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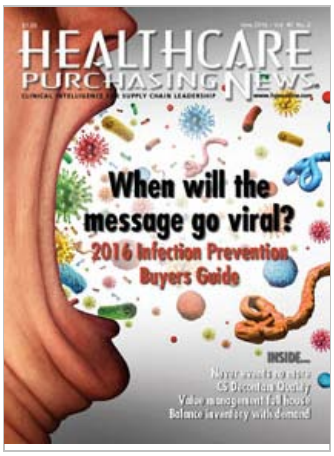

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INSIDE THE CURRENT ISSUE

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The control test-BI relationship; re-cleaning "clean" containers; special footwear in the SPD

by Ray Taurasi

Q I was reading an article that said it is necessary to do a test control when you use a biological control. We use biological indicators in all of our sterilizers each week. Do we have to do a control test with every indicator we use? Would this require us to send a culture to the lab each time?

A A biological indicator control test is run with each lot or batch of biological indicators. Generally, you would only run one biological control test per lot or batch of biological indicators (BIs). One BI is taken from the batch or lot, left unexposed to a sterilization process. This indicator is then incubated for the required time. Following incubation the control biological test should test positive which will verify the viability of the control biological test. This control test is considered representative of the BI lot. The remaining BIs will then be used to verify that the specified sterilization conditions were achieved or not achieved in the sterilization cycle that was tested. It is important to note that a negative BI does not ensure that all items in the load are sterile or that they were all exposed to the essential sterilization conditions.

Achieving sterilization is a probability based on efficacy of all aspects of the sterilization process including:

- proper cleaning
- inspection
- instrument assembly/disassembly
- proper instrument tray assembly (positioning of devices

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in tray or instrument basket)

- proper packaging
- proper loading on sterilizer racks
- proper sterilizer operations and functioning

Q We keep our sterilization containers free from any contamination. The baskets containing the sterile instruments are removed from the containers and placed on the sterile field. The clean containers are all removed from the operating room before the patient enters the room. The empty containers are placed on a clean cart in the sterile core and later returned to the instrument preparation room for reuse. We wipe the containers down with alcohol and change the filters prior to reuse. Recently we had a mock survey conducted by an independent consultant in preparation for The Joint Commission accreditation. In her report the consultant cited me for not running the sterilization containers through the washers. If the containers are not soiled I see no reason to put them through a complete wash cycle. We do between 80 to 100 surgeries a day and many procedures utilize more than one sterilization container. To reprocess all these containers would be impossible as we don't have the staff to manually clean them nor the ability to run them through our washers. Do you see anything wrong with the way we are handling the containers now or any reason why a perfectly clean container needs to be re-cleaned?

A First and foremost you need to refer to the sterilization container manufacturer's instruction for use (IFU) in regards to the care and handling of the containers. Also understand that sterilization containers are considered class II medical devices designed to function in a precise manner that allows for sterilant permeation and the ability to respond to sterilization parameters and dynamics (e.g., pressure, vacuums, etc.). Post-sterilization the container must be able to maintain sterility of the contents until the point of use. This requires a tight seal and secure closure. Containers have movable parts which must function properly (e.g., latches, retention plates, various gaskets, and sometimes valves). It is possible that residual detergents, chemicals, films, water or steam sediments could impede the performance of any of these movable parts compromising the sterilization process. Therefore, you should clean and inspect sterilization containers between each use.

Q I am an RN CIC at my hospital and have been assisting the sterile processing manager with rewriting our work dress code policy. Is there any special requirement for the type of shoes that our Sterile Processing Department staff must wear and do they also need to wear shoe covers?

Protective footwear should be worn in the sterile processing department. Shoes should have enclosed backs, closed toes, low heels, and non-skid soles. Protective shoes may reduce the risk of injury from slips and falls and decrease the possibility of foot injuries. Occupational Safety and Health Administration (OSHA) requires that the employer conduct a risk assessment of each job to determine the associated risk of injury. The employer can then determine if a specific type or foot wear is necessary to prevent the potential of injuries caused during performing specific work duties. The risk assessment should consider potential risks such as:

- hazard of sharp objects penetrating the shoe surfaces or soles

likelihood of injury from heavy objects falling or rolling on feet

- potential of exposure to blood borne pathogens or other infectious materials

OSHA regulations state that, "Shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated." The decontamination area is likely the only area in the Sterile Processing Department that might pose a risk of gross exposure to blood borne pathogens or other infectious agents. That said, certain jobs in the decontamination area may present a greater potential for such exposure and that will govern the type of footwear and/or shoe covers needed (e.g., low-rise shoe covers, impervious boots, High legging style boots, etc.). **HPN**

Ray Taurasi is Eastern Regional Director of Clinical Sales and Services for Healthmark Industries. His healthcare career spans over three decades as an Administrator, Educator, Technologist and Consultant. He is a member of AORN, AHA, SGNA, AAMI and a past president of IAHCSMM and has served on and contributed to many national committees with a myriad of professional organizations, manufacturers, corporations and prestigious healthcare networks. Taurasi has been a faculty member of numerous colleges teaching in the divisions of business administration and health sciences. In addition to this column he has authored several articles and has been a featured speaker on the international scene.

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