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CQI in device decontamination: the role of washer indicators

by Ann Burke, R.N., B.S.

If it isn’t clean, it isn’t sterile: this is the mantra in hospital central sterile services departments (CSSDs). CSSD professionals recognize that the essential first step in sterile processing is the successful cleaning and decontamination of surgical/hospital instrumentation. Increasing vigilance toward continued quality improvement, they have focused more intensely on the washing process and have begun to apply a number of processes with quality controls similar to those used in sterilization.

Cleaning guidance
Standards organizations such as AAMI and AORN acknowledge the difficulty of assuring that instruments have been properly decontaminated and rendered safe to handle and ready for terminal sterilization. These organizations recommend establishing an effective quality management program with quality control processes that include testing the mechanical performance of the department’s automated washers. The ANSI/AAMI ST79:2010 Amendment 4:2013, Annex D text provides detailed guidance on the verification of a cleaning process and recommends, “for verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the automated washer (if used) and the cleanliness of specific devices after manual or automated cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined.”

AORN also recommends that healthcare workers verify the proper functioning of automated washers as part of an ongoing quality assurance program and document the effectiveness on an ongoing periodic basis. The Guidelines for Perioperative Practice, 2015 Edition, Guideline for Cleaning and Care of Surgical Instruments, Recommendation XVII (a) and (a.1) state, “A quality management program should include monitoring of manual and mechanical cleaning. Cleaning is a critical component of instrument processing and can affect the efficacy of subsequent sterilization processes. Items that have been sterilized after inadequate cleaning processes have caused patient injury. Mechanical cleaners should be tested for correct function on installation, at least weekly, preferably daily, during routine use, after major repairs, and after significant changes in cleaning parameters. Adequate cleaning is essential to remove or destroy microorganisms and eliminate endotoxins. Testing washer disinfectors/decontaminators on a regular basis verifies that the equipment is functioning correctly or identifies an opportunity for corrective action. Commercial tests to monitor cleaning efficacy of mechanical washer disinfectors/decontaminators are available.”

The role of indicators in washing processes
Washer indicators verify the cleaning process of automated washers. They have been in widespread use in Europe and Canada for many years. Many U.S. facilities have also implemented the use of washer indicators as part of their quality control processes, to determine whether automated washers meet a predetermined standard of efficacy. First, CSSD staff determines and documents what constitutes optimal washer performance, based on the manufacturer’s data for their specific automated washers. Next, they establish protocols to deal with wash cycle failures. The benchmarks for specific automated washers are typically based on the system’s cycle parameters and the chemistries being used. Once benchmarks are verified and set, the washer indicator can be used to demonstrate when one of the parameters is outside the benchmarked threshold. The indicators should provide a reproducible and consistent test that verifies the performance of the automated washer.

It’s important to note that a ‘passing’ washer indicator doesn’t guarantee that instruments are clean, just as a biological or chemical indicator doesn’t guarantee that a sterilizer-processed load is sterile. However, it can verify the proper performance of an automated washer and, in some cases, the...
proper concentration of cleaning chemistry. Washer indicators also provide valuable data from individual washer cycles that can help identify problems quickly and help diagnose the cause(s) of cycle failures.

**Causes of washing cycle failure**

Cycle failures are caused by a variety of factors, all of which can impact cleaning performance. The most typical causes are incorrect cycle selection and temperature parameters, inappropriate chemistry selection, inadequate chemistry delivery, and mechanical impingement issues. Additional contributing factors include inappropriate preparation and positioning of the instruments, overloading the washer, operator error, equipment malfunction, or inadequate equipment maintenance.

An important example of inadequate maintenance involves internal washer inspection. A quick examination of many automatic washers will uncover small pieces of plastic and debris blocking the unit’s spray arms and making them less effective. A proper preventive maintenance schedule might include a regular scan of the washer’s debris-prone areas, which will keep the spray arms performing optimally. Without an ongoing quality assurance program that regularly monitors cycle performance, these types of impediments might not be routinely detected and might have a negative impact on the overall cleaning process.

**How washer indicators work**

There are a few commercially available indicators on the market; some vary in their design and the representative soils applied to the strip. They usually consist of a chemical indicator that is designed to withstand chemical, thermal, and mechanical assaults that would be found during the normal automated washer process; it is often affixed to the washer basket. To verify proper automated washer functioning, one commercially available product measures the parameters of time, temperature, mechanics (impingement) and chemistry. The washer indicator is designed to provide a benchmarked resistance to those cleaning/disinfection parameters. This resistance not only verifies the established cleaning parameters, but also mimics the challenge of an occluded or blocked surface on instruments (such as box joints, which are notoriously difficult to clean and may not easily be reached by water and detergent during a normal washer cycle).

