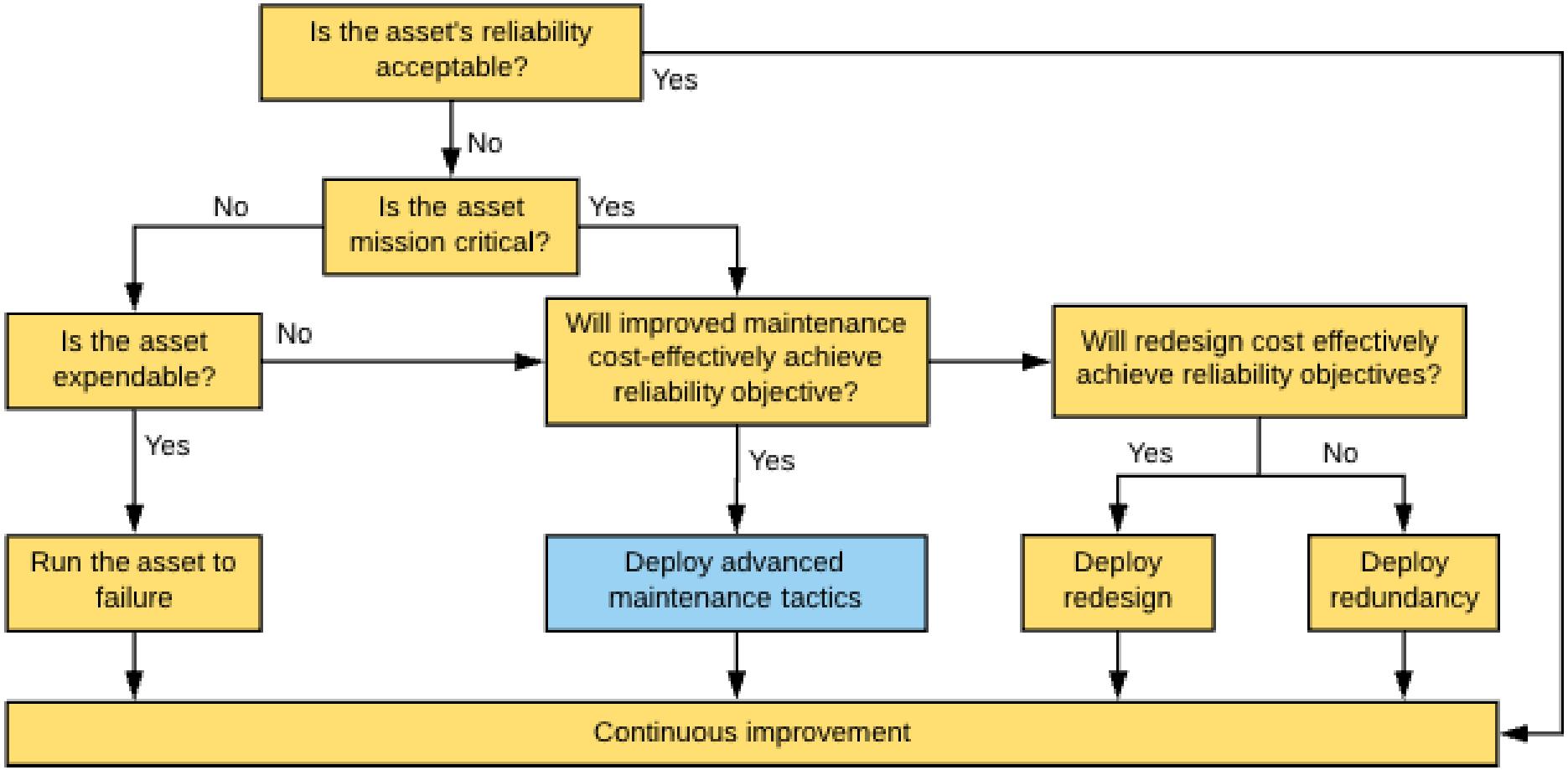
Failure Consequences

- **Hidden failure consequences**: exposes the organization to multiple failures with serious consequence
- **Safety consequences:** hurt or kill someone
- **Environmental consequences**: could lead to a breach of any environmental standard
- **Operational consequences**: affects output, product quality, customer service or operating costs
- **Non-operational consequences**: involves only the direct cost of repair

