HEALTHCARE PURCHASING NEWS

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Beyond the visual

The importance of quality cleaning verification programs

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LEARNING OBJECTIVES

1. *Identify testing types that are available for cleaning verification and discuss how they work.*
2. *Explain the technician's role and responsibilities for cleaning verification*
3. *Discuss the elements of a cleaning verification quality program.*

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As medical technology continues to advance, reusable instruments and devices are becoming more complex. Devices with channels, seams, joints, moving parts and other complex components present serious challenges when it comes to ensuring that they are "clean," which in this case means free from all visible organic and inorganic soils[1] and ready for the next reprocessing step.

Historically, visual inspection was the only tool available to assert cleanliness, but clinical experience has shown that medical devices are not always clean even if the naked eye thinks they are. So-called clean instruments have been documented to cause infectious outbreaks, loss of limbs, and even death, even if they were put through a sterilization cycle after cleaning.

This avoidable patient safety issue has led to the development of numerous tools to help technicians determine whether or not a medical device is verifiably clean and ready for high-level disinfection or sterilization. A review of these tools will help department managers assure they have the right methods and procedures in place for their device inventories.

Cleaning verification

Cleaning verification is the process of confirming that the soil removal goal was achieved, and that the medical device can safely proceed to the next phase, which is either disinfection or sterilization. If any residues remain, whether visible to the naked eye or not, they may prevent the subsequent disinfection or sterilization cycle from being effective and may result in a device that is still contaminated.

While visual inspection (using lighted magnification to inspect surfaces and box locks, and borescopes to look inside channels and lumens) remains a recommended practice and can help technicians discover visible organic soils, residual soil and microbial contamination may remain even though the device looks clean. Residual soil can lead to the formation of biofilm and can inhibit disinfection and sterilization. This is why tools are needed to go beyond *visual* inspection to *verifiable* inspection.

The technician's role in inspection and cleaning verification

Optimal patient safety and outcomes are the objectives of all healthcare functions, including the reprocessing department. Sterile processing technicians are the guardians who stand between contaminated instruments and the next patients on whom they will be used. Because inspection is such a critical step in medical device reprocessing, technicians must have a thorough and detailed understanding of how to visually inspect every type of medical device that comes through their department. They must also know how to use the testing tools available to them to effectively verify that devices are clean.

For example, all techs should receive ongoing education and competency testing in the use of lighted magnifiers and borescopes. If, for whatever reason, a technician doesn't know how to use these tools, or which instruments to use them on, they are responsible for proactively notifying their supervisor or manager. The same applies to competency in the handling and use of verification tools and supplies.

Establish a cleaning verification program

Because of the critical importance of cleaning verification in the health and safety of patients, healthcare facilities should include their cleaning verification program in their quality management system (QMS).

A thorough quality program requires the collaboration of a multi-disciplinary team that represents all departments connected to the reprocessing function. Team members may include sterile processing management and technicians, surgical department representatives, infection preventionists, risk management professionals, materials management/supply chain/purchasing professionals, and any others who may have a stake in the process.

Identify and evaluate available products

Reprocessing managers should begin by identifying the products available in the marketplace and performing an evaluation and trial to select the best products for their facility. Although sterile processing technicians do not typically make supply chain/purchasing decisions, they should have input into the products selected to ensure they are appropriate for the technician's scope of work.

To help with product evaluation, sterile processing personnel should know the ANSI/AAMI recommended criteria for selection of products. According to ANSI/AAMI, testing products should be:

- Rapid in their function
- Easy to perform
- Sensitive (i.e., meet realistic benchmarks)
- Accurate
- Repeatable
- Free of interfering substances
- Robust (i.e., do not require exacting conditions or time constraints that cannot be achieved in routine reprocessing areas)

Next, the team should familiarize themselves with the specific products; what they are, what they do, and which would be most suitable for the specific soils their department deals with. Because they work with these soils every day, technicians may be able to provide valuable input to assist in making optimal product choices.

The verification products on the market today test for:

- Protein – they detect amino acids (small subunits of a large protein molecule).
- Carbohydrates – a glucose oxidase test method that measures glucose.
- Hemoglobin – originally designed to detect blood in stool but is also a bioburden detection tool for SPD.
- Adenosine triphosphate (ATP) – ATP is an energy-carrying molecule present in the cells of all living things. When the cells die, the concentration of ATP decreases over time.

