Decontaminating open sets; separating sharps; ultrasonic testing variables

By ***Ray Taurasi*** - January 25, 2017

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Q If you have to open a sterilized instrument set in SPD to check for a missing item, do you then need to reprocess that tray again beginning with decontamination? Currently that is our practice. We have some staff members that feel this is not necessary and as long as the set is opened in a clean environment, they repackage the set and re-sterilize it. I believe the set, once opened, should be considered contaminated and the entire process should be completed? What are your thoughts on this?

A You stated that your current practice was to reprocess open sets beginning with decontamination. If by "current practice" you mean policy, then it is imperative that all staff handle the reprocessing of opened sets in the same manner in accordance with documented policy and procedure. It is unacceptable and inappropriate for staff members to deviate from established procedures. I believe that any opened sets should be completely reprocessed which includes, cleaning, inspection, assembly, packaging and sterilization. The person who inspects, assembles and packages a set is identifiable and responsible for the quality of the set's contents. If the set was just rewrapped and sterilized there could be breaches in quality assurance as the individual who rewraps and signs the set cannot attest to the condition and or completeness of the contents.

Q Since OSHA, AAMI and AORN all recommend separating reusable sharps, what vessel should we be placing them into for transport?

A Soiled reusable sharps need to be placed into a covered, rigid, puncture-proof containment device which is clearly identifiable and labeled as biohazard. There are many such containers readily available on the market. Clean sharp instruments and devices placed into instrument sets should also be packaged internally to protect the device from damage and to prevent injury of healthcare workers. This may be achieved by the use of instrument tips, or instrument cases and racks which are intended for use in sterilization packaging or containment devices. (See figure 1.)

Figure 1

Q We recently had a mock inspection in preparation for accreditation. The consultant was very focused on quality assurance of the cleaning process. He was pleased to see that we were doing daily testing of our instrument washers and was pleased with the Tosi test method we were using. He reviewed the information on the sonic test we were using and said it was not adequate as it only tested for the presence of detergent. We have been using this test for a few years now with no problems. The surveyor at our last inspection had no issues with the test. The ultrasonic is on a regular PM program and seems to work fine. I am a bit confused regarding the consultant's comments and on what device I am supposed to use.

A I would first check with the manufacturer of the ultrasonic test you are currently using, ask for the validation documentation, the device's technical data, and review this information as well as the product's instructions for use. There are various devices for testing the ultrasonic washer on the market. Most have limitations and cannot test all the necessary cleaning parameters. You want to be sure that you understand what the device is actually testing. As you know, effective cleaning requires three key criteria: detergent, mechanical action, and time – and each must be present at appropriate levels for efficient performance. Detergent must be appropriate for use in an ultrasonic. It must also be used at the appropriate concentration level and temperature to perform effectively. Water quality can also affect the performance of the detergent. The mechanical action of an ultrasonic is cavitation which must be at adequate force throughout all areas of the bath. It is critical that adequate time of exposure to cavitation and cleaning agent is present. There is no universal time requirement; this is contingent upon the performance of the mechanical action and chemicals. It might be necessary to utilize more than one test in your ultrasonic to verify its cleaning ability. Testing for only one of the cleaning criteria is not enough. So you want to be sure the test or combination of testing devices can challenge and verify the efficacy of the cleaning process including:

- Detergent performance (includes optimum temperature)
- Water quality (e.g., PH, hardness, alkalinity)
- Cavitation action throughout bath (may require more than one test strip or vial)
- Adequate time (will be a factor in test outcome)

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