CHL Self-Study Lesson Plan
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Mitigating Risk by Establishing a Risk Management Process

LEARNING OBJECTIVE

1. Explain risk and the importance of identifying it
2. Identify the elements for assessing risk
3. Review risk exposure techniques and tools for identifying and analyzing risk

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CURRENT STANDARDS FROM THE ASSOCIATION FOR THE Advancement of Medical Instrumentation (AAMI) identify device processing areas throughout the healthcare organization that have a responsibility for establishing a risk management process and performing risk assessments on an established schedule, based on the risk level identified.[1,2] As ANSI/AAMI ST90:2017 *Processing of health care products - Quality management systems for processing in health care facilities states*, "It is critical to consider risk management as an ongoing process, not a one-time task that is completed and filed away. It is an ongoing, life cycle process and, consequently, requires continuous awareness, application and action."[2]

Risk concepts shall be applied throughout the planning process and the output of the planning should be in a form suitable for the healthcare organization. Failure to implement such measures places the device processing area and organization at a greater risk of operating in crisis mode when non-conformities occur.

OBJECTIVE 1: EXPLAIN RISK AND THE IMPORTANCE OF IDENTIFYING IT

Workforce turnover, improper use of personal protective equipment (PPE), positive biological indicators (BIs), poor water quality, customer complaints and inadequate staff competencies are just some of the common risks associated with Central Service/Sterile Processing (CS/SP) departments. In a 2015 survey[3], crisis was defined as a result from a single devastating event or a combination of escalating events, and it presents a severe threat to an organization's strategic objectives, reputation and viability. Crisis may occur from the result of an unidentified risk.

A risk is something that can go wrong and result in a loss (wet packs, for example, are a risk associated with steam sterilization). Preventing loss should be the goal. Risks are difficult to predict; they are often hidden, especially when things are going smoothly. Using the steam sterilization example, a risk assessment should be peridically performed on the steam sterilization process to lessen or at least identify process risks in one's department.

The first step departments should take is to identify potential risks. This

is not a trivial activity but rather a critically important one. Identifying risks that are relevant to the processes or department should be done by forming a multifunctional crisis team with broad knowledge of one's department, systems, people and processes.[5] It is important to begin with a list of activities, systems and processes that are used in the department and then go through the list and ask what could possibly go wrong. From there, a list of significant failures that have occurred in the last three years should be made and used to identify additional possible risks.

Once the list of potential risks is created, it will be necessary to assess the importance of each risk to allow the team to prioritize its focus. The team will not be able to work on everything and it will be best to focus efforts on the most important risks. Classical operational risk management (ORM) assesses risk on two factors: severity and probability.[5]

In the classical method, a numerical rating (1, 2 or 3) is assigned to each of the factors to denote the magnitude of the potential loss (e.g., low, medium and high). Next, the team will add the values assigned to each risk factor. The result is a list of potential risks and a numerical value assigned to each that is proportional to the importance of the risk to the business.

In assessing the risks, the estimates should remain grounded in reality. The list of prioritized risks will be used to create awareness in the organization and department of the risks and the importance of each.

There are perceived notions that spending money to prepare for a risk that many assume will likely never occur is a waste of money; however, risks can and do occur, even when least expected; therefore, the planning and investment are both prudent and beneficial.

Like any event, specific terms can be used to describe a process or measure the level of severity associated with risk. Severity is an estimate of how great the loss could be if a risk situation were to occur. Some good questions to ask include: What is the worst that can happen? Is the device processing team aware of the worst that can happen with any given process in the department? Can systems be built to prevent or at least manage a worse-case scenario?

Probability is the likelihood that a risk situation could occur. Consideration should be given to how often the risk situation is likely to occur.

The impact of speed is an assessment of how fast a loss could occur in the event of a risk situation and whether the systems in place are capable of responding quickly enough to prevent a loss. The speed at which a loss occurs demonstrates the value of being aware, prepared when an event occurs[5]. Customers may become outraged at some failures, but not others. The team needs to assess if the potential risks being considered will result in outrage in the event of a failure.

