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LEARNING OBJECTIVES

1. *Identify the elements of a risk assessment.*
2. *List three ways to reduce SPD risks.*
3. *Explain how to mitigate risks associated with extended steam sterilization cycles.*

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SELF-STUDY SERIES

The basics of risk mitigation for the SPD

Assess, change, validate, and control

by Arthur Henderson and Chasity Seymour

Johnny, age 11, was told in no uncertain terms by his mother that there would be no PlayStation games for a week if she caught him sneaking cookies just before dinner. Mom wasn't due home for another 30 minutes, so he took a cookie and ate it. Johnny chose to take this risk based on the probability of Mom coming home early. His assessment: it's unlikely that Mom will come home and catch me, so I probably won't lose my PlayStation privileges.

All of us have been conducting risk assessments of one kind or another all our lives. Yet, when risk assessments are discussed in sterile processing departments, they become intimidating and sound like a foreign language. Risk assessments are simply a tool used to help ensure the safety of staff and patients. They identify, help reduce and manage the risks associated with reusable medical device processing.

Understanding your risks

Risk assessments begin with identifying potential negative outcomes and determining the probability of those outcomes occurring. In order to identify potential risks, it's necessary to have a complete knowledge of a process and all the steps that are a part of that process. Using Johnny as an example, his "process" was: Johnny walks into the kitchen, removes a cookie from the cookie jar, and goes to his room to eat it. But does this really describe everything he does? Johnny had to climb on the kitchen counter to reach the cupboard where the cookies are stored. He had to remove the cookie jar from the cupboard and place it on the counter. He had to unscrew the jar's lid and reach into the jar for the cookie … and so on.

Applying this to sterile processing, what may seem to be a simple process may have many steps and interactions to consider. As an example, let's look at biological monitoring of a steam sterilizer. The description of the process might sound like this:

1. Place biological indicator test pack on bottom shelf over drain
2. After the cycle, remove the biological indicator test pack
3. Incubate the biological indicator
4. If there is a negative result, release the load for use. If there is a positive result, reprocess the load and notify the supervisor

However, there is much more to this process. For example, even before the biological indicator test pack is placed in the sterilizer, the technician must decide whether a BI test pack is needed, which BI test pack to use, and how/where it will be placed on the sterilizer rack. Any one of these steps, if done incorrectly, can have serious consequences, so each step must be assessed for all its potential negative outcomes.

Once all the steps and potential risks have been listed, it's time to determine the chance of a negative result occurring and address the most serious risks. This is referred to as risk mitigation. The need for a facility to act on a potential risk depends on two factors: (1) the seriousness of the event, and (2) the likelihood of it happening. When a result could cause serious harm or even death to a patient, a facility must act to prevent it. However, if the result is merely a nuisance that will not cause harm, it may not be necessary to do anything. Let's look at this process using a real-world example.

Risks for extended cycles

Extended steam sterilization cycles have been a hot topic in the healthcare industry for many years. These cycles have longer exposure and/or dry times than the sterilizer's validated cycles. Several concerns have been voiced by industry leaders and the Food and Drug Administration (FDA) regarding extended cycles. The FDA states in their guidance document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling – Guidance for Industry and Food and Drug Administration Staff that "extended cycles pose serious technical challenges in healthcare settings" … for which there are "limited or no FDA-cleared sterilization accessories" such as biological indicators, chemical indicators and sterilization packaging for use in extended

cycles. How do these technical challenges relate to risks?

Biological indicators (BIs), chemical indicators (CIs) and sterilization packaging are designed and validated to work in standard sterilization cycles. They help to identify sterilization process failures that are based on standard cycle parameters and times. When a cycle parameter is changed, or times are extended, the BIs and CIs are unable to detect failures associated with the changed parameters or extended times. Specifically, a BI may show a passing condition because the necessary parameters for a standard (in this case, a shorter) cycle were achieved, but it's not possible to tell from that indicator's results whether the necessary parameters for the longer extended cycle were achieved. This creates a risk of a potentially contaminated device being used in a procedure, and potetial transmission of infectious materials to the next patient.

