Quality assurance: is your process in control?

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It is the responsibility of all Sterile Processing Departments (SPD) to provide safe, sterile instrumentation for use with their prospective patient population. This is a tall order that requires adherence to protocol, quality measures, and continuous monitoring. Quality assurance requires a commitment to continuously seeking opportunities to improve processes and performance. This article will review common quality measures and provide an example of a comprehensive quality control and improvement program associated with the sterilization process.

A continuous quality improvement program for sterilization encompasses all aspects of the process that occur prior to the medical device being used on a patient. How the device is cleaned, assembled, packaged, sterilized and stored all play a role in providing a safe, sterile product. For example, if there is residual bio-burden on an instrument because it has not been cleaned properly, even after sterilization the device will not be safe for patient use. Adhering to procedures, assessing risks, building in quality checks, training staff, and auditing processes all contribute to success in providing safe products.

Quality assurance

The beginning point for any quality improvement initiative is ensuring that practice standards are referenced and understood. The best resource for practice recommendations for the SPD is ANSI/AAMI ST79 “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.” In section 10 of this document, the recommendations for quality assurance outline the minimum requirements for monitoring the sterilization process. This recommended practice provides guidelines that aid the development of policies and procedures and help ensure that minimum requirements for the safe processing of medical devices are maintained. Familiarity with this standard is strongly recommended as it is the guideline designed to promote sterility assurance and guide healthcare personnel.

As stated in the ANSI/AAMI ST79 standard, hospitals are required to monitor the sterilization process with physical monitors, as well as chemical and biological indicators. Physical monitors measure time, temperature, and pressure and are most often checked by viewing the printout on the sterilizer. External and internal chemical indicators are required on and in the sterilization packages to provide users with a method to distinguish processed from unprocessed items and detect inadequate sterilant penetration. Biological indicators that contain live bacterial spores are used to directly measure the lethality of the sterilization process.

When using chemical and biological indicators to monitor the sterilization process, the healthcare facility is responsible for making sure to monitor at least at the minimum frequency and per the manufacturer instructions. Physical monitors should be accessible for every load. The staff operating the sterilizer should review the printout to confirm the cycle parameters. External chemical indicators should be visible on the outside of all packages. Internal chemical indicators should be used inside every package and be appropriate for the method of sterilization being utilized. For dynamic air removal sterilizers, the sterilizer should be tested with a class 2 indicator, also known as a Bowie-Dick test. The Bowie Dick test is used to monitor the ability of the sterilizer to remove air from the chamber. This test should be performed on an empty chamber as follows: daily before the first load of the day and after sterilizer installation, relocation, or malfunction. Three consecutive Bowie-Dick tests should be run when there is a sterilization process failure, a major repair, or when a sterilizer is newly installed. (ANSI/AAMI ST79)

A Process Challenge Device (PCD) containing a biological indicator should be used at minimum weekly (preferably daily) to perform routine sterilizer efficacy testing. For sterilization loads containing implants, a PCD containing a biological indicator and a class 5 integrating indicator is required in every load. A class 5 integrating indicator provides an immediate visual result once the load is complete. This is beneficial because, in the event the class 5 integrating indicator shows a reject or fail result, the...
sterilizer operator can immediately begin investigating the failure and reprocessing the load instead of waiting for the results of the biological indicator.

All packages being sterilized should be uniquely identified with a lot control number. This lot control number allows the packages to be traced to the sterilizer in which they were processed. Should an item, load, or series of loads need to be recalled, such as when the operating room discovers a failed sterilizer, the lot control numbers help expedite the process. The lot number provides the information necessary to determine which other items were sterilized in that same load or sterilizer.

Complete sterilization records are very important and are considered legal documents. Sterilization records should include the following information: the lot number, specific contents, exposure time and temperature, name of operator, and the results of the biological and chemical indicators, if used.

The sterilization process includes the entire process from cleaning to distribution of the instrument, so remember that washer equipment should also be monitored weekly, at minimum, to verify proper performance. Running a daily washer test enables the user to monitor the functionality of the washer equipment to ensure it is operating properly. These tests are designed to challenge the washer and confirm that the washer chemistries are being delivered adequately and reaching the instruments in the hard to reach areas like the box locks.

