CHL SELF-STUDY LESSON PLAN

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# Risk Assessments: Their Important Role in Promoting Quality in Sterile Processing

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**LEARNING OBJECTIVES**

1. Define key words associated with risk assessment
2. List the tasks performed for each stage of risk management
3. Develop a risk management plan for Sterile Processing

Risk assessments help to set polices, implement necessary quality assurance (QA) tests, and ensure practices promote the best performance of staff and facility processes. Still, few Sterile Processing (SP) standards, guidelines or recommended practices provide details on how to perform a risk assessment, and fewer explain what do to with the results. This lesson will help provide some of that essential guidance.

## Objective 1: Define Key Terms Associated with Risk Assessment

Risk assessments are an ongoing part of an effective risk management program. They are performed to identify lapses in practice or other events that could cause harm and then help determine the likeliness of such events. A risk management system strives to remove the potential for harm by mitigating all the risks found during the risk assessment. Before diving into the risk assessment process, it is important to understand some key terms.

**Harm:** Harm includes injury to people, damage to equipment or facilities, and added monetary expenditure. Examples of harm associated with sterilized items include patient infections, added labor from extra reprocessing, and added costs of replacement instrumentation.

**Nonconformity:** The result of nonfulfillment of a specified requirement. Examples include instruments with residual soil after cleaning, incomplete instrument sets, and late case carts.

**Corrective Action:** Action taken to eliminate the cause of a detected nonconformity or other undesirable situation. This should not be confused with the correction. When the assembly team finds a soiled instrument, it must be recleaned. Recleaning (the correction) must happens immediately. Example: During the investigation, the team found a damaged old brush in use. Establishing a policy to dispose of the brush after each use prevents using an old brush in the future; this is the corrective action.

**Preventative Action:** Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. Examples of preventative actions include preventative maintenance, using pick lists, and regular water quality tests.

**Risk:** The possibility of a nonconformity occurring that may lead to harm.

**Probability:** The likelihood of occurrence.

## Objective 2: List the Tasks Performed for Each Stage of Risk Management

Risk management is the process by which facilities find and manage risk. Risk management includes five distinct stages:

- Identification;
- Assessment;
- Evaluation;
- Mitigation; and
- Monitoring.

Identification searches for all the harm that might occur as a result of nonconformities in the process. A nonconformity can happen any time there is a deviation from the process. Using the wrong sterilization cycle, missing a step in the cleaning instructions, and out of specification humidity levels in sterile storage are all examples.

Some processes are simple, with few steps; other processes are complex, with many steps, multiple pieces of equipment and several technicians involved. The more complex the process, the easier it is to miss potential nonconformities. That is why it is important to map the process. Process maps show all tasks performed, who performs each action, where handoffs and decisions are made, and all tools and equipment needed. The team that develops the process map should include the staff that does the work. It is critical to review manufacturers' written instructions for use (IFU) for equipment, supplies and instrumentation identified in the process map. *Never assume that in the current process, IFU are followed completely and accurately each time.*