Maintenance Strategies

Maintenance Strategy	Action Required	RCM-Based Application
Run to failure (reactive)	Repair or replace upon failure	Costs to control or detect failure exceeds benefits
Scheduled discard or restorative (preventive)	Repair or replace on time	Equipment has a well-documented MTBF and a small standard deviation
On-Condition maintenance (predictive)	Employ condition monitoring to detect early stage failures. Replacement or repair is schedule based on condition.	Equipment fails randomly. Critical nature justifies early detection techniques.
Redesign (proactive)	Changes in hardware, loading or procedures.	Objective is to reduce the failure rate for a given time period
Redundancy	Deploy active shared-load or standby redundant system	Mission-critical equipment for which no other approach is acceptable

Failure Management Decision Tree



Task Evaluation-Failure Consequences

	Task Goal	Schedule failure-finding task?
Safety/environmental consequences	Reduce the probability of experiencing a functional failure to an acceptable level	Yes if reduces risk of failure
Operational and non-operations consequences	Pursue most cost effective option	n/a
Hidden consequences	Reduce the probability of experiencing multiple failures	Yes if reduces risk of failure

Standard Reliability Calculation-Mean Time Between Failure

- Model A, 1 device that fails twice in four years

$$\text{MTBF} = \frac{\text{Device Years}}{\text{Failures}}$$

$$\text{MTBF} = \frac{4}{2} = 2 \text{ years}$$

- Model B, 3 devices that also failed twice each in four years

$$\text{MTBF} = \frac{3 \text{ X } 4}{3 \text{ X } 2} = 2 \text{ years}$$

$$\text{MTB MRF} = \frac{\text{Device Years}}{\text{MRFs}}$$

Defining Your Maintenance Related Failures

- Assumptions/Criteria for Calculations
  - Unique failures
  - Every maintenance related failure (General Repair, Software Repair, and Medical Device Security Incident) is preventable and benefits from preventive maintenance
  - Same PM procedure across Inventory
  - Standardization of Model Nomenclature across Inventory
  - If it is not documented, it didn't happen
  - PM frequency field used to generate PMs in CMMS including off schedule PMs

Other Reliability Calculations-Derived Mean Time Between Failure

Asset Number	Age (Years)	Maintenance Related Failures	MTBF (Age/MRF) *0 failures	Failure Rate (MRFs/Age)
1234	4	0	4	0
1233	7	10	0.7	1.43
1232	5	2	2.5	0.4
			Avg=1.33	Avg=0.61

