

# How do You Know Your Automatic Washer is Safe to Use?

By Stephen M. Kovach

Imagine this scenario: A surveyor for the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) asks a central service (CS) manager, "How do you know your automatic washer is working properly?" The CS manager replies, "My instruments look clean."

It is no longer uncommon for such a question to be posed to CS staff. Central service has become one of the hospital's most highly technical areas. Professional organizations that set guidelines and standards for central service, such as JCAHO, the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Association for the Advancement of Medical Instrumentation (AAMI), have begun to focus on verifying and monitoring the cleaning process, and on implementing quality improvement programs (QIPs.) Their guidelines pertain to ultrasonic cleaners and automatic washers.

The following paragraphs outline the various regulatory organizations' guidelines concerning monitoring the cleaning process. CS professionals can use these guidelines to answer questions such as:

- How do I know my automatic washer and ultrasonic cleaner are working properly?
- What am I doing to ensure that these machines are working the way they are intended to?
- How do I ensure that these machines are rendering items clean and safe for handling by staff and ready for use on a patient?

## JCAHO

Darlene Christiansen, director of standards interpretations and the Office of Quality Monitoring for JCAHO, states, "Sterile processing is an integral part of the care process, so it's important to assess that equipment is being properly maintained, chemicals are being used properly, infection control and (safety) measures are being applied appropri-

ately, and that there is proper ventilation, for example."<sup>1</sup>

Two new JCAHO standards support Christiansen's assessment. Standards EC.6.10 and EC6.20 require organizations to manage the risks of medical equipment and that equipment be maintained, tested, and inspected on a prescribed basis. These standards require the organization to have a written plan in place.<sup>2</sup>

## AAMI

AAMI is the primary resource for domestic and international standards for the medical industry, medical professions, and the government. AAMI's revised TIR 12:2004, 2nd Edition — "Designing, testing, and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers" is an excellent resource for identifying the questions healthcare professionals should ask manufacturers when considering a product for purchase or when devising a reprocessing protocol for a product already being used.

This new document is the most proscriptive thus far when it comes to the monitoring of the cleaning process. It directs device manufacturers to provide not only specific instructions on how to clean their surgical instruments, but also how to verify that proper cleaning has occurred. Suggestions include monitoring water temperature for proper cleaning and disinfection, employing a specific method to test the cleanliness of an instrument, or using a suitable analogous device to verify the effectiveness of the cleaning process.

CS professionals should know that not only does the TIR 12 document direct manufacturers, but also by inference, it empowers the hospital CS department to insist on receiving proper and complete decontamination documentation for each and every instrument.

The revised AAMI standard ST 35, 2003 (decontamination document) recognizes the need for testing and the importance of having

a quality process in place when it comes to cleaning:

- 7.4.1: Effective cleaning is a multi-step process that relies on several interdependent factors: the quality of the water; the quality and type of detergent; an acceptable washing method; proper rinsing and drying; correct preparation of items to be processed by cleaning equipment; the time and temperature parameters and load capacity of the equipment; and operator performance

- 7.4.2 Cleaning agents: Many types of soil could be present on reusable medical devices, but dried blood is especially difficult to clean. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning

- 7.4.4 Verification of the cleaning process: There is an increasing awareness in sterile processing of the need to control and standardize the steps taken to ensure a sterile device for patient use. With the understanding that disinfection and sterilization cannot be ensured unless the cleaning process is successful, it is incumbent upon professionals in the field to seek out whatever means are available and practical to verify this function. A quality system would call for the decontamination processing parameters to be monitored and documented, whether the process was accomplished by hand or mechanically

- 9.2 Quality process: Measurements of process performance allow the system to be monitored and the results compared to a predetermined level of quality. Evaluation of the findings provides a method of identifying problems or shifts in activities, and facilitates informed decision-making on policies and procedures. Ongoing auditing provides data to assess the effectiveness of the process and make ongoing improvements in performance.

## FDA

The FDA document, "Class II Special Controls Guidance Document: Medical Washers and Medical Washer-Disinfectors; Guidance for the Medical Device Industry and FDA Review Staff" states, "The FDA believes that a safe and effective system for cleaning and disinfecting medical devices is important in protecting the public health." (Feb. 7, 2002)

The Safe Medical Device Act of 1990 states that each institution must have processes in place for identifying and implementing the reporting of incidents related to equipment failure.<sup>3</sup> Equipment that fails or is taken out of service must be reported and documented. Failure of an automatic washer certainly warrants documentation and follow-up.

