Moisture events: Is quality management the cure?

by Michele McKinley

D o you agree that a wet pack or a moisture event is every sterile processing department’s (SPD) nightmare? Just the sound of those words in my own head makes my skin crawl. Wet packs make you nervous because they mean something went wrong, and now you or your team must investigate and find the cause. So, you begin the investigative process: you initiate a recall, notify the supervisor and the facility’s engineer, and of course, call the sterilizer manufacturer because there must be something wrong with the sterilizer. Oh, wait, there is one more thing; you discover that the major bone tray that was sterilized in the same load as the wet pack is currently in use. Ugh! You must notify both the operating room supervisor and the infection preventionist. So, you begin the investigative process: you initiate a recall, notify the supervisor and the facility’s engineer, and of course, call the sterilizer manufacturer because there must be something wrong with the sterilizer. Oh, wait, there is one more thing; you discover that the major bone tray that was sterilized in the same load as the wet pack is currently in use. Ugh! You must notify both the operating room supervisor and the infection preventionist. At this point, no one is happy, everyone is defensive, the finger-pointing starts, and all hope of working through the issue is lost. Sound familiar?

Gone are the days of flying by the seat of your pants in reacting to a patient safety-related event. Now that SPD teams are gaining credibility as sterile processing professionals, hospital customers are beginning to view them as subject matter experts (SMEs) in instrument sterilization. It’s no longer acceptable for this department to be passive and reactive; they must be assertive and proactive to ensure patient and employee safety. They must work toward making instrument processing a non-event process.

Moisture events are among the most difficult situations SPD personnel have to deal with, and all departments encounter this issue at some point in time. Investigating a moisture event may leave you feeling as though you are ‘chasing your tail.’ You ask yourself, “Is it even possible to eliminate moisture events?” With the right structure, processes, and accountability for adherence to policy and procedure, it is. At the very least, the risk can be reduced substantially.

Quality management: not just for factories

In healthcare today, quality is a hot topic. It is very common to hear or read about a healthcare organization’s commitment to “high quality care,” “performance improvement measures,” or “quality and patient safety.” In fact, your organization may already have a quality management system for the entire organization, sometimes referred to as “total quality management (TQM),” or may be planning to implement one. What does that mean to you and your department? How can the SPD benefit from a quality management system (QMS)?

A QMS is a “collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is expressed as the organizational structure, policies, procedures, processes, and resources needed to implement quality management.”¹ A well-developed QMS is of great value to any type of organization, whether they are a factory producing a widget, a healthcare system providing treatment and care to community members, or a SPD processing and delivering sterile instrument sets to the operating room.

To better understand the benefit of a QMS, it is helpful to understand what TQM is. This term was coined by the United States Naval Air Systems Command to describe its management approach to quality improvement.² Since then, TQM has taken on many meanings. Simply put, TQM is a management approach to long-term success through customer satisfaction. The method requires the participation of all members of an organization towards improving processes, products and ser-
services, as well as their work culture. When successful, it improves both the culture of the organization and its service community.

**Deming’s principles**

W. Edwards Deming, born in 1900, was a statistical consultant. His work had a “profound influence on the industrial world.” Deming realized that analyzing processes to assess their reliability, consistency, and stability should not be reserved exclusively for manufacturing; they were quality improvement efforts “just as appropriate and vital to many non-manufacturing processes and systems” [e.g., sterile processing]. TQM begins with the management team, but there are valuable lessons to be learned by the whole department.

Deming created 14 Points of Management to help people understand and implement his way of thinking. The twelve most relevant are briefly explained here:

1. **Create constancy of purpose for continual improvement and resource allocation.**
2. **Adopt the new philosophy for economic stability by refusing commonly accepted levels of delays, mistakes, defective material, and defective workmanship.**
3. **Cease dependence on inspection—build quality into the product or service from the beginning.**
4. **Continually seek out problems to constantly and forever improve quality and productivity.**
5. **Institute modern methods of training to make better use of management and employees.**
6. **Focus supervision on helping people do a better job and empowering them to take immediate action when a concern arises.**
7. **Drive out fear—encourage effective two-way communication.**
8. **Break down barriers between departments.** Encourage teamwork to tackle problems and find solutions.
9. **Don’t use slogans, posters, and exhortations** that demand zero defects and new levels of productivity without providing the methods and resources to achieve those goals. Replace them with helpful supervision and aids for continual quality improvement and productivity.
10. **Remove all barriers that inhibit a worker’s right to pride of workmanship.**
11. **Institute a vigorous program of education and retraining to keep up with changes.**
12. **Clearly define top management’s permanent commitment to quality and productivity.**

Many of these guiding principles contribute to establishing a new work culture that strengthens and educates the team, gives them a strong role and voice in the improvement process, and helps them focus on identifying and eliminating problems from start to finish.

**Put theory into practice**

So, where do you begin? First, you must clearly identify the problem that is a challenge to producing a quality product or service. In this case, the problem is a moisture event. Moisture events occur during steam sterilization, so it’s important to understand the steam sterilization delivery system and sterilization process. The graphic below presents a review of the process.

**Building your QMS team**

Since multiple departments and factors influence the steam sterilization process and its outcome, a team of people from several departments is required to develop a moisture event prevention QMS. At a minimum, the team should include, but is not limited to, representatives from the SPD, surgical department, infection prevention, risk management, quality management, surgeons, facilities team, boiler technicians, loaned tray vendors, sterilizer manufacturers and packaging materials manufacturers.