$$\text{Cumulative MTB MRF} = \frac{\text{Device Years}}{\text{MRFs}}$$

$$\text{Cumulative MTB MRF} = \frac{16}{12} = 2.4 \text{ Years}$$

$$\text{MTB MRF} = \frac{1}{\text{Failure Rate}}$$

$$\text{MTB MRF} = \frac{1}{0.61} = 1.64 \text{ Years}$$

AEM Data

Last CDW Extract: 1/28/2018
VISN: 20
Model: ****
ExecutionTime: 2/3/2018

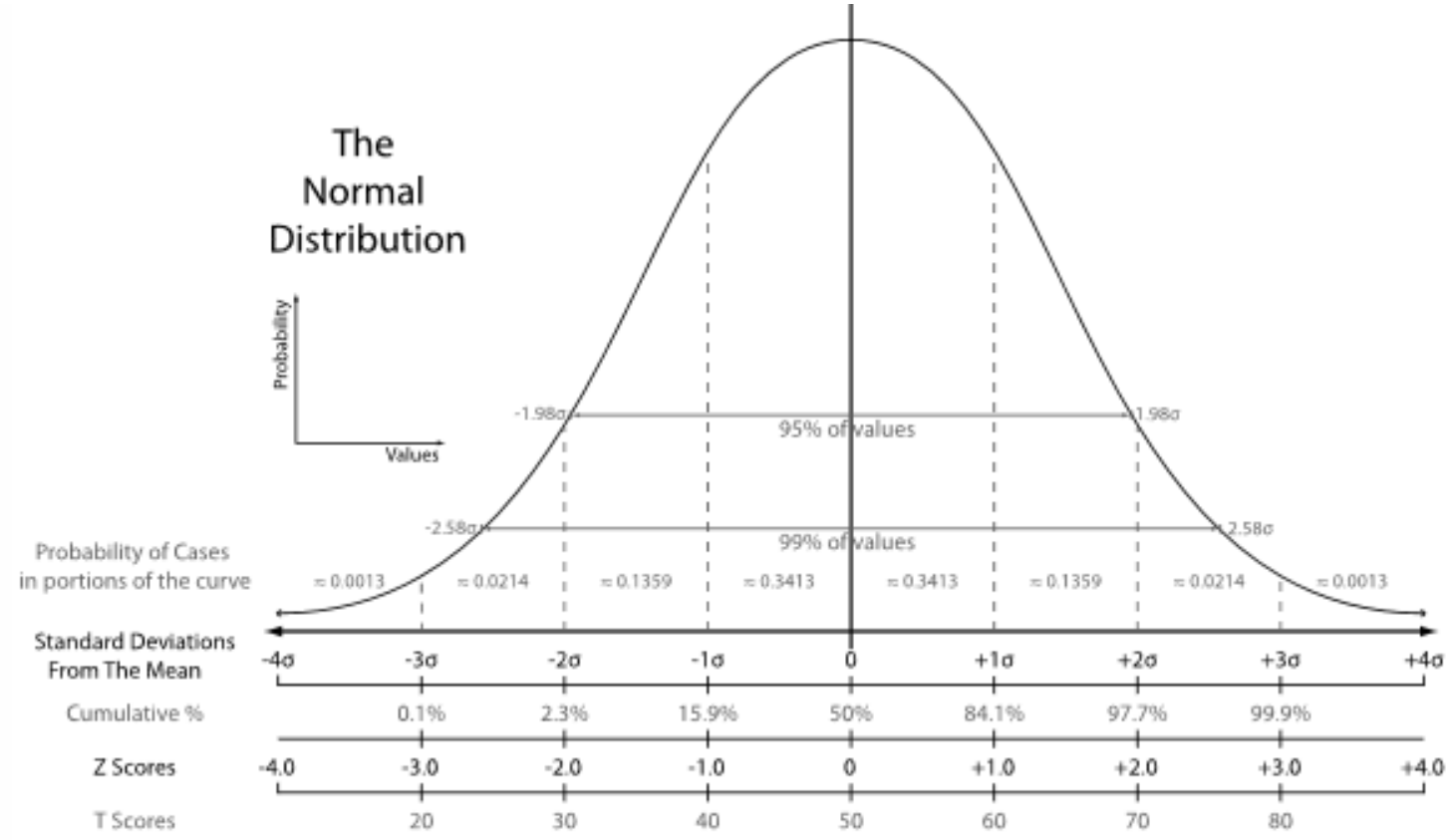
Assumptions
1. Unique Failures
2. Same PM procedure across VISN
3. Every maintenance related failure is preventable and benefits maintenance
4. If it is not documented, it didn't happen
5. WACs used according to HTM DOS guidance
6. PM frequency field used to generate PMs in AEMs/MERs including off schedule;B% WOs do not impact consistency calculation