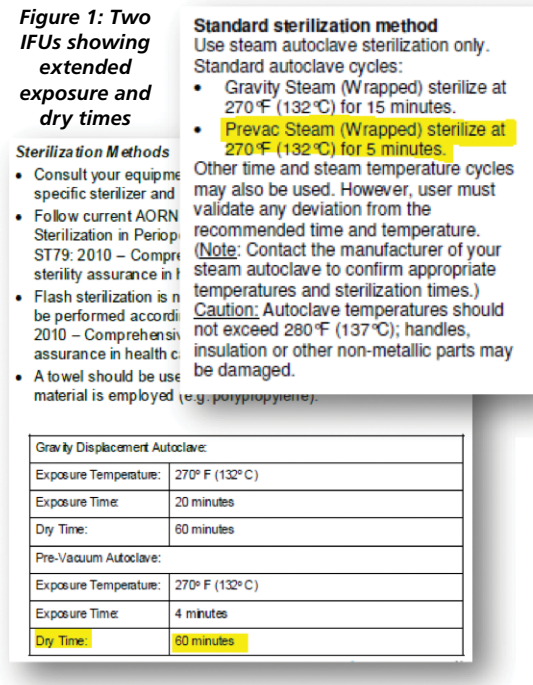

Figure 1: Two IFUs showing extended exposure and dry times

There is another extended cycle risk; it concerns sterilization pouches that can become brittle when exposed to an extended exposure or drying time. This brittleness can cause a premature breach in the package's integrity that allows the devices inside to become contaminated.

In the case of inconclusive BI and CI readings, the technician would not be able to know whether there was a problem during the extended time of the sterilization process. In the case of damaged pouches, the OR may find the integrity breach during inspection of the packaging when preparing it for a procedure. A single patient infection can cause serious complications, suffering and even death for the patient, along with additional costs and penalties for the hospital. For these reasons, it's clearly important that healthcare providers do all they can to eliminate potential infection risks. So, what can be done?

Reducing risk

There are many techniques that can be applied to lower or eliminate the possibility that harm will occur to a patient. One obvious solution is to eliminate the risk entirely by not performing the risky action (using the devices to perform the procedure). But these reusable medical devices help surgeons deliver critical and sometimes life-saving therapeutic treatments for patients, so cancelling the procedure or not using the device are not always options.

Fortunately, there are other ways to reduce the chance of a harmful event. Generally, these risk reduction efforts fall into three categories:

- *Change the process*
- *Validate the process*
- *Increase checks and controls*

Change

Changing a process can significantly reduce or even eliminate the chance of something harmful happening. In the case of extended cycles, using extended cycles poses serious risks when departments use sterilization accessories (BIs, CIs and sterilization packaging) that are not designed or validated for extended cycles. So, changing the process by using only validated standard steam sterilization cycles can remove these risks.

Departments can eliminate the need for extended cycles by working with their sterilizer and surgical device manufacturers. There may be new sterilization guidelines and recommendations available in new or updated manufacturer instructions for use (IFU) that cite validated standard steam sterilization cycles for newer devices. Or, the process can be changed by using an alternative sterilization process. Devices that require extended steam sterilization cycles often can be processed in a standard vaporized hydrogen peroxide sterilization cycle, for example.

If the sterilizer and/or device manufacturers do not offer an alternative solution to eliminate extended sterilization cycles for the devices, the next option is to purchase new surgical devices or sets that perform the same function but are validated for standard sterilization cycles. Since replacing devices can be a very costly and daunting task for a hospital, it's wise to consider sterilization requirements when new surgical devices are being purchased and when they are being replaced. It may also be necessary to put a plan in place to phase out use of the older devices.

Although both these process-change options provide an opportunity to eliminate the risk posed by using and inadequately monitoring extended cycles, they are not always feasible. If changing the process to eliminate risk is not possible, then validating the process may be the way to reduce risk while accepting that some risk still exists.

Validate

Validating a process helps assure that it performs consistently and yields the intended results in a specific process. Validation is "a documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specification … Process validation is specific to the machine, utilities, and processes used in a specific location." (AAMI: Basic Concepts).

