Applying QMS Principles to a Medical Equipment Management Program

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Applying a quality management system (QMS) to existing policies and procedures in healthcare technology management (HTM) departments can better satisfy the needs and expectations of healthcare providers and improve patient care. This article will explain why adopting QMS principles is important and describe how HTM departments can apply QMS principles to a medical equipment management program (MEMP) using a three-step approach.

The Food and Drug Administration's (FDA's) Center for Devices and Radiological Health is responsible for regulating firms that manufacture, repackage, relabel, and/or import medical devices sold in the United States.[1] Manufacturers of medical devices distributed in the United States must comply with the Quality System Regulation (QSR; 21 CFR Part 820).[2] The QSR includes requirements related to the methods used in healthcare facilities, as well as the controls used for designing, purchasing, manufacturing, packaging, labeling, storing, installing, and servicing medical devices.

In the same manner that the FDA regulates the manufacturers/remanufacturers and distributors of medical devices, federal agencies (e.g., Centers for Medicare & Medicaid Services [CMS]) and state health departments require healthcare organizations to manage medical equipment risks. In addition, accreditation agencies (e.g., The Joint Commission [TJC], DNV GL, Healthcare Facilities Accreditation Program [HFAP]) ensure that healthcare organizations comply with those requirements/standards. Original equipment manufacturers (OEMs) often blame HTM departments if equipment fails or is involved in a patient incident when it is not maintained by the OEM, despite HTM departments complying with various regulations.

In March 2016, the FDA announced that a docket would be established "to receive information and comments on the medical device industry and healthcare community that refurbish, recondition, rebuild, remarket, remanufacture, service, and repair medical devices."[3] Various stakeholders engaged in one or more of these activities have responded to the docket, and based on the comments, the FDA held a two-day public workshop in October 2016. In May 2018, the agency issued a report on the quality, safety, and effectiveness of medical devices with respect to servicing.[4] The report also promotes the adoption of quality management principles by medical device servicers as part of their ongoing activities.

The adoption of a QMS is a strategic decision for an organization to improve its overall performance. The potential benefits to an organization of implementing a QMS include:

- Organizational credibility.
- Development of a common, understood system with consistent and repeatable processes.
- Process integration through gained efficiencies by eliminating waste.
- Clarity about what to do and how.
- Better management control and reporting.
- Improved customer satisfaction.
- Increased employee satisfaction.

Key Takeaways

- A healthcare technology management (HTM) department's medical equipment management program (MEMP) can benefit from the application of quality management system (QMS) principles, which include customer focus, process approach, and evidence-based decision making.
- A QMS must use a process approach and risk-based thinking, and HTM departments can develop a process approach by incorporating a plan-do-check-act cycle.
- A simple three-step approach can be applied to improve processes in an MEMP. The approach involves asking (1) What are the needs of your customer?, (2) How do you ensure the needs are met?, and (3) What are the end results?

QMS Principles: Benefits to an MEMP

HTM departments can reap the above-mentioned benefits by applying QMS principles to their MEMP.

Medical equipment is used during both critical and noncritical situations of patient care, and its effective management is of vital importance to healthcare organizations. HTM departments should meet a set of requirements that are put forth by regulatory agencies (e.g., CMS) and accreditation bodies (e.g., TJC, DNV GL, HFAP). HTM departments engage in activities ranging from the selection to disposal of healthcare technology, ensuring that medical equipment is safe, reliable, and available. The activities performed by HTM departments are established in the form of policies and procedures, which are derived from the above-described requirements and serve to guide HTM staff in managing day-to-day operations.

The American Society of Quality (ASQ) defines a QMS as "a formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. A QMS helps coordinate and direct an organization's activities to meet customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis."[5] The processes, policies, and workflow methods embodied in a QMS serve as a framework by which an organization operates, enabling it to meet customer expectations and achieve continuous improvement.[6]

The objective of HTM is to maintain medical equipment and ensure that it is safe and available at all times to clinical staff for patient care. The MEMP, which consists of policies and procedures, helps coordinate and direct HTM departments to meet the objective and regulatory requirements, as well as continuously improve its effectiveness and efficiency through measurable performance indicators (e.g., preventive maintenance [PM] inspection completions, repairs). In other words, an HTM department's MEMP should serve as its QMS.