Overall	National (Last 5 Years)	VISN (Last 5 Years)
Avg MTBF: Age/Failures by Asset (Years)	3.90	3.94
Total MRF	16798	903
PM Correctives	2,798	16.00
Device Years	103,380.00	4,552.83
VARP by Asset	2.04	1.93
STDP by Asset (σ)	1.43	1.39
95% Confidence (μ-(2*σ))	**1.05**	**1.16**
Actual PM Interval	10.66	9.94
Num of Devices	15,430	914.00
Num of Devices	23,549	969.00
Percent Consistent (%)	65.52	94.32
Average Exposure to Hidden Failures (PM Interval/(DeviceYrs/PM Correctives))		
At PM Interval	2.24	0.29
At 2X PM Interval	4.48	0.58

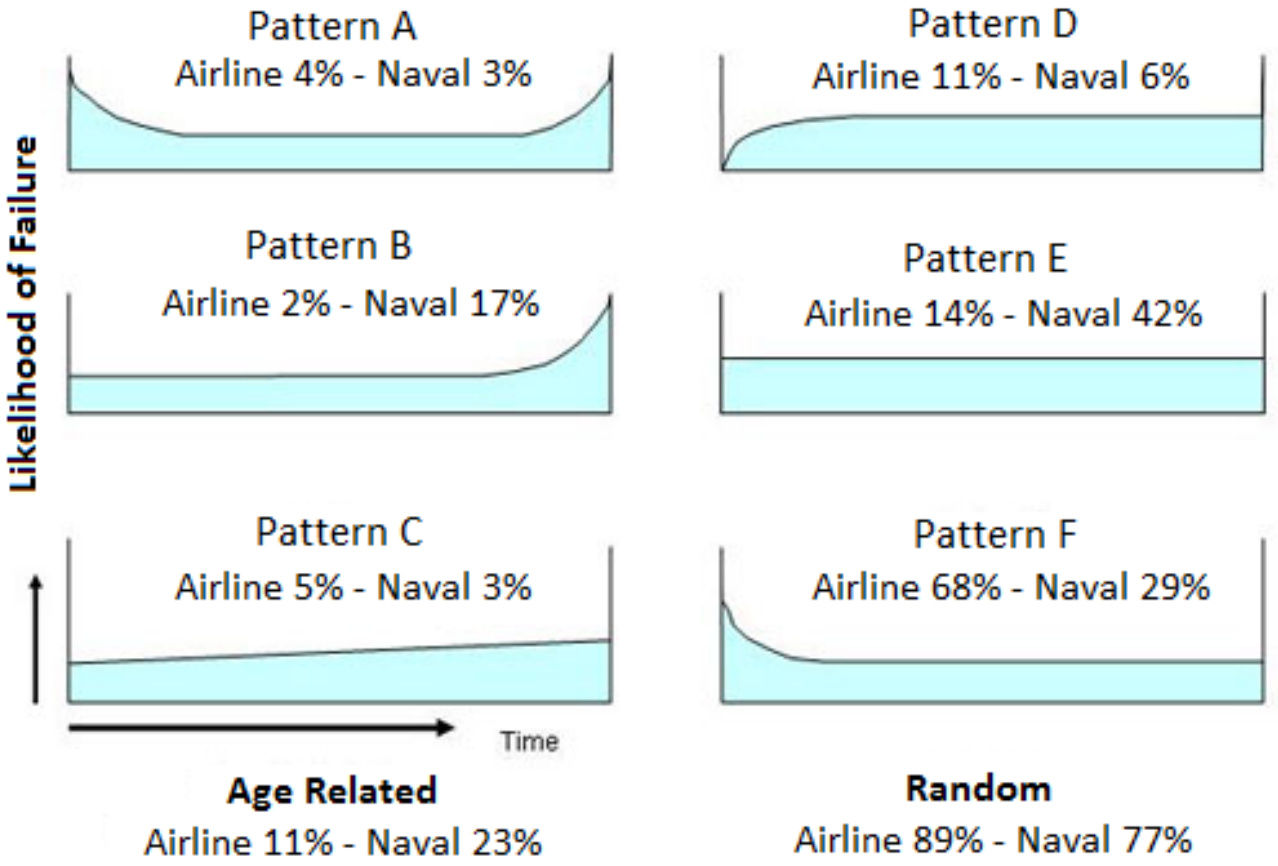
	T-1	T-2	T-3	T-4	Mean over Time (μ)	VARP over Time	STDP over Time (σ)	95% Confidence (μ-(2*σ))
Avg MTBF	0.98	0.98	0.97	0.99	0.98	0.00	0.01	**0.97**
Total MRF	261	196	277	131				
PM Correctives	3	5	3	3				
Device Years	969.00	963.75	904.00	904.00				

