

Raising
the Bar

on Quality in Sterile
Processing: >>

Adopting Failure Modes and Effects Analysis in the Healthcare Setting

By Tim Brooks and Jessica Hackwell

A MISTAKE IN THE WORKPLACE may not be a big deal in some professions, and often the mistake may only affect the person who committed the error. Some mistakes, however, can be far-reaching and can have potentially harmful outcomes. For example, central service/sterile processing department (CS/SPD) employees in healthcare facilities play a critical role in the facility's infection prevention program, and any workplace errors in their environment can have serious repercussions throughout the facility.

When a mistake is made in a hospital CS/SPD, the typical response is to conduct a swift investigation, identify the person(s) responsible, initiate corrective action, perhaps conduct a brief training or retraining session, and then get back to business as usual. Depending on the error, this process may be sufficient; but when patient safety is in jeopardy, a different approach and a thorough review of current quality improvement processes may be necessary.

Yuma Regional Medical Center (YRMC) in Yuma, Ariz. is an exception to the rule. Our 328-bed hospital is the primary healthcare provider within a 180-mile radius. Having no competition in the area, one might expect that YRMC would have a somewhat relaxed attitude toward quality processes. This assumption would be wrong, however, because over the past 12 months, our medical center has initiated an extensive effort to incorporate Failure Modes and Effects Analysis (FMEA) methodology into our daily activities as a means to improve quality and reliability throughout the facility, and specifically to improve the quality of our patient care.

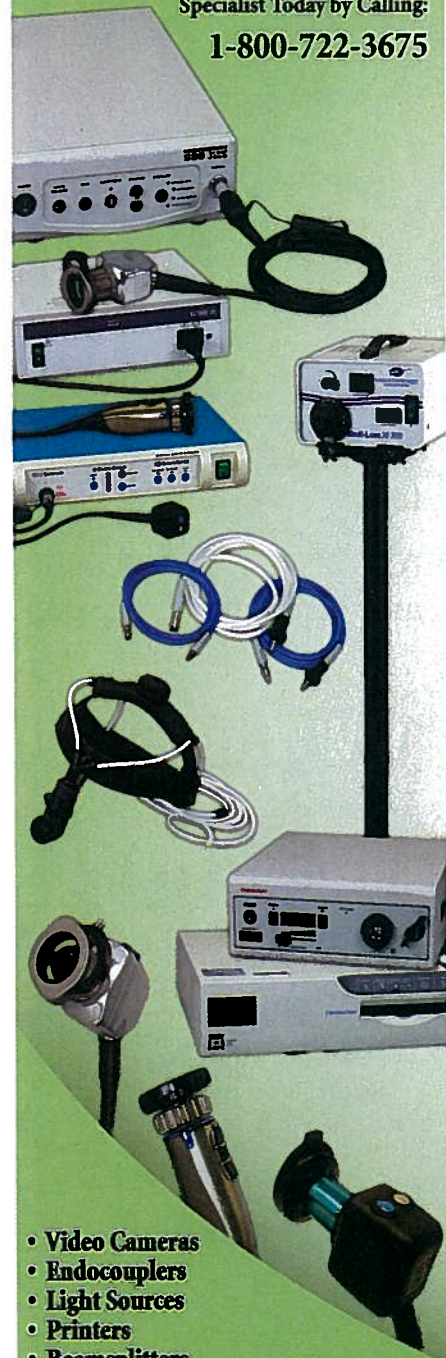
What is an FMEA?

FMEA is not new and has been used extensively worldwide. The methodology was developed by the National Aeronautical and Space Administration (NASA), where it was used to identify potential risks in programs and devices being developed. FMEA was later adopted by other industries, most notably the automotive industry, and is now a globally recognized critical step in the design and control of processes. In the healthcare manufacturing industry, FMEA is required by the Food and Drug Administration in the design and manufacture of all medical devices, pharmaceuticals, and contract sterilization. For example, a medical device would require FMEA to be performed in the manufacturing process, the actual use, and the application of the device. In recent years FMEA has become more widely used by Six Sigma practitioners and is being adopted in many industries.

FMEA can be performed in various ways and for various purposes, but it applies a consistent method, which is a systematic approach to identifying and analyzing what can go wrong, the probability of it going wrong, and the effect when it does go wrong. This way, events that can go wrong or can result in a serious outcome can be identified and prevented. FMEA focus areas fall into the following categories:

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- System – global system functions
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- Software – software functions

Recently, the YRMC Central Service/Sterile Processing Department (CS/SPD) had the opportunity to be actively involved in an FMEA process following an incident involving the release of items for patient care that did not successfully complete a steam sterilization cycle. Although this incident did not have any patient care consequences, the staff recognized that this type of error could be devastating to a department and could have serious short-term and long-term effects.

