How to Build an Endoscope Risk Assessment

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LEARNING OBJECTIVES

1. Identify items to include in an endoscope risk assessment
2. Classify potential risks by likelihood of occurrence and potential for damage
3. Rectify (correct) identified risks and prevent future risks

According to the Centers for Disease Control and Prevention (CDC), "Healthcare facilities should have a reliable, high-quality system for endoscope reprocessing which minimizes infection risks."[1] To achieve this goal, endoscope reprocessing programs must have an infrastructure that supports training and competencies, quality measurement and management. One necessary part of that program is the ability to perform high-quality risk assessments related to evaluating processes, changes and programs pertaining to endoscope processing in healthcare facilities.

When looking at endoscope reprocessing in one's facility, are there certain parts of the process that are knowingly not *quite* compliant? Do you question whether what you are doing is compliant? Whether you answered yes or no, a risk assessment should be used to identify, classify and rectify potential risks. A risk assessment provides the necessary information to guide appropriate response measures.[2] This encompasses risks (or hazards) that might negatively impact patients, staff or the environment. To identify risks, the process must be broken into individual steps. From there, the risk score for each step needs to be determined and a plan implemented to address and correct any deficiencies identified in the risk assessment.

Objective 1: Identify items to include in an endoscope risk assessment

It is critical to assess every step of the endoscope reprocessing procedure; the logical place to begin, therefore, is when endoscope reprocessors first receive the soiled endoscope. Beginning with point-of-use treatment or decontamination (depending on the departmental flow), list—in order—everything thing that must happen to that endoscope. This information may be included in a competency assessment, manufacturers' instructions for use (IFU) or the facility's training documentation, so don't hesitate to start with the materials already in your possession. From there,

cross-reference the procedure with the industry standards the endoscope reprocessing department uses to ensure all of the recommended steps are captured and that any missed steps or steps not currently being performed are added.

Once the procedure and all steps are thoroughly documented, list any additional skills or knowledge necessary for the job. Think about actions and choices staff members may make that aren't as simple as following a step in the IFU and indicate any departmental policies that fill in gaps where the IFU are not specific. These skills may include knowledge of aseptic technique, personal protective equipment (PPE) selection, how to locate the IFU, preventative maintenance and repair procedures, adherence to dirty-to-clean workflow, visual inspection processes, how to complete a test strip quality check, and the facility's drying and storage policies. *Note: Document (list) anything that is not included in standards or IFU because those are critical areas to include in the risk assessment. ANSI/AAMI ST91:2021 has more guidance and considerations for risk assessment of endoscope drying, storage and cleaning verification as well as suggestions for resolving conflicting IFU.*

Once the list is completed, the information should be collected into a single document or spreadsheet. When building a risk assessment to correct a problem or failure that has been identified or to assess risk when developing new procedures, everything on the list may not be needed—only the parts that apply to the specific failure or new procedure. Often, a risk assessment is required as a department's response to an Infection Control survey (or other survey) to prove that the danger was analyzed and addressed. If building a risk assessment to identify or prevent risks across an entire process or to set a baseline for process improvements, all items from the list can be included.

Objective 2: Classify potential risks by likelihood of occurrence and potential for damage

Once the list has been compiled, it is necessary to establish a risk score (or risk level) for each item. A risk score is generally calculated as risk equals impact multiplied by likelihood:

Risk = Impact x Likelihood

The more likely a risk is to occur translates to a higher score in the "likelihood" category. Think of a scale from 1 to 5, where 1 means "very unlikely to happen" (e.g., breaking a leg) and 5 means "very likely to happen" (e.g., stubbing a toe). When calculating impact, the same 1 to 5 scale can be used, but 1 means it has little to no negative impact on patients, staff or the environment and 5 means it may have a severely negative impact.

If a process is currently in line with the IFU and standards, it would be scored as a 1 for "no risk." For example, endoscopes should go through an automated endoscope reprocessor (AER), and the cycle needs to pass for that endoscope to be ready for patient use. It is not very likely that the AER will fail or be skipped, so a score of 1 can be given for likelihood; however, an endoscope that is not disinfected properly could transmit infectious material (bacteria or viruses) from one patient to the next, so the negative impact of missing or failing the AER step is a 5 due to the potential severity or lethality of that kind of infection. To calculate the risk score, one would use 1 x 5 = 5. If it is known that a facility's AERs fail somewhat frequently, one could change that 1 to a 2 (total score of 10) because the potential risk is much higher. Remember, a risk assessment addresses not only what is happening in the moment but also what chance there is that something risky or hazardous will happen in the future.

Risk scores are typically put into a matrix format and color-coded to quickly indicate priority in the risk assessment document. (See **Figure 1**)

If building a risk assessment to fix a list of failures that were already observed, use the risk score to prioritize what needs to be fixed first. If using a risk assessment to identify potential failures before they are found or before a procedural change, set up the risk score ahead of time, so the areas that need review can be prioritized.

Objective 3: Rectify (correct) identified risks and prevent future risks

Once everything that needs to be done in the department has been identified (including all activities and processes that are being done incorrectly), it is necessary to correct existing failures and prepare for the future. This final step begins with keen observation.

To understand where process failures exist, it is necessary to first observe employees in action and ensure that their practices follow the procedures that were developed. This is the opportunity to find and address any failures before they place patients or employees at risk or to immediately fix any process failures that someone else identified. When a failure is found, the risk assessment document is where one records what they observed and works out how to fix it and prevent it from recurring. Often, several steps are needed to fix a single process failure, but having a plan in place will make it easier to track and report the progress. Part of the risk assessment process is

identifying how prepared the facility is to manage failures, because at some point, a failure can be expected to occur.[2]

Adding improvements and fixes to the risk assessment is unique to one's facility—what is currently being done, what *should* be done and the steps between the two. At the end, it is possible to identify all the potential risks in the facility's endoscope reprocessing procedures and establish a step-by-step path to mitigate and rectify those risks. A risk assessment can be repeated at any point to check the progress of process changes, evaluate how employees are performing processes and confirm that process changes are working.

Conclusion

Risk assessments have a core purpose, but how risk assessment documents are organized and developed is up to each facility. There is no one-size-fits-all process, but this lesson can serve as a useful starting point to develop one's own risk assessments. To help in this process, utilize resources already available to the facility, such as ANSI/AAMI standards; the Healthcare Sterile Processing Association's (HSPA's) Endoscope Reprocessing Manual; the CDC's Gap Analysis and Risk Assessment Tool[1]; manufacturers' IFU and training videos; white papers; peer-reviewed literature published in journal articles; webinars, and more. A robust process for performing risk assessments in one's facility will help achieve the CDC's recommendation for having a reliable, high-quality system in place for endoscope reprocessing that minimizes infection risks.

REFERENCES

1. Centers for Disease Control and Prevention. (2018). *Essential Elements of a Reprocessing Program for Flexible Endoscopes – Recommendations of the HICPAC*. https://www.cdc.gov/hicpac/recommendations/flexible-endoscope-reprocessing.html#Toolkit.
2. Association for the Advancement of Medical Instrumentation. *ANSI/AAMI ST91:2021, Flexible and semi-rigid endoscope processing in health care facilities*. Available for purchase at www.aami.org.