Washer indicators are chemical indicators that have been imprinted with a dried test soil formula and a dye. For example, one commercially available product has a soil sample imprinted four times on each indicator. There are two soil stains imprinted on the front and two on the back (Figure 1).

The soil mimics the challenging protein, lipid, and carbohydrate composites typically found on dirty instrument sets in the CSSD. The design of an indicator and its holder should provide a multidirectional challenge to test the effectiveness of spray arm rotational coverage during the washing cycle. In this case, the exposure area presents a horizontal and vertical challenge on both the top and bottom of the indicator. In addition, the soil imprints on the indicator provide specific preset challenges to the mechanical washing action, the time and temperature of the cycle, and the cleaning chemistries used. For example, if no cleaning chemistry is used, the indicator should fail. At the end of a successful cycle, the indicator should be visibly free of all dried soil to record a pass result.

**How washer indicators compare to sterilization indicators**

Like biological indicators and chemical indicators used for sterilization monitoring, washing indicators are specific to certain parameters used during a washing cycle. Both types of indicators provide a challenge to a specific process. Just as process challenge devices provide a physical challenge to the contact of sterilant on a biological indicator, the design of the washing indicator holder presents a challenge to the contact of chemistry, temperature, and mechanical action on the representative soil sample placed on the indicator (Figure 2).

However, unlike biological indicators, spores are not used for washing indicators; and unlike steam sterilization chemical indicators, which use reactive chemicals to test steam process parameters, washing indicators use soil samples and dyes to provide a direct challenge to washing process parameters.

Like chemical sterilization indicators, it is recommended that washing indicators be placed in the middle rack if only one is used per cycle. Ideally, indicators are used on each rack level, but the middle rack is considered the most challenging to clean. In the end, however, the quality assurance preference of the facility will determine how often, on how many levels, and where in the chamber indicators are used.

**Establishing a thorough washing protocol**

Washing protocols can vary widely. AORN recommends a test of mechanical cleaning equipment before its first use, weekly during service and after any major maintenance. AAMI currently recommends at least weekly, and preferably daily testing of mechanical cleaning equipment. Many facilities currently verify the equipment daily before the first load of the day with an indicator on every level of the washer. Some facilities even verify every load.

Before implementing any new process, it is imperative that proper cleaning education, training and protocols be developed by the facility. In order to do this, the department must know what the current parameters of the cleaning process are, what adjustments and corrections to the processes might be necessary, and what outcomes they need to establish as benchmarks for the washing process.

Washer indicators can be used with all current automated washers and many older models as well, to help establish cycle benchmarks. Depending on the washer’s process, cycles can be evaluated to determine the optimal time, temperature, cleaning chemistry and impingement level that provides the most efficient and thorough automated cleaning process. When benchmarking, washer indicators should be placed in an empty washing system.

**Figure 1**

Washer indicators also provide valuable data from individual washer cycles that can help identify problems quickly and help diagnose the cause(s) of cycle failures.

**Figure 2**

How washer indicators compare to sterilization indicators.

**Figure 3**

It’s also important to always incorporate each specific manufacturer’s instructions for use for all equipment and indicators.
being used. For example, one manufacturer recommends placing an indicator in a hinged holder in a wire basket. One half of the holder should be placed flat on the bottom of the basket and the other half positioned at 90 degrees vertically (Figure 3, previous page) for the best challenge to the cycle.

What to do with a failing result
A washer indicator failure result is easily determined by the presence of soil remaining on the indicator at the end of a washing cycle. A failure indicates that something went wrong in the cleaning process and allows staff to investigate the process. The department’s protocols will help in determining the root cause of a failure and the next action steps. The benchmarking process will have provided the facility with predetermined cycle parameters to compare with the failed cycle (e.g., enzyme cycle; minimum of two minutes, water specific temperature range 100-140).

Failures may be related to impingement arm function, chemistry-related issues, or time and temperature factors. Impingement arm failures may be caused by a clogged spray arm, loss of pump pressure, overloading of a rack or basket of instruments, or incorrect positioning of the indicator. Chemistry-related failures may be due to insufficient use of enzymes or insufficient chemistry available (an empty container). Temperature and cycle factors include an insufficient temperature reached or too short an enzyme cycle.

