

YNHH medical equipment database: Standardization of nomenclature and risk assessment procedure

Executive Summary

The department of Clinical Engineering at Yale-New Haven Hospital (YNHH) currently uses two databases within the same computerized maintenance management system (CMMS) to track and manage medical equipment, since Saint Raphael Campus (former Saint Raphael Hospital) became only recently part of the primary teaching hospital for Yale School of Medicine. Considering a standardization process aimed at having uniformity of equipment classification, risk assessment as well as operating procedures, the databases consolidation (i.e. merging the two databases to form a new non-redundant one) has been identified as the first goal to accomplish.

From a management perspective, some of the most important attributes of each device are class (or category, type of equipment) and risk priority (that necessarily corresponds to a certain maintenance strategy). My project, thus, consisted of

1. proposing and implementing the use of a standard nomenclature for class descriptions and codes;
2. developing a proposal for a new risk assessment procedure that could be enforced in the two campuses, also taking into consideration the new TJC (The Joint Commission) standards for medical equipment maintenance, aligned with the updated regulations from CMS (Centers for Medicare and Medicaid Services), announced last July.

The Universal Medical Device Nomenclature System (UMDNS) has been chosen as the standard nomenclature for class description. The proposal for a new risk assessment procedure resulted from a thorough analysis of the procedures currently adopted by the two campuses and from the reading of the relevant literature. This paper will describe the current situation, present how my work has been carried out, and discuss the next steps that need to be taken in order to accomplish the aforementioned goal.

Scope

On September 12, 2012, YNHH acquired the assets of the Hospital of Saint Raphael, making it a single hospital with two main campuses: York Street Campus (YSC) and Saint Raphael Campus (SRC). As a consequence, the two Clinical Engineering departments were joined under the leadership of the same Director, who is also responsible for medical equipment management at Bridgeport Hospital (BH) and Greenwich Hospital (GH). These health institutions are part of the larger Yale-New Haven Health System (YNHHS).

The two YNHH campuses currently use the same CMMS (*MediMizer*®), whereas BH and GH use other database management systems. Thus, it seemed more appropriate and feasible to start with a database consolidation of the two YNHH campuses, and reserve for later the consolidation of the BH and GH databases.

The analysis of the class lists in the two databases drew attention to many examples of non-homogeneity in the class code, description (lower/upper case, singular/plural, words swap and misspelling, jargon), national and international identifiers (e.g. FDA, ECRI), risk score and priority. As for these latter attributes, in one campus the model proposed by Fennigkoh and Smith [1] in 1989 was implemented, whereas in the other campus the model illustrated by Hertz [2] in 1990 was used. As a beneficial side effect of the process, the appropriateness of grouping equipment models into different classes has been evaluated.

Project

A macro-analysis of the two databases was carried out at the end of the month of September, 2014.

	YSC	SRC										
Active Equipment	19,039	10,041										
Number of Models	2,877	1,900										
Number of Classes	411	353										
80% Equipment refer to	54 classes	59 classes										
Class Risk Priority	Range: 1-3	Range: 1-4										
Class Risk Score	Range: 4-20	Range: 1-27										
Relationship Score-Priority	No clear relationship between class risk score and risk priority	<table border="1"> <thead> <tr> <th>Score</th> <th>Priority</th> </tr> </thead> <tbody> <tr> <td>1-6</td> <td>4</td> </tr> <tr> <td>8-9</td> <td>3</td> </tr> <tr> <td>12-18</td> <td>2</td> </tr> <tr> <td>27</td> <td>1</td> </tr> </tbody> </table>	Score	Priority	1-6	4	8-9	3	12-18	2	27	1
Score		Priority										
1-6		4										
8-9		3										
12-18		2										
27	1											

Figure 1

Comparing the two Campuses, we can observe that YSC has about twice the number of assets, but just +16% the number of classes and +50% the number of models, compared to SRC data. Nevertheless, the bulk of the equipment in both cases refers to less than 60 classes of equipment.

