SELF-STUDY SERIES

QMS on the horizon

A thorough approach for optimizing medical device processing in healthcare facilities

by Richard Schule, MBA, BS, FAST, CST, FCS, CRCST, CHMMC, CIS, CHL, AGTS, ASQ CQA

Medical science has achieved many discoveries, inventions, and cures. These defining moments helped shape our approaches to disease and illness, and thereby improved the quality of patient care. However, improvements have typically taken years or even decades to be accepted by the medical community, because breakthrough concepts often go against existing norms or beliefs.

In recent years, healthcare medical device reprocessing functions have been experiencing their own defining moments. The increasing complexity of medical and processing technologies has required new skills, deeper expertise, and new procedures in sterile processing environments. Changing longstanding beliefs, policies and processes can be daunting, but it must be done to address evolving patient safety risks. This brings us to a major crossroad in the medical device processing community—implementing a quality management system (QMS) for medical device reprocessing. This relatively new concept is needed to recognize that there are direct and indirect "customers" who receive value from the medical device reprocessing work performed in various areas of a healthcare facility.

Supporting documents pave the way

There are several industry documents that establish the fundamentals for a reprocessing QMS. International quality standards began with the British Standards Institute (BSI) and the publishing of BS 9000. Years later, ISO 9000 was introduced. Today, several industries make use of ISO 9001:2015, which is far less prescriptive and integrates well with other ISO management standards. One such document is ANSI/AAMI/ISO 13485:2016 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes. This standard specifies the requirements for a QMS that demonstrates an organization’s ability to provide medical devices and related services that consistently meet customer requirements and any applicable regulatory requirements.

All departments responsible for processing medical devices benefit from making a structured QMS part of their culture. Why? If we were to isolate the root cause(s) of any of the recently reported occurrences of cross-contamination, infection or exposure to dirty medical devices, we would find that a specific requirement of a QMS would apply, and could also address the problem. The importance of a QMS in a department responsible for medical device reprocessing is becoming obvious, and having a system in place will help departments meet or exceed customer expectations for patient safety, staff safety and departmental productivity.

Define the scope of the department

Quality management is often confused with, or mistaken for, sterility assurance; the use of products such as biological and chemical indicators, and cleaning or process verification testing. Although these are part of a department’s QMS, there is much more that needs to be included to achieve thorough and complete quality management of this very complex function.

The standard for quality incorporates good business practices and is based on seven sound quality management principles. They are: customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision-making, and relationship management. These principles are not listed in any hierarchy or order, and the importance of each will vary from one organization or department to another, and will likely change over time.

How do we define the minimum requirements for establishing a QMS for all personnel responsible for processing medical devices in a facility? How do we assure that they will be able to effectively, efficiently, and consistently process medical devices and prevent adverse patient events and...
non-manufacturer related device failures? We begin by defining its scope.

Departmental scope
Here’s an example of overall functional scope, taken from an SPD Quality Manual: “The Surgical Processing Quality Manual defines the surgical processing department operating system. Elements that affect the quality of products, processes, or services are contained within this manual. ... This policy is applicable to all surgical processing facilities located within the E-Building, G-Building and M-Building of xxx Main Campus. Each facility is responsible for functioning in accordance with this policy manual and the applicable standards listed above.”

Practice scope
How would staff members identify the role each of them plays in the processing of medical devices? There could be 20 or more different roles identified. Scope of practice and focus are the remaining requirements of a QMS. They support your processing team.

Terms and definitions
Sometimes we work in an acronym-filled technical world. Consider the following instructions:

SPD manager; “Send the new guy up to the OR to pick up Dr. Jones’ A/P cervical fusion tray and bring it to decon for fast track and quick-turn. Check CSIQ for the IFU and confirm IUSS temp setting and cycle. Make sure to run a B1 in a C6 PCD with the load…”

For new team members, this could be impossible to execute if they don’t understand the shorthand. The instrument reprocessing world has a language unto itself, as do other healthcare functions such as the operating room or emergency department.

