Medical technology has evolved dramatically in recent years. Surgical robots, radiosurgery systems, hybrid operating rooms, complex integrated medical systems, high-resolution three-dimensional in vitro imaging, nanotechnologies, clinical decision support systems, and electronic health records are just a few examples of new technologies that represent great advances in healthcare delivery. However, they also represent great challenges to healthcare costs and infrastructure. Many hospitals today are spending eight to 10 times over what they spent annually 10 years ago on medical capital equipment. Because of this, the challenge of selecting, deploying, and maintaining new technologies can seem overwhelming.

A New Support Paradigm

Today’s new medical technology often needs a very different type of technical support from what was required for older technologies in the past. Today’s technologies tend to be less mechanical (i.e., less affected by “wear and tear”), more reliable, and more capable of self-diagnosis and self-calibration. Regular equipment testing and scheduled maintenance, which traditionally represented about 50% of a biomedical equipment technician’s work time, is far less important today for safety or reliability because a dwindling percentage of medical equipment failures can be detected or prevented by routine testing or scheduled maintenance. However, while “maintenance-related” failures are far less common, newer technologies are producing a growing number of failures related to ineffective workflow issues or inadequate staff training on technology systems. Still other significant failures are occurring because today’s systems of systems (SoS) often have unrecognized single points of failure (SPOF) whose individual failure can bring down multiple systems that in turn can have a broad effect on operations and patient care.

Recognizing the need for a new paradigm, the more progressive elements in the healthcare technology management (HTM) community had begun to focus on a risk-based approach toward technology support. As a result, these progressive HTM services have increasingly been concentrating more of their time and resources on the greatest risks ... most of which have nothing do to with maintenance. This risk-based based approach toward technology support has even garnered the approval of healthcare accrediting organizations such as The Joint Commission (TJC) and DNV Healthcare.

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Some examples of other support services suggested by a risk-based approach include:

- Strategic capital planning—ensuring objective information is available to consider the effect of new system deployments, and that objective information is available to prioritize and drive multi-year plans that result in the timely replacement of old and less effective clinical technologies
- Acquisition of new technology—ensuring all necessary deployment and training preparations are made and stakeholders are appropriately engaged in technology use and support
- Total service management—managing in-house and vendor resources in a manner that ensures safety and quality service is delivered in the most cost-effective manner
- Risk and vulnerability assessments—working with appropriate stakeholders to identify those critical clinical systems with significant vulnerabilities and working to establish and manage a plan to mitigate those risks
- Continuing education of clinicians on the proper equipment operation and the redesign of technology related workflows to reduce growing number of use-related failures
- Collaboration with information technology on integration, security, and other areas for the rapidly growing number of networked medical systems
- Compliance—including new TJC, DNV, Centers for Medicare and Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), and Association for the Advancement of Medical Instrumentation (AAMI) standards and requirements

This risk-based approach enables hospitals to apply their finite resources on—what evidence shows—are the real challenges to safety and efficacy of today’s technology.

And One Step Back
In December 2011, CMS generated a memorandum intended to give CMS and state surveyors more explicit guidelines in determining whether hospitals were meeting CMS regulations related to equipment maintenance. The new guidelines require hospitals to apply their finite resources on—what evidence shows—are the real challenges to safety and efficacy of today’s technology.

Follow manufacturers’ recommendations for maintenance procedures and schedules. The small exception was that hospitals could change inspection schedules if the equipment was non-critical (i.e., equipment for which there is no risk of serious injury or death should the equipment fail) and if the hospital could produce evidence of an assessment that demonstrates changing the maintenance schedule would have no adverse effect on patient or staff safety.