	T-1	T-2	T-3	T-4	Mean over Time (μ)	VARP over Time	STDP over Time (σ)	95% Confidence (μ-(2*σ))
Avg MTBF	0.97	0.95	0.95	0.95	0.96	0.00	0.01	**0.94**
Total MRF	4361	5361	4484	3300				
Device Years	23039.17	22217.6	20681.33	19531				

Only 2.3% probability for MTBF being lower than 97.3% of MTBF values



MTBF doesn't contextualize when a failure occurs and differences in rate of failure through time.



What is Survival Analysis (Used to Calculate Probability Risk)?

- A branch of statistics for analyzing the expected duration of time until one or more events happen, such as death in biological organisms and failure in mechanical systems.
  - Kaplan-Meier estimator (Running Failure Rate): the proportion of events over total equipment by time
  - Survival: 1-Running Failure Rate
  - Lower Confidence Interval: 85% is defined as acceptable lower confidence interval (CI) for the proportion of equipment surviving. Thus, if the lower CI is less than 85% a shorter PM interval is required to maintain reliability

Survival Analysis Result

Determine Survivability Age Threshold for PM Interval Change

Time (yr)	Devices	Running Failure Rate	Survival	Lower CI	PM Interval
5	14135	0.14	86%	85%	PM at 5 yr
6	11942	0.06	94%	93%	Annual
7	9672	0.09	91%	91%	Annual
8	7361	0.12	88%	87%	Annual
9	5250	0.18	82%	81%	Annual
10	3184	0.19	81%	80%	Annual

Time (yr)	Devices	Running Failure Rate	Survival	Lower CI	PM Interval
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6	11942	0.06	94%	93%	Annual
7	9672	0.09	91%	91%	Annual
8	7361	0.12	88%	87%	Annual
8.5	5560	0.15	86%	85%	Semi
9	5250	0.03	97%	96%	Semi
9.5	4257	0.11	89%	88%	Semi
10	3184	0.08	92%	91%	Semi

Alternative Equipment Management (AEM) Program-Calculated by Model

1. Severity Risk
2. Probability Risk (likelihood of PM-Preventable Failures)
3. Determine AEM Eligibility

Risk Score = Severity x Probability

Probability	Severity (Consequence) 1 Negligible	2 Marginal	3 Critical	4 Catastrophic
4 Probable	4	8	12	16
3 Occasional	3	6	9	12
2 Remote	2	4	6	8
1 Improbable	1	2	3	4

SLG ©

RCM-Based Risk Assessment

1. Calculate Severity Risk

Total Risk Criteria	Severity Risk Score
Total Risk >=100	4-Catastrophic
40 >= Total Risk < 100	3-Major
10 >= Total Risk < 40	2-Moderate
Total Risk < 10	1-Minor

