The Case for a Quality Management System Standard for HTM

Stephen Grimes

Stephen Grimes, *FACCE, FHIMSS, FAIMBE, is managing partner at Strategic Healthcare Technologies, LLC, in the greater Boston area, and a member of the* BI&T *Editorial Board. Email: stephen.grimes@shcta.com*

The time has come for the healthcare technology management (HTM) services field to establish its own quality management system (QMS) standard. In addition to a QMS standard having clear benefits for HTM, it's likely that unless the field devises a QMS on its own, one may be imposed on it. A QMS standard developed consensually by experts in HTM likely would be far preferable to a standard or regulations designed and imposed by parties less familiar with the practical application of HTM services.

A Rationale for Action

Here, HTM refers to the industry segment whose responsibility generally includes managing—on behalf of healthcare delivery organizations—the processes associated with health technology selection, acquisition, deployment, systems integration, training, technical support (including testing, maintenance, and updates), life cycle analysis, compliance, safety, replacement, and disposal.

An HTM-specific QMS standard is needed for a number of reasons. First, health technology has been rapidly evolving, both in terms of its complexity and its integration into other aspects of the healthcare delivery process. As such, various elements of health technology have become critical to providers' ability to deliver patient care. Compromise or failure of critical medical systems can have potentially devastating effects on the provision of care. An effective QMS can help ensure that HTM is sufficiently flexible, robust, and resilient to adapt to healthcare providers' needs, minimize the risk of compromise, and successfully address compromises should they occur.

Second, although the convergence of health and information technologies is a reality, the HTM and information technology (IT) support services needed to ensure the smooth and effective operation of these hybrid systems often are siloed in their traditional IT and clinical engineering realms. A service management standard that defines appropriate collaborative processes and uses a common syntax could greatly assist in integrating health technology and IT services effectively.

A third reason to consider developing a new QMS is the Food and Drug Administration's (FDA's) push to promote the adoption of QMSs by medical equipment servicers.[1] Although the FDA has the authority to regulate servicing of medical devices, it has not done so thus far. For the present, the FDA would prefer that servicers self-regulate through the voluntary adoption of an appropriate QMS. That could easily change if the FDA were to decide that medical device servicers were too slow in adopting a QMS or the FDA's hands were forced by Congress to require regulation of servicers.

A fourth reason to adopt a health technology service–related QMS is to preempt ongoing attempts by medical equipment manufacturers and their trade organizations to pressure state and federal legislatures to formally regulate medical device servicers. Manufacturers and their representatives have already successfully lobbied the Centers for Medicare & Medicaid Services (CMS) to limit the flexibility of servicers who maintain imaging systems and, subsequently, have been lobbying Congress to regulate third-party servicers. One manufacturer trade association that also functions as a standards development organization (SDO) has been attempting to establish a medical equipment servicing QMS standard. Its initial draft failed to achieve consensus, primarily because it was based on current quality regulations intended for manufacturers that many HTM representatives felt were irrelevant to servicers.

FDA Activity Surrounding the Servicing of Medical Devices: A Brief History

- **March 2016:** The FDA announces it is gathering information from original equipment manufacturers (OEMs), third-party companies, and the healthcare community about the refurbishment, reconditioning, rebuilding, remarketing, remanufacturing, and service of medical devices
- **October 2016:** An FDA forum reveals divergent views among OEMs, third-party vendors, and hospital-based HTM professionals. OEMs called for the FDA to extend the regulations that cover the service and repair of medical devices by manufacturers, known as the Quality System Regulation, to anyone who performs these functions. According to OEMs, some third parties, such as independent service organizations (ISOs), have at times used unqualified personnel to service devices, installed parts that have not been validated, and inadequately documented their work, leading to patient safety concerns. ISOs and hospital-based HTM professionals, however, criticized these examples as anecdotal, not evidence of a systemic problem.
- **August 2017:** The FDA Reauthorization Act of 2017 is signed into law, requiring, among other things, that the FDA produce a report that addresses "the continued quality, safety, and effectiveness of devices … with respect to servicing."
- **May 2018:** The FDA concludes that evidence is insufficient to justify imposing additional regulations on third-party servicers of medical devices. However, the agency goes on to recommend the development of evidence to assess quality, safety, and effectiveness of medical device servicing; the strengthening of cybersecurity practices related to servicing; and the adoption of quality management principles.
- **December 2018:** The FDA holds a public workshop with the intent of having a public discussion about the distinction between medical device servicing and remanufacturing activities, in order to inform the development of future draft guidance.