The International Organization for Standardization (ISO) standard, ISO 9001:2015, defines the requirements for a QMS.[7] This and other standards in the ISO 9000 family are based on the following quality management principles: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision making, and relationship management.[8] Inherently, HTM departments adhere to these principles while performing duties in the hospital such as engaging with clinical staff to resolve service-related issues, reviewing key performance indicators with environment of care committees, and providing recommendations to the capital purchasing team regarding new equipment.

Customers are the primary focus of any organization, and their satisfaction is of utmost importance. Customer focus in a QMS means understanding customers' needs and expectations, monitoring customer satisfaction, and acting on results. The level of customer satisfaction depends on the efficiency of the service and the extra step taken to resolve an issue. Developing a continuous feedback loop with the customer is important. HTM departments should foster the culture of ongoing status updates on repairs, collaborating with and assisting customers in resolving service-related issues in a timely manner.

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For HTM departments, customers are clinical staff and the leadership at healthcare organizations, and their expectation is that all medical devices function and are maintained properly for patient use. Customer satisfaction can be gauged by conducting surveys. For HTM departments, areas of focus for surveys should include questions on communication, including satisfaction related to follow-up on repairs and responsiveness to work orders. Based on the feedback received, HTM departments can develop an action plan for further improvements. Survey results also should be communicated with organization leadership.

HTM leadership should establish MEMP objectives and ensure staff are engaged in achieving the objectives. Recognition, empowerment, and collaboration facilitate the engagement of staff in achieving MEMP quality objectives. HTM leadership also should assess satisfaction by conducting unbiased employee satisfaction surveys.

A QMS also must use a process approach and risk-based thinking. HTM departments can develop a process approach by incorporating a plan-do-check-act (PDCA) cycle. The PDCA cycle can be used to improve the quality and effectiveness of a variety of processes and services within the HTM department, including healthcare technology procurement, PM activities, and equipment disposal. PDCA essentially serves as a feedback loop that allows the user to evaluate how a process is currently being implemented, identify gaps in the process, and determine how the process can be improved through a systematic approach supported by data.

For example, to maintain TJC accreditation as per their standard EC.02.04.01, a healthcare organization must capture its entire inventory of medical equipment used for patient care, irrespective of ownership. The following example shows how PDCA can be used to achieve compliance with this standard.

In a well-functioning healthcare organization, clinical leadership will consult the HTM department during capital equipment replacement planning, and the HTM department will provide recommendations based on a variety of factors.

- **Plan.** The organization should assess the scope of the standard EC.02.04.01 and its impact on various stakeholders, including HTM, purchasing, clinical staff, and external vendors used to lease or rent equipment. Organizations should develop a policy that establishes controls to comply with the standard. For example, who is responsible for initially accepting and inspecting the equipment? Who should vendors contact before bringing the equipment into the facility?
- **Do.** The policy is implemented by communicating it to all stakeholders. Data also are collected, which allows performance to be measured and any concerns that affect performance to be addressed.
- **Check.** The data are analyzed to see if the changes implemented resulted in improvements in the organization's ability to accurately assess its inventory and overall equipment management. The process improvements that resulted in improved performance are captured, and a a root cause analysis is performed to identify faults or problems.
- **Act.** Last, if the plan was successful, the process is standardized and the results monitored continuously. If the the intended goal has not been achieved, further actions for improvement are taken.

In the context of HTM, the PDCA cycle is similar to troubleshooting or performing a PM inspection on medical equipment. HTM staff test the equipment to see if it functions properly, and if it does not meet the specifications, repairs are performed, and the equipment is tested again. This process is repeated until the required specifications are achieved.

One of the main principles of a good QMS is evidence-based decision making. Decision making can be a multifaceted process, and it always involves a certain degree of uncertainty. Facts, evidence, and data analysis lead to confidence in decision making. The process of collecting and analyzing data is not new for HTM departments. For example, in a well-functioning healthcare organization, clinical leadership will consult the HTM department during capital equipment replacement planning, and the HTM department will provide recommendations based on a variety of factors (e.g., medical equipment reliability, manufacturer service supportability, age, compatibility with existing technology).

In addition, medical device service history can be used by HTM staff to determine the effectiveness of maintenance intervals and procedures, in order to implement an alternate equipment management program. Knowledge of service history also is valuable when performing service contract analysis. HTM departments should implement a policy to select and evaluate various vendors based on the services provided (e.g., parts, depot repairs, onsite repairs). Moreover, the policies and procedures developed by HTM should always work toward improving serviceability of healthcare technology and patient care.