When we travel to other countries, we often prepare by learning a few important words in the native language to help us navigate the culture. Helping new reprocessing colleagues learn the SPD language goes a long way towards making them feel welcome, but more importantly, it helps prevent reprocessing nonconformities from occurring. Therefore, it’s important to establish and continue to update a glossary section within the department’s quality manual, to clearly define all terms related to the QMS. The CSSD Dictionary and Reference Guide from IAHCMMM is an excellent industry resource to help teach device processing language.

Normative references
It’s important for all team members to accept that terminology and nomenclature specified in the department’s quality manual is not open for debate or interpretation. Though it is rarely discussed, maintaining consistent definitions is among the most important QMS requirements for building shared knowledge. ISO 13485 refers to a specific document, “ISO 9000:2000: Quality management systems – fundamentals and vocabulary,” in case questions or misunderstandings occur during the implementation and application of standard requirements.

Key QMS elements
A QMS is a way of defining how the device processing department can consistently meet the requirements of customers and other stakeholders affected by its work. The department’s QMS consists of interrelated processes. By understanding how results are produced by this system of processes, the team can optimize the whole system and its performance.

There are several key concepts required for an effective QMS. First, each department must establish authority, responsibility and accountability for managing processes. There should also be a clear understanding of the department’s existing capabilities and resource constraints before beginning a process. Thirdly, the department must manage processes and their interrelations as a complete system, to achieve the department’s quality objectives effectively and efficiently. This also ensures that the necessary information is available to operate and improve the processes, and to monitor, analyze and evaluate the performance of the overall system. Finally, the department must manage risks that can affect outputs of the processes and overall outcomes of the QMS.

QMS guidance doesn’t specify what the objectives relating to “quality” or “meeting customer needs” should be, but it requires the device processing department to define these objectives themselves and continually improve their process to attain or exceed them. In addition, the device processing department must maintain control of its documents, which should be kept up to date for as long as they are needed. Directions must be made available to all users to maintain control of records.

Bottom line: by establishing a QMS, the device processing department is stating what they do, and doing what they say.

Management responsibilities
The leadership of the device processing department must be committed to communicating the importance of patient safety, and meeting the statutory and regulatory requirements that pertain to the medical devices being processed. Leaders at all levels in the department must establish a unity of purpose and direction that enables staff to engage in achieving the department’s quality objectives. Once a culture of unity is created, the department will experience improved process coordination.

In addition, better communication among levels and functions of the department will improve the capability of the staff to deliver desired results. Some basic actions leaders can take to improve communication include:

- Sharing the department’s mission, vision, strategy, policies and processes throughout the department
- Establishing a culture of trust and integrity by creating and sustaining shared values, fairness and ethical models for behavior at all levels
- Encouraging a department-wide commitment to quality
- Ensuring that leaders at all levels are positive examples to people in the organization
- Providing staff with the required resources, training and authority to act with accountability
- Encouraging and recognizing staff members’ contributions on a regular basis

Managers are also responsible for maintaining their device processing department’s customer focus, which must be defined in its quality policy. Ongoing success is achieved when the department retains the confidence of its clinical staff and other customers. Every interaction should strengthen value with the customer, and understanding the current and future needs of clinicians contributes to a positive relationship and builds the success of the department.

There is another level of leadership support and engagement that is critical. The level of C-suite commitment for providing and supporting device processing departments impacts their ability to prevent nonconformities from occurring.

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Kaoru Ishikawa, a well-known and respected quality management expert, believed that all employees have a role to play in product quality. He believed that company-wide participation was required, from top management to the front-line staff, and that every area of an organization can affect an organization’s quality.

Resource management
The device processing department is required to determine and provide the resources necessary to implement and maintain the QMS, to continually improve the system’s effectiveness, and to achieve continual customer satisfaction. This means they must anticipate the need for resources to maintain an efficient system.

Material supplies and services
A well-managed supply chain provides a stable flow of goods and services. The department should create and proactively manage positive relationships with suppliers and third-party services to help optimize the impact on department performance.

To optimally manage resource relationships, device processing managers can:
- Establish collaborative development and improvement activities with suppliers, partners, and other interested parties.
- Recognize and celebrate milestones, improvements, and other achievements by suppliers and partners.

