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Cleaning Verification Update for Flexible Endoscopes: What Changed, What Stayed the Same?

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LEARNING OBJECTIVES

1. Discuss the continued importance of cleaning verification for flexible endoscopes
2. Review new references in ANSI/AAMI ST91:2021 for processing departments to leverage and justify a cleaning verification program
3. Discuss strategies to comply with updated cleaning verification guidance

The idea of using cleaning verification (CV) on environmental surfaces has been a recommendation in the American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) ST91, *Flexible and semi-rigid endoscope processing in health care facilities* since its creation in 2015. This lesson plan will review CV, including what has changed and what has stayed the same in recent guidance.

Objective 1: Discuss the continued importance of cleaning verification for flexible endoscopes

The quality assurance (QA) benefits of a CV program should be evident to anyone knowledgeable about the process. Consider this question: *Would anyone processing instruments knowingly send a soiled endoscope from the decontamination area to the clean side?* Although one would hope that answer would be an emphatic *No*, the practice nonetheless occurs more often than one might assume.

Because flexible endoscopes have so many surfaces that cannot be assessed with the naked eye, someone not using a tool to check these areas would never know if a device was still soiled. Now, let's ask the obvious next question: *How do we solve this problem?* In thinking about it that way, the answer becomes simply, *Find a tool to enhance inspection of the devices*. In other words, implement a system to help processing staff "see" into these hidden spaces. CV allows that to occur.

To fully understand the continued importance of CV, let's discuss why

it is needed. Flexible endoscopes are complex devices, and it is difficult to apply direct friction to many of their surfaces. In manual cleaning, direct friction—the scrubbing/brushing action that lifts soils away from the surface—is significant. Without it, all subsequent rinsing steps have a lesser effect. Since flexible endoscopes have long lumens and tight surface interfaces, simply having brushes of the correct size does not guarantee a clean endoscope. Even when following the endoscope manufacturer's instructions for use (IFU), any damage or changes to the endoscope's surfaces can make effective cleaning impossible. Assessing the effectiveness of the cleaning process is vital to providing safe endoscopes to patients. When considered in this manner, CV is not only a QA tool but potentially an evaluation tool. Repeated failures of a CV test could demonstrate that an endoscope is damaged internally and in need of repair.

The need for CV is not the only guidance unchanged in the new ST91. Let's look at some other factors:

- It is relevant to look for markers or soils in an endoscope after a patient procedure. Both ST91 and ANSI/AAMI ST79:2017 with 2020 amendments, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities,* list several specific, relevant markers that departments can use to assess instrument cleaning efficacy. These soils include protein, hemoglobin, carbohydrates and adenosine triphosphate (ATP), among others.
- Selecting a test that detects the soil(s) one's facility wants to check is a major decision to make when instituting a new CV program. An additional consideration is to find a test sensitive enough to detect the soil(s) in small quantities. Many realistic benchmarks are measured in micrograms but could also be in colony-forming units (CFUs) or femtomoles.
- When evaluating a CV test, determine whether it is user-friendly. If CV testing is too cumbersome, employees will be less likely to perform it or may take shortcuts. On the other hand, if the test is rapid, easy to perform and easy to interpret, there is a much greater chance of compliance.
- Consider internal visual inspection of endoscopes. This is an excellent QA tool, but it takes several minutes to complete properly and still might not show minute traces of residual soil. In comparison, CV could be done in a shorter timeframe and display test results in an easy-to-read, accurate format. Given the choice between the two, internal visual inspection is often reserved for specific endoscopes or scenarios, while CV testing for residual soils is considered possible for every endoscope and every processing cycle.

Objective 2: Review new references in ANSI/AAMI ST91:2021 for processing departments to leverage and justify a cleaning verification program

How will I justify this? This is the big question for departments that need to institute or increase the frequency of their CV program. The how is answered (and something that has changed in the new version of ST91) with the amount of referenceable published literature, following a six-year span between versions of the document. That is why one of the focuses for the new ST91 was to expand the references to provide support for all aspects of endoscope processing, from eliminating the use of simethicone to keeping staff cool in the decontamination area.