### Instrument Set Sterilization

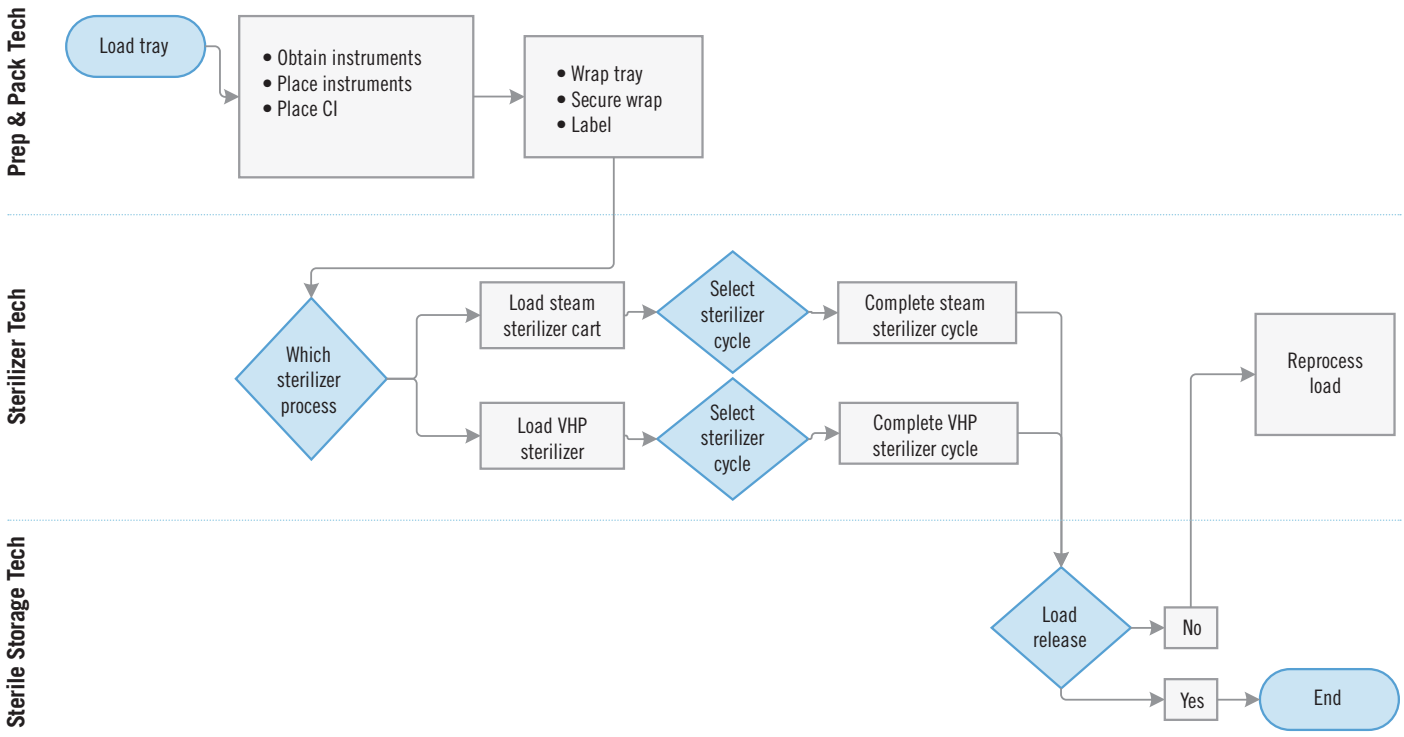


**Figure 1: Example of a process map**

The identification of harm can begin by listing potential harm or by finding potential nonconformities. When starting with a harm, the team brainstorms potential harm. Risk assessment teams use the process map to find nonconformities that could lead to that harm. For example, one harm is to delay the surgery. Using the SP process map, the team would identify all the things that could go wrong that would result in a delayed surgery. The best way to do this is to ask, "Why?"

A single "Why" can have many answers. The delay may have been due to a missing instrument, dirty instrument or failed chemical indicator, for example. Each scenario will be explored, and the root cause discovered, until a comprehensive list is completed.

The second method of risk assessment starts with a nonconformity and determines all the possible harm. The Ishikawa (fishbone) diagram is a common method; it focuses on the five sources of nonconformities: materials, environment, process, personnel, and equipment. Let's look at an example in **Figure 2**. When a spray arm is clogged, residual soil may be left on a device. That soil may be found by SP professionals during assembly or by those in the Operating Room (OR) prior to use. There is also a possibility that it would not be found until it is used in the procedure. The fishbone diagram looks at the effect that each of these events has. If the device was found in the SPD, it would need to be recleaned. The spray arm may require repair before it could be used again. The extra processing time from recleaning could delay the device's return to the OR, possibly delaying the procedure. Increased cost from recleaning the instrument is also possible. If the device was found in the OR, they would need to replace it. Additionally, the device may have contaminated the back table. Both could lead to delayed procedures.

The worst-case scenario is the soil is not detected and leads to a surgical infection. The infection increases cost to the patient and facility. Even worse, the infection could lead to the patient's death.