Exporting the class attributes from the CMMS to an Excel® spreadsheet, it has been possible to identify 128 likely class matches. I proposed to start the standardization process with these classes, which correspond to approx. 10,000 assets for YSC and approx. 4,000 assets for SRC. For example:

Class Code	Class Description	FDA / UMDNS #	Risk Priority	Risk Score
DEFIAN	DEFIBRILLATOR ANALYZERS	'011127	2	5
ANADEF	Analyzer, Defibrillator	11-127	3	8
ECGAMP	ECG AMPLIFIER	30-046	2	10
ECGMOD	ECG MODULE	30-046	3	8
FDPMP	FEEDING PUMP	13-209	2	12
PUMPFO	Pump, Enteral Feeding	13-209	3	8
INFPSG	INFUSION PUMP, SYRINGE TYPE	'0053	2	13
INFUSY	Infusion Pump, Syringe	13-217	3	8

Figure 2

For each of these couples, the class description published by ECRI in the UMDNS has been searched and identified. In fact, I proposed that UMDNS description be used as the standard nomenclature, assuring unambiguous characterization, as it reflects not only device categories but also subcategories. As for class codes, I proposed a set of rules to create easy-to-remember codes. The rules I proposed are:

- max length is 8 characters (database field physical limit)
- if there is an adjective, it goes first
- max length adjective: 4 characters
- max length name: 4 characters

- if the adjective is usually taken for granted (e.g. *electronic* thermometer), it is omitted
- if there is a well-known acronym, it must be used (e.g. electrical surgical unit = ESU)

A few examples of standardization are shown here:

YSC Code	YSC Description	SRC Code	SRC Description	UMDNS #	UMDNS Description	Std Code
INFPMMP	INFUSION PUMP	INFPUM	Infusion Pump	13-215	Infusion Pumps, Multitherapy	INFUPUMP
PHYMN	PHYSIOLOGICAL MONITOR	PHYMON	Physiological Monitor	12-647	Monitoring Systems, Physiologic, Acute Care	PHYSMONI
TELETX	TELEMETRY TRANSMITTER	TELETX	Telemetry Transmitter	13-988	Monitors, Telemetric, Electrocardiography	TELETRAN
SAWBON	SAWS, BONE	SAW	Saw	22-761	Saws, Surgical, Bone	BONESAW
INFPSG	INFUSION PUMP, SYRINGE TYPE	INFUSY	Infusion Pump, Syringe	13-217	Infusion Pumps, Multitherapy, Syringe	SYRIPUMP
FDPMP	FEEDING PUMP	PUMPFO	Pump, Enteral Feeding	13-209	Infusion Pumps, Enteral Feeding	FEEDPUMP
DEFIAN	DEFIBRILLATOR ANALYZERS	ANADEF	Analyzer, Defibrillator	11-127	Testers, Defibrillator	DEFITEST

Figure 3

Proceeding to a second level of analysis, each of these classes has been examined in terms of models and relevant risk parameters, in order to better understand the content and the appropriateness of grouping. In fact, each model (associated with a certain manufacturer) is linked to a definite class, but can have a different risk score and priority than others of the same class. For example, let's consider the class "*Infusion Pumps, Multitherapy, Syringe*". At Saint Raphael Campus, the class has a risk score of 8 and a risk priority of 3. The risk parameters associated to the single models correspond with those assigned to the class, and from model descriptions and model numbers we can conclude that these 32 assets indeed belong to the class "*Infusion Pumps, Multitherapy, Syringe*".

Manufacturer Description	Model Description	Model #	Risk Priority	Risk Score	Asset #
Baxter Health Care	Infusion Pump, Syringe	AS50	3	8	7
Medex Div. Smiths Medical	Infusion Pump, Syringe	2001	3	8	1
Smiths Medical - BCI	Infusion Pump, Syringe Medfusion 3500	MEDFUSION 3500	3	8	24
Grand Total					32

Figure 4

At York Street Campus, the class has a risk score of 13 and a risk priority of 2. The risk parameters associated to the main model (97% of the assets) correspond with those assigned to the class, but the scores assigned to other models do not. We can also observe that the same device (Infusion Pump, Syringe Medfusion 3500) has been inventoried with two different manufacturers in the two databases, presumably because of manufacturer companies' acquisition: "Smiths Medical – BCI" and "Medfusion Systems".