Next, it is important to consider the complexity of the systems and processes in the department. Complex systems that are inflexible and delay response to a potential crisis can make the difference between a minor event and a major loss. Rapid and effective response will minimize the loss. Complex systems that are difficult to navigate will slow down the response and increase the potential loss. If the team considers the situation rationally and calmly beforehand, a protocol can be created to manage it. If one waits for the crisis situation to occur and then tries to navigate a complex situation, the response will be delayed and the loss will increase.

The scope of a potential loss is defined by how broad the impact could be. Is the loss isolated to a specific product, brand, customer, clinical service, department, etc. or could the impact spread more broadly?

The team needs to assess the degree to which uncertainty can impact a potential loss situation. Some situations are inherently more uncertain than others. The information needed to make a good decision may be lacking because of an inability to quantify or even assess the potential loss. The systems that exist inside the department (or outside it) may be inadequate to provide accurate, timely information that is needed to make a good decision. One aspect of assessing uncertainty is to assess the adequacy of the information that will be available in a crisis situation. If one doesn't know their vendors or which kinds of systems they have in place – and has no historical records on their performance – then it will be difficult to assess the risk of a failure.

The element of trust should also be considered. If another party is trusted to be honest and thorough in their communication of a risk event, it provides some confidence in their performance. Conversely, if the other party is not trusted, they will be second guessed, and valuable time will be wasted. Product realization, as outlined in ANSI/AAMI ST90, speaks to the importance of understanding and participating in the purchasing process in one's organization.

OBJECTIVE 2: IDENTIFY THE ELEMENTS FOR ASSESSING RISK

Most people realize that risk is present in their personal life as well as in the organizations in which they work. Risks organizations may face include:

- Events ranging from those that cause minor disruptions to catastrophic events that affect the organization, regardless of its location, financial stability, etc.; and
- Events that can affect each organization differently (e.g., an event that is a minor disruption for one organization but a major disaster for another).

Figure 1: The PDCA steps to take to establish an effective risk management process

Plan: The means by which the organization will: • Identify and define its potential expo sures to loss • Quantify the potential financial and non-financial risks • Examine the feasibility of alternative risk management techniques • Select the best risk management technique	**Do:** Implement a test of the chosen risk management technique(s)
Check: Assess the effectiveness of the technique and make necessary adjustments or select a new alternative	**Act:** • Implement the full process • Roll out the full implementation of the tested technique • Monitor the implemented technique for adequacy of protection

Note: *If the change was not effective, go through the cycle again with a different plan.*

A risk that becomes a negative event can seriously disrupt the department's processes and make it unable to meet customer requirements. Identifying and planning for potential risks is critical in the pursuit of customer satisfaction, organizational stability and profitability, especially under potentially adverse conditions. Proactive CS/SP departments, regardless of their size, will make an assessment of the potential risks to which it is exposed and establish a feasible means to prevent or lessen loss.[6] The Plan-Do-Act-Check (PDAC) process is an effective risk management process (see Figure 1).

OBJECTIVE 3: REVIEW RISK EXPOSURE TECHNIQUES AND TOOLS FOR IDENTIFYING AND ANALYZING RISK

Failure mode and effects analysis (FMEA) is the study of consequences of identified failures[4] and is a technique used to help determine risk (e.g., what could go wrong and what impact it could have on departmental processes and products). The intent is to prevent such failures and their efforts. Cross-functional teams are involved in the final process as well as the customers affected by the process. Take, for example, the review of an instrument set and design upon receipt. Stakeholders will identify specifications needed to produce a useable product at the point of use. Clinical stakeholders will indicate the size and quantity for devices identified on the instrument count sheet. CS/SP stakeholders will indicate point-of-use cleaning, decontamination and sterilization parameters to be followed. When these specifications are not followed, that indicates a non-conformity and the presence of risk; it is this risk or gap in process that an FMEA is performed and potential risk exposure is identified.

The following are suggested techniques and tools for identifying and analyzing loss exposures. *Note: This list is not all-inclusive.*

- **Complete and analyze process maps –** From process maps to key processes, brainstorm where points of risk may be embedded in the process.
- **Conduct a what-if brainstorming session –** With members of the device processing team and other stakeholders, using a cause-and-effect diagram, explore as many possible risk situations as time and feasibility allow.
- **Perform periodic inspections and process audits –** Vigilance and preparedness are maintained with surprise drills. Potential risk-type questions can be incorporated in the internal auditing of the quality management system, as well as in product audits. Continually question whether the department's product, when in the end user's hands ,will be safe to use over the products life cycle, including disposal.

