May 25, 2016

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subject:  FR Doc. 2016-04700

Dear FDA Colleagues,

Thank you for the opportunity to review and comment on the FDA's docket titled Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments.

The comments below are submitted by the Association for the Advancement of Medical Instrumentation (AAMI). AAMI is a diverse non-profit community of 7,000 professionals from many domains in healthcare who are experts on healthcare technology and medical devices. AAMI is a leading developer of national and international standards for medical devices and related healthcare products. It specializes in standards that address the safety and performance of devices and device systems, in particular as they relate to patient safety. AAMI is ANSI-accredited as a standards development organization, and its community of industry, regulators (e.g., FDA, CMS), clinicians, researchers and independent experts together develop standards, technical information reports, and related information about medical devices. AAMI’s focus is on the safe and effective development, management, and use of medical devices and related technologies. AAMI is not an advocacy organization. It is a neutral organization that highly values its neutrality and “honest broker” reputation. Device manufacturers, as well as those who purchase, manage, and maintain medical equipment, make up two significant segments of AAMI’s membership base.

In addition to its membership base, AAMI provides programs, products and services to at least 15,000 to 20,000 additional healthcare technology-oriented professionals through the efforts of the AAMI Foundation, its professional certification program, educational and training, and award-winning publications. Its website is a constantly updated resource with articles, podcasts, seminars, blog posts, and guides for those professionals and the healthcare technology community at large, registering more than two million page views in 2015. Additionally, AAMI is increasingly recognized by specialty publications and the news media at large as an authority on healthcare technology matters, earning coverage in outlets as diverse as The Boston Globe, States News Service, Bloomberg, CBS News, and Reuters.

AAMI does not normally submit detailed, technical comments in response to FDA FR notices. In this instance, we believe that AAMI has the broadest view of the entire service industry, because it is neutral and multidisciplinary. We are hoping that our factual, big picture comments about
the industry help provide context and a deeper understanding of how the entire service industry fits together as a part of the life cycle for medical devices.

**Wide Diversity of Perspectives Across the Service Industry**

There have been a few highly visible adverse incidents in recent years caused by poor maintenance and repairs to medical devices. The number of adverse incidents involving technology is very low compared with overall adverse incidents in healthcare, although it is generally agreed that adverse incidents are underreported. Using assumptions intended to represent a worst case, ECRI Institute has studied the MAUDE database (a number of years ago and very recently) showing that the number of technology related adverse incidents caused by poor maintenance or repairs (a subset of overall technology related incidents) is very low. Also, AAMI published an article in its peer-reviewed bimonthly journal—*BI&T*—in 2013 that, using a statistical analysis based on data provided by The Joint Commission and an AAMI survey of the field, confirmed the ECRI data, even with some worst case assumptions about worst case.

The recent and highly visible problems with endoscopes complicate general perceptions about the quality of service of medical devices. Scopes are complex and difficult to clean and repair, and it is very difficult to ascertain whether there are microscopic cracks or other problems with these unique devices. There are many individuals from the service business generally who believe, without really knowing for sure, that the issues associated with endoscopes taint what would otherwise be an overall positive view about all service.

From the perspective of original equipment manufacturers (OEMs), their service model is advantageous for a number of reasons: They are more confident in the rigor of their quality system and risk management processes, which are highly regulated, documented, validated and audited. They also are more comfortable knowing that their parts are being used in their products, because they know that their parts have gone through a strong purchasing control process. They are more confident in their OEM-trained technicians because they have documentation of the qualifications of their own people, who they know have been trained under their controlled training programs. They understandably would prefer to have more control over what happens with their devices out in the field. And, the feedback mechanisms that tell what’s happening with a device (e.g., software) in general tend to be stronger when their own employees or sub-contractors are performing the service and repairs (that information then feeds into their complaint system, which is part of their quality management system). OEMs also uniquely have access to design information. These stronger feedback mechanisms (and linkage to design information) help provide better feedback into the design and development process for iterative improvements. OEMs also say they are at risk from a liability perspective for poor repairs made by non-OEM service technicians. OEMs also have a business interest in having service and repairs done through OEM contracts, because it is a profit center for them.

Many technicians across this industry move in and out of working for OEMs, directly for hospitals, for independent service organizations (ISOs), for parts companies, etc. And, a growing number of OEMs are multi-vendor service organizations, offering third-party service to healthcare delivery organizations using their own technicians and third-party parts, or sub-
contracting the work to non-OEM third-party repair companies—at times the very same third-party repair companies that compete with them for OEM repairs.

From the perspective of healthcare delivery organizations, they believe that more regulation or other restrictions on service will increase the cost of healthcare. Increased costs could result if such regulations further limit their access to competitively priced service and parts; increase the cost of refurbished equipment or third-party repairs; create a market environment that results in monopoly power for parts and service by OEMs; or impose additional requirements on healthcare delivery organizations that sell their own third-party service and repair to other healthcare delivery organizations (note: in these roles, healthcare delivery organizations become third-party service organizations). For facilities with access to expert on-site technical support (either employees or contracted ISO on-site staff), HTM professionals believe their facilities save significant dollars relative to a typical full service contract from the OEM.

Healthcare delivery organizations, ISOs, refurbishers, third-party repair organizations, and even some OEMs, believe the issues here have a huge potential to shift market power and dominance. Smaller third-party vendors in particular fear they will be forced out of business with greater regulation. In today’s market, they tend to have a niche local business that serves smaller hospitals and rural areas that bigger service organizations are not as interested in serving.

In short, as is often the case with complex issues that involve multiple disciplines, multiple service models, lack of standardization, paucity of reliable data about the industry, uneven lobbying capabilities across the sector, strong opinions, and stories galore, there is a huge risk of unintended consequences from a regulatory answer. AAMI applauds the FDA for taking a conservative approach of requesting information to help it assess the questions it asked in the FR Notice. Many in the industry assume that this is a slippery slope toward regulation. AAMI sees it more as a due diligence initiative, with the potential for increased regulation if the FDA is not satisfied with the status quo based on all of the information it gathers during this due diligence process. No matter what, at the end of the day the entire industry will be better informed and have much more to think about, simply from reading the perspectives that are offered across this very diverse industry in response to the FDA’s FR Notice.

**Landscape of the Medical Device Service Business**

*History of the Service Business*

Fifty years ago, there was virtually no competition for the medical device service business in hospitals—everything was repaired by the manufacturers. There were very few engineers working in hospitals at that time, and the few that did primarily worked on developing new device prototypes and related technology solutions for creative clinicians.

The boom in medical technology started in the 1960s. It started quite slowly with defibrillators, implanted pacemakers, and remote patient monitoring, which was required for patients placed in isolation after they were irradiated in preparation for kidney transplantation. But it grew quite rapidly throughout the latter part of the last century.
With the proliferation of technology, the role of engineers in healthcare delivery organizations began to grow. Then it expanded beyond teaching hospitals to smaller community hospitals as they began to see the value of managing their own technology. This, in turn, stimulated the growth of the independent service sector.

The introduction of the new and complex CT and MRI imaging systems in the 1970s and 80s led to opportunities in the 1990s for manufacturers to adopt the shared service model and compete as multi-vendor service organizations for the maintenance business of their competitors’ imaging devices.

Then, according to experts from the field, OEMs started selling certified refurbished equipment to an initially skeptical hospital audience. Once hospitals began to see the savings that could result from purchasing refurbished equipment, and to trust the reliability of such equipment, the market began to open up even more to non-OEM refurbishment companies.

Scope of the Service Business

According to a 2012 report sponsored by AdvaMed, annual sales of medical devices and in-vitro diagnostics in the United States in 2010 totaled $156.3 billion, or about 6% of our national healthcare expenditures. The common method of estimating the cost of servicing a medical device is to use 5-10% of the cost of the device over the lifetime of the device. For purposes of this discussion, using the conservative number of 5%, the device service market for newly purchased devices today is approximately $7.8 billion per year. If we very conservatively estimate the total medical equipment inventory embedded in the nation’s hospitals to be five times this annual spend, we get an estimated national inventory of medical equipment worth about $1 trillion. And again, to be conservative, if we estimate the expenditures to maintain this inventory to an average 5% per year (which would be on the low end of the spectrum), this pegs the current medical device service aftermarket at about $50 billion per year. Note: these are estimates derived from experienced HTM leaders in the field. Actual data on the monetary scope of the entire service business is sparse.

What Influences Serviceability

The foundation for service begins with the design of the device and is woven into the entire life cycle of a medical device, until it is finally retired—though, even then, it may live on, if some of its parts are harvested for refurbishment and re-use.

The design of the device itself is critical to the lifelong maintenance of the device, because its complexity affects its reliability and thus the need for service. Its design also impacts the ease with which the device can be serviced. The use of non-standard components makes the device

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1 Estimates of Medical Device Spending in the United States, by Gerald Donahoe and Guy King, July 2012. [http://advamed.org/res.download/291](http://advamed.org/res.download/291). Although the data in this report is old, it’s a useful reference for purposes of illustrating the scope of the service business, and would suggest that the overall size of the business is probably even higher than the estimate provided in the above paragraph.
more expensive and can make it more difficult to service. How well the instructions for use and the service manual are written also affects the effective reliability and supportability of the device. One of the most persistent complaints about service from the healthcare technology management community (known as HTM professionals, and encompassing all professionals who are involved in the assessment, purchase, implementation, testing, management, maintenance, and repair of devices and systems) is their difficulty in accessing a well-written service manual.

The quality of the fabrication of the device also affects its reliability. Poor reliability means more frequent breakdowns, sometimes a need for more frequent calibration, and sometimes a greater likelihood of recalls.

While initially it may not seem related to the topic at hand, recall management is an important part of the business overall to anyone who works in the service business, and it needs to be considered in the context of how the various aspects of the service business fit together. Most people and organizations in the service business are impacted by recall management. It’s time intensive, expensive for a healthcare delivery organization, takes needed devices out of inventory, and requires constant due diligence to monitor an extensive network of devices. One speaker at the October 2015 AAMI/FDA Risk Management Summit reported that he manages 200 recalls a month at his large health system. Recalls are also a consideration for parts companies, third-party repair organizations, companies that buy, sell, and refurbish used technology, and of course for the service arms of OEMs.

Decisions on which devices a particular healthcare organization should purchase are also quite challenging and often require a complex analysis. The healthcare delivery organization (or, more commonly today, the healthcare system) must take into account which particular make and model best meets its needs, as well as the device’s serviceability. Most of the device’s total lifetime cost is incurred post warranty, making the overall cost not immediately apparent.

The post-warranty medical device service business is a critical part of the overall life cycle of all healthcare technology. Post-warranty service and support via a full service contract can have ramifications on downtime and the device’s total lifetime cost.

Value of On-Site Technical Support

HTM professionals believe that facilities with access to expert on-site technical support (either employees, contracted ISO on-site staff, OEM staff, or a shared services model involving a mix of these experts) save significant dollars compared with a model that is completely outsourced to a multitude of OEMs that sell a wide variety and scope of medical devices and service to a healthcare delivery organization (e.g., surgical instruments, laboratory equipment, fully outfitted OR suites, imaging equipment, sterilization equipment, infusion devices, ventilators, monitors, alarm systems, beds, etc.).

There are many variations to on-site technical support: fully employed generalists and specialists who are all employed by the health system; a mix of fully employed and shared service (employed by a third-party service or OEM) dedicated on-site staff; on-site staff employed by an ISO; full service contract with the OEM.
There seems to be consensus throughout the industry that the overall effectiveness of a healthcare delivery organization is significantly improved by having some on-site technical staff (whether those staff are employed by the healthcare delivery organization or system, an ISO, or an OEM), for a number of reasons. In general, a majority of repair calls can be handled successfully by an on-site generalist, saving significant downtime for equipment that is needed for patient care, as well as avoiding expensive travel charges. For the service calls that the on-site generalist cannot handle personally, he/she can often accurately describe the problem and negotiate over the phone before calling in a local ISO or OEM specialist—again saving valuable downtime as well as expensive OEM travel charges. Typically, the on-site staff has a keen appreciation of: the technical capabilities of the various service options for those more difficult repairs; where the OEM’s service center is located and who the specialists are (these technicians often move back and forth from OEM to ISO to in-hospital work and know one another from their local professional society affiliations); how solid the specialists are; what kind of complexity is involved and how to balance the hospital’s challenges and needs with that complexity (in essence, risk management); etc. Outside specialists called in to solve special problems are essential for complex issues that are beyond the scope of the expertise of on-site staff (which varies from health system to health system).

Most healthcare technology service industry experts would agree that some type of on-site technical support (again, whether the on-site staff is employed by the healthcare delivery organization, an ISO, or an OEM) improves the overall effectiveness of the service program, because:

1. For most devices, the cost of a managed time and materials repair program is less than a full-service contract from the manufacturer (or a multitude of manufacturers, especially considering the vast array and types of devices from many manufacturers used by a single healthcare delivery organization or health system).
2. The preventive maintenance work is usually documented diligently in the facility’s own records, and documenting service across the broad range of devices (not only different devices but also different makes, models, styles, etc.) would be much more challenging for someone to manage off-site; on-site staff also has easier access to the CMMS (computerized maintenance management software) because that software is usually owned by the facility/system—providing more ready access to information and history about a device. From that documentation, it’s easier to manage the devices from a service and risk standpoint.
3. Being on site means service can be done at the convenience of the user or department (especially preventive maintenance).
4. On-site staff usually performs frequent department rounds and quickly becomes a part of the on-site clinical family, serving as a crucial resource for troubleshooting use errors and other user challenges with the technology. It’s also just in time for a response for help—in the moment versus after the fact.
5. An on-site first responder can quickly take care of the majority of the repair calls, which dramatically reduces equipment downtime.
6. On-site staff can provide incidental in-service user training when indicated by the nature of the repair call (often referred to as “cannot duplicates/no problem found” or “evidence that user needs more training”).