As part of the documented protocol for washing, staff should develop and document a troubleshooting process. Some indicator manufacturers offer troubleshooting guides complete with comparison photos of indicators in various states of failure, which can assist in determining causes. If a facility is creating its own checklist, the document should include all the possible causes listed above. When troubleshooting, all the potential factors should be examined, since there may be occasions when more than one causal factor is involved in a washer failure.

It’s important to note here that a failure result on a washing indicator does not necessarily mean that the load is not clean. Visual inspection always remains the final step in the cleaning process. CSSD staff should carefully examine the instruments and determine if they should be re-washed. If the instruments are visually clean, the load may move on to the clean prep and pack side.

For this reason, it is essential to establish a benchmark that accounts for these washing variables and test the resulting cycle with washing indicators until a passing result is achieved. Once this balance is verified, it can become a best practice that is applied consistently for repeatable results.

Washer indicators can also be used to drive competencies and enforce best practices in the CSSD. For example, one hospital system used washer indicators to help educate their CSSD staff on the dangers of overloading baskets. Following the manufacturer’s instructions for use, they placed the washer indicator in an empty load in the morning, and it passed. The CSSD manager then had the staff run the same type of washer indicator again in a cycle with a load of instruments. This time, the washer indicator failed. The only difference between the two cycles was the presence of instruments. The CSSD manager used this scenario to illustrate to the staff how overloaded the instrument basket was. After loading a new basket with an appropriate amount of instruments and running a full cycle, the washer indicator passed, which made the manager’s point with a concrete object lesson.

Consistent processes and verifications are among the hallmarks of CSSD best practices. Making the best possible use of washing indicators, in combination with careful visual inspection procedures, can significantly enhance the consistency of a department’s cleaning and disinfection processes, and ultimately benefit their entire sterile processing cycle.

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References
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Circle the one correct answer:

1. When a wash indicator shows a failing result, CSSD should:
   A. Review the cycle selection and rerun the washer load
   B. Visually inspect the instruments and determine if they should be re-washed
   C. Investigate the process and determine the root cause of failure
   D. B and C
   E. A and C

2. Washer indicators are used to:
   A. Verify the cleaning process of automated washers
   B. Eliminate the need for visual inspection of instruments after the automated cleaning process
   C. Be part of a quality control process to determine whether automated washers meet a predetermined standard of efficacy
   D. A and C
   E. B and C

3. Washing indicators use live spores and soil as a challenge to the automated washing process.
   A. True
   B. False

4. When implementing washer indicators into an CSSD’s quality assurance plan:
   A. Begin the benchmark process with a washing indicator placed in the most easily accessible position in a fully loaded instrument basket
   B. Begin the benchmark process with a washing indicator placed in the most challenging position in a fully loaded instrument basket
   C. Begin the benchmark process by placing the washer indicator in an empty washing system.
   D. Begin the benchmark process by placing the washer indicator in the middle rack with a fully loaded basket.
   E. All of the above

5. A typical washer/disinfector process equation includes these primary factors:
   A. Time, temperature, and chemistries
   B. Time, temperature, and impingement (mechanical action)
   C. Time, temperature, impingement and chemistries
   D. Time, impingement, ultrasonic action and chemistries

6. When establishing a benchmark for the washing process, CSSD staff should consider the following:
   A. The type of automated washer/disinfector being used
   B. The use of washer indicators to establish an optimal cycle
   C. Following all manufacturers’ instructions for use of equipment and indicators
   D. Differences in a system’s impingement action that may require more strategic selection of cleaning chemistries
   E. All of the above

7. Factors that can contribute to washer indicator failure are:
   A. Chemistry selection and delivery issues
   B. Impingement arm failure and inappropriate water temperature selection
   C. Overloaded instrument trays
   D. All of the above
   E. A and B

8. Professional standards organizations and cleaning indicator manufacturers provide baseline recommendations as to the use of indicators, but each facility determines how they are used in their CSSD, and how often.
   A. True
   B. False

9. A washer indicator failure result is difficult to determine, and the presence of soil must be measured to indicate a pass/fail.
   A. True
   B. False

10. To pass a washer indicator using a low impingement washer you would need to:
    A. Use a less aggressive chemistry (neutral pH)
    B. Use a more aggressive chemistry (high alkaline pH)
    C. Run two cycles to ensure thorough cleaning
    D. a and c
    E. None of the above

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