Manufacturer Description	Model Description	Model #	Risk Priority	Risk Score	Asset #
Graseby Medical Limited	INFUSION PUMP, SYRINGE TYPE	3400	2	0	1
Harvard Apparatus Co	INFUSION PUMP, SYRINGE TYPE	975	2	0	1
Harvard Apparatus Co	INFUSION PUMP, SYRINGE TYPE	2922	2	0	1
Harvard Apparatus Co	INFUSION PUMP, SYRINGE TYPE	4400-001	2	0	1
Harvard Apparatus Co	INFUSION PUMP, SYRINGE TYPE	55-1689	2	0	1
Harvard Apparatus Co	INFUSION PUMP, SYRINGE TYPE	55-2226	2	0	1
Harvard Apparatus Co	INFUSION PUMP, SYRINGE TYPE	55-2275	2	0	1
Medfusion Systems	INFUSION PUMP, SYRINGE TYPE	3500	2	13	241
Grand Total					248

Figure 5

To sum up, the beneficial "side effects" that this analysis brought about are:

- highlighting those situations in which models have different risk parameters than the relevant class;
- highlighting those situation in which a certain model of equipment is associated with two different manufacturers;
- highlighting those situations in which a certain model of equipment has been erroneously classified (e.g. a transilluminator found in the light sources class);
- highlighting those situations in which assets belonging to the same model have different risk parameters.

Each of these potentially inaccurate situations has been presented to the two supervisor clinical engineers at the two campuses, for assessment and remediation.

From the list of 128 "class couples", 15 units at a time have been chosen according to a relevance criterion in terms of number of assets and shown to the supervisor clinical engineers for approval; then, the class files in both databases have been updated with the standard description, code and univocal UMDNS number. Risk parameters have not been modified, as the new risk assessment procedure has not been approved and implemented yet. Just for the first group of 15 class couples, the test database (an exact copy of the production database) was used in order to observe the impact of the change on the other entities (models, check lists, pieces of equipment).

Only once no detrimental effects were detected, the class files were updated in the production database. The updates were scheduled in concert with the two CE teams, so that nobody else would use the CMMS at the same time, in order to avoid unexpected, unwanted events.

When physically updating the classes, in some cases it has also been necessary to merge two or more of the existing classes, as they referred to the same equipment type and the system offered such a functionality. For example, the following six classes have been merged, and the resultant class was turned into the standard one: INFUPUMP - Infusion Pumps, Multitherapy.

Class Code	Class Description
INFPUM	Infusion Pump
INFUPUMP	Infusion Pump
IP6100	Infusion Pump
IP6200	Infusion Pump
IP8100	INFUSION PUMP
IP8500	INFUSION PUMP

Figure 6

Then, as anticipated, the risk assessment procedures in force in the two campuses were investigated. As a terminology clarification, with the expression “scheduled maintenance” I will refer to both preventive maintenance (PM) and safety and performance inspection (SPI).

At YSC, an approach inspired by the model proposed by Fennigkoh and Smith [1] is implemented, and risk characterization is performed at the model level. It is possible, therefore, to have models within the same class that have, for some justified reason, different risk scores. Risk score for each model is given by the sum of four components:

- Equipment function, with a score range from 1 to 10
- Physical risk upon malfunction, with a score range from 1 to 5
- Maintenance Requirements, with a score range from 1 to 5
- Incident/Failure History, with a score range from 0 to 3

Thus, the minimum possible score is 3 and the maximum is 23. Risk priority 1 is assigned to a model if its score is in the range 15-23, priority 2 for scores in the range 10-14 and priority 3 for scores in the range 3-10. In the case of priority 1, scheduled maintenance is performed according to manufacturer’s recommendations; in the case of priority 2, scheduled maintenance is performed every 12 or 24 months depending on the specific model; in the case of priority 3, there is no scheduled maintenance and only repair in case of failure.