From a patient care perspective, an error of this type could result in a surgical site infection, or worse. From a department perspective, this error immediately results in the lost productivity, waste and expense necessary to retrieve and reprocess the effected items. Potential long-term effects would take the form of a loss of confidence by internal customers and a reputation tainted by the perception of poor quality service. Because the consequences of such an error can be complex and widespread, the CS/SPD staff wanted to ensure that this type of incident didn't happen again.

Conducting the Analysis

With the close guidance of our quality services department, which had been overseeing quality improvement processes in other direct patient care areas of the hospital, the FMEA process was initiated and carried out in the CS/SPD over a six-month period.

Phase One: Development of the Flow Chart

Phase One consisted of a 45-day process and was spent developing a flow chart of the entire YRMC instrument processing workflow, including

a complete list of all activities within each area of the workflow. The flow chart began as a simple diagram, and evolved into an extremely detailed model that included all the steps involved with each activity in the workflow process.

At this stage in the process, all sterile processing staff members attended a one-hour weekly meeting that was dedicated to this project.

Phase Two: Development of the Failure Mode Model

After mapping out the instrument process workflow, the next 30 days were spent in Phase Two, which required identifying workflow areas where there was a potential for something to go wrong. In phase two, in order to identify these potential "failure points," a more in-depth analysis of each point in the workflow was performed and a list of risk points (potential failure points) were identified and documented in a Failure Mode Model spreadsheet. Since each potential failure point in the instrument processing workflow could be associated with very different levels of concern and weight, the failure points had to be scored to determine their potential impact. Each failure point was scored in three separate categories according to the severity of the failure, the probability of a failure, and how detectable a failure would be. A score of 1 to 4 was assigned to each risk point identified in each of the three categories to determine the risk priority number (RPN). For each category, scores were determined based on the following criteria:

Severity

- 1 = No problem (not severe)
- 2 = Small problem – slight concern
- 3 = Problem – concern
- 4 = Very severe

Probability

- 1 = Remote (0-25 percent)
- 2 = Uncommon (25-50 percent)

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3 = Occasional (50-75 percent)

4 = Frequent (75-100 percent)

Detection

1 = Detection always occurs (75-100 percent)

2 = Detection often occurs (50-75 percent)

3 = Detection rarely occurs (25-50 percent)

4 = Detection never occurs (0 -25 percent)

After each risk point was scored, the RPN was determined by multiplying the numbers in each category; S x P x D. The RPN could range anywhere

from 3 to 64, depending on the risk level. The risk priority number was then used to set priorities and determine the action level of each potential failure mode.

Phase Three: Development of Action Plan

During Phase Three, the intensive process improvement work was set into action. Over a six-month period, the FMEA focus group narrowed from weekly meetings with the entire department to a team of five key team leaders. In order to