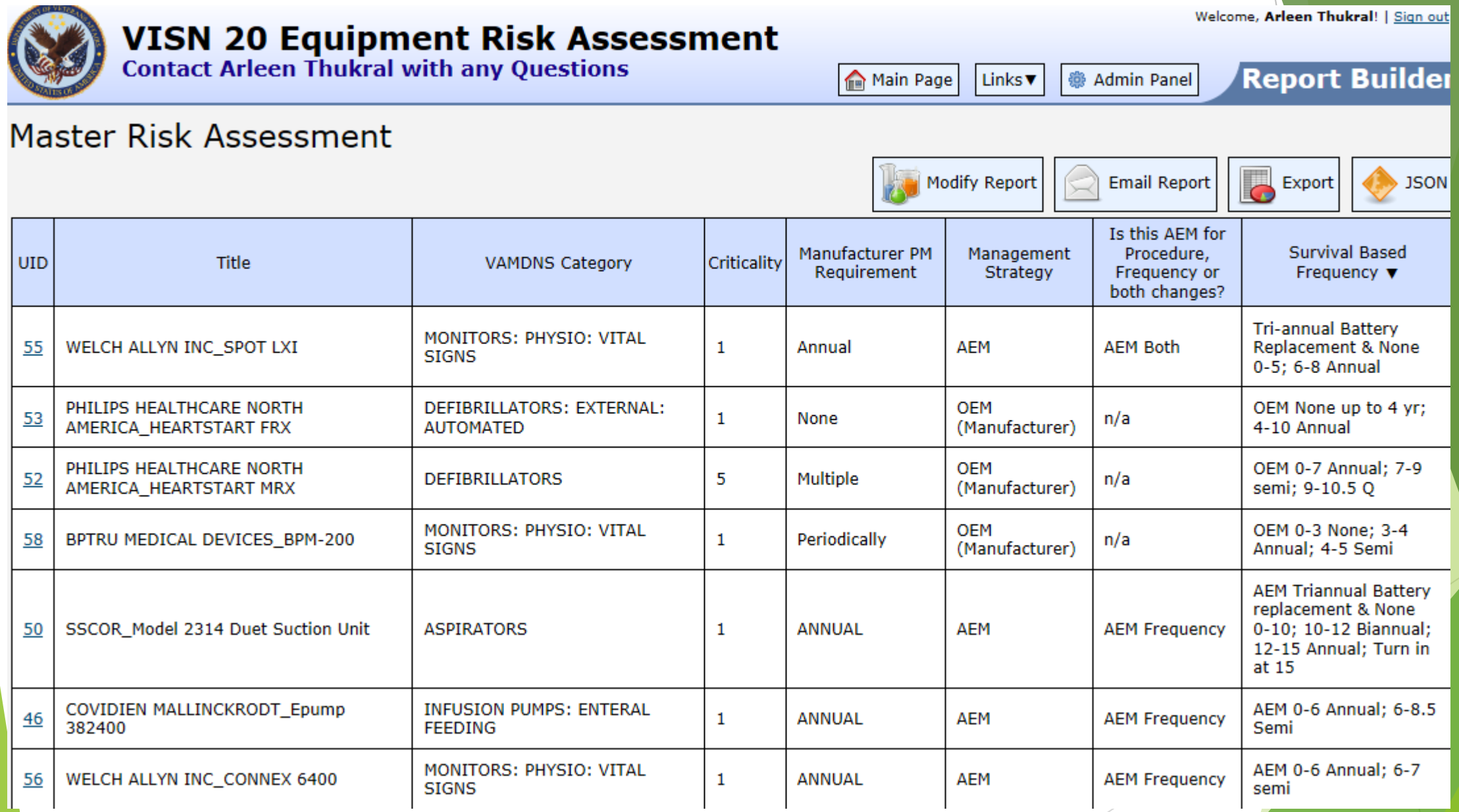
Total Risk = Equipment Function + Equipment Risk + Equipment Maintenance + Location + Equipment Alarm

2. Calculate Probability Risk (likelihood of PM-Preventable Failures)

Survival Analysis PM Interval Criteria	Probability Risk Score
Acceptable Survivability with Monthly or Quarterly PM	4-Probable
Acceptable Survivability with Semi-Annual or Annual PM	3-Occasional
Acceptable Survivability with Bi-Annual PM	2-Remote
Acceptable Survivability with > Bi-Annual PM	1-Improbable