7. The on-site staff is essential at accreditation survey time, because of their knowledge of the entire inventory and documentation. They have (or should have) a superior maintenance documentation system and knowledge. This also provides a true process improvement opportunity (from discussions with the accrediting body) rather than a reactive response.

8. The on-site staff is available to provide invaluable expertise and support to any number of hospital teams, by participating in capital planning, equipment purchasing decisions, interoperability, device integration, standardization, life cycle management, and integration, as well as suggesting cost-saving alternatives such as refurbished equipment when appropriate.

9. They are usually responsible for handling device recalls, and are often called in to support investigations of any device-related patient incidents, in support of the requirements of the Safe Medical Devices Act (SMDA). This is an important part of an on-site role.

10. Flexibility: There are no contractual lock-ins. Strong partnership relationships with OEMs and third-party repair and parts organizations are essential for the strongest service programs, some of which may include full service contracts for certain types of specialized devices. Again, having on-site technical staff helps a facility/system to know what types of arrangements are best for that facility/system based on available service and repair resources in the community, the facility/system inventory of devices, and the complexity of the clinical care (e.g., complex robotics surgery versus community hospital general surgical services).

In short, the flexibility and local assessments provided by on-site technicians support the strongest system—one that provides the right service at the right time, with the right specialists and parts, and the least down time.

On the other hand, unless that on-site program is structured as a strong partnership between the healthcare delivery organization and its service partners, there can be weak links in the system caused by a failure to trust (in both directions); a failure to document (by or for the healthcare delivery organization); a failure to communicate (e.g., it is especially important for OEMs to have consistent feedback mechanisms to help with iterative design improvements, for on-site staff to have open lines of communication from OEMs, etc.); and a failure to see risk management as a shared responsibility.

Many smaller healthcare delivery organizations find some additional advantages to contracting with an ISO or multi-vendor OEM for on-site support rather than setting up an in-house department, particularly if there is only enough regular work for one or two FTEs (or even just a portion of a single FTE). Examples include:

1. The staff is overseen by professional managers who are familiar with risk management, inventory control, document management, the necessary personnel qualifications and appropriate salary ranges, and all of the other idiosyncrasies of the business. The
hospital’s HR department will appreciate not having to go to school on this, and the employee(s) will usually appreciate not having to educate the HR people on necessities such as technical training.

2. There is guaranteed staffing continuity if a key person leaves, gets sick or needs to take vacation time.

3. There is usually regional support to cover emergency absences and to share infrequently needed resources such as specialized test equipment.

4. ISOs and multi-vendor OEMs also usually have an array of specialist technicians under contract (plus economies of scale).

The Refurbishment Business

For equipment that is considered to be primarily utilitarian or workhorses rather than a part of the reputation-sensitive frontline showpieces (e.g., a new MRI or a new surgical suite), hospitals are increasingly considering the purchase of a reliable refurbished device. Again, on-site technical experts can be very helpful in judging when this is a good option for the facility. An assessment on serviceability is an important part of this equation.

The medical device service business has certainly evolved and grown over the years to satisfy these critical technical support needs and take advantage of the evolving market opportunities. Many of the independent service organizations are also good sources for both new and refurbished parts and devices. Some of the companies dedicate themselves to certain niches, such as probes and parts for ultrasound machines, or third-party repairs for endoscopes, anesthesia machines or certain popular brands of patient monitors. Some also offer important conveniences such as low-cost loaners for equipment that must be shipped for repair. Some of them are small “Mom and Pop” shops (especially filling a need for rural and smaller hospitals), and some have grown big enough to participate in the international marketplace. And, of course, the total picture includes everything in between.

Refurbished medical equipment is a relatively small but important part of the medical equipment service business. According to a published market research report from Markets and Markets (a market research company), the global market for refurbished medical equipment is forecast to reach $9.37 billion by 2019, at a compound annual growth rate of 12.5% from 2014 to 2019. The factors listed in the report as contributing to the growth in this business are: a growing demand for low-cost medical devices due to financial constraints, increasing privatization of healthcare outside the U.S., and rising adoption of refurbished medical devices in emerging countries. As of the time of writing the report (2014), North America holds the largest share of the global refurbished medical equipment market, followed by Europe. The biggest growth is expected, though, in the Asia-Pacific region (13.7% growth over the same period of 2014-2019, as opposed to the overall growth rate prediction of 12.5%).

Home Healthcare Will Continue to Result in More Changes in the Service Business, In Ways Yet to Be Imagined

Finally, it’s important as well to consider the quickly changing marketplace around how medical devices are being moved out of hospitals and into patient homes. Historically, the market for medical devices for home use was filled by the same companies that also provided canes, wheelchairs, and walkers. Larger home health organizations also have their own HTM organizations or resources that service and repair the used medical devices that come back out of service between patient usages. Their service challenges are in some ways the same as every other service organization (e.g., getting replacement parts, getting service manuals, etc.) and in some ways very different (cleaning the remnants of household vermin, smoke/ashes, food, and dealing with consumer abuse of equipment). The payment model for home health is also very different from that of acute care, and the slim margins make it is even more challenging: proper training of staff, comprehensive service and repairs of equipment, inventory management, issues with calibration from transport, home readiness, patient readiness, and the like. Most importantly, however, every complex medical device that goes into a patient’s home for a set period of time and back out of the home needs to be cleaned, assessed, serviced, and refurbished as needed, before it is sent back out for use by another patient. This is a growing and changing business model that needs to be considered in the total picture of the service industry.

Landscape of the HTM Field

The HTM profession consists of approximately 60,000 individuals in the United States (according to Department of Labor statistics). It is comprised of clinical engineers, biomedical engineers, biomedical engineering technology professionals, biomedical equipment technicians, and other skilled professionals who use their expertise to ensure the safety, efficacy, deployment, and availability of healthcare technologies. These professionals may be employed in any number of types of organizations that provide service, repair, refurbishment, training, or customer support to healthcare delivery organizations, or directly by a healthcare delivery organization.

HTM professionals who work on-site in a healthcare delivery organization might be employed by a single hospital, a health system, an ISO, a healthcare delivery system that provides ISO services to other hospitals outside of that system (e.g., in a region or state), a third-party repair organization, a parts company, a consulting business, a group purchasing organization, or an OEM. As noted earlier, they tend to move in and out of these various models, usually because of opportunity, personal preference, or simply to remain employed in today’s world of intense consolidation of hospitals and market shifts.

The activities of hospital-based HTM departments (also sometimes referred to as “biomed” or “clinical engineering” departments) are governed by the U.S. Centers for Medicare & Medicaid Services (CMS) as well as an accrediting body.

A hospital that wishes to participate in Medicare must meet CMS standards—Medicare Conditions of Participation for Hospitals—and receive accreditation from an organization that CMS approves as a “deeming authority.” Currently, The Joint Commission, DNV Healthcare,
and the American Osteopathic Association are the acute care hospital accrediting bodies approved by CMS for that role.

**AAMI’s Initiatives on Supportability**

*Supportability Task Force and Forum*

This FDA docket is very timely. Last fall, AAMI hosted a forum on the issue of device supportability—a term that encompasses product design; product support; and procedures that facilitate acquisition, serviceability, maintainability, and management of medical equipment. AAMI defines supportability as “the degree to which a medical device or system can be effectively and economically supported, in terms of its design features and product support (information, training, technical support, tools, spare parts), throughout its lifecycle.” The event brought together key stakeholders who manufacture and support healthcare technology to address supportability-related challenges. An FDA staff person attended the event.

The primary desired outcome was to create a clearly defined list of supportability issues and then identify ways to address them in the future. Along with issue clarification and high-level solution identification, the forum also aimed to help the different stakeholder groups gain a better understanding and appreciation of each other’s challenges and positions.

HTM professionals, who work across the entire service business, pride themselves on their ability to manage, maintain and repair medical devices. It is difficult for them to understand the reluctance of manufacturers to provide service manuals and parts.

Manufacturers want to ensure that repairs are done right, in compliance with OEM specifications and regulatory expectations. For manufacturers, there is a cost to providing technical expertise, training, and service information to hospital-based service providers.

For healthcare delivery organizations, containing costs is an increasing imperative. Many view in-house servicing as more cost-effective and efficient than services provided by OEMs.

Stakeholders across the entire service industry share some common goals, though, including:

- Ensuring patient safety through proper service and repair
- Clearly defining responsibilities between OEMs and HTM professionals
- Verifying the competencies that are necessary to support medical equipment
- Coming to agreement on the types of OEM resources and documentation that should be available to end-users

AAMI held the supportability forum because it became clear that servicing healthcare technology demands a new paradigm, one in which industry and service providers work together to promote safety, efficiency, and cost-effectiveness.

The forum was an outgrowth of other recent efforts from AAMI's Supportability Task Force, including a published leading practice document on supportability (Attachment 1), and a
checklist to help prevent adverse events related to the improper use of replacement parts (Attachment 2). The leading practice document offers practical tips and guidance to help HTM professionals and device manufacturers work toward mutually beneficial relationships and results.

The Supportability Task Force is composed of representatives of both device manufacturers and the HTM community (including HTM professionals who work for medical device manufacturers, ISOs, and healthcare delivery organizations). These participants are committed to finding workable solutions to challenges that have divided manufacturers and HTM professionals for many years.

It may be both helpful and encouraging for the FDA to be aware that the supportability forum took place, and that explorations into these important issues are ongoing.

AAMI would welcome the opportunity to work with the FDA on these and other supportability-related issues in a multidisciplinary setting, with patient outcomes and patient safety as paramount priorities.

AAMI Standards on Medical Device Service

AAMI publishes standards on various aspects of the management of healthcare technology. Two important standards address medical equipment maintenance/service:

1) ANSI/AAMI EQ56 (2013): Recommended Practice for a Medical Equipment Maintenance Program

2) ANSI/AAMI EQ89: Guidance for the Use of Medical Equipment Maintenance Strategies and Procedures

EQ56 specifies minimum criteria for a management program designed to minimize certain risks associated with equipment that is used during the routine care of patients in a healthcare delivery organization. The standard addresses the structure of the program, documentation requirements, staffing, and the resources allocated to those responsible for maintaining medical devices.

EQ89 is intended to identify and describe various maintenance strategies and methods for efficient, effective, and timely maintenance of medical devices in healthcare facilities. The standard neither mandates nor requires that any of these specific strategies be used, but instead discusses the uses of these methods and their potential advantages and disadvantages.

The FDA (and other bodies including The Joint Commission, DNV, and ASHE) has had representation on the committee that developed and revised EQ56, and that developed EQ89.

Because the FDA is interested in deepening its understanding about the topic of risk with respect to the service industry for medical devices, AAMI would recommend that the FDA review both of these standards for an additional understanding of the foundational elements—the basics—of an effective service and repair program for medical devices. In particular, AAMI highlights
Section 4.2.4 of EQ89, which provides guidance on risk assessment for maintenance procedures on specific items of devices:

4.2.4.2 Risk assessment
Before implementing or revising a maintenance procedure for a specific set of equipment, risk should be assessed by considering:

a) The possible impact of the proposed change.
b) The probability of that impact.
c) The history of incidents from like devices.

HTM departments should consult with their appropriate committees or departments (e.g., risk management, safety, environment of care). Other resources include the FDA's Manufacturer and User Facility Device Experience (MAUDE) database and ECRI Institute data.

Evidence-based maintenance (EBM) programs such as those discussed in EQ89 have been widely utilized across the United States for decades, and have become an integral part of quality improvement processes within HTM. Some aspects of an EBM approach have been adopted by most medical device service operations in the United States, regardless of size, ownership, or mission.

AAMI believes that the growing service industry would benefit from more consensus-based standards to guide the industry, and its strategic plan includes this as a priority for AAMI. On an immediate basis, AAMI has already developed a New Work Item Proposal to develop a consensus-based standard on terminology, so that all of the various terms used in the FDA’s FR Notice and throughout the service industry are standardized. AAMI addresses this issue in more detail in the section below on Definitions.

As a standards development organization (SDO), AAMI in general prefers standards over regulation and believes that consensus-based standards by strong SDOs like AAMI can solve most technology oriented problems. Decisions made by the FDA, working alone, tend to have unintended consequences. Likewise, decisions made by industry or healthcare delivery organizations while working alone in their own silos tend to have unintended consequences. Standards that are developed through an open consensus-based approach—with all stakeholder perspectives represented in the process—tend to solve problems without creating new ones, and also tend to build the strongest buy-in from all stakeholders because they contributed to the solution rather than being told what they must do.

As noted in the section below on Definitions, AAMI believes it would be preferable to set industry standards for the service industry through a consensus-based standard rather than by the FDA, and that the FDA’s perspective would be heard through the standards development process, as is customary across a wide array of important patient safety oriented standards that AAMI manages.

In addition to the development of a new standard on terminology used in the service industry, other standards in the works or that may be considered include:

- Equipment acquisition considerations, processes, and policies
Core competencies for technicians (AAMI has developed the core competencies, but they have not been turned into a standard)
Core elements of verification, validation, calibration and testing of devices that are repaired or refurbished
Service documentation
Inventory management
Quality assurance for component parts
Quality assurance for refurbished equipment

AAMI’s diversity, standards development competency, and reputation as a neutral organization, make it the ideal organization to take on some of these issues for the development of new standards. As noted above, AAMI’s strategic plan calls for it to increase the number of medical device service oriented standards in its portfolio, so the timing is also right from the perspective of fitting in with AAMI’s strategic priorities.

Beyond Standards

In addition to adhering to standards and regulations, HTM departments have customarily benchmarked their performance on a variety of metrics against those of HTM departments at other facilities. A few of the most commonly benchmarked metrics include:

- Staffing levels allocated to management, maintenance and repair, and other responsibilities
- Hours spent on maintenance and repair
- Personnel qualifications and responsibilities
- Reporting structures
- Number of devices maintained

AAMI offers a benchmarking tool to help HTM professionals with this kind of performance measurement.