SEMI-QUANTITATIVE PROBABILITY LEVELS	QUALITATIVE SEVERITY LEVELS					
	Negligible	Minor	Serious	Critical	Catastrophic
Frequent					
Probable					
Occasional					
Remote					
Improbable					

Figure 2: Qualitative severity levels by semi-qualitative probability levels (ANSI/AAMI/ISO 14971:2007)[2]

RESPONDING TO RISK EXPOSURES

The CS/SP department must determine how to respond to identified risk. There is no guarantee that responses to all exposures will be possible or feasible. After the department has identified risk exposures and computed the potential for financial loss, one or more of five actions may be initiated:

1. Find a way to avoid the exposure.
2. Find ways to reduce the potential loss.
3. Find ways to prevent the occasion for the loss to occur.
4. Segregate the loss exposures to concentrate efforts on those exposures most likely to occur and/or cause the greatest loss (e.g., exposure triage as minimum, medium or maximum).
5. Transfer the risk (e.g., through other contractual arrangement or services).

Assessing the potential risks for a new product at the design and development stage and taking preventative actions is extremely cost-effective. Take, for example, the introduction of a new instrument set/tray; the FMEA would be the tool to use in this assessment activity.

COMPUTING POTENTIAL FOR LOSS AND TAKING ACTION

To generate a credible estimate of the organization's potential loss, consider the following steps[6]:

1. Prioritize the identified risks. A Pareto chart (a type of chart that contains bars and a line graph; individual values are represented in descending order by bars and the cumulative total is represented by the line) is helpful.
2. For each of the top eight to 10 risks, envision a worst-case scenario. List all potential consequences. Brainstorming, mind mapping and cause-and-effect diagrams are effective techniques and tools.
3. Categorize the consequences into clusters of similar happenings. An affinity diagram (a tool that gathers large amounts of language data such as ideas, opinions and issues, and organizes them into groupings based on their natural relationships) is useful for this.
4. Assign dollar estimates of losses to each cluster. Some of the line items to consider when assigning a value include:
   a. Temporary department shutdown;
   b. Product recall costs and/or wasted materials; and
   c. Shortages of raw material, energy sources, transportation, staffing and so on.
5. Determine what it would take (cost of additional resources) to mitigate the accumulated potential dollar loss for each cluster/scenario. Factors to consider include:
   a. Improved response and preparatory procedures (contingency plans);
   b. Lean techniques to reduce or eliminate inventory; and
   c. Outsourcing part or all of a process.
6. Decide how often and when to take action.

7. Periodically reassess the decisions made and make necessary adjustments.

Risk mitigation, also called risk reduction, can be used to reduce the risk impact, severity and probability of occurrence in order to deem a risk acceptable. Risk mitigation is done by performing a gap analysis between the root cause and the resulting risk, and identifying activities or changes that can minimize or prevent the risk from occurring and, thereby, improve the risk score[2] (see Figure 2).

Too often, risk assessment is made a difficult and mysterious process. The result then becomes paralysis and inactivity. A simple process that enables the team to assess the situation and then take effective action to manage, minimize or eliminate the identified risks[5] is a more effective approach.

It is important to establish an audit team that will assess each device processing area in the healthcare facility (or for smaller healthcare facilities, assess each shift of the device processing area). The locations/shifts with the highest scores will have the highest risk. Picking 10-20% of the areas with the highest risk scores and focusing efforts over the next year will help reduce the risk. This process will be repeated annually. The result is a structured, focused effort to reduce risk under a constraint of limited resources. It also serves as an effective way to educate the team about device processing areas.

CONCLUSION

It is prudent for healthcare leaders to review some of the elements of risk management with their device processing team to build awareness of the need for assessing and managing risks that can impact the department.

Establishing a departmental risk management process takes time, but it is not difficult. Healthcare leaders can drive the department's culture for managing risk and they can insist that a risk assessment be performed for every project or decision. In doing so, leaders can make risk management part of their department's culture. Reviewing the department's risk management process will be time well invested and those efforts will be appreciated by the customer and all stakeholders. C

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