
LOW
RISK
MODERATE
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CRCST SELF-STUDY LESSON PLAN
Lesson No. CRCST 169 (Technical Continuing Education - TCE)

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Risk Analysis: Integral Component of a Quality Management System

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LEARNING OBJECTIVES

1. Understand the quality management system and the role of risk analysis in the process
2. Identify the specific steps involved in the risk analysis process
3. Understand how to manage risk and implement effective risk communication strategies

Unexpected events and occurrences can be disruptive to a Sterile Processing department (SPD) and produce a domino effect throughout the healthcare facility. As part of a quality management system (QMS), such disruption may be prevented or minimized by proactively undertaking a risk analysis to strive to produce a system that performs as intended and consistently over time to achieve zero defects – and, as a result, zero harm. While certain risks are out of Sterile Processing (SP) professionals' control, others can be eliminated or minimized.

Objective 1: Understand the quality management system and the role of risk analysis in the process

ANSI/AAMI ST90 defines QMS as a collection of business processes focused on consistently meeting customer requirements and enhancing customer satisfaction. It is expressed as the organizational structure, policies, procedures, processes, and resources needed to implement quality management.[1] The QMS must have the full support of facility leadership and upper management as well as staff in the SPD in order to succeed and sustain gains. The risk analysis process is a key part of continuous quality improvement (CQI) and an integral part of a QMS to ward off unexpected or unplanned disasters.

What is a Risk Analysis?

Risk analysis is a process with three distinct components: risk assessment, risk management and risk communication.[2] The sterilization risk [medical device processing] analysis should be part of the overall infection prevention and control risk analysis in accordance with accreditation agency requirements.[2] An SPD risk analysis will be facility specific and will vary based on complexity of the organization (e.g., hospital versus office-based practice). In March 2019, The Joint Commission

Risk analysis is all about preparation ahead of a disaster or an untoward event. As humans, we perform risk analysis every day as part of our activities of daily living, but never think of it in such terms. We assess the risk of being hit by a car if we cross against the light, and we wait for the walk symbol; we assess the risk associated with not wearing a seat belt, and we buckle up. Just as we do in our daily lives, a risk analysis should be performed for all aspects of the sterilization process in an effort to identify any probable risk that can impact patients and personnel.

(TJC) published its top five challenging standards for facilities undergoing survey and cited IC.02.02.01, the organization reduces the risk of infections associated with medical equipment, devices, and supplies in office-based surgery practice (63.55%), hospitals (70.85%) and ambulatory settings (60.65%).[3] Immediate threat to life citations from regulatory bodies such as the Centers for Medicare and Medicaid Services (CMS), TJC and other accrediting agencies have resulted in reactive efforts to correct these deficiencies to avoid loss of CMS funding or facility accreditation. TJC has enhanced the way surveyors evaluate and score the highest risk steps in the processing of devices, instruments and equipment.[4,5]

Risk analysis is all about preparation ahead of a disaster or an untoward event. As humans, we perform risk analysis every day as part of our activities of daily living, but never think of it in such terms. We assess the risk of being hit by a car if we cross against the light, and we wait for the walk symbol; we assess the risk associated with not wearing a seat belt, and we buckle up. Just as we do in our daily lives, a risk analysis should be performed for all aspects of the sterilization process in an effort to identify any probable risk that can impact patients and personnel. Performing a risk analysis (on a process or a device) is a proactive strategy in preparing not to fail or reducing the risk of failure. Failure to prepare oftentimes will lead to a sentinel event. The analysis may have many parts that are subjective and others that are objective. It looks at the inputs (people, devices, instruments, equipment) and outputs (sterilized devices/instruments, storage, transportation to the point of use, record keeping) and the potential for causing future harm. It is critical to avoid underestimating that there is or may be a risk for failure; there is risk in every step of the sterilization process, even steps that seem straight forward, because there is human involvement and humans make mistakes (by either omission of steps or the addition of steps). Therefore, it is necessary to understand the risk to make informed decisions about strategies for mitigation or prevention. One of the safe practices recommended by TJC is for for healthcare organizations to systematically identify and mitigate patient safety risks and hazards with an integrated approach in order to continuously drive down preventable patient harm.[6] The risk analysis should identify, define and quantify the risk, and identify actions that can be taken to resolve or prevent the risk. It should be monitored to ensure that the risk has been corrected or prevented.[6]

Objective 2: Identify the specific steps involved in the risk analysis process

The risk analysis process requires the involvement of a cross-functional, collaborative and committed team of individuals with varying viewpoints and a shared vision and goal for continuous quality improvement. This team should include but not be limited to the risk manager, infection preventionist, frontline SP technicians and managers, Operating Room managers and/or directors, and quality department personnel. The committee should not be too large to hamper the process but should be large enough to allow for an agile process. A chairperson should be enlisted to coordinate the development of terms of reference for the committee to outline roles and expectations and clearly define the boundaries or scope (e.g., will the risk be limited to a single process such as processing of endoscopes, or a specific department that is performing SP functions – or will it be broader to take in all instruments and devices? Will the committee examine risk solely to the patient, or will it cover risk to employees?). Out-of-the-box thinking

and the avoidance of over-simplification of what could happen may be needed.