The response of the HTM community to CMS’s new guidelines on how to assess hospitals’ compliance with their maintenance-related requirements was overwhelmingly negative. Some of the most common reasons given for the community’s concern included:

- Manufacturers generally develop their “recommended” maintenance procedures based on worst-case scenarios (i.e., worst environment, harshest treatment, highest utilization.). The reality is that very few pieces of medical equipment are subjected to the worst-case scenario. Clinical engineers working in hospitals are generally trained and, with access to manufacturers’ recommendations, are capable of determining what maintenance procedures and schedules are appropriate for the equipment in that environment.
- The new guidelines were contrary to the risk-based approach toward medical equipment maintenance previously taken by a growing number of HTM programs. TJC and DNV had adopted a more flexible, outcome-based maintenance approach that had previously received the blessings of CMS.

Manufacturers generally develop their “recommended” maintenance procedures based on worst-case scenarios (i.e., worst environment, harshest treatment, highest utilization).

- The new CMS guidelines will likely result in substantially increased costs because they will result in substantially more maintenance—additional maintenance for which there is no real evidence to suggest safety or quality of care would be improved.
- Hospitals already are challenged with limited resources, and the challenges of

About CMS
Most U.S. hospitals receive a substantial portion of their income for care given to patients covered by the Centers for Medicare & Medicaid Services (CMS). To be eligible for these CMS reimbursements, hospitals must be able to demonstrate they comply with CMS’s Conditions of Participation (CoP), or standards, as set forth in federal regulations. Evidence of compliance may come from a survey conducted by a state agency on behalf of CMS, or it may come from a survey done by a national accrediting organization that has been granted “deeming” authority. TJC and DNV have both been granted “deeming” authority, and consequently hospitals that are successfully accredited by either organization are considered as having been “deemed” by CMS as meeting their certification requirements.
dealing with the consequences of increasingly complex technologies and SoS. The new CMS guidelines would have the effect of diverting those limited resources from a growing number of demonstrated problems associated with complex devices and systems to maintenance activities of questionable benefit.

A group of industry experts and leaders in HTM (including representatives from TJC and DNV) under the sponsorship of AAMI, met with CMS representatives over the last 18 months to share their concerns and provide evidence that would cause CMS to revise their December 2011 guidelines and allow hospitals more flexibility in how they conduct equipment maintenance. During that period CMS listened and agreed not to cite hospitals for non-compliance until CMS could consider the group's case.

The New CMS Guidelines
On December 20, 2013, CMS released its memorandum (S&C 14-07-Hospital) with updated guidelines that became effective immediately.

The updated CMS guidelines now allow hospitals to adjust maintenance procedures and schedules from manufacturer recommendations for non-excluded equipment based on a risk assessment by qualified personnel. CMS defines deviation from manufacturer recommendations as an Alternative Equipment Maintenance (AEM) program. CMS excludes those hospitals must strictly adhere to the AEM procedures and schedules they have established.

TJC Revises Its Standards
To maintain their “deeming” status, TJC and DNV needed to revise their accreditation standards to align with the new CMS guidelines. In June 2014, TJC announced it had revised its Environment of Care (EC) standards to address the changes made by CMS.

Specifically, TJC made the following revisions to their Elements of Performance for Standards EC.02.04.01 and EC.02.04.03:

**Standard EC.02.04.01**
The hospital manages medical equipment risks.

**Elements of Performance for EC.02.04.01**

**EP 2.** The hospital maintains a written inventory of ALL medical equipment. *(See also EC.02.04.03, EPs 1 and 3)*

[Note that hospitals not using TJC accreditation to maintain “deemed” status have the option of retaining risk-based inclusion]

**EP 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 equipment fail.

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

**EP 4.** The hospital identifies the activities and associated frequencies, in writing, for maintaining, inspecting, and testing all medical equipment in 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.
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EP 5. The hospital’s activities and frequencies for inspecting, testing, and maintaining the following items must be in accordance with manufacturers’ recommendations:

[Note that this EP 5 does not apply to hospitals who do not use TJC accreditation to maintain “deemed” status]

• Equipment subject to federal or state law or Medicare Conditions of Participation (CoP) in which inspecting, testing, and maintaining be in accordance with the manufacturers’ recommendations, or otherwise establishes more stringent maintenance requirements

• Medical laser devices

• Imaging or radiographic equipment (whether used for diagnostic or therapeutic purposes)

[Current TJC comments suggest this does include all medical equipment using ultrasound]

• 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 to the hospital contractors

• Information made public by nationally recognized sources (e.g., ECRI, AAMI, etc.)