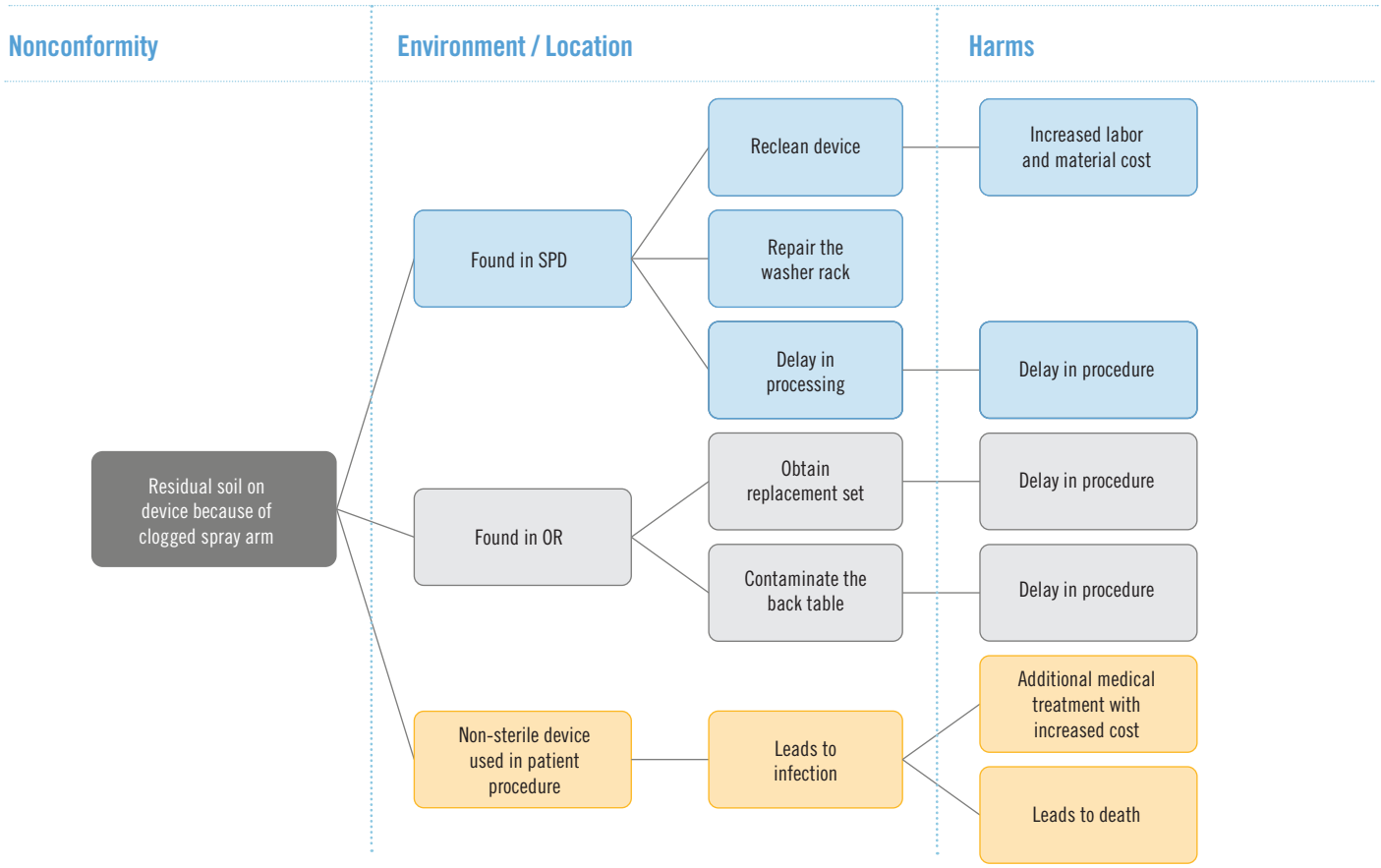


**Figure 2: Fishbone diagram example of residual soil on device**

| Harm | Nonconformity | Probability of nonconformity resulting in harm | Severity of the harm |
|---|---|---|---|
| Increased labor and material cost from recleaning device with residual soil | Washer spray arm is clogged | Likely | Negligible |
| Patient infection | Washer spray arm is damaged | Not likely | Catastrophic |
| **Patient death** | **Washer spray arm is damaged** | **Improbable** | **Catastrophic** |

**Figure 3: Example of a risk assessment**

**HARM: Surgical Delay**

- Why was the surgery delayed? A vendor instrument set was late.
  - Why was the vendor instrument set late? SPD delivered the tray late to the OR.
    - Why was the instrument tray late from SPD? The instrument vendor delivered the instrument tray late to SPD.