What Is Quality Management, and How Did It Evolve?

The concept of quality management goes back as far as the middle ages, when craftsmen formed guilds. Guild members agreed on quality standards for their services and could be fined or professionally banned for failure to meet the standards. Quality assurance enabled guild members to command a higher price for their services.

As the world moved into the industrial age, more people worked together to produce greater volumes of products and services. To ensure the quality of this growing volume reached a level of consistency, best practices were identified and adopted. Eventually, formal standards evolved by consensus of relevant stakeholders. These standards were designed to control product and process outcomes, with a focus on meeting client requirements and enhancing client satisfaction.

By themselves, standards do not necessarily have the force of law. Standards are voluntary and do not represent legal requirements. Only standards adopted by a regulator (i.e., an authority having jurisdiction) carry the force of law.

Since the 1990s, the International Organization for Standardization (ISO) has produced the ISO 9000 family of standards, which have come to guide most of the world's quality management practices. ISO 9001 (*Quality management systems—Requirements*)[2] (Figure 1) details requirements an organization must fulfill in order to achieve compliance with the standard. Today, more than 1 million organizations in over 170 countries have been certified as 9001 compliant.[3]

Although the 9001 standard has become something of a "gold standard" for QMSs, some industries have considered it insufficient in terms of specifying quality management requirements for organizations in those industries. As a result, 9001 often is used as a starting point for developing industry-specific QMSs.

In the 1990s, the medical device industry used 9001 as a template for developing ISO 13485 (*Medical devices—Quality management systems—Requirements for regulatory purposes*),[4] which is an international QMS standard intended for organizations that design, develop, produce, store, distribute, install, or service medical devices. In addition to having all relevant elements of

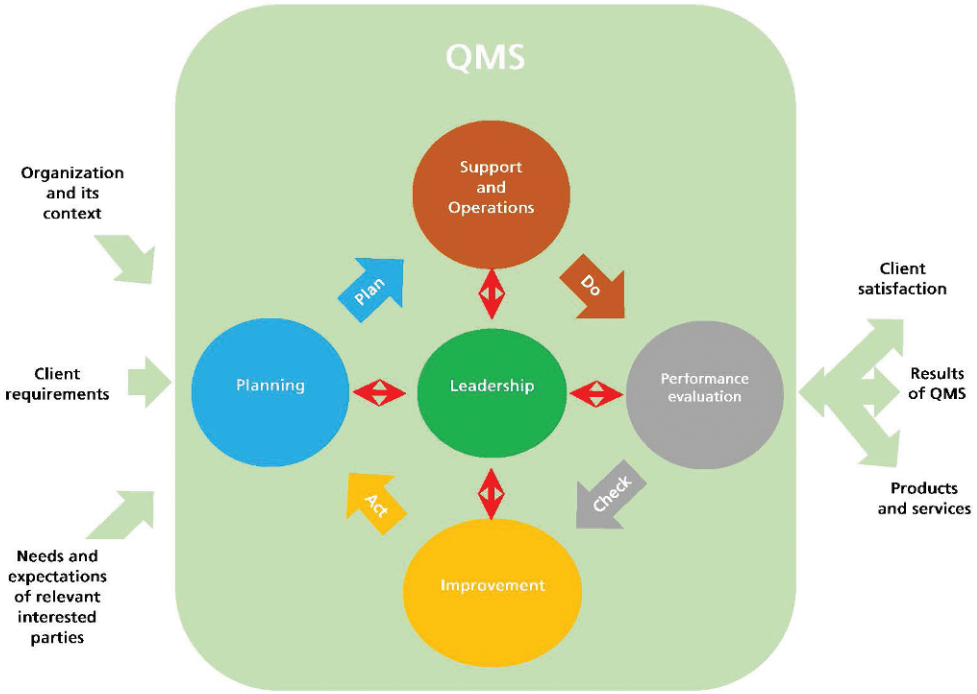

Figure 1. Structure of plan–do–check–act cycle in ISO 9001:2015.2 Abbreviation used: QMS, quality management system.

