

Education Nation: Sterile Processing Quality Management Systems



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“Quality” appears to be the healthcare industry’s new buzzword. Sitting high amongst other phrases like “let’s take that offline” and “state-of-the-art,” a variety of professions use the word in their own ways. Originating from the craftsmen of the medieval era, guilds would compose strict guidelines that required their products to be inspected for defects. These practices remained present,

surviving through the Industrial Revolution,¹ and have evolved into the quality management systems seen in the 21st century. From medieval craftsmen that created the first quality control program to the first quality assurance program in the 1920s, quality control has been present throughout history.¹ Over time, quality programs began to emerge in industries not necessarily specific to the factory setting. As the healthcare

industry incorporates quality systems into daily operations and patient care, professionals face the challenge of defining what it means to provide “quality care” within an organization that serves patients. There is an even greater challenge to professions like Sterile Processing (SP), whose quality management systems are directly linked to an entirely separate profession’s ability to perform their quality of care.

Learning Objectives

1. Define quality in the context of the healthcare industry, particularly in Sterile Processing.
2. Understand the purpose of a Quality Management System and key factors to consider when developing one.
3. Be able to differentiate between Quality Assurance, Quality Control, and Quality Culture, and explain how they contribute to better outcomes in the Sterile Processing department.

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Clarity in Quality

While the application of quality in the healthcare setting may vary from profession to profession, the concept of quality is not so ambiguous. Quality is “the standard of something as measured against other things of a similar kind; the degree of excellence of something.”² Quality sets the foundations for the expectations of our work, therefore it is a tangible, physical, and measurable concept. Thus, if it is accurately defined in accordance with the outcomes a Sterile Processing department is expected to achieve, then a program for consistency can be trained.

Quality is essentially the fulfillment of promises that have been defined by the collective individuals involved. In order to do this successfully, Sterile Processing must know how success is defined by its partnering perioperative professions. A Surgical Technologist may define this as having the accurate instruments in an instrument set. The circulating Nurse may achieve success when the wrappers do not have holes, all while the Surgeon anticipates a surgical site infection-free recovery for the patient. An effective quality practice permits SP departments to fulfill these promises to their patient care colleagues. This is why a successful quality program feels like any other smooth day on the job for all parties involved. It is also why multiple professionals are negatively impacted when a quality defect is discovered. Hence, robust SP quality programs must specifically define indicators within their own departments that will inevitably create the outcomes other departments depend on.

The Quality in QMS

With this working knowledge of what quality is, SP leadership can develop a structure for professional expectations and practices to grow upon. This structure is a quality management

system (QMS). A QMS is a system of documented processes, procedures, and responsibilities that SP use to achieve objectives (Figure 1).³ QMS permits SP leadership to conceptualize the direction that they need their frontline professionals to move towards. A few key factors to consider when a QMS is in development is that they:

- Are unique to the organization (i.e., facility, industry, association, etc.).
- Should align with the purpose & strategic direction of the organization and contributing departments.
- Enhance satisfaction of their customers (the patient, the OR team, etc.).

This is how leadership moves from a reactive state of decision making to a proactive expectation of outcomes. It also provides them with the opportunity to make quality a collective department effort by essentially incorporating strategic markers for their team to strive towards.

This is achieved through the three major components of any healthy and sustainable QMS: quality assurance, quality control, and quality culture. These components are made up of standard works, best practices, and standard operating procedures that detail how to perform a process in order to achieve a quality outcome. More often than not, these terms are used interchangeably and are treated like synonyms. This could not be further from the truth. Quality assurance, control, and culture are their own entities that contribute to a QMS (Figure 2). Too much of one and not enough of another affects the outcome of processes and misses opportunities to articulate the actions necessary to achieve and maintain quality in SP.

Quality Assurance

Quality assurance and control are key components of a QMS. Quality assurance programs ensure that the correct processes are performed to

Lesson:

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August 2024

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Quiz Answers:

1. B, 2. A, 3. B, 4. D, 5. B, 6. C, 7. B, 8. A, 9. A, 10. A

achieve the anticipated final outcome, taking a proactive approach to preventing defects and failures. For example, opening surgical instruments and placing them neatly in the tray or on the stringer before sending them through the washers is an SP industry best practice. The department's standard works describe this step in detail, resulting in debris-free instruments on the clean side. The steps are evaluated for compliance and technical ability. This ongoing process is quality assurance in practice. The practices are consistently evaluated for adherence.

Quality Control

Quality assurance programs rely on quality control follow up. Quality control is a reactive method as it is focused on the outcomes, good and bad, at the end of the process. Quality control identifies whether a process has failed or passed by providing a foundation to detect mistakes. Auditing is an effective way to carry out quality control programs. For example, if a sterile instrument set

is randomly inspected, leading to the discovery of no indicator, this audit has caught a quality defect before the end user is impacted. This is quality control in practice, as the end result was inspected for completion. When quality assurance and control are implemented together in an SP department the desired outcomes and processes are defined, leading to recognition of success and prevention of patient safety concerns.

Quality Culture

The only way to make quality more than a buzzword in the SP department is to assess how it is viewed by the Perioperative team. This team is made up of SP, Nurses, Doctors, Surgical Technicians, and every other profession that contributes to the overall positive patient outcome. The separate impressions held by each group defines the collective belief in everyone's ability to sustain quality programs. Quality assurance, control, and QMS need to be rooted in the team's day-to-day operations. At that point, quality will develop a culture of its own.