## CDC

Currently, the CDC is reviewing its "Guideline for Disinfection and Sterilization in

Healthcare Facilities." The final guideline will be published following revisions. The CDC's current recommendations can be found at its Handwashing and Hospital Environmental Control page: "Cleaning is the necessary first step of any sterilization or disinfection process... If the surface is not cleaned before the terminal reprocessing procedures are started, the success of the sterilization or disinfection process is compromised."<sup>4</sup>

### Industry

Companies serving the infection control market are beginning to supply users with information on how to test their automatic cleaning equipment. For example, in May 2005, Smith & Nephew updated its Cleaning and Sterilization Guide for Orthopedic Instruments on its Web page. The new user guide includes the following recommendations:

- The quality of water should be carefully considered for use in cleaning reusable devices. Water hardness is a concern because deposits left on medical devices may result in ineffective decontamination. The use of deionized water will reduce the mineral deposits on the devices.
- Ultrasonic cleaners should be monitored routinely to ensure that they are working properly. Recommended monitoring methods are Sonocheck monitoring vials from Healthmark

Industries Co. which change color when the ultrasonic cleaner is supplying sufficient energy and conditions are correct. Getinge also has developed a performance-monitoring program that allows users to independently verify the key parameters of the automatic cleaning equation under their control.

- On the subject of verifying the cleaning process, Linda Clement and Heide Ames of STERIS Corporation state, "Now you must investigate the entire sterilization process, beginning with cleaning: a) verify that the washing equipment is working properly (spray arms aren't obstructed and water heating element isn't malfunctioning, for example); b) verify that the washing equipment monitoring devices are functioning correctly; c) ensure that all cleaning chemistries used in the washer are appropriate for the equipment and the devices being processed, and that they are being dispensed correctly."<sup>5</sup>

### Why Test in the First Place?

Regulatory agencies and industry are promoting the implementation of QIPs to monitor the cleaning process. Even with the advent of such guidelines, some people question the need to monitor. The following real-life examples illustrate why hospitals should implement QIPs for their automatic washers and sonic equipment.

- **Switched at Birth:** A CS manager implemented a cleaning QIP which included the use of a standardized blood soil test. The failed test result, which included residual blood soil on the stainless steel coupon, indicated that water temperatures were not correct for the various cycles. Upon investigation staff discovered that the washer had been installed 10 years prior with the cold and hot water delivery pipes reversed. This resulted in excessive pre-wash temperatures for the equipment cycle setting. After the problem was corrected the washer was again tested and received a passing mark.

- **How to Save Detergent:** Shortly after switching brands of detergents for their automated washers, staff at one hospital reported a blood odor in the machine after the cycle was complete. The staff followed the recommended QIP, including use of a standardized blood soil test. They determined that the new detergent had produced excessive sudsing and that the detergent concentration had been set to nearly zero. Although this certainly would have saved the hospital a great deal on its detergent budget, the instruments were not getting clean.

- **I'm Melting:** After implementing a new QIP program for the automated washer, a CS department quickly discovered that a plastic supply line for the detergent had, for a period of time, been in contact with a non-insulated portion of the hot water line. The

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tube had melted closed, completely eliminating detergent supply to one of the washers. No one knew how long this condition had been in place.

- **An Expensive Soaking Tank:** A hospital's sonic cleaner looked and sounded like it was functioning properly, but when staff used a new test designed to detect cavitation energy, the sonic cleaner failed. A follow-up visit by an independent service company confirmed that the transducers were not working. No one in CS knew how long the cleaner had been malfunctioning; they had simply let the machine run longer (sometimes up to 15 minutes) until they felt the instruments were clean.

- **True Confessions from the Author:** In my own experience as CS manager I have seen the need for monitoring the cleaning process. In one case I was using a different detergent than what my washer company required. After visual inspection we determined that the instruments were not clean. The washer company blamed the failure on our use of the wrong detergent, but the detergent company defended its product. All I had was a visual assessment; I had no independent test that could determine why my instruments were not as clean as they had been before. Eventually we discovered it was a dilution problem, but only after a lengthy, frustrating investigation that could have been avoided had we had a proper test.

I had a similar experience loading trays in

my automatic washer. The hospital where I was working had a problem processing trays; the CS department was very busy and the decontamination area kept backing up. A representative of the equipment company told me to double-stack the baskets because the machine could handle it. He also told me I could put the trays in without rinsing them, which would speed up the process. After running about five loads this way my staff informed me that the instruments were not clean. We immediately stopped this process. Had I taken the time to learn more about how my equipment worked and the impact of all the factors of the cleaning process, I could have solved my problem more easily and with less frustration. At that time I not only lacked education and training, I had no real method for monitoring my cleaning process.

These examples illustrate the frustration CS managers experience when cleaning instruments. This is not a new problem, nor has it gone unrecognized by the public. The following news headlines appearing over the past few years attest to public concern about monitoring the cleaning process:

- "The process of sterilization should not replace the process of cleaning. Soil is still soil, even though it may have been sterilized."<sup>8</sup>
- "The quality of reusable equipment depends on the reliability of cleaning and sterilizing procedures."<sup>9</sup>

- "Inadequate cleaning of medical or dental instruments can threaten the sterilization process."<sup>8</sup>

- "Surgery halted over 'dirty' instruments, in England."<sup>9</sup>

- "North Carolina surgeons unwittingly used dirty tools."<sup>10</sup>

- "In order to sterilize medical devices effectively, all organic debris (e.g. blood, tissue, and other bodily fluids) have to be removed from the item prior to disinfection and/or sterilization."<sup>11</sup>

Concern is growing about the effectiveness of decontamination techniques for reusable instruments in healthcare facilities. These techniques have a direct impact on patient outcomes. Studies have shown the ability of sterilization technologies, which under normal conditions achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt.<sup>12</sup> Residual organic debris on processed surgical instruments is a concern, and visual inspection is not 100 percent accurate.<sup>13</sup>

The best way a medical facility can determine whether its equipment is working properly is to implement a quality improvement program. The QIP should be used daily and after equipment is installed or relocated. It should also be used after a machine malfunctions, a process fails, or any major repair

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is made on the equipment. The QIP should include, but not be limited to, daily inspection of equipment (cleaning screens, spray arms, interior of the chamber, etc.), testing via a blood soil type test, and continuous staff training.