AAMI also offers a number of other resources to help HTM professionals, departments, and organizations measure their performance objectively:

1. *HTM Levels Guide*—a tool to help HTM departments assess the value they currently provide to their healthcare organizations and to help them identify what they might consider adding to their scope of services offered
2. *Leading Practice: Flexible Solutions for Device Supportability*
4. Benchmarking resources
5. Numerous articles in AAMI publications geared toward particular service challenges
6. Shared practices and sample documents
7. Annual Conference oriented to HTM professionals
HTM Competency and Certification

The HTM field is composed of clinical engineers, biomedical equipment technicians, human factors experts, lab or radiology specialists, and others involved in the overall management of healthcare technology, including all aspects of service. In general, and historically, there have been no standardized requirements for education or training of individuals who perform service and repair, whether working for an OEM, a third-party service organization, or in a hospital. As another strategic priority, AAMI has spent considerable time in the past seven years moving the service industry toward standardization of competencies. These initiatives have included:

1. **Core Competencies**: In an effort to establish standardized competencies for entry-level technicians, AAMI has published a core competencies document to provide academic institutions and employers who want to assure they are hiring for the right set of competencies with the following:
   a. A standard set of competencies that graduates of technician training programs (certificate, diploma, or degree) are expected to possess upon program completion.
   b. Recommended topics that a program curriculum should include for students to learn and possess the core competencies identified in the guide.

The competencies and topics in the guide are relevant to HTM technicians entering the workforce, and the topics reflect the knowledge and skills that entry-level technicians are expected to perform successfully in entry-level positions regardless of the employment setting (e.g., hospital, clinic, independent service organization, military, manufacturer).

Competencies and topics in the guide were developed and agreed upon by an AAMI committee of experts from academia, hospitals, independent service organizations, device manufacturers, employer institutions, the U.S. Department of Defense, and the U.S. Veterans Administration. A second edition of the guide will be published this year.

2. **Standardized job descriptions that are based on the levels of competency**, available at this [link](http://www.aami.org/productspublications/content.aspx?ItemNumber=2943).

3. **Career Planning Handbook**

4. **Leadership Development Guide**

5. In 2015, AAMI became the lead society with ABET for accreditation of biomedical engineering technology education programs at North American universities and colleges. This means that AAMI will now be the professional society that sets guidelines and assists in accreditation efforts for colleges offering biomedical engineering technician or biomedical engineering technology programs leading to an associate degree or bachelor’s
degree. Additionally, AAMI will provide evaluators to visit colleges to determine if their programs meet the criteria for accreditation.

6. Certification: The AAMI Credentials Institute (ACI) awards various competency-based certification credentials to HTM professionals. As healthcare technology becomes more complex, certification offers a way to demonstrate and showcase competencies. HTM professionals seek certification as a means to demonstrate their accomplishments, mastery of skills, and their experience in core competencies.

These certifications include: certified biomedical equipment technician (CBET), certified radiology equipment specialist (CRES), certified laboratory equipment specialist (CLES), and certified healthcare technology manager (CHTM).

Approximately 4,000 professionals within the HTM field (mostly in North America) hold at least one certification through AAMI. These professionals have a confirmed mastery of HTM principles and best practices through their initial examination, and are committed to staying on the cutting edge of technology through the recertification process that requires continuing education. For more information about certification: [http://www.aami.org/professionaldevelopment/content.aspx?itemnumber=1134&navItemNumber=577](http://www.aami.org/professionaldevelopment/content.aspx?itemnumber=1134&navItemNumber=577)

Managing Risk

An essential element of all medical device service, whether it is routine preventive maintenance, repair, or refurbishment, is managing risk. The service industry culture, training, and expertise has, at its very core, the management of risk, including: risk to patients, risk to staff, and risk to institutions. It is a core and distinguishing feature of being an HTM professional as opposed to being an IT professional or a facilities engineer. For example, electronics technicians from outside of healthcare are solid prospects for training and education programs because they tend to have a natural aptitude in the service and repair of devices. What they lack in that background—and must receive in order to safely service medical equipment—is training on medical devices along with training on the clinical aspects of healthcare and patient safety (e.g., AAMI’s certification exam includes questions about human anatomy).

HTM professionals as a field are trained to use a risk-based approach to service, and this mindset is embedded into the culture of the profession. As an example, one approach to estimating the risk level of a particular type of equipment is to use algorithms, which was first proposed by Larry Fennigkoh in 1989. This approach became widely used after it was included in the Plant, Technology and Safety Management series of educational publications from The Joint Commission. For each type of medical device, Fennigkoh suggested that an equipment management (EM) number be calculated, and those devices with an EM greater than 12 would be included in the equipment management program. The EM number was the sum of the numbers assigned to the equipment’s critical function (a value from 2 to 10), physical risk associated with clinical application (a value from 1 to 5), and required maintenance (also a value from 1 to 5).
Many individual organizations have adopted something similar to the above Fennigkoh approach, while others have moved on to even more complex models.

The following are just a few such examples:
- Attachment 3: BI&T Article, September/October 2008
- Attachment 4: Horizons Article, Spring 2015

How Serious Is the Problem of Improper Medical Device Service?

Routine service and maintenance activities are only a portion of the strategy for managing risks associated with devices. For instance, there is evidence of fewer use-related errors when HTM staff time is spent working directly with device users to support how the equipment is used and how it actually works (e.g., technicians and engineers generally have a much better understanding than nurses of how an infusion pump operates with fluid mechanics, which is a critical aspect of understanding the proper operation of a pump, as well as its calibration).

Repairs of devices are as important as routine service, and one of the underlying questions in the FDA’s Request for Information is, “Just how serious is the problem of ‘improper’ medical device service?” As noted earlier, an article in the Jan/Feb 2013 issue of AAMI’s journal, BI&T, found a very low occurrence of patient incidents traceable to maintenance practices (Attachment 5). The analysis in the article is supported by a field survey, as well as (more importantly) a study conducted by ECRI Institute based on MAUDE database incidents involving medical devices. It should be noted that the ECRI Institute research has been updated and still affirms the conclusions drawn by the authors of the article in BI&T. The article recommended that HTM professionals shift some of their attention to “involvement in technology management and, especially, user training and assistance, to address the most frequent root causes” of adverse incidents related to technology.

The BI&T article notes that although patient incidents involving medical equipment are fairly common, what was less clear is how many of those incidents are actually caused by maintenance omissions (improper or lack of scheduled and unscheduled maintenance).

Proposed FDA Definitions

Regarding the FDA’s request for definitions of various terms, in short, AAMI recommends that the FDA not attempt to define these terms, because any such regulatory oriented definitions would not be consensus-based. As outlined below, AAMI has initiated the process to assign responsibility for developing a consensus-based standard on service terminology.

AAMI has reviewed all of its American National Standards, including the medical device maintenance standard ANSI/AAMI EQ89 and national adoptions of ISO standards, and found that the six terms referenced in the FDA docket for public comment (Recondition, Service, Repair, Refurbish, Remanufacture, and Remarket) are not currently defined in the standards.

ANSI/AAMI EQ56, Recommended Practice for a Medical Equipment Management Program, contains two terms that relate to service:
3.10 service agent: Individual providing inspection and/or other maintenance services on medical equipment on behalf of a service provider.

3.11 service provider: Group with the responsibility for inspection and/or other maintenance services on medical equipment within a health care organization. 
NOTE—A service provider may be a department within the health care organization, an equipment manufacturer, an independent service organization operated by a third party, a shared service, or other similar organizations. For this document, a service provider is not a vendor who is called in to perform maintenance intermittently by the above defined service provider.

One of the six terms and two similar terms are defined in an IEC standard, IEC 62353, Medical Electrical Equipment—Recurrent Test and Test After Repair of Medical Electrical Equipment. This standard has not been adopted nationally but was developed with AAMI input through U.S. participation in the IEC committee. The terms included in IEC 62353 are:

3.25 MODIFICATION
Changing constructional or functional features of ME EQUIPMENT or an ME SYSTEM in a way not described in its ACCOMPANYING DOCUMENTS
This definition should not be confused with “change of ACCESSORIES” because the latter means changing of ME EQUIPMENT or ME SYSTEMs in a way described in its ACCOMPANYING DOCUMENTS.

3.39 REPAIR
Means for restoring to a safe, functional, NORMAL CONDITION.

3.41 SERVICING
Combination of all means for maintaining the ME EQUIPMENT or ME SYSTEM within requirements of the MANUFACTURER

AAMI believes that the terms Recondition, Service, Repair, Refurbish, Remanufacture, and Remarket—as well as a number of other terms used in this industry—should be defined in American National Standards and, as noted above, has developed a New Work Item Proposal to start this work. The development of a consensus-based American National Standard would be preferable to a regulatory approach, because it provides a forum for all stakeholders (including the FDA) to work together to develop, refine and have buy-in on definitions that everyone can support.

Conclusion

AAMI hopes that these detailed comments provide some clarity to the FDA’s important inquiry. Again, AAMI applauds the FDA for taking a conservative approach of requesting information to
help it assess the questions asked in the FR Notice. As noted earlier, as is often the case with complex issues that involve multiple disciplines, multiple service models, lack of standardization, paucity of reliable data about the industry, uneven lobbying capabilities across the sector, strong opinions, and stories galore, there is a huge risk of unintended consequences from increased regulation involving healthcare technology. No matter what, at the end of the day the entire industry will be better informed and have much more to think about, simply from reading the perspectives that are offered across this very diverse industry. And, no matter what, at the end of the day it should be clear that everyone has the same end goal: the safety of the patients whose life depends on safe and effective healthcare technology.

We appreciate this opportunity to comment. Please feel free to contact us if you have any questions.

Sincerely,

Mary K. Logan, JD, CAE
President/CEO, AAMI
(703) 253-8265
mlogan@aami.org

List of Attachments

1. Leading practice document on supportability
2. Checklist to help prevent adverse events related to the improper use of replacement parts
3. BI&T Article, September/October 2008
4. Horizons Article, Spring 2015
5. Article from Jan/Feb 2013 issue of AAMI’s journal, BI&T
Flexible Solutions for Device Supportability
A Guide for Manufacturers and Healthcare Technology Management Professionals

Martha Vockley
Flexible Solutions for Device Supportability
A Guide for Manufacturers and Healthcare Technology Management Professionals

Martha Vockley
What is a Leading Practice?

AAMI's Leading Practice series are concise documents that provide practical information and guidance on a wide range of specific topics facing medical technology professionals. These documents are written by experts in the field and undergo peer review before publication.

What is this document about, and who should be interested?

This Leading Practice document discusses the concept of medical device “supportability,” which encompasses product design, product support, and other company procedures that impact the management of healthcare technology. The document offers practical tips and guidance to help Healthcare Technology Management (HTM) professionals and device manufacturers work toward mutually beneficial relationships and results.

Who wrote this document?

Martha Vockley is principal of VockleyLang, LLC, a communications and marketing firm based in Reston, VA. Email: mmv@cox.net.

Members of AAMI’s Supportability Task Force, composed of device manufacturers and HTM professionals, also contributed to the development of this Leading Practice.

Disclaimer about Leading Practices

The views expressed in this publication do not represent the views of AAMI or any AAMI Standards Committee or U.S. Technical Advisory Group administered by AAMI. Standards and information concerning the content of standards that the external authors may include within these materials are subject to change as a result of ballot and public review. This publication is intended to be a helpful information resource. It is not to be construed as an interpretation of AAMI standards, nor does it constitute legal or regulatory advice.
The Challenge
Healthcare technology management (HTM) professionals—including clinical engineers and biomedical equipment technicians—pride themselves on their ability to maintain and repair medical devices. Meanwhile, manufacturers want to ensure that repairs are done right, in compliance with OEM specifications and regulatory expectations.

This document offers practical tips and guidance toward mutually beneficial relationships and results.

Supportability—Supportability is the degree to which a medical device or system can be effectively and economically supported, in terms of its design features and product support (information, training, technical support, tools, spare parts), throughout its life cycle. Servicing medical equipment demands a new paradigm, in which industry and service providers work together to promote safety, efficiency, and cost-effectiveness. It encompasses product design; product support; and procedures that facilitate acquisition, serviceability, maintainability, and management of medical equipment throughout its life cycle.

Cost is high—For manufacturers, there’s a cost to providing technical expertise, training, and service information to in-house service providers. For healthcare organizations, containing costs is an increasing priority, and some view in-house servicing as more cost-effective than services provided by OEMs.

Safety is an issue—Manufacturers express concerns about patient, operator, and technician safety if their equipment is not properly serviced. Their equipment performance—and their reputation—is on the line. Manufacturers also encounter varying competencies among service providers. For their part, HTM professionals feel pressured to maximize equipment uptime with safe, quick, and effective service and repair.

Issues are complex—A separate concern for HTM professionals is the appropriateness of the methodology and frequency of OEM recommendations. Service is much more effective, they say, when OEM recommendations consider multiple other factors, such as the type of device and its use, environment, mission criticality, and resources available to service providers. OEM recommendations that assume a worst-case scenario for every service situation could lead to wasteful practices that do not contribute to medical device safety, availability, and quality—and in some cases could introduce unnecessary failures.

Learn More
For an in-depth look at the issues, see the Nov./Dec. 2012 issue of AAMI’s Biomedical Instrumentation & Technology.

Leading Practices—Advice You Can Use
There is no one-size-fits-all solution, but here are some basic guidelines, including a sample checklist for medical technology supportability, a comprehensive list of information that should be covered in service manuals, and tips for manufacturers and HTM professionals.
Sample Checklist for Medical Equipment Supportability

This sample checklist is a starting point for manufacturers and HTM professionals to assess medical equipment supportability, and to help remove barriers to supportability. Specific supportability needs might differ, depending on such factors as the type of device and institutional resources, capacity, and competencies. Decide what’s important to you to develop a customized checklist—and add your own requirements to what’s here.