Validation must be performed when it is not possible to objectively confirm that a product meets its design specifications. In this case, the sterility of reusable medical devices processed through an extended cycle cannot be objectively confirmed for the reasons discussed above. Since microbial contamination is not visible to the human eye, and testing devices after processing would result in a contaminated device that could not be used, validating the sterilization process in specific equipment at a specific facility would be a necessary and valuable component of a risk reduction effort.

The first step in a process validation initiative is the validation master plan. This structured approach identifies each process and processed "product" that requires qualification and testing. It also establishes the acceptable results that will be used to validate the process.

In the case of extended cycles, validating the process would require testing the ability of the medical devices, sterilizers and sterilization packaging to consistently achieve and maintain sterility. The sterilization process must demonstrate its ability to kill one million *Geobacillus stearothermophilus* spores, placed in or on each device in difficult-to-sterilize locations , when it is packaged according to hospital procedures and device

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Self-Study Test Answers: 1. A, 2. B, 3. D, 4. B, 5. A, 6. D, 7. A, 8. B, 9. C, 10. C

IFU. These processed devices must also function to manufacturers' specifications and be free of toxic or hazardous residue after sterilization. Extended-cycle processed packaging must demonstrate that it remains a barrier to contamination for the desired storage time. Since hospitals are not usually equipped to conduct validation testing, they rely primarily on manufacturers to provide validated parameters and processes for their devices and products.

Check and Control

The third method to reduce risk is to implement additional checks and controls designed to capture events that could lead to a potential negative outcome. Tests, measurements and inspections can identify conditions that could lead to harm.

All sterilization processes carry the risk of failing to deliver the critical parameters of sterilization during a cycle. This can result in a non-sterile medical device being used during a procedure and causing serious consequences. Since they're invisible, the possible existence of surviving microorganisms can only be deduced by using biological indicator tests, chemical indicator tests, cycle parameter data and visual inspection of packaging for breaches in the sterile barrier. These tests and observations help identify whether a cycle failed to deliver the parameters necessary to sterilize, or whether a pouch has maintained sterility of the medical devices inside it. The risk always exists, but the use of checks and controls reduces the possibility that negative events will go undetected, and therefore it also reduces the overall risk of negative consequences.

There are two types of risk controls; *preventative* and *detective*. **Preventative controls** are used to identify conditions that could cause a failure before they occur. Bowie Dick testing is a preventative control. It detects a condition in the sterilizer's performance that could cause the sterilizer to fail during its sterilization process**. Detective controls** identify failures during the process. Biological indicator tests, for instance, are loaded with the instruments into the chamber and are run through the cycle to detect whether the sterilizer completed all parameters for that cycle (passed) or did not achieve sterilization conditions (failed).

Figure 2: Specialized test pack designed for 10-minute prevac cycles operating at 270°F.

Regardless of the risk control type, it must be designed for the process it is being used to test. If a risk control is unable to detect a specific failing condition, it cannot lower the related risks. Standard steam sterilization cycles have well-defined risk controls identified in ANSI/AAMI ST79 (2017) including steam quality tests, Bowie Dick tests, BIs, CIs, and others. When controlling for the risks associated with extended cycles, users must ensure that the tests and products they use for testing will actually detect failure and therefore help reduce the risk of serious consequences from a failed extended sterilization cycle.

Let's assess two risk control tests as examples. A Bowie Dick (BD) test is required by ANSI/AAMI ST79 each day that a prevacuum (prevac) steam sterilizer is in operation. This *preventative* test uses a special cycle designed to measure the air removal efficiency of the prevac sterilizer before loads are run. Whether a standard or extended prevac cycle is used, the vacuum preconditioning phase is the same, so the BD test is appropriate for both standard and extended cycle sterilization processes.