At SRC, on the other hand, Hertz approach [2] is implemented: each model of equipment has been assigned a severity score according to its relative probability to be broken, and, if broken, to its relative probability to be noticed by the user before use, and to its relative probability to actually cause an injury. Specifically, the severity score equals the multiplication of these three probability values:

$$\text{Severity Score} = \text{RP}(\text{Broken}) \times \text{RP}(\text{Notice}) \times \text{RP}(\text{Injury}).$$

Since each probability value can assume values in the range [1-3] (contrary to the usual definition of probability, which can assume values between 0 and 1), the severity score will be in the range [1-27]. Risk priority 1 is assigned to models with a severity score of 27, priority 2 to models with a score of 18; priority 3 in case of scores in the range 8 – 12, and priority 4 for scores under the

value 8. Priority 4 models do not receive scheduled maintenance activities, priority 3 models have annual SPI and PM, priority 2 models have SPI every 6 months and priority 1 models have SPI every 3 months (whereas PM is always every 12 months).

The two campuses, as just described, use different procedures to identify equipment to be included in the scheduled maintenance program and to assign inspection and preventive maintenance intervals. As a result, the same model is subject to two different management strategies within the same hospital. I was then charged with developing a new, common procedure for a common risk-based maintenance program. Since the strategies in use date back to the 1990s, I have done some research on how maintenance strategies have evolved in these 20+ years and developed a procedure [Annex 1] inspired by some of the papers listed in the Bibliography.

Specifically, the following thesis was often presented: because of the evolution of technology design and manufacturing, along with the availability of better materials, today medical devices are safer and more reliable. For this reason, “traditional” periodic inspections and preventive maintenance frequencies could have become excessive. Moreover, a debate on PM intervals was discussed, as it was noted that some devices that appeared to be very similar in their function and design had manufacturer-recommended intervals that varied by a factor of two or more. The doubt whether those interval were based on meaningful test data was inevitable. Hence, the message that current maintenance strategies, which are often based on 1990s models, might have been effective, but there was no clear evidence whether they were efficient.

Wang and Levenson [7] stated that Fennigkoh & Smith interpretation was *“reflective of an era in which everything was patient-centered and, therefore, concentrated on risks; the question of how significant a device’s function is to the patient’s well-being or the organization’s mission was not considered”*. They continue arguing: *“Instead of asking whether the function of a particular device is for diagnosis, care, treatment or monitoring, it seems more relevant to find out how critical it is for the fulfillment the hospital’s mission”*.

It can be observed, as a matter of fact, that in the majority of cases functionality and potential harm are linked. In fact, only a few cases have the two scores that would differ much one from the other, specifically some laboratory equipment and accessories, support and miscellaneous equipment that, in case of failure, may determine serious consequences for the patient (e.g. UPS, centrifuges, blood type analyzer, blood gas analyzer, freezers, cleaning and disinfection equipment, DI workstations, blood bank refrigerators, traction units). These device types have a low score for equipment functionality and a high score for potential harm. In the new model, the safety factor is preserved, and the equipment role in the healthcare organization, regardless of the major category (therapeutic, diagnostic, analytical or miscellaneous), is considered in order to give priority to those device types that are more critical for the fulfillment of the hospital’s mission.

I discussed with the CE Director and the two supervisor clinical engineers the possibility of reinterpreting the equipment function criterion as the equipment importance within the organization’s global mission, so that risk to a single patient could be balanced with the organization’s commitment to its entire community, and they agreed on this change.

At the same time, as anticipated, the new procedure had to comply with the new TJC standards for medical equipment maintenance, aligned with the updated regulations from CMS, and announced last July. The procedure is attached to this paper.

Involvement

Since the project was assigned to me, I took care of all the steps described above. I was helped by co-workers from the CE department (supervisors, technicians, BMDI – biomedical device integration team) with technical issues related to our CMMS (I was given access to the CMMS, I was granted the right to edit class files, and a non-default report was created ad hoc by the CMMS provider for some analysis I performed on scheduled maintenance frequencies) and with the documents I needed (I was provided with the current procedures in force and I was given an ECRI account). I regularly discussed with the CE Director the developments and the barriers I faced along the way. I did not “revolutionize” the method, as it can be noticed reading the Annex, I just tried to make it in accordance with the current views on maintenance strategies, as well as compliant with the new regulations and standards that YNHH has to observe.