Protein soils are the most common surgical soils, which makes protein tests a good choice for residual soil testing on reusable medical devices. There are many proteins encountered during invasive procedures, so a protein test that detects a broad spectrum of protein-based substances is ideal.

Carbohydrate tests only detect glucose, which is one of a variety of potential surgical soils.

Likewise, hemoglobin tests detect only blood, which may also be far too specific to account for all possible surgical and procedural soils on instruments.

ATP tests require the use of a luminometer, which adds an extra step to the verification process. Since a test should ideally be simple to perform, having to use an additional piece of equipment and potentially maintain multiple luminometers in the department is inefficient and can become costly. In addition, the fact that the concentration of ATP decreases as cells die may make detection less accurate.

Once the tools are understood and matched to the soils the department is addressing every day, the ANSI/AAMI criteria can be applied to select the optimal products for the facility and its needs.

Build the steps for the verification program

A cleaning verification program involves more than selecting the product and then telling staff to use it. To assure that the cleaning verification program is successful and sustainable, verification steps need to be developed and staff need to be trained. The program should also be audited for compliance to current standards, during which gaps in the process can be identified and process improvement steps can be developed to address the gaps.

There are three parts to cleaning verification:

- Inspecting cleaned devices with appropriate tools (e.g., lighted magnifiers, borescopes)
- Testing cleaned devices with cleaning verification products
- Testing cleaning and inspection equipment using testing products

Conduct training

Once the verification products have been selected, technicians will need to be trained on the new products and have their competence assessed.

Figure 1: ANSI/AAMI ST91 states that high-risk endoscopes should be tested every time they are processed.

The training should include but not be limited to:

- Reviewing the testing product manufacturer's written instructions for use
- Providing hands-on instruction on how to use the product
- Requiring handwashing and donning of clean gloves before performing the testing to reduce the risk of cross-contamination
- Teaching the appropriate storage of the product
- Documenting expiration dates (if applicable)

Decide on device types and frequency

The next step is to determine which instruments/devices need to be tested and how often. Guidance for this can be found in the device manufacturer's written instructions for use, in ANSI/AAMI standards, and from risk assessments performed in the department. This is where the multi-disciplinary team can also be valuable. Each stakeholder will have a different perspective on risk and device complexity, and each may add important information to the decision-making process.

For example, ANSI/AAMI ST91 lists high-risk scopes as endoscopes associated with infections due to documented cross contamination or outbreak events. These include bronchoscopes, cystoscopes, duodenoscopes, endobronchial ultrasound endoscopes, linear ultrasound endoscopes,

Self-Study Test Answers: 1. B, 2. D, 3. D, 4. E, 5. A, 6. B, 7. C, 8. E, 9. D, 10. A

ureteroscopes, and others as determined by the facility. High-risk endoscopes are recommended to be tested every time they are processed. However, if a device is not classified as high risk, it becomes the responsibility of the facilities to determine testing frequency.

It is also important to stay informed about outbreaks within your community and nationwide, to determine if scopes previously considered low risk should be treated as high risk. Ultimately the team may choose to test every flexible endoscope to reduce the risk of any cleaning failures.

Because it would not be efficient to test every cleaned instrument/device, the department should establish criteria for identifying those that will be tested on a routine basis. Criteria such a device's complexity, cleaning difficulty, and/or associated surgical site infections are a good place to start. Surgical and reprocessing staff would be good sources of information for selecting these instruments, which could include laparoscopic, robotic, orthopedic, neuro and specialty items.

Once the instrument/devices are identified, the frequency must be established. To be consistent with the system for flexible scopes, high-risk, medium-risk and low-risk items can be categorized. High-risk items would be tested every time, while medium and low-risk items would be tested less frequently.

Test the equipment

A thorough quality management system should also include routinely testing the cleanliness of the borescope, to reduce the risk of cross-contamination causing a positive result when testing the endoscopes.

Document the testing

The tests and their results should be entered into a log sheet. If the department has a tracking system, this can be created in the database. If not, then a manual log can be created.

In addition, a policy, procedure, and work instructions should be written so technicians can respond appropriately to failed cleaning verification tests. Standard practice is to send failed items back through the decontamination process, then perform cleaning verification testing again. If there is another failure, the department should consider removing the item from service to determine whether it should be tested further (cultured, e.g.) or sent back to the manufacturer or a repair company for examination and refurbishing, if appropriate.