9001, 13485 addressed safety and critical postmarket support issues. Although the FDA has a quality system regulation for medical equipment manufacturers and remanufacturers (referred to as Title 21 of the Code of Federal Regulations Part 820 [21 CFR Part 820]), the agency has indicated its intent to harmonize the regulation with 13485.[5]

Similarly, in the 2000s, the IT industry used 9001 as a template for developing ISO 20000 (*Information technology—Service management system requirements*).[6] This became an international QMS standard for IT service management and often is used with governance best practices such as the Information Technology Infrastructure Library (ITIL)[7] or the Control Objectives for Information and Related Technologies (COBIT).[8] ISO 20000 differs from (but complements) ITIL and COBIT; 20000 lays out requirements for elements that an organization delivering relevant services must address, while ITIL/COBIT offer best practice guidelines for how to address those requirements. Organizations (but not individuals) can be 20000 certified, whereas individuals (but not organizations) can be ITIL or COBIT certified.

Along with the QMS standards, complementary documents called technical reports (TR) or technical information reports (TIRs) often are developed. These TR/TIRs generally do not include requirements but may explain how a standard may be implemented. TR/TIRs may serve as practice guides, providing information useful to organizations of different size, organizations specializing in limited health technology services (e.g., maintenance only), organizations with in-house services versus organizations that are independent or offer vendor-based services, or organizations or individuals who may take on the role of auditor to certify an organization's compliance with the standard.

Considerations in Developing a QMS Standard for HTM

ISO 9001 would offer a starting point toward developing a QMS standard for HTM. However, as with QMS standards focusing primarily on medical device manufacturing or IT, additional elements are required. Some but not all of these elements can be drawn from the 13485 and 20000 standards. ISO 13485 addresses some medical device support issues, and 20000 provides a description of many elements that should be included to