### The Future

CS professionals need and are receiving support from regulatory agency guidelines to implement quality improvement programs to monitoring the cleaning process. Yet still we must answer to the public who read the headlines and ask, "How do you know your instruments are clean?" Likewise, we may have to answer to a JCAHO surveyor who, as in the opening of this article, asks, "How do you know your automatic washer is working properly?"

It is my experience that if you ask 10 CS managers what sterilization parameters they use, all 10 will respond, "273 degrees Fahrenheit for four minutes." When you ask about the parameters used for cleaning, however, you are lucky if 50 percent know the answer for their equipment. This lack of knowledge makes it very difficult to optimize the cleaning process.

Many CS professionals are already taking steps to monitor the cleaning process. These individuals responded as follows when asked the original question, "How do you know your washer is working properly?"

- Penny Sabrosky, a senior manager at Spectrum Health: "We currently use the product TOSI to test the efficacy of our washer units on a weekly basis and when we discover problems with unusual soil, or rinsing problems. We recently signed up for a preventative maintenance program from the manufacturer of the equipment and receive quarterly maintenance and service upon request for breakdowns. Typically we would run a TOSI test after the service is performed for verification of the maintenance."
- Betty Strickland, director of materials management at Christus St. Joseph Hospital: "I use the TOSI daily."
- Nyla Japp of Banner Health: "I know my automatic washer is safe to use because I validate my cleaning process in every washer once a week and following any needed repairs. I do this by a process called TOSI cleaning effectiveness indicators. I log the results as to whether or not they pass or fail this challenge. If they do not pass this challenge, the washer manufacturer is called in for repairs and the washer is taken out of service until it successfully passes the TOSI challenge."
- Denise Coatsworth, CS manager at Botsford General Hospital: "(This question) can open up a can of worms. I don't believe a visual inspection of instruments defines

cleanliness because cleanliness can be subjective. As a manager, I would look to CS organizations to establish standard protocols for what conditions and testing determine a 'clean' instrument. An instrument may appear clean once it comes out of the washer, but is there any way that the appearance and condition of that instrument can be improved? We also want to ensure that the instrument is safe for handling. As we know, an instrument cannot be determined sterile unless it is clean. Standard protocols have been established and written for our institution and a routine quality test must be run weekly to maintain and document the quality of the wash cycle. The TOSI test is an easy and reliable test for the wash cycle, but once that test is run and obtains less than optimum results, as the manager I must then be willing to take action to get the washer to the optimum level. In good conscience, I could not run the test, obtain less than optimum results, and then take no action."

The following quotations summarize why CS departments should monitor their cleaning process.

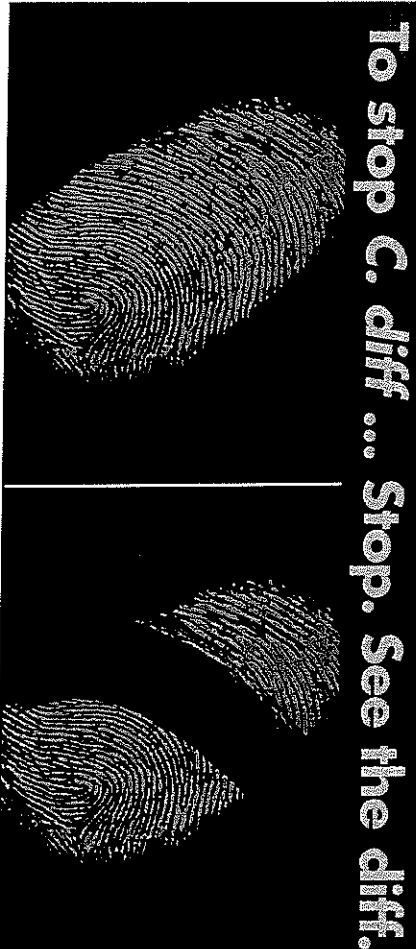
- "A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected."<sup>14</sup>
- "Cleaning, not sterilization (or disinfection) is the first and most important step in any instrument processing protocol. Without first subjecting the instrument to a thorough, validated, and standardized (and ideally automated) cleaning process, the likelihood that any disinfection or sterilization process will be effective is significantly reduced."<sup>15</sup>

Ensuring safety and quality is an active practice, not a passive one. Isn't it time for everyone to understand and monitor the cleaning process? When monitoring—whether manual or automatic—occurs, the winners are both patients and staff.

ICT

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