1. DESIGN

| • Equipment is designed for serviceability in the field. |

2. INFORMATION AND TOOLS

| • Service manuals are available and useful. |
| • Service notes and technical updates are accessible. |
| • Access codes, passwords, and/or dongles are available. |
| • Error codes/logs are available, clear, and decipherable. |
| • A calibration process and test equipment are available for checking calibration accuracy in the field. |
| • Information on granularity of replacement parts (e.g., part vs. sub-assembly) is available. |
| • Bundling policies are specified and clear (e.g., any restrictions on software upgrades and updates?). |
| • A copy of application software and operating system are available (preferably an image disk). |

3. TRAINING

| • Effective service training is offered. |
| • Field service providers can accompany and learn from vendor service personnel on site (how open are they?) |

4. TECHNICAL SUPPORT

| • Website access to service information is provided. |
| • Phone support is available. |
| • There is an easy method for communicating with vendor technical staff directly. |
| • Service contract options are available and are favorable to field service and bundling practices that maintain viability of in-house services. Software upgrades, training, and manuals are not tied to service contracts. |
| • OEM technical support and materials are available—and response time is reasonable and specified (with no ties to service contracts). |
| • Parts-only agreements are available and reasonably priced. |

5. SUPPORTABILITY

| • In-house partnerships with OEMs, with flexible service plans, are offered (e.g., training, documentation, connectivity support). |
| • Equipment planning support is available (e.g., life cycle planning, guidance documents on equipment replacement, end-of-life notification). |

OTHERS?

| Plus . . . Charges for any of the above are specified and reasonable. |
What Every Service Manual Should Include

Operating Information
• A complete description of how to use the equipment (typically, this is included in the instructions for use or operator manual and should be repeated in the service manual)
• The theory of operation—life cycle description or charts with input/output (I/O) designations or mapping during life cycle

Precautionary Information
• Potential hazards
• Safety warnings and cautions to patients, operators, and service providers

Service Information
• Procedures to fully test and verify the operation of the equipment
• Criteria by which to evaluate whether the device or system is operating as designed (calibration verification procedures)
• Identification of any required specialized tools or test equipment
• Identification of probable failure modes with troubleshooting guides that lead to probable repair solutions
• Repair and replacement procedures for complex components
• Parts identification and list for ordering replacements
• Recommendations for periodic or preventive maintenance, if applicable

System Information
• Software version history, specifications, and menu structure
• Error codes

Visual Information, such as:
• Block diagram
• Wiring diagram
• Detailed schematics
• Exploded assembly diagrams or photographs

Questions Every Service Manual Should Answer
• How does the equipment work?
• How can it be demonstrated that the equipment is working as designed?
• How can the cause of a failure be diagnosed?
• What steps are necessary to repair a device once the cause of the failure has been identified?
• What needs to be done to best ensure that the equipment works as designed over a long period of time?
• How can repair or replacement parts be identified?
Tips for Manufacturers

Design
• Design products for supportability.

Service Manuals
• Provide service manuals to customers when equipment is purchased.
• Update service manuals as needed.
• Make service manuals readily available, in print and online versions, and useful in the field.

Training
• Specify any special skills or certifications required for servicing equipment.
• Provide training in multiple formats (e.g., in-person training at OEM and/or customer sites, “shadowing” of OEM service providers, online training).
• Offer pre-assessment testing for training programs.

Technical Support
• Offer technical support in multiple formats (e.g., phone, online, and on-site assistance, multimedia tools).
• Specify any proprietary or special equipment required for servicing equipment and, whenever possible, specify “or equivalent” requirements. Provide customer with any proprietary tools and installed software.
• Identify parts and make spare parts readily available.
• Provide a copy of application software and operating system (preferably an image disk).

Service Agreements
• Offer flexible service contracts that meet customers’ diverse needs, ranging from full OEM servicing to full in-house servicing.
• Develop criteria to help customers select the service options that best fit their needs and capabilities.
• Do not tie software upgrades, training, and manuals to contracts.

Communication, Collaboration, and Partnerships
• Aggregate known product issues and alert other product users to these issues.
• Notify customers in advance of any remote updates to systems or software.
• Work with healthcare delivery organizations to support the full life cycle of medical equipment—including planning, budgeting, acquisition, implementation, servicing, replacement, and decommissioning—to ensure safe, efficient, and cost-effective supportability.
• Create online technical forums and/or a customer advisory board to support service and to develop and improve medical equipment.
Tips for HTM Professionals

Service Manuals
- Ask for service manuals with any product demonstrations or tryouts: “demo stickers” are not adequate assurances of safety.
- Make the provision of service manuals a purchase order condition for new equipment—and consider holding back 5% or 10% of the total contract until the manuals are delivered.

Training
- Ask manufacturers to specify any special skills or certifications required to service their equipment.
- Take advantage of vendor-provided training.
- Consider requiring service providers to become Certified Biomedical Equipment Technicians (CBETs), or earn other relevant certifications, and to update their certifications regularly, to demonstrate competencies for servicing medical equipment to manufacturers.

Service Agreements
- Formalize an acquisition process that requires service manuals to accompany incoming new equipment.
- Expect to pay a reasonable cost for quality technical documentation and training.
- Ask for manufacturers’ assistance in assessing in-house, institutional capacity and capabilities for servicing equipment.

Communication, Collaboration, and Partnerships
- Help manufacturers make a business case for service manuals and technical information and tools (e.g., these services demonstrate manufacturers’ interest in safe, effective service of their equipment; are worth a reasonable cost; and contribute to productive, long-term vendor–customer relationships).
- Ask for manufacturers’ assistance to support the full life cycle of medical equipment—including planning, budgeting, acquisition, implementation, servicing, replacement, and decommissioning—to ensure safe, efficient, and cost-effective supportability.
- Provide service history to manufacturers in a unified system to enable aggregated tracking of trend data and inform product improvements and new product development.
Case Study
Supportability is more than a concept in healthcare. Leading practitioners are already moving in this direction.

A Manufacturer Offers Flexible Solutions to Support In-House HTM Professionals

Issue
In 2010, a manufacturer of high-end diagnostic and intervention imaging equipment\(^1\) began a more concerted effort to offer a menu of comprehensive and flexible service options to meet the changing needs of customers.

Two market changes influenced this business decision, which was shaped with input from a customer advisory panel. First, the Affordable Care Act is spurring everyone to drive costs down, according to Pranav Patel, general manager, GE Healthcare. Second, many hospitals and other healthcare delivery organizations are consolidating in an effort to reduce costs and improve the quality of care.

“As systems consolidate,” Patel says, “their footprint becomes bigger and they can start to think, ‘Do we have enough shared services where the economic model works? Do we have enough need for this high-end labor such that we can provide those services within our operation?’”

More healthcare delivery organizations are concluding that, yes, they do have that capacity. In 2007, the in-house service market was about 8 percent; today, it’s about 20 percent, Patel says. But in-house service providers still need support to make it work.

Solution
The manufacturer offers four major types of support for their customers:

1. **Training.** With the “technology revolution,” healthcare institutions introduce or upgrade major equipment every six years, on average. “When technology moves that fast, they need to be able to train their people,” Patel says. A large training institution helps biomed skill up.

2. **Access to technical support.** “If customers don’t have the resources to solve a particular problem,” Patel says, they want access to online technical support.

3. **Materials.** For specialty repairs, customers want the circuit board- and chip-level components to replace parts themselves and improve their total cost of ownership.

4. **Remote monitoring, diagnostic, and efficiency-of-operation tools.** For a fleet of equipment, customers want remote monitoring and diagnostic tools, so if something goes wrong they know exactly what the problem is and can fix it expeditiously, which improves equipment uptime and workforce productivity. The company also offers a problem solution database, which allows customers to enter information about a device glitch or event and determine what to do about it.

The company aggregates issues from all customers, so it has a comprehensive database across its full fleet of medical equipment.

Many of these services are not new. “Honestly, we’ve always provided people with monitoring diagnostics if they wanted them,” Patel says. “What we realized is that most people never used it. It was there and they didn’t know how to use it.”

What’s new is the still-evolving, concerted outreach to “field engineers” and the flexibility of choices for service arrangements. Larger healthcare delivery organizations might have sufficient expertise, a critical mass of equipment, and the resources to send in-house HTM professionals to regular training sessions. For smaller facilities, this might not be economically feasible.

“It’s an economic equation at work,” Patel says. “There is a tipping point, and that varies from hospital to hospital and system to system, because everybody has a slightly different cost structure and policy.” They work with customers to help them decide how best to service their equipment—and the company respects their decisions and provides whatever level of service they want.

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\(^1\) This case study is based on an interview with Pranav Patel, general manager, GE Healthcare.
A Corporation Listens and Responds to Supportability Needs

A manufacturer of infection prevention and surgical products explains how HTM needs are changing and how the company is responding to improve supportability of its medical equipment in the field.2

Q. What supportability problems or opportunities are you seeing or hearing about?

A. We recognize that in-house biomed customers want:
   • Better access to documentation, service tips, and sharing of common issues and updates
   • Better communication and relationships with OEM technicians when they are on site servicing products
   • A larger variety of service contracts and options to support or augment in-house biomeds
   • More options and support on service part distribution
   • A variety of training options, including classroom, online, and on-site
   • Improved product obsolescence communication and equipment planning support
   • Products that are easier and cheaper to service

Q. How is your company responding?

A. We follow standard protocol when authoring service maintenance manuals for all new capital products. As a result, equipment owners can expect to receive a comprehensive document that, if followed, will allow them to properly maintain equipment and troubleshoot issues. While service manuals are only available for purchase in hard copy today, active projects are in place to deliver the same content electronically. Additionally, we provide technical support via the telephone and live chat online.

   Our service engineering department of 30-plus people is dedicated to analyzing the extensive data captured by our field service organization on installed equipment and using that data to optimize preventive maintenance (PM) protocols. PM requirements are documented in our service manuals. Captured repair data can help to identify the most common parts and fixes for identified problems. Service engineers conduct monthly product reviews of PM and repair records to drive cost-to-service improvements, such as:
   • Reducing PM frequency requirements. For example, sterilizer PMs went from every three months to every six months, with the same level of work but less disruption.
   • Adding or removing parts and procedures to optimize uptime between PMs.
   • Driving design improvements to improve serviceability.

   We launched a service program specifically designed to help HTM professionals. This in-house partnership program consists of a variety of non-contract services that are completely flexible and customizable to meet specific HTM needs. We recognize that every facility’s needs may be different and aim to provide the right services, not more or less, to meet specific needs.

   We offer HTM professionals the ability to cost-effectively manage their parts and non-contract service needs through a variety of programs and promotions. We launched a loyalty program to this end, as well as piloting auto shipment of PM parts for just-in-time delivery of parts necessary to properly maintain equipment to OEM standards.

   In addition to classroom and on-site training, the company offers blended online/on-site customer training programs to reduce training costs and provide more flexible and efficient training options, as well refresher training.

   Our field service technicians and service engineers on all new capital product development teams drive serviceability throughout the product design and development process, acting as the voice of HTM in our R&D process.

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2 The Q&A was conducted with John Brown, director of Infection Prevention Technologies (IPT) Service Engineering at STERIS.
Q. What makes your solutions different or innovative in terms of supportability?
A. Our vast field service organization of over 900 technicians in North America, in combination with over 30 service engineers and associate engineers, work effectively through the capture of data—and implementation of best practices, standard processes, and continuous improvement—to focus on increasing serviceability and optimizing service routines and parts to improve service quality and maximize equipment uptime.

Through our in-house service advisory council, we are taking proactive measures to better understand customer needs and develop programs with real customer value.

Q. What could other companies learn from you?
A. Direct customer communication with service professionals is key to understanding customer needs and challenges and developing programs to support them. Companies need a robust service data collection and database system to conduct in-depth analysis of service records to optimize service and reduce cost-to-serve, while maximizing equipment uptime.

FAQs
AAMI’s Supportability Task Force answers frequently asked questions about service manuals.

Q. Are manufacturers required to provide service manuals free of charge?
A. There’s no such requirement. It’s up to customers to negotiate for service manuals because there is a cost to develop them. This fee could be included in the cost of the equipment.

Q. Does the FDA get involved in service materials?
A. The FDA’s Medical Device Quality Systems Manual requires manufacturers to “establish and maintain instructions and procedures for performing and verifying that the servicing meets the manufacturers specified requirements.” That information may be used with other information to “help show a prospective contractor the scope and expected quality of the servicing.” Manufacturers are not required to provide service manuals, however.

www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/ucm122714.htm

Q. What if I don’t receive a service manual?
A. For new equipment purchases, make it a condition of the purchase order that service manuals must be provided. For existing equipment, enlist the support of decision makers in your institution who can make this request a priority.

Q. Should service manuals be paper, digital or web-based?
A. Service manuals can be supplied in any or all of these formats. For paper manuals, expect originals, not photocopied versions. Digital or web-based versions can be updated more quickly and, in some cases, produced more cost-effectively. Let manufacturers know your preferences.

Q. What if I receive and accept a service manual and discover later that it is inadequate?
A. Provide feedback to the manufacturer, with specific details on recommended improvements, and urge the manufacturer to supply missing information or make revisions to improve the manual’s usefulness.

Reading List


To help prevent adverse events related to the improper use of replacement parts in healthcare technology, AAMI's Supportability Task Force has compiled two checklists regarding the proper development, selection, and use of replacement parts. One checklist is geared toward healthcare technology management (HTM) professionals, while the other is aimed at manufacturers. Is anything missing from the lists? Send feedback to Patrick Bernat, AAMI's director of HTM, at pbernat@aami.org.

Replacement Parts Checklist—HTM

• Is the part an exact replacement from the manufacturer of the device, or from the manufacturer of the part?

• If it is not, are the specifications identical?

• Does the part affect the accuracy of the device?

• Does the parts provider offer a warranty at least equal to the manufacturer?

• Does the parts provider fully test each part before making it available?

• Does the parts provider have ISO or another type of quality certification?

• If the parts provider isn't the manufacturer, do they have a relationship with the manufacturer?

• Is the parts provider financially sound and likely to be around for a while?

• If you send a device out for repair, how do you verify the quality of the repair when it comes back?
• Does the parts provider offer a wide selection of quality parts or is it a niche provider?