**Identifying the risk of error**

In the SPD, there is a high risk of error because the sterilization process is complicated, involves many steps, and requires staff to have a good understanding of the theory behind their practice. Common risks inherent with the sterilization process include:

- **Instrument fleet size:** Having inadequate instrumentation to support daily case volume can increase pressure on processing personnel to shorten a procedure due to time constraints. In addition, personnel who are rushing to complete a task may forget important steps such as adding a biological indicator or signing off a sterilizer printer strip.
- **High volumes:** When a large amount of instrumentation is pending processing, this may cause staff to rush through tasks to keep up with demand.
- **Equipment age and function:** Equipment that is not maintained is more prone to malfunctioning. When equipment malfunctions it interrupts the process flow, may create rework, and increases the risk of a product inadvertently being distributed without being efficaciously processed.
- **Department distractions:** Personnel who have to answer phones and multitask while operating the sterilizer are at an increased risk of forgetting to complete documentation and may even select the wrong sterilization cycle.
- **Training, competencies, and certification:** Staff with limited experience, training, or without certification can increase the likelihood of quality lapses.
- **De-centralization:** Oversight and monitoring of the process and employee performance is difficult if cleaning, assembly, and sterilization is happening in multiple locations.
- **Lack of standardization:** There is an increased risk of process failures if procedures are not standardized.
- **Instrument complexity and variety:** The variety and complexity of instrumentation can increase the odds of a process failure due to users failing to follow special cleaning and/or sterilization requirements. Complicated and lengthy cleaning procedures increase the risk of a device not being cleaned properly. Having to process devices using different sterilization cycles increases the risk of staff selecting the wrong cycle. In addition, it decreases efficiencies, throughput and may increase the risk of a set sitting for an extended period of time pending sterilization.

Each facility should evaluate their processes and determine what risks are present in their environment. Supervision of personnel performing sterilization functions is highly recommended to ensure that procedures are being followed. In fact, because of the risks identified above, it is advisable to audit your sterilization loads for the required elements and accuracy. Table 1, on page 04, shows a simple sterilization audit form.

Once the risks are known and the process has been assessed, process improvements should be undertaken to mitigate risk and improve outcomes. Failures or errors can be rated as high impact or low impact. High impact is defined as any error that could cause patient harm or create rework. Examples of high impact errors are failing to document everything contained on a specific sterilization load or any error related to the biological indicator. A low impact error is one that poses little or no risk of patient harm such as failing to sign the sterilizer printout. Quality checks should be in place so errors are caught before there is an opportunity to cause patient harm; this is a very important aspect of a good — and effective — quality control program.

**What are sterilization deviations?**

Errors can occur when sterilizing instrumentation, including, but not limited to, the following:

- **Incorrect sterilization:** An incorrect cycle or the wrong parameter can be selected by the sterilizer operator if there are distractions. Unless the department has an instrument tracking system that interfaces with the sterilizers, the operator may select the wrong cycle and the device could be damaged or inadequately sterilized. This is often a concern with complex devices like flexible endoscopes that have channels requiring specialized cycles.
- **Failed or missing biological indicator:** A biological indicator is to be run in steam sterilizers at minimum weekly (preferably daily) and with all implantable devices. If a biological indicator is positive, all instrumentation should be recalled back to the last negative biological indicator result.
- **Improperly labeled biological indicator:** A biological indicator that has not been processed or labeled correctly could prevent a load from being monitored appropriately.
- **Assignment of an inaccurate lot number:** The lot number is critical in identifying when, what, and where instrumentation was sterilized. All sterile processing departments should have a mechanism to recall instrumentation.
- **Missing documentation:** It is recommended that cycle parameters be verified after the completion of the cycle and before items are released for use.
- **Incorrect positioning of items on the sterilizer cart:** How packages are positioned on the sterilizer cart can impact sterilization effectiveness. Per the recommendations, peel packs should be on their sides, wrapped sets should be above containers, instrument sets should not be stacked, and sufficient space should be maintained between all items.
- **Incomplete or inaccurate sterilizer testing:** Testing of the sterilizers is required to ensure proper functioning. Testing is performed for new installations, for routine efficacy, and after equipment repairs. Personnel operating the sterilizers should have a good understanding of when testing is to be performed. Depending on the age and condition of the equipment, it is common for sterilizers to break down and need repairs. Major repairs require more extensive testing. The technicians repairing the sterilizer should communicate to
the SPD the extent of a repair so adequate testing is performed before the sterilizer is put back into use.

**Improvement initiatives**

Once the recommendations are understood, risks are identified, and the process is assessed, it is time to look for ways to improve the process and decrease the risk of error. The following are some examples of potential improvement initiatives for optimizing the sterilization process and minimizing the risk of error.

Writing and implementing a standard operating procedure (SOP) is one way to improve the safety of your sterilization process. An SOP is a controlled document that provides detailed steps on how to perform a procedure. Over time, a procedure can break down if not written down and controlled. If a staff member is observed performing a task differently, an employee may assume the procedure has changed and adopt the new method without question. This is prevented when an SOP is in place.

A sterilizer operator competency checklist and performance assessment can be developed and used as a standardized measurement tool to allow employees to demonstrate their knowledge and comprehension of the sterilization process. Competencies can be measured during orientation, initial training, or as an annual tool to reassess or verify an employee’s ability, and as a performance improvement tool to identify specific areas where an employee should be focusing efforts or receiving additional training to improve results.