Conclusions

The procedure I developed is a sound base on which the CE leadership team can work in order to obtain an “up-to-date” and TJC-compliant risk-based maintenance procedure. I am currently working on some simulations as for scores and priorities for the most common technologies, and assessing the impact of the change in terms of workload for the technicians. I am also making sure we have the possibility in our CMMS to categorize the “degree” of equipment failure (major versus minor, where equipment remains operational and does not compromise safety) and to categorize the “type” of equipment failure (maintenance preventable, spontaneous failure or use related failure). In this way, it will be easier to review the service history when determining a risk score for a certain model. As for the class description and code standardization, it is not but a first step towards the database consolidation: manufacturers, vendors and models’ names will be the next step. Service manuals will be uploaded in the CMMS and linked to the relevant models. Maintenance and inspection scheduling, then, will be uniform as soon as the new procedure is implemented, and the procedure will be extended to the whole Health System (BH and GH included). The work has just started, but everyone is determined to complete this project as soon as possible.

I would like to thank all my friends and co-workers at YNHH for their help, especially Joe Ouellette for his careful editing and proofreading.

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Annex 1: YNHHS Medical Equipment Risk Assessment

To determine maintenance and inspection activities and frequencies, Clinical Engineering (CE) complies with manufacturers' recommendations and with an alternative equipment maintenance (AEM) program, described below (ref. **standard EC.02.04.01, EP 4**), depending on the specific risk priority assigned to equipment.

The method applied by CE to categorize and prioritize inspection and maintenance activities for equipment included in the Medical Equipment Management Program (MEMP) is risk-based. The ranking is comprised of four criteria: equipment importance within the Health System, potential harm, maintenance requirements, incident and failure history. Risk is determined at the equipment model / manufacturer level: all like-model devices will be assigned the same priority and will receive Preventive Maintenance (PM) and Safety and Performance Inspections (SPI) according to the same frequency schedule. CE, in conjunction with the appropriate Safety or Environment of Care Committee, may decide to adjust the frequency based on equipment history. Frequencies of maintenance are documented in the equipment database.

Formula

All medical equipment that directly supports patient care, or that is located within the patient care setting, regardless of ownership, is included into the MEMP (**ref. standard EC.02.04.01, EP 2**). A numerical value (Maintenance Score, MS) is assigned to each device model, during incoming inspection, by classifying its importance within the Health System, its potential harm, its required maintenance and its incident and failure history. Adding the sub-scores from each criterion yields a Maintenance Score as follows:

$$MS \text{ (Maintenance Score)} = C + H + M + I$$

Risk Assessment Criteria:

1. Mission Criticality (C) – Equipment role or importance within the healthcare organization [1-5]
2. Potential Harm (H) – Likely consequences of equipment failure, malfunction or user error [1-5]
3. Maintenance Requirements (M) – Level of scheduled maintenance recommended by the manufacturer [1-5]
4. Incident and Failure History (I) – Both within the healthcare organization and as reported by generally available sources outside the healthcare organization [- 2 - +2]

a. *Categorization and Prioritization:*

Those equipment models that have a MS greater than or equal to 6 are included in the scheduled maintenance program. Based on the scoring outcome, then, equipment is assigned a risk priority of 1, 2, 3 or 4.

- MS between 1 and 5: Priority 4 (without recurrent inspection and maintenance)
- MS between 6 and 8: Priority 3
- MS between 9 and 11: Priority 2
- MS between 12 and 17 or*
Criticality score is 5 or*
Potential Harm score is 5: Priority 1

* *Inclusive or*: it is true when *at least one* of the conditions is true

Exceptions (**ref. standard EC.02.04.01, EP 5**)

Priority 1 is also assigned, regardless of MS, to:

- Equipment subject to federal or State of Connecticut laws or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements
- Medical laser devices
- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

During the incoming inspection, any new device will be categorized. If the device model has not been previously evaluated, a new device classification will be created; it will be evaluated according to the outlined procedure to produce a MS and will be included in the inventory. If it receives a MS greater than 5, a performance and safety inspection and preventive maintenance procedure will be written for the new device model (complying with manufacturers' recommendations in case of "priority 1" equipment). All patient care related equipment including therapeutic, monitoring, diagnostic, or analytical equipment that did not receive a MS of 6 or above will still be included in the hospital's biomedical equipment inventory and will be covered on a repair only basis.