• If you have used third-party parts and require manufacturer assistance, will the manufacturer require you to replace those parts with its parts before doing any work?

Replacement Parts Checklist—Manufacturer

• Are there restrictions on what cannot be serviced by the customer? What types? Training required, special test equipment, etc.?

• Is it clear what can and cannot be serviced by the customer (e.g., what is restricted)?

• For items that cannot be serviced by the customer, is there an explanation as to why? For example, is a special calibration fixture or test setup required? Without an explanation, the repair personnel cannot defend to management why OEMs must make certain repairs when, at first glance, those repairs appear to be able to be performed in-house or by a third party.

• Consider providing drawings that indicate what components/subassemblies are and are not user-replaceable.

• For restricted components/subassemblies that are likely to be serviced, consider labeling them as "not user replaceable" and providing an explanation in the service manual.

• Consider tamper-evident seals for access to restricted components.

• When a device is returned for repair, inspect it to determine if unauthorized repairs were made. For example, does the batch/lot number of a critical part match the DMR record of when it was originally assembled? Are the calibration parameters the same as they were originally? If not, these are signs that the device might have had unauthorized work performed.
Applying Risk Management Principles to Medical Devices Performance Assurance Program—Defining the Process

Tidimogo Gaamangwe, Agustina Krivoy, Petr Kresta

Over the years there has been increasing recognition that performance assurance (PA) program implementation is a risk management issue. To that end there has been concerted effort to identify the key risk categories and define the risk assessment technique, which deals with inclusion of medical equipment in the PA program. However, there is still no general consensus on the risk categories and the inclusion criteria.

While effort has been put into identifying risk and risk assessment technique, the need to understand how the PA program is linked to the overall risk management decision-making process has received very little attention. This paper presents a framework for linking the PA program to the overall risk management decision-making process. The paper also proposes new risk categories and appropriate risk contributing factors that will assist in defining the appropriate risk assessment technique. A new inclusion criterion, based on the new proposed categories, is a subject of further investigation. (Biomedical Instrumentation & Technology 2008; 42:401–406).

The management of medical devices entails a number of essential components. These include technology assessment, acquisition, inventory control, repair service, in-service education, performance assurance (PA), etc. The PA program, in some cases referred to as preventive maintenance (PM), deals with device operation, performance, and safety. In this paper, PM is regarded as a specific subcomponent or activity of the PA program.

The PA program is defined as “a planned and scheduled method of performing inspections for performance verification, preventive maintenance, and safety testing.” In this context, performance verification (PV) entails testing according to a written procedure to ensure that equipment is performing within specified performance limits and PM is a planned periodic procedure for cleaning, lubricating, adjusting, and replacing components whose failure may impair equipment function. Safety testing (ST) in this context is performed to verify that equipment is in compliance with electrical safety requirements. Therefore, PA=PV+PM+ST. A similar equation was described by Ridgway but with slightly different terminology. In practice, performance assurance includes management of the program and development of test protocols/procedures.

Program Implementation

Over the years there has been a tremendous shift in PA philosophy, from do it all to do as little as possible. As the pendulum swings to less PA and the concept gains acceptance, the question of how to select devices for inclusion in a PA program arises. Some are beginning to ask if the program is needed at all. These questions have highlighted the fact that PA is implemented for risk management. The risk management aspect is now recognized by most clinical/biomedical engineering departments and associations.

The understanding that a PA program is developed and implemented for risk management is fundamental for clinical engineering departments. It is a necessary and mandatory risk management service performed by clinical engineering for their enterprise. So whether a clinical engineering department does or does not have a PA program is not the real question. The real question is whether there is a methodology for the profession to determine how the program is implemented. This can be controlled by each clinical engineering department based on its own justification or on collective professional justification. But the basis of the program remains the same.

Program Basis

The basis of a PA program is risk management, which has two components: risk financing, which deals with insurance, and risk control, which deals with controlling losses. Risk control is defined as “any conscious action (or decision not to act) that reduces the frequency, severity,
or unpredictability of accidental loss.” Therefore, PA is implemented for risk control. This aspect is recognized by national accreditation/regulatory authorities who in turn have made PA a requirement for any healthcare organization that values accreditation. Specific enterprise policies are often based on these overarching requirements.

In Canada, the program is a requirement of Accreditation Canada (formerly the Canadian Council on Health Services Accreditation or CCHSA), Canadian Standards Association (CSA), and the Canadian Medical and Biological Engineering Society’s Clinical Engineering Standards of Practice for Canada. In the United States it is based on the requirements of the Joint Commission. Thus, the program is implemented as part of a clinical engineering department’s risk management services to meet accreditation/regulatory and legal requirements.

Since the basis of the program is risk management, the management and implementation of the program should follow risk management principles. General risk management principles are addressed in CSA and AAMI documents. A simplified model of a risk management decision-making process is presented in Figure 1.

It is important to understand that effective risk management requires a risk management team. This is because there is a lot of information to take into account: technical, regulatory, stakeholder interest, etc., not only during the risk identification and assessment process, but throughout the whole process. For example, risk control measures may introduce unforeseen risks for some stakeholders, whether perceived or real. In addition, monitoring may uncover some issues that will require reassessment of risk, such as changes in technology or a change in the environment where the device is used. Therefore, in line with the risk management decision-making process, it is advisable for a clinical engineering department to consider forming a standing committee that takes responsibility for all PA issues and thus acts as a risk team in PA matters.

Risk Categories

By owning and using medical devices, the enterprise faces a number of risks. Previous authors have identified three categories—function risk, physical risk, and maintenance requirement—as the main risks. While these are valid risks and have been used by a number of clinical/biomedical engineering departments, there is still no general consensus that they are the right categories of risk. In addition, these risks are limited to devices and patient and user safety.

There has, however, been recognition that it is important to take enterprise-level risk into account by including mission criticality as one of the categories, Mission criticality was adopted by Brewin et al. in developing their system. We think this is a step in the right direction, but at this point the categories are not broad enough to address enterprise-level risks. Therefore, there is still a need to define appropriate enterprise-level risk categories.

In this paper we propose new enterprise-level risk categories that are linked to ownership and use of medical devices. The proposed risk categories are:

- financial risk
- legal liability
- patient and staff safety

The importance of these new risk categories is that they are broader than the previously used categories of function risk, physical risk, and maintenance requirement. Fennigkoh and Smith have defined function risk in terms of the main equipment function categories: therapeutic, diagnostic, analytic, and miscellaneous. The authors defined physical risk in terms of the risks emanating from the clinical application of the equipment: death, injury, inappropriate therapy, or misdiagnosis. Maintenance requirement has been defined in terms of the level of maintenance inspection required: extensive, average, and minimal. The definitions of these categories suggest that they fall within the new proposed risk categories.

The use of equipment in any of the function categories as defined above has safety, legal, and financial implications for the enterprise. In addition, the risks emanating from clinical application as defined above also have im-

Figure 1. Simplified risk management decision-making process.
applications on safety, legal liability, and financial risk. Also, maintenance requirement, as defined above, means that if inspections are not performed, the consequences for the enterprise could be one or all of the following: compromised patient and staff safety, increased legal liability, and financial risk. Therefore, the previously defined risk categories are covered within the new categories.

By addressing risks from the enterprise perspective it is easier to see how actual device risks link to the broader risk categories. The device risks are merely drivers or inputs to the broader risk categories. The newly identified risk categories emanate from a number of contributing factors, some of which are inherent in equipment design, some of which are related to the equipment use, and some of which are regulatory, as illustrated in Figure 2.

The risk contributing factors are elaborated below, under three broad factors:

**Equipment design factors**

i) Incorrect diagnostic information: Diagnostic equipment that may give the user wrong information without the user being aware. Wrong diagnosis, based on wrong information that the user cannot easily verify, e.g., a blood pressure measuring system giving inaccurate blood pressure measurement, would result in wrong treatment, which poses patient safety, legal liability, and financial risk for the enterprise.

ii) Inappropriate energy output

a. Therapeutic equipment that has output to patient, which may cause injury to patient and/or staff. Equipment output to patient (thermal, electrical, gaseous, chemical, mechanical) may be dangerously high or low if equipment malfunctions, which may result in injury or endanger patient’s life, e.g., hypo/hyperthermia units and defibrillators. This would pose patient safety, legal liability, and financial risk for the enterprise

b. Radiation equipment that may harm a patient with high energy output

iii) Maintenance requirement: Equipment that needs regular cleaning/lubricating or replacement of parts to perform without impairment. Some types of equipment have filters that need regular cleaning/replacement. Some have batteries that need replacement on a regular basis because they are used for transport. If the cleaning or replacement functions are not done, there is increased risk of equipment failure and life cycle cost.

iv) Function degradation: Device has a fan or filter and the failure of the device poses risk to patient.

**Figure 2. Illustration of how risk categories emanate from risk contributing factors.**
Equipment use factors

i) High usage: Equipment that experiences high usage and rough handling. Transport equipment such as infant incubators may experience rough handling and, as a result, there is likelihood of damage to the electrical cable, posing electrical safety risks to both the patient and the staff.

ii) Use area requirement: Equipment where the same models may be used in two areas that have different tolerance for error, e.g., patient scales—errors may be tolerated in the general area of the hospital but not in dialysis or renal program, where accurate patient weight information is used to make treatment decisions.

Regulatory factors

i) Compliance with codes: Devices that are required to be tested for accreditation purposes if used for direct or indirect patient diagnosis or treatment, e.g., biological, radiation, lab.

All the above factors have implications, to varying degrees, on patient safety, legal liability, and financial risk for the enterprise. Before any measures can be taken to mitigate these risk factors, it is important to assess the acceptability of the risk factors through risk assessment.

Risk Assessment

Risk assessment (risk analysis and risk evaluation) allows the organization to estimate the probability and severity of risk and to evaluate the acceptability of risk. There are various risk assessment techniques, but most statistical techniques, such as probability and regression analysis, require data to be able to make an objective decision. The question of which technique to use depends not only on the availability of data but also on the type of data.

Therefore, the risk assessment technique for PA implementation also depends on the availability and type of PA data. Risk assessment is done through inclusion criteria, which defines the delineation process for separating the inventory into two subsets—devices that need to be in the PA program (need regular inspection because they pose unacceptable risk to the organization) and devices that do not need to be inspected on regular basis (excluded from PA). The first task is to define appropriate and acceptable inclusion criteria, which determines the size of each subset.

While reliability engineering methods are used in some industries for identifying possible device failures, the type of analysis involved is normally quite complex and time consuming. These methods include life cycle cost, failure mode and effect analysis (FMEA), mean time before failure, and other analysis techniques. Not all these analysis techniques are appropriate for all the devices. Therefore, they are not generally used in PA programs. One may find some aspects of one or more of the techniques applied in some fashion. Due to the difficulty of applying these strategies to a large and complex inventory of medical devices, there has been concerted effort in clinical/biomedical engineering to develop alternate appropriate inclusion criteria.

Several authors have previously addressed issues of PA inclusion or exclusion criteria. Most of the criteria involve risk-level scoring, which has evolved from the Fennigkoh and Smith model. Their model assigned risk assessment scores to their identified risk categories: function risk, physical risk, and maintenance requirement. A number of shortfalls with this method have been identified and modified versions proposed. While some authors have modified the weighting values of the risk categories, some have also redefined the risk contributing factors and thus produced different inventory subsets. There has also been a proposal to use a decision-making tree algorithm.

The development of several assessment strategies indicates that there is no general consensus on the inclusion criteria because there is no consensus on risk categories, weighing each of the currently used risk categories on the total risk, defining the risk contributing factors, and scoring each risk-contributing factor.

This paper proposes enterprise-level risk categories that others can consider adopting. We propose that the risk categories be equally weighted unless there is direction from the enterprise, taking other information into account. The risk contributing factors to be used are those defined above. We propose criteria that would be based on the risk factors.

Since risk-contributing factors are the cause of risk categories, any changes in the risk-contributing factors or quantities derived from them would cause changes to the risk categories. Therefore, risk-contributing factors or quantities derived from them can be used as indicators for risk or inclusion criteria parameters. The inclusion criteria parameters provide the specification against which risk can be assessed. The specification will determine the types of data required for the risk assessment.

In this case, where the proposed inclusion criteria parameters are derived from risk-contributing factors,
the information required for risk assessment would be available in any healthcare enterprise, with or without historical data. This is important because there are no constraints placed on PA implementation by historical data. Retrospective data from monitoring the program is used for reassessing risk.

The detailed definition of the inclusion criteria and how they are applied is beyond the scope of this paper. What is important to understand about the proposed model at this point is that enterprise-level risk categories flow from the risk contributing factors, which in turn form the basis for the inclusion criteria.

**Risk Control Measures**

Risk control measures are specific actions or activities intended to reduce the frequency and/or severity of loss. In the risk management decision-making process, before any decision is made on a specific action to control any identified risk, a broad strategy question—whether the risk can be avoided, prevented, or reduced—is usually asked. This process is important because there may be no need for the enterprise to devise any elaborate specific activities, e.g., if the best strategy is to transfer the risk to another party.

There are six recognized broad risk control strategies:

(a) exposure avoidance, e.g., not manufacturing a device, which reduces probability of loss to zero; (b) loss prevention, e.g., PM, which reduces frequency of loss but not necessarily severity; (c) loss reduction, e.g., rapid alarm activation, which reduces severity of loss; (d) separation of exposure, e.g., maintaining inventory at several warehouses, which reduces severity of individual loss; (e) duplication of exposure units, e.g., providing backup or spare parts reduces overall severity of loss; and (f) contractual transfer of risk control obligation to another party, e.g., service contract, which transfers responsibility to the vendor.

The question of which strategy to use depends on the problem at hand. Clearly, for PA the clinical engineering department is concerned mostly with loss prevention and loss reduction. This is important information because the knowledge of the appropriate control strategy narrows risk control options or measures to be considered.