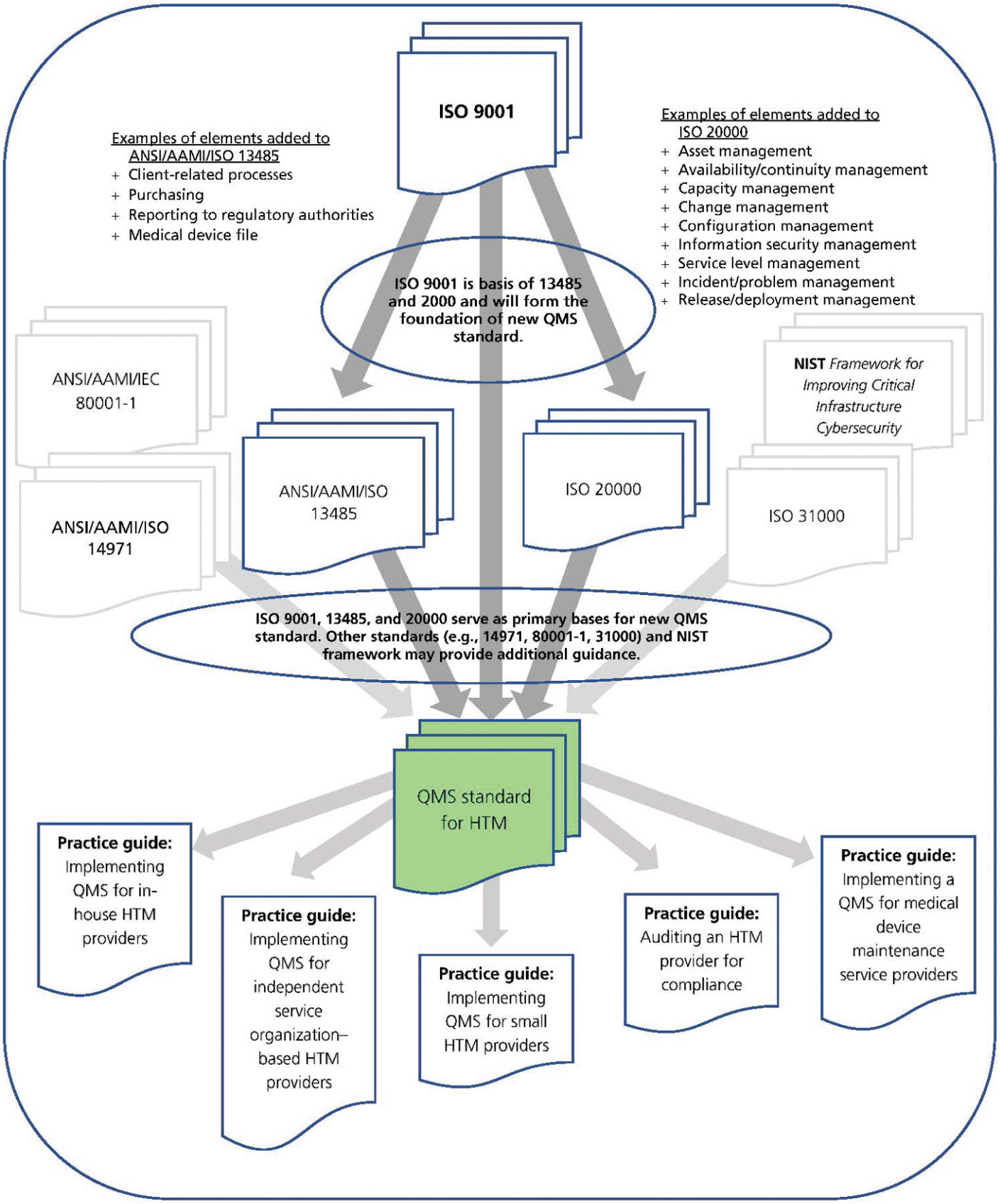

Figure 2. An evolutionary path for a quality management system standard for healthcare technology management and examples of possible related practice guides. Abbreviations used: AAMI, Association for the Advancement of Medical Instrumentation; HTM, healthcare technology management; IEC, International Electrotechnical Commission; ISO, International Organization for Standardization; NIST, National Institute of Standards and Technology; QMS, quality management system.

support today's sophisticated health technology and align HTM more effectively with IT.

Other standards offering useful guidance, particularly regarding the risk management aspects of QMS, are ANSI/AAMI/ISO 14971:2007/(R)2016,[9] ANSI/AAMI/IEC 80001-1:2010,[10] and ISO 31000:2018.[11] Medical device cybersecurity also represents a growing challenge for HTM providers, and any relevant QMS should include elements that address the management of medical device security in the healthcare environment. A report from the National Institute of Standards and Technology (*Framework for Improving Critical Infrastructure Cybersecurity*)[12] provides a generic guide for building processes to manage cyber risks, and a publication from AAMI (*Medical Device Cybersecurity: A Guide for HTM Professionals*)[13] provides additional guidance and a list of resources specific to the management of medical device security.

Figure 2 illustrates an evolutionary path for a QMS standard for HTM, principally deriving the proposed standard from 9001 and incorporating appropriate elements from 13485, 20000, 14971, 80001-1, and 31000.

The proposed standard, as is the case with 9001 and its derivative standards, generally should have the following characteristics.

High-Level Requirements

The QMS includes key, high-level requirements but does not specify details on how those requirements are to be achieved. For example, rather than saying, "Leadership shall review policy every 12 months," the standard might simply say, "The policy is reviewed by leadership for continued suitability." The organization is required to conduct a review but has the flexibility to identify and justify a time frame that is appropriate to the impact of the policy on the organization. This flexibility also enables organizations of different types and size to scale their activities in a manner that best suits their situation.

Requirements for Engaged Leadership

Successful implementation of a QMS requires both leadership participation and commitment. The organization's leadership must provide support (e.g., buy-in, resources, regular communications) in all aspects of the QMS implementation.

After successful implementation of a QMS standard for HTM, organizations could voluntarily elect to be audited by an accredited party and certified as compliant with the standard. Certification to the standard typically carries considerable weight with clients and potential regulators.

Client Focus

The requirements of clients and the expectations of relevant parties (i.e., patients, caregivers, device owner/operators, manufacturers, ancillary support services) are inputs into the QMS. The success of any service is judged by how well it meets the client's needs and by the client's ultimate satisfaction with the services.

Continuous Improvement

The QMS process incorporates a cyclical process that (1) starts with a plan designed to meet client requirements, (2) provides support and implements operations that do meet those client requirements, (3) conducts a performance evaluation that checks the adequacy of those operations, and (4) implements an improvement process that will act to adjust future planning in the right direction. This generally is referred to as the plan–do–check–act cycle (Figure 1).

Risk Based

Design and implementation of the QMS must be based on continuous consideration of risks and opportunities. Although each organization has the flexibility to scale operations according to its type and size, it also must factor in the risks associated with the type and degree of services provided. Under a QMS, properly assessing risks and opportunities facilitates prioritization of the most critical services and the assurance that those services are delivered with an appropriate focus on quality.

Ability to Serve as a Basis for Certification

Standards such as 9001, 13485, and 20000 serve as the bases for the certification of organizations that wish to demonstrate their compliance. After successful implementation of a QMS standard for HTM, organizations could voluntarily elect to be audited by an accredited party and certified as compliant with the standard. Certification to the standard typically carries considerable weight with clients and potential regulators.