The risk analysis should follow all applicable federal, state or local regulatory guidance, CMS conditions of participation (COP)[7], manufacturer's written instructions for use (IFU), evidence-based guidelines or national standards and other documents, as relevant or needed.

The risk analysis process is not a onetime event, but rather a continuous loop. Frequency of the risk analysis should be at least annually or when there are major changes to practices or processes. This frequency may be impacted by a consensus decision of the committee members and the outcomes of previous risk analyses. The committee membership may vary based on discussion topics.

Identified Risk	Probability (Likelihood of Occurrence)			
	Frequency/ High	Occasional/ Medium	Uncommon/ Low	Rare/None
Risk Score	3	2	1	0

Identified Risk	Outcome Severity (Harm)			
	Life Threatening	Permanent Disability, Prolonged Hospitilization	Temporary, Recoverable, Treatable	None
Risk Score	3	2	1	0

Identified Risk	Preparedness			
	Life Threatening	Permanent Disability, Prolonged Hospitilization	Temporary, Recoverable, Treatable	None
Risk Score	3	2	1	0

Conduct a risk assessment

The risk assessment is part of the overall infection prevention and control risk assessment. It includes identifying and characterizing areas of vulnerability with the sterilization process (e.g., gap analysis). Determining where to begin the risk assessment may seem daunting initially. One approach is for the committee to assess risk with high volume, high risk and problem-prone activities using a desktop exercise on paper by following or tracing the path and touch points that the device or instrument will take to the point of use and back to the processing area. This can be accomplished by developing and using a process map/cause-and-effect diagram (e.g., Fishbone or Ishikawa diagram) that includes all steps of the sterilization process (the way it was intended versus the actual) to identify potential failure points. The committee can begin planning and brainstorming for the "What ifs." There may even be "Why" questions that need to be addressed if past incidences have resulted in near misses or outright failures; answering these "Why" questions can avoid future occurrences. The determination of the consequences of likely and unlikely events and discussions for the pros and cons of each identified issue or failure will prevent fulfilling the Swiss cheese theory[8], where the holes align, and errors reach the patient.

There are two processes that can be used. The first is a root cause analysis (RCA), which is more reactive and answers the "Why" of a failure. The second is a failure mode and effects analysis (FMEA), which is a proactive approach to assessing the impact of a potential failure, error or problem (the "What ifs").

Some examples that can help jumpstart the assessment include, but are not limited to, the following:

- CMS COPs[7] and Hospital Infection Control Surveyor worksheet[9] related to cleaning, sterilization and disinfection;
- Compliance with policies and procedures/evidence-based guidelines and standards;
- Previous SPD RCAs – repeated recalls of instruments and devices;
- Outbreaks (e.g., duodenoscope);
- Compliance with manufacturer's IFU;
- Human error due to turnaround time pressures, fatigue, staffing resources, and inadequate training (see one, do one, teach one);
- Quality monitoring practices;
- Endoscope processing (e.g., sterilization versus disinfection, processing delays, cleaning verification, use of sheaths, hang time, etc.);
- Loaned instruments;
- Contract services;
- Toxic Anterior Segment Syndrome;
- Centralize versus decentralize instrument and device processing;
- Environment of care [e.g., construction/renovation, utility (water and electrical) disruptions, etc.]; and
- Preventive maintenance of processing equipment.

Risk communication should include a continuous interactive dialogue and exchange of information related to the identified risks, both real and perceived, as well as the reason for the management strategy selected throughout the process with all stakeholders (SPD, managers, directors, user areas, and infection prevention personnel) to determine if there are any unintended consequences related to the action plan prior to implementation.[2] Prior to plan implementation, the importance of communication cannot be overstated as it demonstrates a sensitivity to the operations of the SPD.

Objective 3: Understand how to manage risk and implement effective risk communication strategies

Risk management includes making a determination as to which of the failure modes identified in the risk assessment require immediate management, and then developing and selecting an appropriate action plan for prevention and control prior to proceeding to implementation.[2] The identified risks may result from behaviors, design and structure of department, work environment, technology, and knowledge and skills. The identified risks are quantified and prioritized by using a risk assessment matrix (see example matrix on previous page).