Limitations of Survival Analysis

- Proportion of failure over total equipment must be statistically significant
  - > 30 assets by model
- Definition of acquisition date vs in use date
  - Equipment incoming inspection may be tied with vendor install or construction limitations such that Time spent between Inventory entry and In Use date may cause increase in % survivability



VISN 20 Equipment Risk Assessment

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Master Risk Assessment

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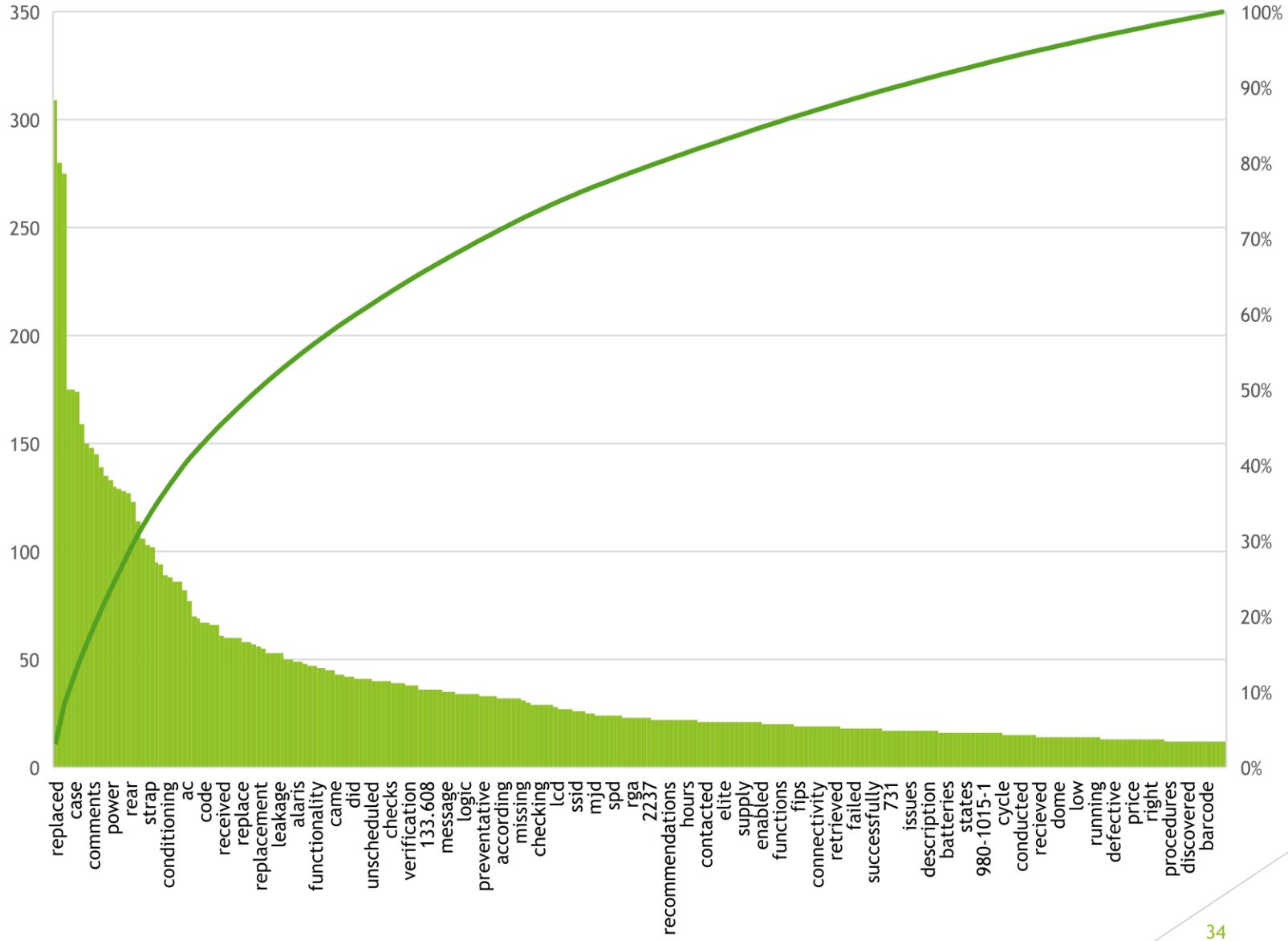
UID	Title	VAMDNS Category	Criticality	Manufacturer PM Requirement	Management Strategy	Is this AEM for Procedure, Frequency or both changes?	Survival Based Frequency ▼
55	WELCH ALLYN INC_SPOT LXI	MONITORS: PHYSIO: VITAL SIGNS	1	Annual	AEM	AEM Both	Tri-annual Battery Replacement & None 0-5; 6-8 Annual
53	PHILIPS HEALTHCARE NORTH AMERICA_HEARTSTART FRX	DEFIBRILLATORS: EXTERNAL: AUTOMATED	1	None	OEM (Manufacturer)	n/a	OEM None up to 4 yr; 4-10 Annual
52	PHILIPS HEALTHCARE NORTH AMERICA_HEARTSTART MRX	DEFIBRILLATORS	5	Multiple	OEM (Manufacturer)	n/a	OEM 0-7 Annual; 7-9 semi; 9-10.5 Q
58	BPTRU MEDICAL DEVICES_BPM-200	MONITORS: PHYSIO: VITAL SIGNS	1	Periodically	OEM (Manufacturer)	n/a	OEM 0-3 None; 3-4 Annual; 4-5 Semi
50	SSCOR_Model 2314 Duet Suction Unit	ASPIRATORS	1	ANNUAL	AEM	AEM Frequency	AEM Triannual Battery replacement & None 0-10; 10-12 Biannual; 12-15 Annual; Turn in at 15
46	COVIDIEN MALLINCKRODT_Epump 382400	INFUSION PUMPS: ENTERAL FEEDING	1	ANNUAL	AEM	AEM Frequency	AEM 0-6 Annual; 6-8.5 Semi
56	WELCH ALLYN INC_CONNEX 6400	MONITORS: PHYSIO: VITAL SIGNS	1	ANNUAL	AEM	AEM Frequency	AEM 0-6 Annual; 6-7 semi