• Records of the hospital’s experience over time

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:

[Note that this EP 6 does not apply to hospitals who do not use TJC accreditation to maintain “deemed” status]

• How the equipment is used, including the seriousness and prevalence of harm during normal use

  • Likely consequences of equipment failure or malfunction, including seriousness 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 info on defining staff qualifications, refer to Standard HR.01.02.01]

EP 7. The hospital identifies medical equipment on its inventory that is included in an alternative equipment maintenance program.

[Note that this EP 7 does not apply to hospitals that do not use TJC accreditation to maintain “deemed” status.]

EP 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.

EP 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.

**Element of Performance for EC.02.04.03**

EP 1. 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)

[Note that for hospitals who do not use TJC accreditation to maintain “deemed” status, EP 1 reads: Before initial use of medical equipment on the medical equipment inventory,
Does the industry have the manpower to comply with new regulations?

A recent American Hospital Association (AHA) guide listed over 5,300 healthcare organizations in the United States with a total of more than 921,000 beds. A fair industry estimate would be 15 medical devices per bed, which would put the number of medical devices in U.S. healthcare organizations somewhere north of 13.8 million.

Let us consider the implications of following manufacturers’ recommendations on 13.8 million medical devices. Assume that:

• All medical devices require maintenance once per year (many manufacturers often recommend two to four times per year)

• Scheduled maintenance on all medical devices requires 30 minutes (15 minutes is barely enough to write up paperwork, and many devices may actually require from an hour to many hours depending on the device complexity)

In this very conservative scenario, it would require 6.9 million hours per year to conduct scheduled maintenance on medical equipment in U.S. organizations. Estimating that one full time equivalent (FTE) has 1,288 productive hours available (after deducting 80 hours each for vacation, holiday, and sick and assuming a generous 70% productivity level), it would require 5,360 full-time service technicians working without a break 9 a.m. to 5 p.m. solely on scheduled maintenance. Can the current number of BMETs in the U.S. handle this scheduled maintenance as well repair and other support requirements? And remember, the time and frequency numbers used above are conservative in the extreme.

The hospital performs safety, operational, and functional checks.

EP 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 that 100% of high-risk equipment must be maintained on schedule as life-support had been previously.]

EP 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; PC.02.01.11, EP 2)

These updated TJC standards became effective in July 2014.

How Can Hospitals Prepare to Meet The New Requirements?

Full compliance with the new requirements is likely to require U.S. hospitals to expend substantially more resources in time and money than what they previously spent for medical equipment maintenance. Given the demands for their limited resources, many hospitals may feel it will be difficult, if not impossible, to fully comply with the new standards. However, regardless of any difficulty they might impose, these standards are the new reality and should be addressed.

Hospitals should begin to take steps now that will prepare them for compliance and will also demonstrate to any surveyors that they are making a good faith effort to comply. Following are some key steps hospitals should be taking now to prepare for compliance:

1. Meet as soon as possible with hospital leadership and compliance office to inform them of the new standards. Keep them informed of:
   – Plans to achieve compliance and the progress made in executing those plans
   – Resources (including manpower and financial support) necessary to achieve compliance

2. Verify medical equipment inventory is complete. Include equipment regardless of ownership (i.e., loaners, leased, rentals, etc.) or source of service (e.g., in-house, contractor, time and materials), regardless of risk.