**EVENT: Late tray delivery from instrument vendor**

**Risk Metrics**

| Probability / Impact | Highly Likely | Likely | Not Likely |
|---|---|---|---|
| Catastrophic | 6 High | 5 High | 4 Medium |
| Critical | 5 High | 4 Medium | 4 Medium |
| Marginal | 4 Medium | 3 Medium | 2 Low |
| Negligible | 4 Medium | 2 Low | 1 Low |

When identifying nonconformities that could lead to potential harm, it is important to look at all areas of failure sources, including environment, utilities, materials, equipment, process, and personnel.

Once all the harms and events leading to harm are identified, it is time to assess the risk. Risk is the combination of the harm and the likelihood the nonconformity will happen. Just as harm and probability of occurrence are not the same, all risks are not equal. The SP assembler is more likely to find dirty devices than the OR staff. An infection that causes death is less likely to happen than an infection that requires medical treatment. Facility risk management departments have policies and procedures for assigning risk values. *It is important to always use the facility's severity and probability rules when assessing risks.*

Once the risk assessment is complete, it's time to evaluate the risks. ***Evaluation*** ranks the risks, finding—by probability and impact—those that are not acceptable. Having to reclean an instrument occasionally is something that a facility may find acceptable, for example. However, a patient dying would be unacceptable. Once again, turn to your organization's risk management policies and procedures.

Typically, risk metrics are used to make that call. The risk metrics will identify the probability and severity combinations deemed unacceptable by the facility.

The purpose behind risk management is to reduce or eliminate risk. Mitigation is the action or actions taken to reduce risk. Severity cannot be changed. An infection will always be serious and a death will always be catastrophic. The only way to reduce risk is to reduce the likelihood of the nonconformities that lead to the harm.

Reducing risk follows three methods. The first and best method is to remove the risk entirely. One way to eliminate risks associated with failure to sterilize a reusable device, for example, would be to move to sterile disposable devices. However, this is not possible. Often, risks cannot be eliminated but they can be reduced.

Minimizing the probability of occurrence is the second method. Preventative actions, task and tests are employed to reduce the likelihood that a nonconformity would occur. SPDs use many minimizing techniques. Preventative maintenance, training and competency, biological indicator tests, replacing manual steps with automation, and instrument inspections are all examples of tasks that minimize the probability.

Reduction of risk does not mean elimination. Warning of remaining risk is the last method to reduce risk. Procedures, placards and other tools point out the risk to the technician. Of the three tools, this is the least effective risk mitigation.

A tool often used in risk management is the Failure Mode and Effects Analysis (FMEA). This tool combines the identification of root causes with the analysis of risk controls. First, a failure mode is identified; then, the effect of the failure mode is listed. From there, current risk reduction methods are identified, and a risk level is assigned. Any added task, process changes, material or equipment used to reduce the risk are evaluated and a new risk level is assigned. *Always remember that a task used to reduce risk for one event may increase risk of a different event.*

It is important to evaluate any proposed risk mitigation for new potential risks. Table 1 introduces two new risk mitigation activities:

| Failure Cause | Failure Effect | | Current Risk Control | Current Risk Level | | | Proposed Mitigation | New Risk Level | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | Local Effect | End Effect | | S | P | Risk | | S | P | Risk |
| Improper loading of washer-disinfector prevents soil removal | Device must be recleaned | Added labor and cost | • Magnified inspection | N | HL | 3 | • Magnified inspection<br>• NEW Protein detection test<br>• NEW Borescope inspection<br>• Prophylactic antibiotics given | N | HL | 3 |
| | | Delayed procedure | | M | L | 2 | | M | L | 2 |
| | Residual soil prevents sterilization of the device. | Cross contamination resulting in infection | • Magnified inspection<br>• Prophylactic antibiotics given | CR | NL | 3 | | CR | I | 2 |
| | | Cross contamination resulting in infection & death | | CA | NL | 4 | | CA | I | 3 |