The scope of a QMS will affect an organization's ability to (1) consistently provide services that meet customer needs and applicable accreditation standards and regulatory requirements and (2) to enhance customer satisfaction through the effective application of the QMS, including processes for improvement.

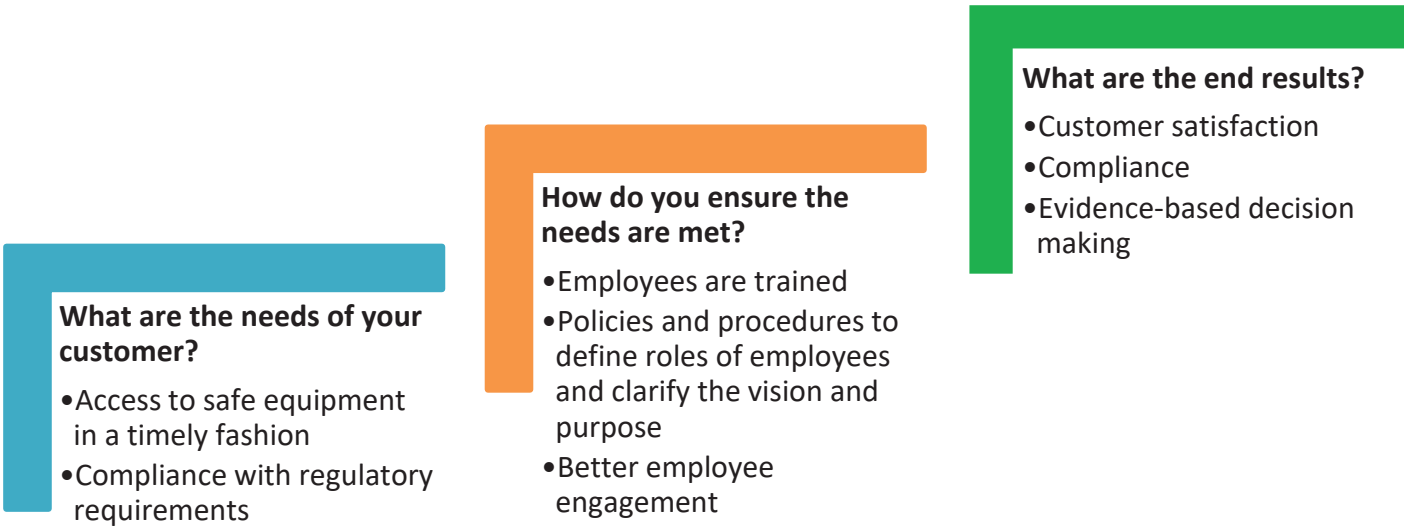

Figure 1. Example of using a simple three-step approach to improve processes in a medical equipment management program

The primary objective of an MEMP is to provide a safe patient care and treatment environment by managing risks associated with the use of healthcare technology. This objective is no different from the requirements of a QMS and can be achieved using a simple three-step approach, as illustrated in Figure 1.

Simple Three-Step Approach

The following is a basic example of how the three-step approach can be applied to processes in an MEMP, such as scheduled maintenance activities:

- **What are the needs of your customer?** The clinical staff need the healthcare technology to be checked for the functionality and accuracy of outputs, in order to ensure that equipment can be safely and reliably used for patient care.
- **How do you ensure the needs are met?** HTM departments should have policies and procedures that address their scheduled maintenance activities, as well as actions to be taken if maintenance is not completed as stated in the policy (e.g., customer follow-up if equipment cannot be located or is in-use).
- **What are the end results?** On-time completion of maintenance satisfies customers by giving them access to safe and reliable equipment for patient care, in addition to meeting regulatory requirements. Feedback should be taken from staff to identify gaps in effectiveness, and data should be analyzed to further improve the efficiency of the process.

This is only one example of the many processes detailed in an MEMP. The three-step approach can be applied to any process to identify the needs, methods implemented to achieve the needs, goals accomplished, and data analysis to find the gaps for continuous improvement.

Conclusion

In the recent past, much activity has occurred around the practices of servicing healthcare technology. This article sought to show HTM departments that a QMS can be developed by making minor changes to existing MEMP practices. Implementing a QMS provides a sound basis for a coherent, effective, and cost-efficient approach to ensuring optimal levels of safety and effectiveness related to healthcare technology.

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