### Table 1

<table>
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<th>Load Linked Properly</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tr>
<td>Instacount and Tape Parameters Match</td>
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<td>Cycle Parameters Met Requirements</td>
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<td>Operator Signature</td>
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<td>Correct Cycle Standard/Express...</td>
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<tr>
<td>Filter and Locks in Place</td>
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<tr>
<td>Wrap Intact and Blue Transport Tray Present</td>
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<tr>
<td>Peel Packs Packaged Correctly</td>
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<tr>
<td>Production Label matches Container / Assembly Sheet</td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>

**REMINDER**

Check Production and Serial Numbers/Container Matches Production Label

**Load Contents Match Documentation?**

- Extra Peel Pack
- Extra Set
- Missing Peel Pack
- Missing Set

**Was a BI required?**

- Control Present and Labeled Correctly?
- BI Processed/in incubator
- BI Labeled
- BI Documented in Instacount
- BI Missing/not done

**Is Challenge Pack / Chemical Indicator Required?**

- Logged in Instacount
- Documentation Complete on Result Sheet
- Passed
- Failed

**DEVIAN FINDINGS/CORRECTIVE ACTIONS TAKEN:**

____________________________________________________________________________________

____________________________________________________________________________________

AUDITOR SIGNATURE: ___________________________ DATE: ___________ TIME: _______

Form CS-0004, Revised 2/18/2014

ATTACH STERILIZER “LOAD TRACKING” DOCUMENTATION

There is always a risk that non-sterile sets could mistakenly be distributed before being sterilized. Creating areas in the sterile processing department that are visibly and physically separated can help personnel understand which items are processed and which are unprocessed. Placing processed and unprocessed items in separate areas in the department and creating a pre-sterilization staging area and post-sterilization cooling area can help to differentiate between the two. Visual cues such as flags or signage can be placed on carts and floors to alert and direct staff. Figure 1 shows how signage communicates important information such as that the cart is hot, the biological indicator is in the incubator, and the approximate time the load will be ready for distribution.

A monitoring initiative can be implemented to ensure that all items pending sterilization remain within the control of the sterile processing department at all times. If a set is assembled, awaiting sterilization, and cannot be located, it could have been sterilized but not documented or unprocessed and inadvertently moved into the storeroom or case cart area. To effectively monitor sets awaiting sterilization, all sets should be identified to document status and location. At Johns Hopkins Hospital, we confirm all items pending sterilization at minimum daily.

Sterilizer record reconciliation and biological indicator verification are important parts of the quality assurance protocol. It is important to check the sterilizer documentation in order to verify that the documentation matches the sterilization tapes. It is equally important to verify that the correct items are in the load and that the parameters documented match the sterilizer printout. Biological indicator verification is necessary as a quality measure to ensure that the biological indicator has been handled, processed, and documented correctly.

Communication and performance feedback should be encouraged to further promote quality improvement. Open communication and continuous feedback will allow the sterilizer operator to understand what areas can be improved and what areas they excel in. In order to provide performance feedback, all deviations should be reviewed with each sterilizer operator.
Summary
In summary, quality improvement initiatives can be identified by reviewing the recommended practices, developing policies and procedures, and performing audits to measure compliance. Once the process is assessed, deficiencies can be noted, improvement initiatives implemented, and the process reassessed. Continuous monitoring, whether random or 100%, is determined by the error rate. A process in control and with a high accuracy rate would need less monitoring than a process with a low accuracy rate. It cannot be stressed enough how important it is to monitor the entire sterilization process and reconcile sterilization documentation to ensure the process is in control. HPN

References:

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Circle the one correct answer:

1. ANSI/AAMI ST79 is the “go to” document for best practices related to the processing of instrumentation in the healthcare setting.
   - A. True  B. False

2. It is not necessary for staff to perform tests to verify the functioning of their washer and sterilizer equipment because the equipment manufacturer is responsible for making sure the equipment functions properly.
   - A. True  B. False

3. The risk of making an error when sterilizing instrumentation is low because the process is very simple.
   - A. True  B. False

4. Healthcare facilities processing medical devices are NOT required to follow the manufacturers’ Instructions for Use.
   - A. True  B. False

5. Auditing the sterilization process helps a healthcare facility identify sterilization deviations that may impact outcomes and patient safety.
   - A. True  B. False

6. Instrument fleet, high volumes, and department distractions can create opportunities for staff to make errors when sterilizing.
   - A. True  B. False

7. Missing documentation, such as not identifying all packages contained on a sterilizer load, is a sterilization deviation that could impact patient safety.
   - A. True  B. False

8. Performing sterilization audits allows the Sterile Processing Department to assess accuracy and determine if the process is safe and in control.
   - A. True  B. False

9. A standard operating procedure (SOP) is one way to improve the safety of the sterilization process in your facility.
   - A. True  B. False

10. Process challenge devices (PCDs) are used to assess the performance of the sterilization process.
    - A. True  B. False

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