From a risk control point of view, the subcomponents of PA, as identified under the definition of PA, are actually risk control measures. Depending on the device, these risk control measures (PV, PM, ST) can be applied individually or in combination. Once the risk control measures have been identified, it is important to decide on the appropriate activities to undertake for each measure to be effective.

**Implementing the Measures**

The activities or detail of inspection undertaken under any of the above risk control measures are sometimes based on manufacturer procedures/protocols or protocols developed in-house, depending on a number of factors, such as whether the devices are specialized, the number of devices in the inventory, etc.

Besides deciding on the activities, it is important to decide on the frequency of activities, i.e., inspection frequency. The inspection frequency is often based on information from a number of factors, such as manufacturer recommendation, facility experience, recalls/alerts, repair, and incidents.

**Monitoring**

Monitoring is an important part of risk control to ensure that the measures are effective in achieving the desired outcomes and to adapt the program whenever necessary. Monitoring in PA is done for three reasons:

- **Adaptation**: monitoring to ensure that the appropriate risk control measures are always identified to address the risk contributing factors that may arise due to changing circumstances, e.g., change in technology, change in the environment where the device is used, etc.
- **Effectiveness**: monitoring to ensure proper implementation of risk control measures and activities. Monitoring activities ensures that the right inspection procedures are done to address the identified risk contributing factor.
  Implementation of risk-control measures is monitored through performance indicators. The performance indicators can be established by industry, developed by consensus, or developed from in-house best practices. A number of repair and maintenance indicators have been previously discussed. There is still need to develop consensus on the key parameters and their definitions in order to facilitate benchmarking.
- **Communication**: monitoring to ensure that stakeholders understand and perceive the program to be effective. Stakeholders would generally be interested in broader issues such as patient and staff safety, compliance with codes, reduced risk of
failure, reduced life cycle cost, improved clinical outcomes, etc. This is addressed through effective communication with stakeholders. Some of the information communicated is gathered through periodic customer satisfaction surveys. It is important that communication addresses not only the PA relation to the risk categories but any other strategic issues that may arise from time to time. This usually gives them piece of mind.

Information from the monitoring process feeds back to the risk assessment process so that the PA program is continuously driven by current information.

Discussion
As the basis of PA is risk management, it is important for clinical engineering departments to understand that PA has merit on its own, regardless of accreditation requirements. It is clinical engineering risk management prudence to develop and implement PA programs.

While there has been increasing recognition that PA is implemented for risk management, there has been little effort to relate the PA processes to the overall risk management decision-making process—only some PA decisions, such as inclusion criteria, have followed the risk assessment process. In this paper we have defined how PA is linked to the overall risk management decision-making process. The risk management view assists in several ways: defining appropriate risk categories, defining appropriate risk contributing factors, applying appropriate risk assessment techniques, and defining appropriate risk control measures and appropriate monitoring processes.

It is hoped that by viewing PA as an overall risk management decision process, clinical engineering departments will consciously relate all their PA decisions to risk management process.

Conclusion
This paper has presented a framework for linking PA to the overall risk management decision-making process. It is hoped that others will adopt this view and start applying risk management principles in PA decisions. It is hoped that with this view, there will be renewed interest to revisit some of the PA issues that have been debated over the years, such as inclusion criteria. The renewed interest should assist in an attempt to build consensus.

References

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A need exists for healthcare technology management (HTM) services to embrace a new risk management paradigm, in order to identify, analyze, and control risks related to the growing and increasingly complex array of healthcare technology making its way into healthcare delivery organizations (HDOs).

These risks generally involve potential compromises to patient/staff safety, operations, and/or finances that can occur when a medical device or system does not operate or is not operated “as intended.” For example, a perfectly functioning device/system could be associated with a hazard if it used by untrained operators.

In the parlance of risk management, a medical device/system that does not operate (or is not operated) as intended is considered a hazard. Exposing people (e.g., patients, staff) or assets (e.g., physical, financial) to a medical device/system that does not operate or is not operated “as intended” is considered a hazardous situation. Actual harm occurs when people are injured, patient care is compromised, or assets are lost or damaged as a result of exposure to a hazardous situation. Risk is defined as a combination of the probability of occurrence of harm and the severity of that harm. In turn, risk management is defined as the systematic application of management policies, procedures, and practices to the tasks of analyzing, evaluating, controlling, and monitoring risks.

To effectively manage a spectrum of healthcare technology risks, HTM professionals need to establish a risk management paradigm that is both relatively simple and demonstrably effective. Complexity discourages implementation; therefore, the paradigm should be simple. It also should be demonstrably effective because any paradigm or tool that fails to yield actionable and beneficial results is an unnecessary diversion and a waste of resources.

After risks have been identified and prioritized using an established paradigm, priority first should be given to managing the highest risks, as well as the most easily controlled risks (i.e., the “low-hanging fruit”).
Perspectives on Risk Management

A Brief History of Medical Equipment Risk Algorithms

In 1989, Fennigkoh and Smith\(^3\) published an algorithm for scoring medical equipment based on its function, physical risk, and maintenance requirements. The resulting score was intended to serve as a guide for hospitals that were looking for a rationale and method of selecting the most appropriate equipment for inclusion in the medical equipment management program. Subsequent variations of this algorithm often included a scoring element for equipment service history (in addition to the original function, risk, and maintenance requirement elements). This algorithm and its derivatives have since widely (but inaccurately) become characterized as a “risk-based” approach to maintaining a medical equipment inventory.

The initial appearance of the algorithm in a publication by The Joint Commission resulted in its quick and widespread adoption. In fact, this 25-year-old algorithm, or some variation thereof, remains in use today. Unfortunately, for the vast majority of hospitals, the recent change in regulations from the Centers for Medicare & Medicaid Services removes any flexibility they once had in selecting medical equipment for inclusion in their inventories, thereby eliminating the original rationale for the algorithm of Fennigkoh and Smith. As a result, the risk elements of the algorithm are no longer able to meet the risk management needs of an effective current-day medical equipment management program.

Developing the Paradigm

Prioritizing efforts requires a means of ranking or scoring risks. Because risk generally is defined as a combination of (or function of) the severity of harm and the probability of harm (i.e., risk = function [severity, probability]), evaluating relative severity and relative probability can help establish relative risks and facilitate prioritizing the management of those risks.

A scale (Figure 1) showing increasing probability on the y-axis and increasing severity on the x-axis is useful in comparing various risks. This scale illustrates how an increase in either the severity or probability of harm increases risk. Therefore, the position of risk 2 in Figure 1 represents a higher risk than risk 1 because, although their probability levels are comparable, the severity of risk 2 is measurably higher than risk 1. Risk 3 is the highest risk of the three because it is associated with both a higher probability and a higher severity than either risk 1 or 2.

Actually determining the relative risks associated with various medical technologies requires a progressive scale for indicating the degree of severity and the degree of probability associated with technology-associated harm. Although no universally used scales exist for severity or probability, a fairly common four-level scale (i.e., resulting in a 4 x 4 matrix) has been chosen for the purpose of the current work. Although the illustrated model uses a 4 x 4 matrix with these criteria for severity and probability, other applications and industries (e.g., aviation, energy) may use 3 x 4, 5 x 5, or another matrix with variation of these criteria based on application to the given situation.

Figure 2 juxtaposes the risks and scale shown in Figure 1 with a 4 x 4 matrix using the defined levels for severity and probability (from Tables 1 and 2). The defined levels of severity and probability are useful for placing risks within a risk matrix, thereby illustrating their relative risk levels.

Although risk = function (severity, probability) is not a pure mathematical relationship, the level number given to severity and probability

![Figure 2. Risk matrix with defined levels of severity and probability](image2.png)

![Figure 3. Risk matrix](image3.png)
can be used to establish a risk level number by multiplying the severity level number by the probability level number. Figure 3 shows the result of incorporating this view of risk level number and definitions into the risk matrix.

In addition, establishing a classification for risk levels enables us to describe risks in a manner that facilitates prioritizing and escalating our response in controlling risks. As with severity and probability levels, no standard risk levels exist and it remains for industries and organizations to select the most appropriate number of levels and definitions. For purposes of illustration, Table 3 uses a three-level risk classification scheme.

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### Applying the Risk Matrix to Medical Devices/Systems

When first evaluating medical technology risks (particularly for large numbers of devices), assessing risks at the device category level usually is most advantageous. The severity and probability of harm that can be caused when a medical device does not operate (or is not operated) as intended varies according to the type of device (e.g., pacemaker versus ophthalmoscope) and can vary among models of similar categories or even among the same device model used in different environments. As time and experience permit, taking a more granular view of risk beyond the device category level will prove useful. However, assessing risk while taking into account all devices (regardless of manufacturer, model, or environment) in a particular category is a practical starting point.

Using the criteria in Table 1, a team that, at minimum, includes clinicians and HTM professionals (and may include administration and finance) should first assess the severity of harm that can be caused by a device that fails to operate or be operated as intended for each medical device category used within the organization. When focusing on patient care and safety (i.e., clinical) issues, clinicians’ input generally should be weighed most heavily in this assessment because they are most aware of the implications for patients when a medical device fails to operate or is not operated as intended.

Using the criteria in Table 2, HTM professionals (who typically are responsible for maintaining medical device histories) should assess the probability of a device failing to operate or not being operated as intended for each medical device category using available incident (e.g., service) histories. HTM professionals should focus on the incident/service histories that represent “major” device issues (i.e., where devices were nonoperational or had a safety deficit) and should filter out minor issues (e.g., cosmetic issues or where the device remains operational and otherwise remains safe).

A modified Ishikawa (or fishbone) diagram can be a helpful visual tool in the risk assessment process. The diagram can be useful for illustrating the relationship between possible hazards (and their underlying root causes) and the possible hazardous situations and harm that can result as a consequence of exposing patients, staff, or assets to those hazards.

### Table 1. Risk severity levels

<table>
<thead>
<tr>
<th>Level no.</th>
<th>Risk level description</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Negligible</td>
<td>No or negligible adverse effect (e.g., little or no health effect)</td>
</tr>
<tr>
<td>2</td>
<td>Marginal</td>
<td>Reversible adverse effect (e.g., minor injury)</td>
</tr>
<tr>
<td>3</td>
<td>Critical</td>
<td>Permanent adverse effect (e.g., serious injury)</td>
</tr>
<tr>
<td>4</td>
<td>Catastrophic</td>
<td>Loss of life, mission, financial collapse</td>
</tr>
</tbody>
</table>

### Table 2. Risk probability levels

<table>
<thead>
<tr>
<th>Level no.</th>
<th>Risk level description</th>
<th>Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Improbable</td>
<td>Very unlikely to occur ≥20 years; &lt;5% per year</td>
</tr>
<tr>
<td>2</td>
<td>Remote</td>
<td>Unlikely but possible to occur ≥10 and &lt;20 years; &gt;5% and ≤10% per year</td>
</tr>
<tr>
<td>3</td>
<td>Occasional</td>
<td>Likely to occur ≥5 and &lt;10 years; &gt;10% and ≤20% per year</td>
</tr>
<tr>
<td>4</td>
<td>Probable</td>
<td>Very likely to occur &lt;5 years; &gt;20% per year</td>
</tr>
</tbody>
</table>

### Table 3. Risk levels

<table>
<thead>
<tr>
<th>Level no.</th>
<th>Level description</th>
<th>Severity × probability = Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Low</td>
<td>1,2,3,4; Acceptable risk without additional review</td>
</tr>
<tr>
<td>2</td>
<td>Medium</td>
<td>6,8; Requires mitigation to further reduce risk or director of service authorization to proceed at this risk level</td>
</tr>
<tr>
<td>3</td>
<td>High</td>
<td>9,12,16; Requires mitigation to further reduce risk or senior leadership authorization to proceed at this risk level</td>
</tr>
</tbody>
</table>
### Hazards/root causes*

<table>
<thead>
<tr>
<th></th>
<th>Examples of potentially appropriate controls and mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintenance-related failures (progressive &quot;wear and tear&quot;)</td>
<td>Scheduled maintenance (e.g., preventive maintenance, calibration)</td>
</tr>
<tr>
<td>Spontaneous (unpredictable) failures</td>
<td>Replace with more reliable equipment and/or obtain backup</td>
</tr>
<tr>
<td>Inappropriate/inadequate instructions/procedures/process</td>
<td>Reengineer process, improve training</td>
</tr>
<tr>
<td>Unqualified operator</td>
<td>Obtain qualified operators and/or educate to achieve necessary qualifications</td>
</tr>
<tr>
<td>Mishandling / misuse by staff, patients</td>
<td>Establish handling/use guidelines, educate, and monitor</td>
</tr>
<tr>
<td>Vulnerability to malware (e.g., virus)</td>
<td>Regular updates of antivirus software/definitions, regular patches, software updates to eliminate known vulnerabilities</td>
</tr>
<tr>
<td>Sabotage/vandalism/hacking</td>
<td>Introduce and/or update security measures (e.g., isolated networks, firewalls)</td>
</tr>
<tr>
<td>Theft (or other loss) of device containing personal health information (PHI) or theft (i.e., copy or removal) of PHI for device</td>
<td>Introduction of physical, administrative, and/or technical safeguards (e.g., alarms, disable unnecessary ports, connections)</td>
</tr>
<tr>
<td>Damage (e.g., fire, smoke, flood, contamination, electrical accident)</td>
<td>Environmental precautions (e.g., alarms, protection, training)</td>
</tr>
<tr>
<td>Hidden failures (e.g., failures not detectable until use)</td>
<td>Preuse testing by operator, scheduled maintenance</td>
</tr>
<tr>
<td>Inadequate or poor-quality utility (e.g., water, electricity, gas/vacuum, network) or other necessary component or element</td>
<td>Establish redundant and backup capabilities, training</td>
</tr>
<tr>
<td>Inappropriate/inadequate supplies/accessories</td>
<td>Resource management and quality control, training</td>
</tr>
<tr>
<td>Interference (e.g., electromagnetic interference) or interaction</td>
<td>Precautions (e.g., distance, shielding, other &quot;hardening&quot;)</td>
</tr>
</tbody>
</table>

*One or more compromises to patient safety, quality/timeliness of care, data availability/integrity (i.e., security), or operations.