Additionally, the document now references the Manufacturer and User Facility Device Experience (MAUDE) database. The MAUDE database houses medical device reports submitted to the U.S. Food and Drug Administration by mandatory reporters (such as manufacturers, importers and device user facilities) and voluntary reporters (including healthcare professionals, patients and consumers). Anyone wishing to learn about the difficulties of flexible endoscope processing and the impact of poor practices and maintenance of endoscopes should review the MAUDE reports.

Specific to CV, reference to peer-reviewed and non-peer-reviewed articles can help processing departments justify requests for additional resources necessary to comply with the new ST91 guidance. For example, if a facility is instituting a new CV program, then selecting a test is only the beginning. Other aspects—such as creating a space for the testing, setting up a documentation process and potentially purchasing more endoscopes—are all considerations that require resources.

Even if a CV program is not new to one's facility, there may be a need for additional resources. With the added definitions of "high-risk" and "non-high-risk" endoscopes comes new guidance on CV frequency. High-risk endoscopes are defined as having been associated with infectious outbreaks or those with a design that presents a challenge to the cleaning process. This includes duodenoscopes as well as bronchoscopes, cystoscopes, endobronchial ultrasound (EBUS) scopes and ureteroscopes. Under the new guidance in ST91, these endoscope types shall be tested with some form of CV each time they are processed. Even with non-high-risk endoscopes, the facility shall test those endoscopes

at a statistically significant frequency. While the exact frequency is left to the facility to decide, it may initiate an increase in CV frequency, if the facility was not performing much testing in the past. *Note: Remember that "shall" is the strongest recommendation statement AAMI can make. If a facility states that it complies with ST91, then CV will have to be performed in order to be compliant.*

Objective 3: Discuss strategies to comply with updated cleaning verification guidance

Strategies for complying with the guidance in the new ST91 will depend on a facility's current CV program. All endoscope processing departments, however, should begin with a gap analysis; this is true whether CV is new to a facility or has been part of facility policy for some time. As with any quality improvement initiative, comparing current practices to the initiative's end goals is critical. This could also be helpful if a survey is imminent. While a facility or department may not currently comply with the new guidance from ST91, if they have created an action plan to become compliant, a surveyor may take that into consideration when reporting their findings.

A complete inventory and classification (high-risk versus non-high-risk) of the facility's endoscopes should occur as part of the initial analysis. Also, remember that there is an expectation that endoscope processing procedures will be standardized across all departments that perform the tasks. If the procedures are not standardized, the discrepancies should be reconciled.

If a CV program exists within one's facility, complying with the updated standard may not take much more than these initial steps and increasing the current testing volumes. Conversely, facilities with no CV program in place will need to make many more decisions. The following are three significant considerations:

- **Which test(s) will be used?** Because there are a variety of tests on the market (some with the capability of detecting multiple soils in a single test), the facility may want to perform a trial(s). This would ideally allow it to see which test suits it best.
- **Where will the testing be done?** Depending on the test type (flush versus swab), the facility may need to create a vertical space as a flush-type test (for the most effective results, this should be performed with the endoscope hanging).
- **How will the testing be documented?** A well-organized, referenceable method for recording the results of the CV testing should be created. Remember, as the saying goes, "If it wasn't documented, it wasn't done."

With a critical-thinking approach and the help of a multidisciplinary team, a facility will be on the right track to complying with the updated ST91.

Conclusion

CV continues to be one of the most important tools available to flexible endoscope processing departments. Without these methods of enhancing inspection of endoscopes, dirty and damaged endoscopes may go undetected. By adding a way to classify endoscopes by their risk for residual contamination, the new ST91 provides actionable recommendations to increase the quality of any department's processing procedures. When CV is implemented correctly and frequently, risks associated with dirty endoscopes may be mitigated.