**Table 1: Example of Failure Mode Effects Analysis Table**

| **Example: Measuring effectiveness of the HVAC system to control temperature and humidity, preventing contamination of sterile items in storage** | | | |
|---|---|---|---|
| Event/Failure | Mitigation | Measurements | Risk management Assumptions that are confirmed |
| The temperature, humidity or both are outside the specification of 65-70°F and 30-60% RH causing contamination to penetrate or grow on the sterile packaging. That contamination then leads to cross contamination during procedure, and a surgical site infection. | Install an HVAC system capable of maintaining 65-70°F and 30-60% | • Record the temperature and humidity for the sterile storage area<br>• Review surgical site infection data that may be tied to this event. | • Likelihood of sterile storage room to go out of specification<br>• The probability that a surgical site infection would occur under these conditions |

(1) Protein detection test and (2) borescope inspection. Though these reduce the probability of residual soil remaining in a lumen, the borescope may introduce a new risk of cross contamination if it was not properly cleaned following insertion into a lumen containing residual soil. This risk would be added to the list and evaluated accordingly.

The final stage in risk management is monitoring. Monitoring measures the effectiveness of the risk mitigation techniques and looks for changes that may show a drift in the process. Monitoring also confirms that the assumptions made about probability were correct. The measurements are dependent on the mitigation efforts.

## Objective 3: Develop a Risk Management Plan for Sterile Processing

Establishing a risk management plan begins with facility risk management policies and procedures. First, it is essential to understand which departments must be involved and the reporting structure and approvals that may be needed.

The second step to planning is establishing the extent of the project. Sterile Processing touches a wide array of departments, instrumentation, reprocessing equipment, and materials. It is important to identify the departments that SP services. These departments are the customers. It is a mistake to assume customers' expectations and needs. It is vital to meet with customers and discuss and document their needs and the services SP provides. This can provide realistic expectations for the customers and provide accurate information for the risk management plan.

Next, choose where to begin. The Sterile Processing department (SPD) involves a complex set of activities that cannot be assessed in one day. Use the natural flow of items through the department or focus on one customer at a time, whichever makes sense for the SPD, and schedule out the workload to ensure sufficient time and access to the area. Also, be sure to allow sufficient time to assess each area completely and thoroughly.

Assemble teams to work on each segment of the process. Be sure to include facility Risk Management/ Prevention, Infection Prevention, Biomedical technicians, SP technicians performing the tasks, representatives from affected departments, and customers who receive the goods. The final risk management documentation should be reported in a similar fashion as it was assessed. Once the assessments are complete, mitigations are in place and training is done, the risk management plan should be reviewed and approved, per facility procedures.

The risk management plan is not a static document; the plan and assessment should be regularly reviewed. Updates to the risk management plan are necessary prior to implementation of new processes, instrumentation or materials; when monitoring reveals a discrepancy between the risk assessment's estimated probability and real-time recorded probability; and any time a previously unknown nonconformity is discovered, or a new corrective action is implemented.

## Conclusion

Risk assessment is more than words on a guidance document's page. It is a deliberate review of process, people, environment, materials and equipment, with a single goal of risk reduction. That includes risk to the facility, risk to the technician and, most importantly, risk to the patient.

**RESOURCES**


1. ANSI/AAMI ST79:2017 *Comprehensive guide to steam sterilization and sterility assurance in health care facilities*
2. ANSI/AAMI ST90:2017 *Processing of Healthcare Products – Quality Management Systems for Processing in Health Care Facilities*
3. *Guidebook for the Preparation of HACCP Plans.* http://www.haccpalliance.org/sub/haccpmodels/guidebook.pdf