3. Obtain manufacturer recommendations regarding maintenance procedures and schedules. Use the medical equipment inventory to create a list of unique manufacturer/model combinations and request manufacturers to provide recommendations for their models (keeping records of communication attempts).

Also require vendors to provide manufacturer recommended maintenance procedures and schedules for all new acquisitions.

If necessary, remind manufacturers of the NFPA 99 and ANSI ES60601-1 standards requiring they provide maintenance-related procedures and frequencies:

• NFPA 99 (2012) Health Facilities Code states:
  – “The manufacturer of the appliance shall furnish documents containing at least a technical description, instructions for use, and a means of contacting the manufacturer
  – These documents shall include ... preventive and corrective maintenance and repair procedures

• AAMI/ANSI ES60601-1:2005 (R)2012 Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance states:
  – “Equipment shall be accompanied by ... instructions for use and a technical description
  – Instructions for use shall instruct the OPERATOR or RESPONSIBLE ORGANIZATION in sufficient detail concerning preventive maintenance, maintenance, and calibration to be performed by them, including the frequency of such maintenance.”

4. In the “complete” medical equipment inventory maintained in the hospital’s computerized maintenance management system (CMMS), there should be the ability to flag:
   – Equipment considered “critical” (CMS term) or “high risk” (TJC term) because qualified hospital staff agrees “there is a risk of serious injury or death if the equipment should fail” (CMS and TJC requirement)
   – Equipment identified as “AEM ineligible” (e.g., medical lasers, imaging, and...
therapeutic radiology equipment)
- Equipment as “AEM” if analysis by qualified hospital staff has resulted in the decision to apply an “alternative equipment maintenance” approach (CMS & TJC requirement)
- Manufacturers recommendations regarding maintenance procedures and schedules are on file (attached or linked to specific devices in the CMMS as PDF where possible)
- Source of service (i.e., in-house staff, name of vendor if time and materials or contract) and indicate location of file with credentials or attach PDF with credentials where possible

5. In corrective maintenance records maintained in the CMMS, hospitals should have the ability to:
   - Categorize the “degree” of equipment failure where:
     - Major describes when equipment is “hard down”
     - Minor describes when equipment remains operational and does not compromise safety (i.e., hospitals should be able to focus on “operational” failures or “safety-related” failures when analyzing histories)
   - Categorize the “type” of equipment failure where:
     - Maintenance preventable (i.e., wear and tear) related failure (i.e., gradual degradation of one or more equipment components over a period of time that may be detected by regular testing or prevented by recalibration or prophylactic parts replacement
     - Spontaneous failure (i.e., where no reasonable number or frequency of inspections, testing, or preventive maintenance could have predicted or prevented failure)
     - Use or process related failure (i.e., failure caused by factors external to the equipment) (i.e., be able to focus on “maintenance preventable” failures in service histories)

6. Revise or establish hospital policies and procedures to:
   - Describe under what circumstances deviation from manufacturer recommended maintenance procedures and schedules will be considered
   - Describe the process for assessing risks to determine when deviating from manufacturers’ recommendations is acceptable, specifically describe a process that assesses the:
     - Severity of consequences to the safety of patients and others should that equipment fail
     - Probability of equipment failure due to inadequate or insufficient testing, inspection, or preventive maintenance
     - Risk -- calculated as a function of severity and probability (see ISO 14971:2007 Application of Risk Management to Medical Devices as a reference)
   - Identify the multidisciplinary team that will participate in judging severity and probability of equipment failures (the basis of risk assessment). Typically this team would include clinicians, clinical engineers, risk management, safety officer, and others as appropriate

7. Document sources of service histories used to conduct risk assessments (e.g., in-house, ECRI, AAMI, or other authority)

8. Document the credentials of those participating in the risk assessment process (e.g., degrees, certifications, training certificates, etc.)