Table 4. Root causes and corresponding controls/mitigation
After creating a diagram of possible hazards and hazardous situations and harm, a probability score can be assigned to the listed hazards and root causes and a severity score can be assigned to the possible hazardous situations and harm. The Ishikawa diagram shown in Figure 4 illustrates examples of possible hazards or “root causes” of a medical device failing to operate or not being operated as intended. Each of these root causes can be assigned a probability level. Figure 4 also illustrates examples of hazardous situations, each of which can be assigned a severity level. Associating a probability level with each root cause is important, not only because of how probability helps determine the overall risk but also because different root causes require different approaches to control and mitigation (e.g., maintenance, education, updated procedures, physical safeguards). The root causes representing the highest probabilities require the most appropriate mitigation and control.

If an organization’s incident/service histories do not provide sufficient detail to identify the probability of individual root causes (e.g., $P_1$, $P_2$, $P_3$, $P_4$, $P_x$), then the probability of all possible root causes ($P_{1,2,3,4,...x}$) should be used and broad mitigation or controls applied. An organization’s incident/service histories generally are preferable as a data source for determining probabilities. However, in the absence of sufficient organization data, data from other credible sources can be used (e.g., AAMI, ECRI Instiute, independent service organizations, other comparable healthcare provider systems).

Going forward, organizations that do not already track the most common root causes in their incident/service histories should begin doing so in order to optimize the efficiency of risk analysis and control. Examples of common root cause categories include:

- $P_1$: spontaneous failure (i.e., component failure that reasonably could not have been anticipated or prevented by maintenance)
- $P_2$: mishandling, misuse
- $P_4$: inadequate/inappropriate instructions/procedures/process
- $P_5$: maintenance-related failures (i.e., “wear and tear”)
- $P_6$: sabotage, vandalism, malware, hacking
- $P_7$: theft (including theft of electronic protected health information)

The probability associated with these potential root causes can be mapped in a risk matrix (Figure 5). In this example, the worst case consequences (i.e., the maximum severity $S_{1,2,3,4,...}$) are considered to be critical, while the probability of various root causes ($P_1$, $P_2$, $P_3$, $P_4$, $P_5$, $P_6$, $P_7$) range from probable to improbable.

When first defining and categorizing root causes against which probability levels will be assigned, consider using root cause categories that suggest corresponding controls or mitigation that are actionable (i.e., root causes that can be associated with identifiable counter-

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**Figure 4.** Ishikawa diagram illustrating examples of hazards (root causes) scored for probability and hazardous situations scored for severity.
measures). A list of appropriate controls and mitigation, along with common root causes, is provided in Table 4.

The risk mitigation worksheet (Figure 6) is a useful tool for HTM professionals who manage medical device/system risks. The worksheet typically would include descriptions of major devices/systems along with “identifying” information such as manufacturer, model, age, quantity (for “group” equipment like infusion pumps), and location. For each device/system under consideration, the worksheet also would list the following:

- Potential root causes of harm
- Type of vulnerability under consideration (e.g., clinical, financial, operational)
- Severity level or score as determined by a knowledgeable group of stakeholders
- Current probability level or score determined by an analysis of incident/service histories for root cause
- Overall risk = function (severity, probability)

A mitigation plan generally would be added to the worksheet for root causes with a risk level deemed to be unacceptable (generally any designation other than a low risk). Specifically the mitigation plan would include the following:

- Description of mitigation plan elements (e.g., scheduled maintenance, training, backup systems, security measures)
- Designation of party/parties responsible for various elements of the mitigation plan (e.g., owner/operator, HTM services, clinical education, information technology)
- Target date(s) for completion of various elements of the mitigation plan
- Probability level or score for root cause leading to a hazardous situation after control/mitigation
- Overall risk, where risk = function (severity, probability after mitigation)
- Appropriate signoff (by organization leadership or department manager if remaining risk generally exceeds acceptable level after mitigation)

The overall HTM risk management process should be iterative (Figure 7). The process and its results should be regularly audited to determine whether the desired results are being adequately achieved. As the HTM risk management team gains experience and evaluates audit results, their practices can be refined and the most critical risks can be identified, prioritized, and controlled effectively.

Figure 5. Risk matrix with root cause probabilities mapped
Table 1: Risk mitigation worksheet. Abbreviation used: AEM, alternate equipment maintenance.

Figure 6. Risk mitigation worksheet. Abbreviation used: AEM, alternate equipment maintenance.

Figure 7. The iterative healthcare technology risk management process.
Addressing New Requirements

The risk management process described here can help considerably in meeting the new requirements of the Centers for Medicare & Medicaid Services (CMS), The Joint Commission (TJC), and DNV GL.

Healthcare providers now are required to identify all equipment in their inventory whose failure could result in loss of life or serious injury to a patient or staff member (classified as critical by CMS and DNV GL and high risk by TJC). In the risk management process described here, any device category whose severity (consequence of failure) has been identified as either critical or catastrophic would be included in the critical/high-risk category of CMS, TJC, and DNV GL.

Healthcare providers are allowed to consider an alternate equipment maintenance (AEM) program (i.e., not required to strictly adhere to manufacturer recommendations regarding maintenance procedures and frequencies) for certain medical devices if the provider can produce device incident/service histories demonstrating that there is no increase in risk to patient or staff safety when deviating from manufacturer recommendations.

If risk of maintenance-related failure (= severity of failure × probability of maintenance-related failure) is low, a medical device (except for lasers, imaging, and radiologic devices that CMS has elected to exclude from consideration) can be placed in the AEM program and kept in the program as long as the risk to patients or staff does not increase.

Figure 8 shows a partial list of medical device categories that have been given severity designation by a review team and have had their probability levels calculated based on their corrective maintenance histories (i.e., annual “harm” rates or mean time between harm). Equipment categories that have been given a severity level of either catastrophic or critical have been flagged as critical/high risk in Figure 8. Equipment categories that are not flagged as AEM ineligible (as per CMS) and that have a calculated risk level of low (severity × probability) are flagged as AEM included in the figure.

Incident/service histories that are flagged to indicate which medical device failures are due to insufficient or improper maintenance (activities or frequencies) are critical to an effective maintenance management process. Only by collecting and analyzing incident/service histories with this information can organizations hope to focus their limited resources on real patient safety issues while still meeting the new requirements of CMS, TJC, and DNV GL.

Figure 8. Risk levels by device category. Abbreviation used: AEM, alternate equipment maintenance.
Using severity, probability, and risk scores and criteria given in the examples above, Table 5 illustrates how a medical equipment inventory with a fairly representative mix of more than 100,000 items breaks down according to risk score and risk level.

**Conclusion**

The rapidly growing influx of increasingly complex and sophisticated healthcare technologies poses many challenges for healthcare delivery organizations and their HTM services. Among those challenges are the growing numbers of vulnerabilities associated with these new medical devices and systems as well as a new series of requirements from CMS, TJC, and DNV GL that affect how organizations maintain those devices/systems.

A workable and effective HTM risk management program is the best way to address these vulnerabilities and the new compliance requirements. HTM professionals, clinicians, risk management experts, and other key stakeholders should be working together to ensure that a risk management process exists for identifying, analyzing, and controlling risks associated with technology vulnerabilities. To that end, the concepts and methods illustrated here can serve as a template for an effective healthcare technology risk management process that can evolve according to the needs of individual organizations and the industry as a whole.

### Table 5

<table>
<thead>
<tr>
<th>Risk score</th>
<th>No. of devices</th>
<th>Percent</th>
<th>No. of device categories</th>
<th>Risk level</th>
<th>No. of devices</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>4,517</td>
<td>4.4%</td>
<td>191</td>
<td>Low</td>
<td>58,276</td>
<td>56%</td>
</tr>
<tr>
<td>2</td>
<td>17,477</td>
<td>16.9%</td>
<td>271</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>20,858</td>
<td>20.1%</td>
<td>280</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>15,424</td>
<td>14.9%</td>
<td>376</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>19,552</td>
<td>18.9%</td>
<td>108</td>
<td>Medium</td>
<td>41,891</td>
<td>40%</td>
</tr>
<tr>
<td>8</td>
<td>22,339</td>
<td>21.6%</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>7</td>
<td>0.0%</td>
<td>3</td>
<td>High</td>
<td>3,374</td>
<td>3%</td>
</tr>
<tr>
<td>12</td>
<td>1,430</td>
<td>1.4%</td>
<td>15</td>
<td></td>
<td></td>
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<tr>
<td>16</td>
<td>1,937</td>
<td>1.9%</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>103,541</td>
<td>100.0%</td>
<td>1,405</td>
<td></td>
<td>103,541</td>
<td>100%</td>
</tr>
</tbody>
</table>

Table 5. Example of a breakdown by risk score/level of a representative inventory of medical equipment.

**References**


RESEARCH

An Estimate of Patient Incidents Caused by Medical Equipment Maintenance Omissions

Binseng Wang, Torgeir Rui, and Salil Balar

Abstract

Patient incidents involving medical equipment are fairly common, but it is unclear how many of them are actually caused by maintenance omissions, i.e., improper or lack of scheduled and unscheduled maintenance. This question is important because hospitals have been allowed by The Joint Commission (TJC) to develop their own maintenance practice instead of following manufacturers’ recommended frequencies and procedures. This study reports an attempt to estimate the magnitude of such incidents using the sentinel events database collected by TJC. Using worst-case assumptions, the estimates ranged 0.14-0.74 in 2011, which translates into .00011-.0006 per million equipment uses. These extremely low values were confirmed by a survey conducted by AAMI in which 1,526 participants reported no known patient incidents traceable to maintenance practice. Therefore, it seems unwise to mandate clinical engineering (CE) professionals to refocus their attention to manufacturers’ maintenance recommendations versus active involvement in technology management and, especially, user training and assistance, to address the most frequent root causes of sentinel events.

1. Introduction

Like other health technologies, medical equipment is an essential tool for physicians and other healthcare professionals to deliver care. Unfortunately, medical equipment can also cause harm to both patients and users if used improperly or it fails to perform safely and according to specifications.

While rarely featured among the top five causes of patient incidents, medical equipment is implicated in a fairly large amount of incidents every year. According to The Joint Commission (TJC), there were a total of 176 “sentinel events” related to medical equipment in the period of 2004-2011 and 39 in 2011 alone.1

While it is certain that at least a piece of medical equipment was involved in all these incidents, it is unclear how many of those were caused—at least in part—by equipment failure. This is because the root-cause analysis (RCA) data reviewed by TJC uses “physical environment” to capture problems found in the environment of care, including general safety, fire safety, security systems, hazardous materials, emergency management, smoking management, equipment management, and utilities management, but do not specify how many are caused specifically by equipment management.

Even though accurate data is not available, it would be helpful to obtain at least a ballpark estimate of the failures (hereafter termed “maintenance omissions”) that could and should have been prevented or detected by clinical engineering (CE) professionals. This would allow healthcare leaders and CE professionals to determine how effective the investment of resources in equipment management has been, as well as to ascertain

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improvements needed to reduce further equipment-related incidents.

The issue of maintenance omissions was raised in 1997 when the Food and Drug Administration (FDA) published an Advance Notice of Proposed Rulemaking (ANPR) “announcing its intention to review and as necessary to revise or to amend its compliance policy guides and regulatory requirements relating to the remarketing of used medical devices and the persons who refurbish, recondition, rebuild, service, or remarket such devices.” According to the ANPR, the FDA was apparently concerned that some of those devices may not be “as safe as the originally marketed finished device[s].” In response to the ANPR, the ECRI Institute conducted an extensive review of FDA’s Manufacturer and User Facility Device Experience (MAUDE) database and concluded that there was no evidence of significant maintenance omission to warrant application of regulatory requirements by the FDA to refurbishers, reconditioners, rebuilders, servicers, or remarketers.

Questions regarding appropriate maintenance of both medical and facility equipment resurfaced in late 2011 when the Centers for Medicare & Medicaid Services (CMS) issued a clarification of hospital equipment maintenance requirements contained in the State Operations Provider Certification manual. This clarification stated that “critical equipment” must be maintained at the frequency recommended by the manufacturer, whereas the frequency of noncritical equipment can be modified using evidence-based assessment. Furthermore, the maintenance procedure recommended by the manufacturer must be followed regardless of whether the equipment is considered critical or not. This requirement is much more restrictive than the TJC standards for equipment maintenance practiced by the majority of American hospitals, so one would wonder how many patient incidents are actually caused by maintenance omissions and if these incidents could be reduced by following the new CMS mandate.

This article describes an attempt to estimate the amount of patient incidents that could have been caused by maintenance omissions based on sentinel-event data collected and analyzed by TJC.

2. Material and Methods
Sentinel event data collected and analyzed by TJC published on its website were used to estimate the amount of patient incidents that could have been caused by maintenance omissions. As all healthcare organizations accredited by TJC are asked to report these incidents voluntarily, TJC cautions that it “represents only a small proportion of actual events. Therefore, these data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.”

The vast majority of the reported events originated from hospitals, although other types of accredited organizations, such as psychiatric hospitals, ambulatory care facilities, emergency departments, ambulatory surgical centers, and home care organizations also provided data. A noteworthy detail is that the total number of reported events increased steadily and significantly from 2007, as compared to the seemingly stable period of 1999 to 2006. This may help understand the large number of medical equipment-related events in 2011 when compared to the period of 2004-2011.

Sentinel event data collected and analyzed by TJC published on its website were used to estimate the amount of patient incidents that could have been caused by maintenance omissions.

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Keywords
Medical equipment maintenance, improper maintenance, scheduled maintenance, patient safety, patient incident, sentinel event.