Priority 1: These devices are given the highest priority for preventive maintenance, safety and performance inspection and repair. Devices in this group have SPI and PM according to manufacturer's recommendations. This group includes equipment types listed in the **standard EC.02.04.01, EP 5** and cited above.

Priority 2: Every effort will be made to complete PM, SPI and repairs on devices in this group, but only after Priority 1 device requirements have been completed. Devices in this priority group have SPI and PM according to manufacturer's recommendations or according to an alternative equipment maintenance (AEM) program.

Priority 3: Every effort will be made to complete PM, SPI and repairs on devices in this group, but only after Priority 1 and Priority 2 device requirements have been completed. Devices in this priority group have SPI and PM according to an alternative equipment maintenance (AEM) program.

Priority 4: Devices in this priority group do not have scheduled SPI and PM, but are visually inspected during hazard surveillance rounds and repaired when needed. Periodic review of repair records and surveillance findings are used to determine whether a device stays in this category or needs to be re-prioritized.

Medical equipment included in the AEM program is identified on the inventory (**ref. standard EC.02.04.01, EP 7**) through a dedicated field in the Computerized Maintenance Management System (CMMS).

b. Definition of the Criteria

Mission Criticality or “operational impact” (availability for patient care) takes into account utilization rate and availability of backups / alternative devices. It can be defined as the extent to which a device is crucial to the care delivery process of the healthcare organization.

Value of (C)	Mission Criticality Description
5	Mission Critical: highly used, no alternative devices
4	Critical: highly used, one alternative device OR average use, no alternative devices
3	Essential: highly used, more than one alternative devices OR average use, one alternative device
2	Important: average use, more than one alternative device OR low use, no alternative devices
1	Necessary: low use, one or more alternative devices

When assessing the utilization rate, one should consider as “being utilized” any equipment that is required to be available, but not necessarily used. For instance, a defibrillator in the surgical suite should be considered as “being utilized” whenever a surgical procedure is performed.

Potential Harm takes into account the consequences to the patient or operator if the device fails to perform its clinical function, specifically the worst-case scenario. It is not limited to the physical risk related to the breakage of the device. It is inevitably linked to the device’s functionality, in that death or major injury are related mainly to therapeutic devices, whereas misdiagnosis or inappropriate therapy are related mainly to diagnostic and analytical devices.

Value of (H)	Potential Harm Description
5	Death
4	Major Injury, Disability
3	Minor injury, Inappropriate Therapy, Misdiagnosis, Increased Recovery Time
2	Inconvenience or Delay
1	No Significant Identified Risk

Note: “High-risk medical equipment” (ref. standard EC.02.04.01, EP 3) is identified through this criterion, and corresponds to those models that have the relevant sub-score equal to 4 (serious injury) or 5 (death).

Maintenance Requirements is used to assess and categorize a device model’s maintenance needs: type and level of scheduled maintenance.

Value of (M)	Maintenance Requirements Description
5	Extensive: Routine Calibration & Part Replacement Required (“True PM”)
4	Above Average
3	Average: Performance Verification & Safety Testing (SPI)
2	Below Average
1	Minimal: Visual Inspection & Safety Testing

Incident and Failure History

Any available information regarding incident and failure history will be considered, if known, when evaluating the device model. Specifically, the answers to the following two questions will determine the score for this criterion.