Managing professional resources
Device processing managers must develop competent, empowered, and engaged staff at all levels of the department, and continually maintain a work environment that promotes success, achieves conforming product, and supports professional growth. Professional support and education will enhance initiative and creativity, staff satisfaction, and trust and collaboration among team members. It will also increase the team’s attention to the shared values and among team members. It will also increase the product’s intended use, even if they have not been specified by the customer.

Then, they must determine the steps to assure that the product can be realized to meet all requirements.

To assure proper product realization, the device processing department must:
- Understand the purchasing process, have access to purchasing information, and have an established process to verify purchased product.
- Put process controls in place that include verification.
- Check the product, or if that is not possible, check the process.
- Maintain identification and traceability – the specs must match the job, show whether items are acceptable or not, keep track of what’s provided.
- Control monitoring and measuring devices; use the equipment in the proper environment, and periodically check the equipment calibration.

Measurement, analysis and improvement
Successful departments have an ongoing focus on improvement, which is essential to maintain even current levels of performance. Managers must plan and implement the monitoring, measurement, analysis, and improvement processes that demonstrate conformity of the products, and ensure the conformity and continuing effectiveness of the QMS. For example, the department correctly measuring what the customer defines as “quality”? Fortunately, quality can be physically measured. If all the measurements add up to what the customer defined or needed, then the department has provided quality.

A QMS standard is organized in the same logical order as you would perform a task. First, you plan it. Then you do it. Next, you check and analyze what you did. Finally, you improve on any weaknesses.

The system is a group of processes working together to achieve a specified objective. The processes must be managed to achieve the department’s ultimate goals.

The department must also monitor and manage customer satisfaction, through verbal conversation or periodic surveys.

Results are measured to ensure that the process has been maintained, and that customers realize their expectations have been met or improved through process adjustment.

Finally, device processing departments must analyze the data they collect and figure out what it means. Decisions based on data analysis and evaluation lead to greater objectivity and confidence, and are more likely to produce quality results. But, decision-making is a complex process that always involves some uncertainty. There will be multiple types and sources of inputs, as well as multiple subjective interpretations. It’s important to understand cause-and-effect relationships and be aware of potential unintended consequences.

QMS: not an “if” but a “when”
Device processing departments play a greater role in total healthcare quality than ever before. It’s no small task to ensure that employees are aware of the relevance and importance of their activities, and understand how they contribute to the achievement of quality objectives.

Device processing departments must not only identify problems; they must fix the causes and verify that their changes worked. Continual improvement processes identify problems, potential problems, and causes, and corrective or preventive actions assure they will not recur. This is one of many benefits of quality management systems.

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References
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Circle the one correct answer:

1. ISO 9001 history began with BS 9000.
   A. True
   B. False

2. ISO 13485 states an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements.
   A. True
   B. False

3. The standard for quality is based on five sound quality principles.
   A. True
   B. False

4. Which is not a quality management principle?
   A. Engagement of people
   B. Evidence-based decision making
   C. Financial responsibility
   D. Customer focus

5. What is defined by a QMS?
   A. Quality
   B. How the device processing department can meet requirements of the customer
   C. How many FTEs are needed
   D. How many lights are required in the assembly area

6. What must leadership be committed to communicating?
   A. Patient safety, unity of purpose, statutory and regulatory requirements
   B. “It’s my way or the highway”
   C. Divide and conquer
   D. None of the above

7. What actions can management take to support department staff?
   A. Establish a culture of trust and integrity through shared values
   B. Establish fairness and ethical models for behavior at all levels
   C. Encourage department wide commitment to quality
   D. All the above

8. What is essential for a department to enhance its capability to create and deliver value to the customer?
   A. Competent staff
   B. Empowered and engaged staff
   C. Both A and B
   D. None of the above

9. What are some of the challenges leadership face?
   A. Maintaining a work environment that promotes success
   B. Achieving conforming product
   C. Supporting professional growth
   D. All the above

10. In what order is a QMS standard organized?
    A. First you do it, then improve any weaknesses, then plan it, then check and analyze
    B. First you plan it, improve any weaknesses, then check it, then do it
    C. First you plan it, then do it, then check and analyze it, then improve weaknesses
    D. First you do it, then check it, improve on weaknesses, and plan it

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