**Performing failure analysis**

The goal is to prevent the occurrence of moisture events. A preventative action plan is a key component of a quality management system. It is the responsibility of the QMS team to identify known or potential risks in the process that may result in a moisture event.

In the case of preventing moisture events, there are two functional elements that are independent but interrelated, so both must be analyzed; the steam delivery system and the steam sterilization process. For each of these, the QMS team must consider what could go wrong in the process, and the effects of a failure. This is referred to as identifying a failure mode – or identifying a risk by analyzing its potential or known root cause.

The QMS team performs risk identification as a collective effort. It is recommended that team members use multiple sources for data collection (e.g., observation of personnel activities and reports from other departments, including inspection findings, complaints, recalls, and incident reports) to create a comprehensive list of risks. Keep in mind that risks can be actual, potential or perceived, and not all risks will be identified in the initial analysis.

There are several methods available for finding root causes. One method is ‘process failure modes and effects analysis’ (PFMEA). It aims to identify and reduce the
risk of process failures. Let’s review this method’s typical steps.

Begin the PFMEA by defining the process functions and requirements. For the steam delivery system and the steam sterilization process, the QMS team must consider what could go wrong, and the effects of a failure.

Once a root cause of each risk has been identified, the next step is to determine the probability of that event occurring, and if it does what its severity (how serious the impact to patient safety and the healthcare organization) would be. A common method is to calculate a “risk rating” for each risk by assigning quantitative and/or qualitative values to key risk criteria. This requires using these risk ratings to analyze and evaluate how acceptable the risk is. For example, qualitative risk severity levels determined by the healthcare organization can be plotted in a matrix against the determined semi-quantitative probability levels, to arrive at risk ratings. The team then compares these risk ratings to their predetermined risk goals to decide if a risk is acceptable or unacceptable. An unacceptable risk “may require mitigation to reduce or minimize one or more of the key risk criteria.”

The QMS team is expected to recommend risk mitigations (i.e., preventive/corrective actions) for each unacceptable risk, to reduce its potential impact. The preventive and corrective actions are then tested, and based on test results, adjustments are made. The PFMEA should be performed and corrective actions restated as needed. The department should also continue with routine audits and reporting.

**Documentation is king**

Thorough documentation is important for reporting and for future analysis of the process. Tools such as checklists, work instructions and standard operating procedures, for example, should be developed to assure proper documentation, assist in ongoing audits, ensure compliance and promote training and education. See examples below.

**Conclusion**

The word ‘quality’ is used so often today that we may be numb to its meaning; “the degree of excellence of something.” When you purchase a product or service, don’t you expect that the product or service will be excellent? Of course, you do; we all do. Healthcare customers, whether internal (operating rooms) or external (patients, the community) share the same expectation. In fact, in healthcare, quality is assumed.

The surgical department is the SPD’s largest customer, and they expect quality “products” all the time and every time. The SPD has an obligation to assure optimal quality, not only for their direct customers but also to support the reputation of the organization as a whole.

Customer satisfaction is being actively monitored internally and externally these days. When a moisture event occurs, regardless of the cause, the consequences can lead to very poor patient and surgeon satisfaction. To assure that quality services and products are consistently delivered, the SPD must develop and implement a quality management system that prevents moisture events and other avoidable “never events.” And the department culture must assure the participation of every team member. As the Navy would say, “All hands on deck!”

**References:**

5. Google online dictionary (n.d.). Retrieved from https://www.google.com/search?q=what+does+quality+mean%3F&aqs=chrome.69i57j0l5.11951j0j8&sourceid=chrome&ie=UTF-8

**Sample of a moisture event preventative action planning document**

**Department POTENTIAL CAUSES PREVENTION STRATEGY**

<table>
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<tr>
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**Sample potential causes and prevention strategies checklist, including department responsible, possible causes, and recommended preventative strategy to be executed**

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Circle the one correct answer:

1. Creating a constancy of purpose toward continual improvement is the responsibility of department management and ____________?
   A. SPD shift-leader
   B. OR manager
   C. Quality department
   D. Organization leadership

2. TQM requires that all members participate in improving ________, ________, and ________.
   A. Processes, products, and customer satisfaction
   B. Customer satisfaction, service, and quality
   C. Products, services and processes
   D. Services, processes, and quality

3. TQM is a management approach to long-term success through ________.
   A. Moisture event prevention
   B. Customer satisfaction
   C. Policies and procedures
   D. Resources and processes

4. W. Edwards Deming believed that quality improvement efforts are appropriate for manufacturing and non-manufacturing processes and systems.
   A. True
   B. False

5. W. Edwards Deming’s philosophy for economic stability implies that common levels of delays, mistakes, and defective material are acceptable on rare occasions.
   A. True
   B. False

6. Identifying the risk for failure in a process can be accomplished by a ________.
   A. Risk assessment
   B. Process analysis
   C. FEMA
   D. PFMEA

7. A moisture event QMS key component includes a preventative action plan. Which of the following is not part of the preventative action plan?
   A. Multi-disciplinary team
   B. Kick-off meeting
   C. Hiring an outside consultant
   D. Development of tools (e.g., checklists)

8. Potential causes and preventative strategies are executed by the ________.
   A. Responsible department
   B. The multidisciplinary team
   C. Management
   D. SPD

9. Thorough documentation is important for:
   A. Reporting and future process analysis
   B. Ensuring compliance
   C. Promoting training and education
   D. All of the above

10. Conducting a risk assessment of the steam delivery system is only necessary after you have experienced a moisture event.
    A. True
    B. False

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