Next Steps

Substantial benefits can be realized by adopting a QMS that is relevant to the

current-day field of HTM. However, if an overarching QMS standard is not established, the industry likely will face problems, including the real possibility of new regulations.

A reasonable and commonly used pathway (e.g., through 9001 and adding other elements found in 13485 and 20000) could get the industry to a relevant, international QMS standard in relatively short order. Because most standards (including QMS) are revisited and often revised every few years, the initial QMS produced might be a "modest" version. Then, after achieving significant industry buy-in and feedback, a more robust version of the standard could be developed.

All that is needed is for an SDO to take on the QMS as a work product, then for that SDO to convene a group of relevant stakeholders to review and reach a consensus on the final QMS. AAMI is an SDO, and one of its standards committees could elect to adopt this as a work product. Currently, AAMI is working on a revision to ANSI/AAMI EQ56:2013.[14] However, although some hope existed that EQ56 might meet the HTM field's needs for a QMS, the proposed revision falls short of a true QMS, and the "standard" seems more in the model of a practice guide.

The HTM field should encourage AAMI to adopt this as a work product, convene appropriate stakeholders, follow the 9001/13485/20000 path, and publish a QMS that can be adhered to by all HTM providers regardless of organization type, size, or service catalog. A well-formed QMS standard would serve as a guide for all HTM providers on how to ensure quality and continuous improvement of their services and to ensure that those services are tailored to meet the actual needs of clients.

If you agree, please email **standards@aami.org** with subject line "QMS for HTM" and express your support. And if you can, please consider volunteering with AAMI for participation in the standards committee.

References

1. Food and Drug Administration. FDA Report on the Quality, Safety, and Effectiveness of Servicing Medical Devices. Available at: www.fda.gov/downloads/RegulatoryInformation/LawsEnforcedbyFDA/SignificantAmendmentstotheFDCAct/FDARA/UCM607469.pdf. Accessed Oct. 13, 2018.
2. ISO 9001:2015. *Quality management systems—Requirements*. Geneva: International Organization for Standardization.
3. International Organization for Standardization. ISO 9000 family: quality management. Available at: www.iso.org/iso-9001-quality-management.html. Accessed Oct. 12, 2018.
4. ANSI/AAMI/ISO 13485:2016. *Medical devices—Quality management systems—Requirements for regulatory purposes*. Arlington, VA: Association for the Advancement of Medical Instrumentation.
5. Association for the Advancement of Medical Instrumentation. FDA Considering Updates to Quality System Requirements. Available at: www.aami.org/newsviews/newsdetail.aspx?ItemNumber=5811. Accessed Oct. 12, 2018.
6. ISO/IEC 20000-1:2018. *Information technology service management—Part 1: Service management system requirements*. Geneva: International Organization for Standardization.
7. Association of Modern Technologies Professionals. Infrastructure Technology Infrastructure Library (ITIL) Guide. Available at: www.itinfo.am/eng/information-technology-infrastructure-library-guide. Accessed Oct. 21, 2018.
8. ISACA. Control Objectives for Information and Related Technologies (COBIT). Available at: https://cobitonline.isaca.org. Accessed Oct. 21, 2018.
9. ANSI/AAMI/ISO 14971:2007/(R)2016. *Medical devices—Application of risk management to medical devices*. Arlington, VA: Association for the Advancement of Medical Instrumentation.
10. ANSI/AAMI/IEC 80001-1:2010. *Application of risk management for IT Networks incorporating medical devices—Part 1: Roles, responsibilities and activities*. Arlington, VA: Association for the Advancement of Medical Instrumentation.
11. ISO 31000:2018. *Risk management–Guidelines*. Geneva: International Organization for Standardization.
12. National Institute of Standards and Technology. *Framework for Improving Critical Infrastructure Cybersecurity*. Available at: https://nvlpubs.nist.gov/nistpubs/CSWP/NIST.CSWP.04162018.pdf. Accessed Nov. 13, 2018.
13. Grimes SL, Wirth A, eds. *Medical Device Cybersecurity: A Guide for HTM Professionals*. Arlington, VA: Association for the Advancement of Medical Instrumentation; 2018.
14. ANSI/AAMI EQ56:2013. *Recommended practice for a medical equipment management program*. Arlington, VA: Association for the Advancement of Medical Instrumentation.