If the failure is traced to a borescope, the policy and procedure should include the steps to clean and disinfect the borescope before using it on another item. The inspection workstation should also be cleaned and disinfected. Once staff members have identified a cleaning failure, they should wash their hands per facility policy.

In the same manner as sterilization data, all failures should be documented and routinely reported to the infection preventionist, including details such as:

- The number of items tested
- The number of identified failures
- The number of cleaning equipment tests
- The number of cleaning equipment test failures

Documenting the numbers and failures will also support a sustainable, high quality process because staff are aware that data is being collected and reported.

Audit and investigate causes

A physical audit of the reprocessing function should be performed by observing the actual reprocessing workflow and every step of the process to confirm compliance and/or identify gaps. An audit of the records should also be performed routinely to ensure that testing is being performed to the established schedule and that it follows relevant manufacturers' written instructions for use.

Once a failure has been identified, a root cause analysis should be performed to identify potential causes for the cleaning failures. A multi-disciplinary team may be necessary to find the root cause because equipment testing failures can be the result of water quality issues, equipment malfunction, process drift, gaps in the process, lack of training, and other variables overseen by various experts. The medical device manufacturer may also need to be a part of the investigation to ensure that the cleaning process is compliant with manufacturer's written instructions.

Optimize your cleaning verification program

To be effective and reduce infection risks, the cleanliness of medical devices must be verified through a robust process that includes more than just a visual inspection of cleaned items. A number of cleaning verification products are available today, and each reprocessing department must select the testing tools that are appropriate for their inventory of devices. While each type of test has value, protein testing provides the ability to detect the widest range of retained soils, which may make it the most efficient tool for most departments.

The cleaning verification protocol must also be included in the department's quality management system to assure continuous improvement and quality of the process. Among other elements, a high quality cleaning verification program establishes the items to be tested and the frequency of that testing. This includes selected medical devices and cleaning equipment. It also requires that testing be documented and routinely reported to maintain a sustainable process and identify failures and root causes quickly. Ongoing staff training is another element that helps reduce the risk of processing failures.

It may be wise to review your existing cleaning verification process to assure that it's a thorough, high quality program. If you don't have a formal cleaning verification protocol, these guidelines can help you get started. An evidence-based program that reduces infection risk is worth the effort. **HPN**

References

1. https://www.cdc.gov/infectioncontrol/guidelines/disinfection/introduction.html#anchor_1554392545.

2. https://www.aami.org/st91: ANSI/AAMI ST91:2021, Comprehensive guide to flexible and semi-rigid endoscope processing in health care facilities.

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1. **Cleaning verification is the responsibility of:**
   A. EVS
   B. Sterile Processing Technicians
   C. Infection Control
   D. Facilities
   E. None of the above

2. **Cleaning verification includes:**
   A. Visual inspection with lighted magnification
   B. Borescope
   C. Validated cleaning verification products.
   D. All of the above

3. **The decision on what cleaning verification product to use is the responsibility of:**
   A. Materials management
   B. Risk Management
   C. Periop Director
   D. A multi-disciplinary team of stakeholders
   E. The CFO

4. **Cleaning verification products available today measure/detect:**
   A. Protein
   B. Carbohydrates
   C. ATP
   D. Hemoglobin
   E. All of the above

5. **Per ANSI/AAMI recommendations, a cleaning verification product should be:**
   A. Rapid and easy to perform
   B. Expensive
   C. Stored at a certain temperature
   D. Colorful
   E. From your favorite rep

6. **The most common procedural soil contains:**
   A. Fats
   B. Proteins
   C. ATP
   D. Sugars
   E. Sweat

7. **Cleaning verification should be performed:**
   A. Daily
   B. Weekly
   C. As determined by the facility risk assessment
   D. When there is time
   E. Never

8. **Criteria to select items to be tested can include:**
   A. One of every type
   B. Complex devices
   C. Devices that are hard to clean
   D. Devices that are designated as high-risk
   E. B, C, D

9. **Cleaning failures can be determined by:**
   A. Visible soil
   B. Failed equipment test
   C. Failed cleaning verification test
   D. All the above
   E. None of the above

10. **Stakeholders for a cleaning verification quality team could include SPD technicians and management, an OR representative, an infection preventionist, a risk management professional, and a supply chain professional.**
    A. True
    B. False

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