- What is the likelihood of occurrence? High/Medium/Low/None
- What is the outcome severity (harm)? Life threatening/permanent disability/temporary/none
- What is the level of preparedness for the occurrence? Good/Fair/Poor/None

Probability X Outcome X Preparedness = Risk Priority score
(≤6 = No Risk to Low;
7-11 = Medium risk;
>12 = High risk)

A structured mitigation plan is then developed to address the highest risk first. The committee may decide that certain risks will be accepted and others with be prioritized for action. The plan may recommend using levels or hierarchy of controls[10] such as:

- **Elimination –** Discontinue the practice/process to eliminate the hazard/risk
- **Substitution –** Automated systems such as endoscope reprocessors to eliminate manual processes
- **Engineering Controls –** Utilities and space requirements (construction/renovation), ventilation and airflow, temperature, humidity
- **Administrative Controls –** Policies and procedures (new or revised) for education and training, including competency assessments, resources for staffing, equipment, centralized processing, technology (electronic tracking systems, etc.)
- **Personal Protective Equipment –** Proper mask, glove, correct level of gowns, etc. to protect personnel and patients

Risk Communication

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From the outset of the process, it is very important to maintain open lines of communication with all who will be affected by the changes. This is especially critical in a multi-facility organization.

Communication may occur in writing or by convening regular key stakeholder meetings. Another benefit of open communication is to avoid blindsiding staff as changes in one area/process may unintentionally impact another. Open communication helps avoid conflicts and more readily facilitate changes and hardwire the compliance.

Record Keeping and Documentation

QMS requires detailed record keeping. This involves:

- Maintaining a record of risk analysis based on facility policies and procedures.
- Documenting the process used to determine risk.
- Establishing a timeline for keeping records (this will be dictated by federal/state/local regulations, as well as facility policies and procedures).
- Documenting that all gaps/hazards were assessed thoroughly in all areas where a sterilization process takes place, especially if decentralized.

Risk Monitoring and Reassessment

The committee should assign an individual or individuals who are responsible for proactive monitoring and data gathering, as well as the frequency of such audits moving forward. This individual should report back to the committee any findings related to the effectiveness of the plan, once implemented, to determine if additional risks have been identified. To make further performance improvements, the audit data may require going back to the risk assessment step to address newly identified risks.

If SP activities are decentralized, it may be more efficient to target one location to test the plan. This will allow for more speedy modifications, if needed. Once all the issues have been addressed, a facility-wide implementation may be done.

Conclusion

Risk analysis is an integral part of a QMS. Through risk assessment and risk management of all steps of the sterilization process, action plans can be developed to mitigate risk and prevent harm to patients and employees. Proactive review and continuous oversight by using the audit process to identify failures is a necessity. Continuous audits and data gathering, along with open communication amongst key stakeholders, are important.

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CRCST Self-Study Lesson Plan Quiz - Risk Analysis: Integral Component of a Quality Management System

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1. Risk analysis includes the following components:
   a. Assessment and communication
   b. Communication and procedures
   c. Assessment and continuous quality improvement
   d. Communication and training

2. Risk analysis inputs include:
   a. Storage
   b. Instruments
   c. Record keeping
   d. Transportation

3. One safe practice recommended by The Joint Commission is for healthcare facilities to identify and mitigate patient safety risks.
   a. True
   b. False

4. Members of a risk analysis process team for Sterile Processing should include:
   a. Sterile Processing technicians
   b. Employee health professionals
   c. Human resources professionals
   d. Physicians

5. A risk assessment should be performed on which of the following processes?
   a. Those that are high risk
   b. Those that are problem prone
   c. Those that are high volume
   d. All the above

6. When determining which failure mode requires immediate attention, which of the following should be considered?
   a. Probability and harm
   b. Preparedness and frequency of task
   c. Probability and error rate
   d. All the above

7. Structured hierarchy controls in a mitigation plan include:
   a. Risk communication
   b. Personal protective equipment
   c. Record keeping
   d. Risk priority

8. Administrative controls include:
   a. Policies and procedures
   b. Competency assessment
   c. Technology
   d. All the above

9. A quality management system requires detailed record keeping that includes documenting the process used to determine the risk.
   a. True
   b. False

10. Which process is a key part of continuous quality improvement?
   a. Competency development
   b. Department organization
   c. Risk analysis
   d. ANSI/AAMI ST79

11. Identifying and mitigating risk is recommended by:
   a. The US Food and Drug Administration
   b. The Association for the Advancement of Medical Instrumentation
   c. The Association of periOperative Registered Nurses
   d. The Joint Commission

12. The risk analysis chair is responsible for:
   a. Education and training
   b. Determining risk priority
   c. Developing terms of reference for the committee
   d. Committee membership

13. Risk analysis should follow regulatory guidance, including:
   a. The US Food and Drug Administration's quality management system standards
   b. Recommendations set forth in ANSI/AAMI ST79
   c. The Joint Commission's infection control standards
   d. The Centers for Medicare and Medicaid Services' Conditions of Participation

14. A fishbone diagram may be useful:
   a. To follow the path and touch points of an instrument from point of use to processing
   b. To develop a departmental quality management system policy
   c. To identify key people who are important to the risk analysis process
   d. All the above

15. The two processes that help identify potential failure to a system are:
   a. Failure mode and effects analysis and conditions of participation
   b. Failure mode and effects analysis and root cause analysis
   c. Root cause analysis and instructions for use
   d. Instructions for use and quality monitor practices

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