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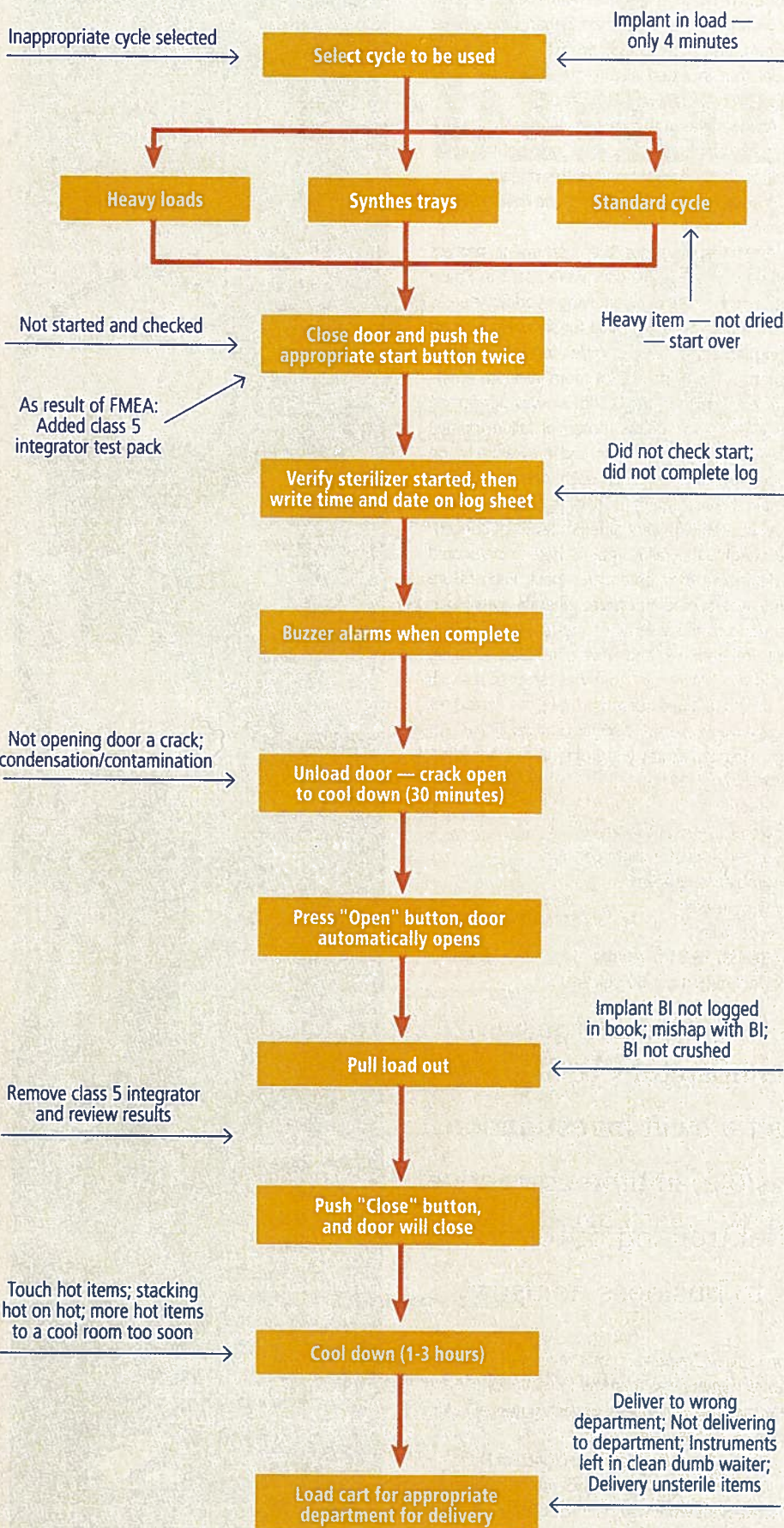
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ensure that all failure points were appropriately addressed, the team worked diligently to prioritize each failure point based on its risk priority number. Any failure point with an RPN score of 12 or less was addressed in routine in-service education programs. Failure points with scores greater than 12 were placed in the Action Items Follow-up document.

Once in the follow-up document, each action item was prioritized and the responsibility for each action item was assigned to one of the five team leaders. The team leaders then set target completion dates and were responsible for all activities involved with their assigned action items.

At the conclusion of activities for each action item, the team leader was also responsible for documenting "measurements of effectiveness" as part of the action items follow-up document.

FMEA in Action

The immediate area of concern that led to the initiation of the FMEA process was the steam sterilization workflow and protocol. In focusing on potential failure modes in this area, several were identified with risk priority numbers higher than 24. The action items within this area included:

1. Changing the sterilization load record to add documentation space for identifying implantable devices in the load and space to document if a biological indicator was included in the load.

2. Developing a load protocol for sterilizers (product mix, load contents, product sterilization parameter requirements and implant content, for example).

3. Reviewing staff scheduling for the second shift (from 2:30 to 11 p.m. — at YRMC this is also the last shift of the day) to ensure that the last steam sterilization load of the day is started by 9:45 p.m., and initiating a process to ensure that a staff member is present to remove that last load when it's complete.

4. Reviewing sterility assurance products currently available for use as a "safety net" to provide the sterilizer operator with an additional visual assurance that the sterilization cycle was successful.

Another interesting discovery during the FMEA process was in identifying instrument sets that the CS/SPD staff wanted to label as "Priority One" sets. These would include any set that contained an implantable device or any one-of-a-kind set. Surprisingly, the staff discovered that 224 out of 356 sets routinely processed belonged in the Priority One category. A decision was made to label these sets with permanent labels to alert staff members that these sets must be processed first. This change had such a visual impact that even surgeons began to inquire about the Priority One labels. Now the staff has an extremely helpful tool that they did not have before to ensure that they process these instruments before any others.

By making these simple work practice alterations, our medical center's CS/SPD has achieved a high level of assurance that the process failure they

previously experienced will not reoccur.

The added benefit of using FMEA to address quality issues has been that the entire instrument processing workflow has been thoroughly analyzed and many process improvement initiatives have been implemented as a result. Although this analysis was conducted as a quality improvement project, FMEA has now become an ongoing work-in-progress and has firmly established a new quality process mind set for all CS/SPD staff members at YRMC.