- 1) How often a problem occurred that could have been mitigated or prevented by Inspection and/or Preventive Maintenance (IPM)?
- 2) Have any failures created a dangerous condition for patients or employees? (concept of “Fail-safe”, a feature that automatically counteracts the effect of an anticipated, potential source of failure)

Service history information will be reviewed periodically to determine if a device model should be considered for upgrading into or downgrading it out of the program. The following table is used to evaluate each device model:

Value of (I)	Incident and Failure History Description
+ 2	History of recalls and adverse events with significant patient injury and / or unacceptable mean time between failures that could have been prevented by IPM
0	History of recalls and adverse events, if any, without significant impact to patient injury and / or acceptable mean time between failures that could have been prevented by IPM
- 2	No history of recalls and adverse events related to patient injury and acceptable mean time between failures that could have been prevented by IPM

c. Definition of Scheduled Maintenance activities

Preventive Maintenance (PM): scheduled replacement of (wearable) parts, filter cleaning, recalibration, etc. to prevent a predictable failure (i.e. before their respective mean-times-between-failure, MTBF have been reached). As the reliability of medical equipment has improved remarkably, the need for PM has been drastically reduced. Often there are no serviceable parts or the MTBF is longer than the average useful life of the equipment

Safety and Performance Inspection (SPI): scheduled actions performed to verify that a piece of equipment is performing within original specifications and that there are no obvious detectable safety hazards related to abuse or deterioration. An SPI should be performed after each PM and repair that affect either safety of performance. Equipment that does not require PM may benefit from an SPI.

They are independent but not mutually-exclusive of each other.

Annex 2: The Joint Commission Environment of Care (EOC) Standards – effective July 2, 2014

Standard EC.02.04.01

The hospital manages medical equipment risks.

Elements of Performance for EC.02.04.01

C 2. [...] For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital maintains a written inventory of all medical equipment. (See also EC.02.04.03, EPs 1 and 3)

C 3. The hospital identifies high-risk medical equipment on the inventory for which there is a risk of serious injury or death to a patient or staff member should the equipment fail.

Note: High-risk medical equipment includes life-support equipment.

C 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.

Note: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice. *

* An example of standards for a medical equipment program is the American National Standards Institute/Association for the Advancement of Medical Instrumentation handbook ANSI/AAMI EQ56: 2013, Recommended Practice for a Medical Equipment Management Program.

A 5. For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements
- Medical laser devices
- Imaging and radiologic equipment (whether used for diagnostic or therapeutic purposes)
- New medical equipment with insufficient maintenance history to support the use of alternative maintenance strategies

Note: Maintenance history includes any of the following documented evidence:

- Records provided by the hospital's contractors
- Information made public by nationally recognized sources
- Records of the hospital's experience over time

A 6. For hospitals that use Joint Commission accreditation for deemed status purposes: 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 harm during normal use
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or back-up equipment in the event the equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

(For more information on defining staff qualifications, refer to Standard HR.01.02.01)

C 7. For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

A 8. The hospital monitors and reports all incidents in which medical equipment is suspected in or attributed to the death, serious injury, or serious illness of any individual, as required by the Safe Medical Devices Act of 1990.

A 9. The hospital has written procedures to follow when medical equipment fails, including using emergency clinical interventions and backup equipment.

Standard EC.02.04.03

The hospital inspects, tests, and maintains medical equipment.

Elements of Performance for EC.02.04.03

C 1. [...] For hospitals that use Joint Commission accreditation for deemed status purposes: Before initial use and after major repairs or upgrades of medical equipment on the medical equipment inventory, the hospital performs safety, operational, and functional checks. (See also EC.02.04.01, EP 2)

A 2. The hospital inspects, tests, and maintains all high-risk equipment. These activities are documented. (See also EC.02.04.01, EPs 3 and 4; PC.02.01.11, EP 2)

Note: High-risk medical equipment includes life-support equipment.

C 3. The hospital inspects, tests, and maintains non-high-risk equipment identified on the medical equipment inventory. These activities are documented. (See also EC.02.04.01, EPs 2 and 4; and PC.02.01.11, EP 2)

Standard EC.02.05.01

The hospital manages risks associated with its utility systems.

Elements of Performance for EC.02.05.01

C 2. [...] For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital maintains a written inventory of all operating components of utility systems. (See also EC.02.05.05, EPs 1, 3-5)

C 3. The hospital identifies high-risk operating components of utility systems on the inventory for which there is a risk of serious harm or death to a patient or staff member should the component fail.