In a sense, quality culture is quality that is achieved for its own sake. This culture is based on the successes or failures of setting the foundations underlying the team's expectations. The ability to maintain quality programs is based on the professionals' views on quality improvement. An SP department could have the best quality management systems in place, but without participant buy-in, it will not result in improved outcomes. Take a quick assessment of how the OR team reports bioburden, evaluate how the SP technician determines what instrument is requested on a phone call, and/or analyze the general disposition of the entire team when process failure is reported. These scenarios, and many others, can provide insight into the current disposition towards quality.

Conclusions

The SP department has a significant opportunity to incorporate the quality concepts that have developed over the years. If department foundations include clear expectations, then

The Seven Wonders of QMS

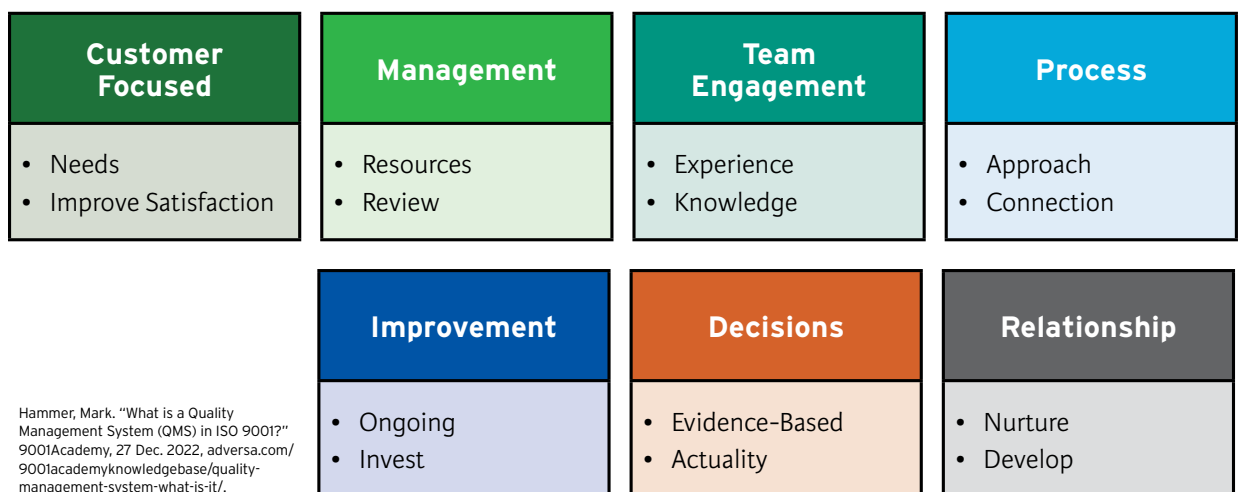


Figure 1. The goals and processes of effective Quality Management Systems (QMS)

everyone involved can achieve consistency in quality outcomes. Appropriately designed quality programs provide opportunity to reach clearly articulated goals by utilizing QMS. Through a robust quality assurance process and quality control protocol, the SP department learns to collaborate and support each other. As a result, quality culture can provide opportunities for growth, collaboration, and incorporating all aspects of the positive patient safety outcome. **HPN**

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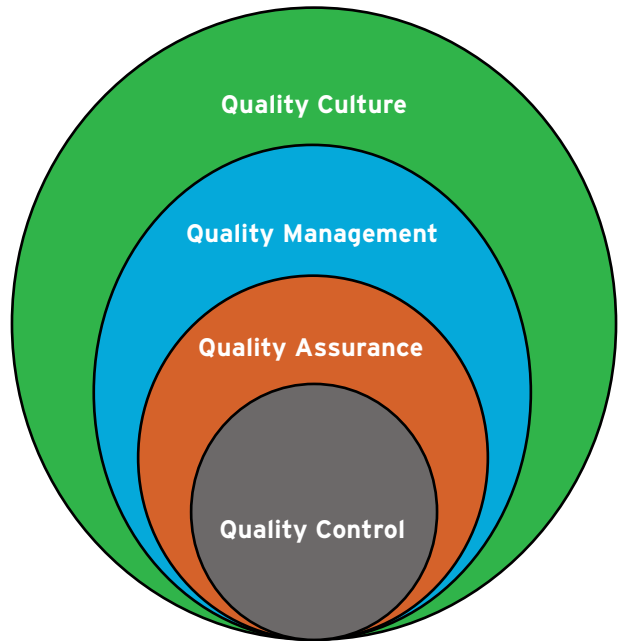


Figure 2. Illustration of how quality components arrange together to improve outcomes

Education Nation: Sterile Processing Quality Management Systems - Practice Quiz

1. **The concept of quality originated in the 1920s industry boom.**
 - A. True
 - B. False
2. **Quality culture is defined by positive and negative quality instances.**
 - A. True
 - B. False
3. **The Perioperative team consists of Doctors and Nurses only.**
 - A. True
 - B. False
4. **A robust quality management system includes:**
 - A. Quality Culture
 - B. Quality Control
 - C. Quality Assurance
 - D. All of the above
 - E. None of the above
5. **Quality management systems provide SP leadership with an opportunity to tell their team what to do.**
 - A. True
 - B. False
6. **QMS key factors to consider include:**
 - A. They are not unique to the facility
 - B. Leadership is responsible for its success
 - C. The needs of contributing departments
 - D. All of the above
 - E. None of the above
7. **Quality control and quality assurance can be used interchangeably.**
 - A. True
 - B. False
8. **Quality programs provide a foundation for expectations.**
 - A. True
 - B. False
9. **Quality:**
 - A. Is a measurable concept
 - B. Specific to the SP department
 - C. Do no consider department goals
 - D. All of the above
 - E. None of the above
10. **QMS, Quality Assurance, and Quality Control need to be rooted in the team's day-to-day operations**
 - A. True
 - B. False