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† CMS did not provide a definition for critical equipment, but stated “[e]quipment that is critical to patient health and safety is not a candidate for an alternative, less frequent maintenance activity schedule. Such equipment must be maintained at least as often as the manufacturer recommends. At a minimum such critical equipment includes, but is not limited to, life-support devices, key resuscitation devices, critical monitoring devices, equipment used for radiologic imaging, and other devices whose failure may result in serious injury or death of patients or staff.”
3. Results

3.1 Analysis of TJC Sentinel Event Data
Figure 1 shows the classification of 2011 sentinel events reviewed by TJC as a percentage of the 1,242 events reported that year. Medical equipment-related events totaled 39 (3.1%) and represented the 10th highest category. These values are consistent with prior years’ data, as there were 176 events related to medical equipment in the period of 2004-2011, representing 2.9% of the grand total of 6,093 events and the 11th highest category.

Healthcare organizations that report sentinel events to TJC are required to share its RCA results and TJC reviews them and assign one or more root causes to each event. Multiple causes are often assigned for each event because the outcome is typically the consequence of the failure or inefficiency of one or more processes instead of a single cause.

Figure 2 shows the root causes of the medical equipment-related events as determined by TJC for the medical equipment-related events for the period of 2004-2011 as a percentage of the 620 causes identified. Since TJC did not provide the root causes of the 39 medical equipment-related events reported in 2011, it was not possible to assess if these causes differ significantly from those of prior years.

3.2 Estimate of Sentinel Events Caused by Maintenance Omissions
As mentioned, the cause called “physical environment” covers a wide range of failures and inefficiencies, and there is no data specific to “equipment management.” Some assumptions need to be made to obtain ballpark estimates for events caused by equipment maintenance omissions. Two estimation methods were used and described below. A summary is shown in Table 1.

3.2.1 Estimation Method A (Percentage of Root Causes)
One way to estimate the amount of sentinel events caused by equipment maintenance omissions is to assume that all the physical-environment causes were due to equipment management or, more specifically, medical equipment failures. This is clearly the worst-case scenario, as one would expect that all the other factors included in the physical environment (i.e., general safety, fire safety, security systems, hazardous materials, emergency management, smoking management, and utilities management) would have contributed somewhat to those sentinel events. Since 111 of the 620 multiple causes identified in the period of 2004-2011 were assigned to physical environment, one would expect 18% (i.e., 111/620) of medical...
equipment-related events would have been caused by equipment failure. As there were 39 medical equipment-related events reviewed by TJC in 2011, in the worst case 7 (i.e., 18% of 39) of them would be related to equipment failures.

Since not all medical-equipment failures could and should have been prevented or detected by CE professionals, a multiplication factor must be applied to the causes assigned by TJC. According to Wang et al., only 1-3% of the failures were within direct control of CE professionals (i.e., failures classified as hidden, potential, predictable and preventable, and service induced). Assuming 2% is a reasonable estimate for the percentage of maintenance omissions, only 0.14 (i.e., 2% of 7) events in 2011 would be caused by maintenance omissions.

To put this number into perspective, one needs to consider the number of equipment uses in the healthcare organizations that reported sentinel events to TJC. This is analogous to defect analyses in manufacturing where the amount of defects is compared to the opportunities for failures in the production process. Since the actual number of equipment uses is not available from TJC-accredited hospitals, an estimate is needed. One way to obtain a ballpark estimate is to use the number of patient days and outpatient visits in community hospitals. Assuming that each patient day translates into three uses of medical equipment on average and one use occurred for each outpatient visit, then the total number of equipment uses in the year 2010 would be 1,220 million, as there were 189.6 million patient days and 651.4 million visits. Therefore, an estimate of the number of maintenance-omission caused incidents would be 0.00011 per million (i.e., 0.14/1,220 million) of equipment uses.

### Table 1. TJC sentinel event data and estimates of patient incident caused by maintenance omission.

<table>
<thead>
<tr>
<th></th>
<th>DATA</th>
<th>2011</th>
<th>2004-2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total # sentinel events</td>
<td></td>
<td>1242</td>
<td>6093</td>
</tr>
<tr>
<td># of events related to medical equipment</td>
<td>39</td>
<td>176</td>
<td></td>
</tr>
<tr>
<td># of multiple causes related to medical equipment</td>
<td>N/A</td>
<td>620</td>
<td></td>
</tr>
<tr>
<td># of multiple causes of 176 incidents due to physical environment</td>
<td>N/A</td>
<td>111</td>
<td></td>
</tr>
</tbody>
</table>

### Assumptions and Calculations

Method A

| Assumed % physical environment issues caused by equipment failure | 100% |
| Assumed % equipment failures under CE control (maintenance omission) | 2% |
| # events could have been caused by maintenance omissions | 0.14 |
| # in-patient days in community hospitals in 2010 | 189,593,000 |
| # out-patient visits to community hospitals in 2010 | 651,424,000 |
| Estimated # equipment uses in 2010 | 1,220,203,000 |
| Estimated # sentinel events per million equipment uses | 0.00011 |

Method B

| Assumed % physical environment issues caused by equipment failure | 100% |
| Assumed % equipment failures under CE control (maintenance omission) | 3% |
| # events could have been caused by maintenance omissions | 0.74 |
| # in-patient days in community hospitals in 2010 | 189,593,000 |
| # out-patient visits to community hospitals in 2010 | 651,424,000 |
| Estimated # equipment uses in 2010 | 1,220,203,000 |
| Estimated # sentinel events per million equipment uses | 0.00060 |

A different way to obtain an estimate using the TJC sentinel event database is even more rigorous and assumes that medical equipment failures alone would result in a sentinel event. The “Swiss cheese” model proposed by Reason are ineffective in precluding serious injury or death—an extremely unlikely scenario.

In this case, the 111 causes determined by TJC for the period of 2004-2011 should be divided by 176 instead of by 620. Therefore, of the 39 medical equipment-related events reviewed by TJC in 2011, one would now expect 63% (i.e., 111/176) of them, or 24.6 (i.e., 63% of 39) events, to be classified as physical environment. This would also be the number of events caused by equipment failures if one again assumes the worst-case scenario as above. Furthermore, if one takes the upper limit of 3 percent reported by Wang et al., then one would end up with 0.74 (i.e., 3% of 24.6) as the number of events caused by maintenance omissions in 2011.

Using the equipment utilization rate calculated above, the second estimate of the number of maintenance-omission caused incident would be 0.0006 per million (0.74/1,220 million) of equipment uses (Table 1).
4. Discussion and Conclusions

The estimates of sentinel events caused by maintenance omissions provided a ballpark range of 0.14-0.74 in 2011 or 0.01-0.06% of all sentinel events reported each year. These extremely low values are consistent with the conclusions of prior analysis of FDA MAUDE data.¹

As numerous assumptions were used to derive these estimates, challenges can be raised to question the validity of these estimates. The most important challenge is likely to be the fact that sentinel event reporting is voluntary and, as stated by TJC itself, it likely “represents only a small proportion of actual events.” One possible correction is to use the 44,000 - 98,000 deaths per year estimates provided by the Institute of Medicine⁹ instead of the 1,242 sentinel events recorded by TJC. In addition, one can assume that there are five times more serious injuries than deaths. This means the estimates above would have to be multiplied by 213-473. The maintenance-omissions events estimated for 2011 would increase from 0.14 to 30-349 (using the range provided by both estimation methods). However, the percentage would remain in the range of 0.01-0.06% because the total number of sentinel events would have been increased by the same factors.

On the other hand, this increase would likely be compensated by the worst-case scenario assumptions made. In estimation method A, two assumptions were made. The first assumption was that all physical environment causes are solely attributable to equipment management. As there are eight sub-causes under physical environment, it is likely that equipment management accounts for not much more than 1/8 (12.5%) of the events. The second assumption is that 2-3% of equipment failures could and should have been prevented or detected by CE professionals. Even though the four types of failures (hidden, potential, predictable and preventable, and service-induced) classified by Wang et al.⁶ as “under CE direct control” can indeed be impacted by maintenance actions, it is unlikely that every such failure can and will be detected or prevented. An analysis of medical equipment repairs showed that the most often replaced parts are printed circuit boards,¹⁰ which contain electronic components that fail in a totally random manner at a low, constant rate.¹¹,¹². Therefore, there is no proven method to prevent these failures. Furthermore, some of those failures may never cause a serious incident at all. For example, a ventilator is certainly a life-support equipment that could cause patient harm in case of undetected catastrophic failure. However, excessive electrical leakage current (by definition a “hidden failure”⁶) is extremely unlikely to cause any problems to the patient as the ventilator does not have any electrical pathways to the patient and users are immune to small leakage current.

The assumptions made in estimation method B are even more rigorous than those used in method A. First, it was assumed that the equipment failure would not be caught in time by clinicians or resisted by the patient’s own defenses. This is extremely unlikely according to Reason,⁵ as most modern medical equipment that incorporates microprocessors has embedded continual self-monitoring hardware and software designed to trigger alarms and other precautionary functions to call the attention of the caregivers when a failure occurs. In addition, the percentage of failures under CE control was increased to 3%.

Therefore, regardless which estimation method is accepted, the conservative assumptions adopted likely compensate the under-reporting pointed by TJC. Even if one were to admit that the 213-473 factor needs to be applied, the estimates of the number of maintenance-omission caused incidents would only increase from .00011-.0006 to 0.024-.286 per million of equipment uses, which are still much lower than the Six Sigma goal of 3.4 DPMO.

A different line of challenge would be the adoption of equipment use as “opportunity” in DPMO calculations. Healthcare is essentially a service industry that uses clinical processes to provide care to patients. Medical equipment is

¹A more refined method, called physics-of-failure reliability modeling, has been gaining wide acceptance, as it is capable to account for “infant mortality” and “wear-out” phenomena, especially in complex electronic systems where multiple failure modes can occur.¹² For this order-of-magnitude study, it does not seem worthwhile to deploy such sophisticated method, as there are thousands of different brands and models of medical equipment.
used in the clinical processes much as machines are used in manufacturing processes to transform raw material into the desired products. Each time the product being manufactured is manipulated by a machine—with or without human intervention—there is an opportunity for creating a defect. Likewise, each time a piece of medical equipment is used on a patient or his/her biological sample, there is an opportunity for creating an incident. Therefore, equipment use seems to be a legitimate measure of “opportunity” for DPMO calculations instead of number of in-patient discharges or outpatient visits, as the latter two would be analogous to number of products manufactured.

Since there is no data on how many equipment uses each patient encounters during his/her visit or stay, a very conservative estimate was made. Each patient day would require the use of at least three pieces of medical equipment (e.g., vital signs monitor, laboratory analyzer, and imaging equipment), whereas each outpatient visit would require the use of one piece of equipment (e.g., sphygmomanometer). Higher estimates would decrease even further the DPMOs calculated. One could question the validity of using values collected from community hospitals instead of TJC-accredited hospitals. The American Hospital Association (AHA) defines community hospitals as all non-federal, short-term general and specialty hospitals, including children’s, whose facilities and services are available to the public. In other words, it excludes 213 military and Veterans Administration hospitals, and an unknown number of long-term care hospitals. While not all community hospitals are accredited by TJC, the total amount of community hospitals is similar to TJC-accredited hospitals. In 2011, there were approximately 4,168 hospitals accredited by TJC, while the AHA database shows there were 4,985 community hospitals in 2010. Since there were a total of 5,754 hospitals of all types in the U.S. in 2010, it is likely that there is a significant overlap between the community and TJC-accredited hospitals. Furthermore, there is no plausible reason to believe that patient incidents in TJC-accredited hospitals are different in quantity or root cause from those in hospitals accredited by other organizations.

The results described here are consistent with the results of a survey conducted by the Association for the Advancement of Medical Instrumentation (AAMI) per TJC request and presented at the AAMI 2012 Conference & Expo. The survey was responded by 1,526 persons and >94% of them stated that they follow TJC standards (i.e., the EC.02.04.01 standard) to establish medical equipment inventory and maintenance strategy, frequencies and procedures. These respondents were almost uniformly distributed among hospitals in terms of size—as measured by the number of beds and piece of equipment incorporated. Twelve of the 1,526 respondents stated that they had a least one adverse outcome because of “modified [the] PM procedures or frequencies from the manufacturer’s recommendations, using The Joint Commission process identified in EC.02.04.01 EPs 2–4.” However, only three of the 12 provided additional information and none of the sentinel events they described were truly caused by maintenance omissions but use errors, damaged equipment, and user refusal to perform pre-operational test.

Besides providing the statistics needed for the estimation of sentinel events caused by maintenance omissions, Figure 2 provides two important insights. First, the dominant root cause of medical-equipment related incidents is human factors. This is a well-known challenge for medical devices in general and, in particular, for infusion pumps and medical-device alarms. Second, while “physical environment” is the third highest root cause at almost 18%, all the remaining root causes, totaling >82%, are outside of realm of CE. For this reason, CE professionals have increasingly devoted more time to address clinical users—through training and consultation—in addressing human factors and other challenges. In addition, cooperation with other support departments (e.g., Purchasing, Material Management, Facilities Management, and Information Technology) has yielded better planning, purchasing, and replacement of medical equipment, accessories, and supplies, as well as prompt resolution of utilities and network issues that affect safe and proper function of medical equipment.
In essence, the analysis reported in this paper shows maintenance of medical equipment is being performed appropriately, if not exceeding well, in American hospitals because of the commitment and sound decisions made by CE professionals. Although most healthcare organizations deviated from the frequencies and procedures recommended by equipment manufacturers, there is no evidence this practice has created any detectable level of risks of harm to patients and users. On the other hand, it is clear that patient injuries are still occurring at an unacceptable level in American healthcare organizations due to other root causes.\textsuperscript{1,9,19}

Therefore, it seems unwise to mandate CE professionals to change their focus back to maintenance as they used to do more than three decades ago. This would curtail the valuable contributions they have been able to make in the better management of healthcare technology and, most importantly, in reducing the amount of patient incidents caused by human factors and other non-physical environment issues reported by TJC. Allowing CE professionals to continue current practice and improve it with evidence-based assessments would be the best way to achieve the overall aim of improving quality and safety of healthcare, while reducing costs at the same time.

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