The second test, which is used as a *detective* risk control measure for prevac sterilizers, is a BI within a process challenge device (PCD). BI PCDs show that the sterilizer delivered the conditions necessary to sterilize for specific time and temperature parameters. Each PCD is designed to deliver a challenge for a specific sterilization cycle. A PCD that is labeled for a 4-minute, 270°F prevac cycle is designed to show passing conditions at the end of the 4-minute prevac cycle. It will show a failing result if the critical parameters of this cycle are inadequate. Since a 10-minute 270°F prevac cycle requires 6 additional minutes, a challenge pack labeled for 4 minutes would not provide the additional challenge necessary to detect the failure of a 10-minute cycle.

Residual risk

Even after all mitigation efforts are in place, some risk may remain. There may even be times when the risk cannot be reduced. For example, there is no biological indicator test pack with specific claims for a 5-minute sterilization process, so the department may be unable to apply a risk control to that cycle. In these situations, the team must weigh the benefits of using the extended cycle and its associated medical devices against the amount of residual risk that remains after all controls are in place. Sterile processing management, the hospital's infection control professionals, and the risk management team should be involved in this decision.

Risk management is worth the effort

SPD teams continuously strive to improve the processes that deliver sterile reusable medical devices in a safe and timely manner. But to assure the safety of everyone who comes into contact with these devices, they must understand all the risks inherent in their processes. Risk assessments help SPDs identify the specific risks patients and staff may face from the processes, procedures and individual steps technicians perform in their facility. Once these risks are identified, mitigation efforts help reduce the chances of negative outcomes for patients and financial consequences for hospitals. A thorough SPD risk assessment and mitigation initiative can help the department discover and manage unrecognized risks and contribute to safe processes and more consistent results. This, in turn, can make the SPD a major contributor to their hospital's risk management program and to its bottom line. HPN

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CONTINUING EDUCATION TEST • SEPTEMBER 2019

The basics of risk mitigation for the SPD

Assess, change, validate, and control

Circle the one correct answer:

1. **What does a risk assessment allow SPD managers to do?**
   a. Identify, reduce and manage risks
   b. Identify, reassign and manage risks
   c. Identify, reduce and migrate risks
   d. Identify, reassign and mitigate risks

2. **The likelihood of an event occurring is paired with which other factor to assess the importance of a risk?**
   a. Probability/chance of occurrence
   b. Severity/seriousness
   c. Location of the risk
   d. Quality control variables

3. **Why do extended cycles pose a "serious technical concern" in healthcare facilities?**
   a. The steam sterilizers last too long
   b. The medical devices break sooner
   c. Container systems must be used
   d. There are limited risk control accessories, such as BIs, cleared for these cycles

4. **Which is an example of a process change used to reduce risk?**
   a. The manufacturer provides a new IFU that shows a standard steam sterilization cycle option
   b. The item is sterilized in a vaporized hydrogen peroxide system instead of an extended steam sterilization cycle
   c. Employing a chemical indicator strip within the pack
   d. The process is validated to ensure that the process can sterilize the medical device

5. **Validation is a documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with a predetermined specification.**
   a. True
   b. False

6. **What does the master validation plan identify?**
   a. Products, test methods and sales contracts for the equipment
   b. The risks associated with the process
   c. BIs, CIs and BD tests to be performed regularly
   d. Processes, products, and the required acceptance criteria

7. **What is a preventative risk control?**
   a. A test, measurement or inspection that identifies a problem that may cause a product failure
   b. A test, measurement or inspection that identifies a product failure
   c. A test, measurement or inspection that occurs after the product is processed
   d. A test, measurement or inspection that uses performance history

8. **What is an example of a detective risk control?**
   a. Bowie Dick Test
   b. BI PCD
   c. Both a and b
   d. None of the above

9. **What should be considered when identifying tests for controlling risks?**
   a. Measurements should be taken before and after
   b. The test should be hard to use
   c. The test should be appropriate for the risk being controlled
   d. The test should be for steam sterilization

10. **Which professionals should be involved when evaluating residual risks in sterile processing?**
    a. Maintenance and risk management
    b. Risk management and the ER
    c. Infection prevention and risk management
    d. Infection prevention and maintenance

CONTINUING EDUCATION TEST SCORING

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