Conclusion

Sterile processing professionals are committed to doing their part in providing quality patient care. The CS/SPD professionals at YRMC have taken their work to the next level; they have raised the bar with their efforts to find better methods to identify every possible scenario in which their processes could fail, developed solutions to eliminate these potential failures, and provided education or altered current processes to meet their quality improvement goals. The use of FMEA in the healthcare setting is a proven process and an invaluable quality improvement tool that should be considered by any sterile processing department committed to improving their processes.

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Tim Brooks is director of surgical services materials management/CS/SPD at Yuma Regional Medical Center. He has 20 years of experience in sterile and supply processing management and serves on the Infection Control Committee, Value Analysis Committee, and OR Throughput Six-Sigma Committee at YRMC. Brooks is a member of the American Society for Healthcare Central Service Professionals (ASHCSP). Jessica Hackwell is the performance improvement coordinator at Yuma Regional Medical Center. In this role, she has facilitated performance improvement teams, task forces, focus groups, root cause analysis (RCA), and failure mode effects analysis (FMEA). She is board-certified in healthcare quality (CPHQ). Hackwell is a member of the Arizona Association for Healthcare Quality (AZAHQ), and will serve on their board as the education team leader-elect.

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Joint Commission Seeks Examples of Hand Hygiene Measurement Methods

OAKBROOK TERRACE, Ill. -- The Joint Commission is seeking comprehensive, innovative and cost effective hand hygiene measurement methods that address adherence to hand hygiene guidelines to share with healthcare organizations throughout the world, as part of its Consensus Measurement in Hand Hygiene (CMHH) project.

The proven strategies identified through this initiative will be published in a free, educational monograph that recommends promising practices for measuring hand hygiene compliance. The monograph, planned for publication in early 2008, will be the culmination of an 18-month project by the Joint Commission in collaboration with the Association for Professionals in Infection Control and Epidemiology (APIC), the Centers for Disease Control and Prevention (CDC), the Society for Healthcare Epidemiology of America (SHEA), the World Health Organization (WHO) World Alliance for Patient Safety, the Institute for Healthcare Improvement (IHI), and the National Foundation for Infectious Diseases (NFID).

Measuring compliance with hand hygiene practices during the delivery of care has long been complicated because of the resources needed to monitor the practices of many different care providers in numerous locations for meaningful periods of time. The absence of standardized approaches to measuring hand hygiene performance makes it impossible to determine whether overall performance is improving, deteriorating or staying unchanged as new strategic interventions are introduced.

Examples of promising practices for measuring compliance with hand hygiene guidelines are being sought from across a variety of settings, including hospitals, ambulatory care, home care, long term care, and behavioral health. Organizations submitting examples are asked to include supporting documentation, such as published studies or summaries of results regarding the use of the method, as well as a sample of data in the manner it is displayed (i.e., charts or graphs).

Submissions will be confidentially reviewed by an expert panel under the direction of Elaine Larson of Columbia University. If the expert panel determines that a submitted example has potential value to other healthcare facilities, the organization will be contacted for additional information and permission to include it in the monograph.

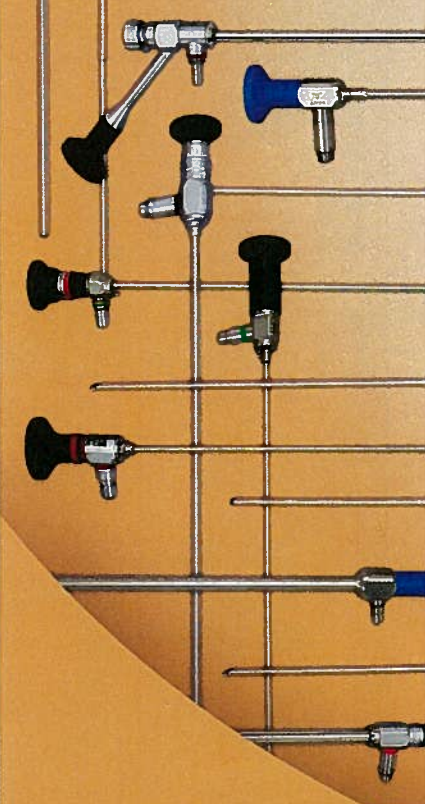
Examples may be submitted electronically at: http://www.jointcommission.org/AccreditationPrograms/hand_hygiene, or by mail to: Linda Kusek, Division of Research, The Joint Commission, One Renaissance Boulevard, Oakbrook Terrace, Ill., 60181, or via fax to: (630) 792-4616.

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