9. Include language in service contracts and agreements that requires vendors to:
   - Follow manufacturer recommended procedures and frequencies for medical equipment not included in the hospital’s AEM program and follow AEM program procedures and schedules for equipment included in the program
   - Document all service performed (according to the service documentation requirements established by the hospital)
   - Demonstrate the qualifications of the vendor staff providing service

10. Assign responsibility for monitoring compliance of CMS and TJC requirements regardless of service source and document the credentials of the assignee
**Moving to the AEM Program**

Until they have analyzed service histories associated with medical equipment in their inventories and conducted the appropriate risk assessments that would allow them to move some eligible equipment into the AEM program, hospitals are required to follow manufacturers’ maintenance recommendations for all their medical equipment (see sidebar).

Once they have completed all the necessary preparations, collected the appropriate histories, and established the necessary policies and procedures for the AEM, hospitals may then review the equipment histories to assess what changes could be made to manufacturers’ recommended maintenance procedures and frequencies without increasing risks to patients or staff. Only when the risk (i.e., severity times probability) of failures due to inadequate or insufficient testing, inspection, or preventive maintenance is acceptably low should equipment be included in an AEM program. Once included in the AEM program, the equipment histories should be monitored to ensure maintenance related failures do not pose a risk to patients or staff.

**Risk Assessment Tools: Determining Probability, Severity, and Risk**

There are some basic risk assessment tools that will be key to transitioning to an AEM.

Figure 1 is an Ishikawa diagram that illustrates one approach to scoring the probability underlying causes of failure and the severity of the consequences of a failure.

Note on the right of Figure 1, there is a scale for ranking the severity of the consequence of failure of a medical device. Life support equipment would have a severity score of 4, indicating failure of this equipment could be catastrophic and result in loss of life. Equipment with a severity score of 3 would be critical (or high risk) because failure of that equipment could result in a permanent adverse effect (serious injury). Clinicians who generally best understand the consequences of a medical device failure are normally the primary resource for determining severity scores.

Using this model, all equipment given a severity score of 3 or 4 would be considered critical (by CMS) and high risk (by TJC).

To use this as a tool for determining the need for maintenance for a piece of medical equipment, one would identify those factors contributing to failure (on the left of the diagram) that could be mitigated by maintenance (e.g., “wear and tear” related failures).

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**Figure 1.** Ishikawa diagram used to score probability of cause and severity of effect

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and assign them a probability score (e.g., 1 for “improbable” or extremely unlikely in the equipment lifetime through 4 for “probable” or very likely to occur several times during the equipment lifetime). Clinical engineering professionals who generally best understand how maintenance (or the lack thereof) can contribute to failure are normally going to be the primary source for determining probability scores.

Figure 2 illustrates a risk matrix that combines the probability and severity arrived at in Figure 1 to produce a total risk score. In this matrix, high probability and high severity yield high risk (upper right quadrant) while low probability and low severity yield low risk (lower left quadrant).

Equipment whose failure may represent a severe consequence (e.g., severity score = 4) can still be “low risk” if the probability of failure is low (e.g., probability = 1), yielding a risk score of 4.

Figure 3 illustrates a partial list of equipment categories where the above-described approach is used to arrive at severity, probability, and total risk scores.

**Conclusion**

Adhering to the letter of the new regulations is clearly going to be challenging for all hospitals. Compliance will require considerably more time and money over what hospitals have traditionally spent for medical equipment maintenance. Unfortunately, the new regulations appear to be a “fix” where there is no evidence to show anything is broken. It is doubly unfortunate because leaders in the HTM field have recognized that there are real challenges associated with the current state of medical technology that will likely now receive less attention and resources because so much must be diverted to comply with the new regulations.

All that said, these regulations are a fact and must be addressed. It is extremely important that we begin taking steps now to comply and that we keep hospital leadership and compliance officers aware of these issues. If we are diligent in our efforts, perhaps someday we will be able to produce sufficient evidence to demonstrate the benefit (or lack thereof) of these new regulations and see them once again revised.
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