Note: High-risk utility system components include life-support equipment.

C 4. The hospital identifies the activities and associated frequencies, in writing, for inspecting, testing and maintaining all operating components of utility systems on the inventory. These activities and associated frequencies are in accordance with manufacturers' recommendations or with strategies of an alternative equipment maintenance (AEM) program.

Note 1: The strategies of an AEM program must not reduce the safety of equipment and must be based on accepted standards of practice. *

Note 2: For guidance on maintenance and testing activities for Essential Electric Systems (Type I), see NFPA 99, 1999 edition (Section 3-4.4).

* An example of guidelines for physical plant equipment maintenance is the American Society for Healthcare Engineering (ASHE) book Maintenance Management for Health Care Facilities.

A 5. For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital's activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers' recommendations:

- Equipment subject to federal or state law or Medicare Conditions of Participation in which inspecting, testing, and maintaining be in accordance with the manufacturers' recommendations, or otherwise establishes more stringent maintenance requirements
- New operating components with insufficient maintenance history to support the use of alternative maintenance strategies

Note: Maintenance history includes any of the following documented evidence:

- Records provided by the hospital's contractors
- Information made public by nationally recognized sources
- Records of the hospital's experience over time

A 6. For hospitals that use Joint Commission accreditation for deemed status purposes: A qualified individual(s) uses written criteria to support the determination whether it is safe to permit operating components of utility systems to be maintained in an alternate manner that includes the following:

- How the equipment is used, including the seriousness and prevalence of harm during normal use
- Likely consequences of equipment failure or malfunction, including seriousness of and prevalence of harm
- Availability of alternative or back-up equipment in the event the equipment fails or malfunctions
- Incident history of identical or similar equipment
- Maintenance requirements of the equipment

(For more information on defining staff qualifications, refer to Standard HR.01.02.01)

C 7. For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital identifies operating components of utility systems on its inventory that is included in an alternative equipment maintenance program.

A 14. The hospital minimizes pathogenic biological agents in cooling towers, domestic hot- and cold-water systems, and other aerosolizing water systems.

A 15. In areas designed to control airborne contaminants (such as biological agents, gases, fumes, dust), the ventilation system provides appropriate pressure relationships, air-exchange rates, and filtration efficiencies. (See also EC.02.06.01, EP 13)

Note: Areas designed for control of airborne contaminants include spaces such as operating rooms, special procedure rooms, delivery rooms for patients diagnosed with or suspected of having airborne communicable diseases (for example, pulmonary or laryngeal tuberculosis), patients in "protective environment" rooms (for example, those receiving bone marrow transplants), laboratories, pharmacies, and sterile supply rooms. For further information, see Guidelines for Design and Construction of Health Care Facilities, 2010 edition, administered by the Facility Guidelines Institute and published by the American Society for Healthcare Engineering (ASHE).

A 16. The hospital maps the distribution of its utility systems.

Standard EC.02.05.05

The hospital inspects, tests, and maintains utility systems.

Note: At times, maintenance is performed by an external service. In these cases, hospitals are not required to possess maintenance documentation but must have access to such documentation during survey and as needed.

Elements of Performance for EC.02.05.05

C 1. [...] For hospitals that use Joint Commission accreditation for deemed status purposes: The hospital tests utility system components on the inventory before initial use and after major repairs or upgrades. The completion date of the tests is documented. (See also EC.02.05.01, EP 2)

A 3. The hospital inspects, tests, and maintains the following: High-risk utility system components on the inventory. These activities are documented. (See also EC.02.05.01, EPs 2 and 4)

Note: High-risk utility system components includes life-support utility system components.

A 4. The hospital inspects, tests, and maintains the following: Infection control utility system components on the inventory. These activities are documented. (See also EC.02.05.01, EPs 2 and 4)

C 5. The hospital inspects, tests, and maintains the following: Non-high-risk utility system components on the inventory. These activities are documented. (See also EC.02.05.01, EPs 2 and 4)