Master Risk Assessment

Semantic Analysis/Word Count Frequency

- Review trends in failures to (Word Count, Entities, Key Phrases Analysis)
- Once common failures are identified, PM tasks can be evaluated for effectiveness
- Quality of Documentation is critical to evaluation and determination of PM Task Improvements

Word Count Frequency



Other Data Considerations

- The use of PM effectiveness metrics is recommended
  - Could device functionality have been improved by a defined PM task?
  - Is PM interval effective?
    - Too long: rejuvenated parts are in worse physical condition than expected
    - Too short: rejuvenated parts are found to be in better physical condition than expected
    - About right: rejuvenated parts in expected physical condition

http://htmcommunitydb.org/wiki/index.php?title=HTM_ComDoc_6.

Average Exposure to Hidden Failures (AEHF)

- AAMI recommendation: AEHF = 0.5 x PM Interval / $MTBF_{HF}$
- So for a $MTBF_{HF}$ of 50 yrs and a PM Interval of 6 months, the AEHF is:

  (0.5 x 0.5/50) = 0.005 or 0.5%

  (0.5 x 0.5/5) = 0.05 or 5%
- So for a $MTBF_{HF}$ of 50 yrs and a PM Interval of 12 months, the AEHF is:

  (0.5 x 1.0/50) = 0.01 or 1%

  (0.5 x 1.0/5) = 0.1 or 10%

- Due to limitations of CMMS:
  - VISN 20 AEHF = PM Interval / (Device Years/PM Correctives)
    - PM Correctives assumed to be Hidden Failures

http://htmcommunitydb.org/wiki/index.php?title=HTM_ComDoc_6

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Sustainment

A PM program that is based on RCM philosophy must be dynamic. Review and refinement of the PM program must be an ongoing process.

- Age exploration tasks
- Trend Analysis

Questions?