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When to reprocess stored scopes; CS department practice assessment

by Ray Taurasi

Q My organization is currently debating the definition of "reprocess" in the context of recommendations regarding how long flexible endoscopes can be stored without being reprocessed before use. Regardless of how many days our multidisciplinary team decides to set as the limit, the question of which steps, exactly, should be performed to reprocess the scope after reaching the limit is one where I have not been able to find a clear recommendation. My understanding is that the scope should be fully reprocessed, including all of the normal steps. Others argue that this approach is overkill, and not only causes needless wear to such infrequently used endoscopes, but also wastes resources. These folks claim that a cycle through the automated endoscope reprocessor (AER) is all that is required to get the scope ready again for patient use. We need expert advice.

A To answer your question let's consider why the scope is being reprocessed in the first place. The answer of course is that the scope may have become contaminated while in storage. The nature and degree of that potential contamination is uncertain. The area or parts of the scope that are contaminated are unknown. Is the contamination organic, bacterial, or some other soil source?

The general rule and practice in sterile processing is that when a surgical instrument or medical device, such as an endoscope,

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becomes contaminated or is potentially contaminated the entire device including all it's parts are to be reprocessed. This means that all steps in the cleaning, decontamination and disinfection process are to be followed in accordance with the device manufacturer's IFUs. Many AERs do not have a cleaning phase, they only provide a disinfection cycle, thus the scopes must be thoroughly cleaned via a manual cleaning process prior to being placed in the AER for disinfection. In order for the disinfection process to be effective a device must first be cleaned. Residual soils can act as a barrier to the required intimate contact between all surfaces and parts of the medical device and disinfectant. There can be no short cuts to reprocessing protocols.

Q I am the director of nursing for perioperative services. I was at a recent conference which discussed the alert issued by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration home page (FDA) relative to epidemic failures in reprocessing, sterilization and disinfection procedures in hospital CS departments. The alert requires that hospitals should immediately have a professional assess the performance of their central sterile processing department to ensure they are doing things correctly. Would it be acceptable for me to assign one of my OR nurses to conduct this assessment or do I have to hire a professional consultant to do this?

A In September 2015, the FDA and the CDC did release an alert titled "Immediate Need For Healthcare Facilities to Review Procedures for Cleaning, Disinfecting and Sterilizing Reusable Medical Devices." This was in response to the high number of well documented breaches and failures in compliance to reprocessing protocols which have led to several adverse patient care outcomes including deaths. This alert was not directed toward any one hospital department. The alert included all healthcare facilities, hospitals, ambulatory surgical centers, clinics and offices. The alert did state that healthcare facilities should arrange for a healthcare professional with expertise in device reprocessing to immediately assess their reprocessing procedures.

The assessment should ensure that reprocessing procedures are done correctly to allow the required time for reprocessing personnel to follow all steps in the device and equipment manufacturer's IFUs precisely. The alert also stated:

- Staff should be retrained with competencies documented.
- Manufacturer's instructions for use should be obtained and followed.
- Sufficient time should be allowed to comply with all IFUs (this would include processing equipment, medical device, chemistries, cleaning devices, testing tools, etc.).
- Ensure that availability of the appropriate number and types of processing equipment is available (e.g., sonic washers, accessories, flushing devices, manual wash stations and sinks).
- Perform regular audits of the cleaning , disinfection, sterilization and storage processes.

It should be noted that this alert is not solely directed to the Sterile Processing Department — it includes any area in a facility or organization that performs any cleaning, disinfection or sterilization of medical devices. I have found that most hospitals have some degree or portion of reprocessing being conducted outside of the sterile processing area (e.g., OR, Clinic, Physician office, L&D, Endoscopy, GI Lab, etc.). Thus any and all areas that perform any aspect of reprocessing of medical devices should be included in the assessment.

You asked if it would be acceptable to have one of your OR nurses conduct this assessment. If the nurse was a "healthcare professional with expertise in device reprocessing" and had the professional sterile processing credentials then it might be acceptable to have them conduct the assessment. I am sure as a perioperative director you are aware there is nothing in the

nursing curriculum which provides the necessary education in the special skills and knowledge required to be proficient in sterile processing technology. It would be unfair and inappropriate to place one of your staff nurses in the position of having to conduct such an assessment, without the required education and expertise. There is no need or requirement for you to hire an outside consultant to do this assessment provided you have a qualified, credentialed Sterile Processing professional on staff with the expertise.

In accordance with the Association for the Advancement of Medical Instrumentation (AAMI) standards the sterile processing manager and supervisory personnel should be qualified by way of proper education, certification and continuing education. I believe that any sterile reprocessing done throughout the healthcare facility should come under the direction and management the Sterile Processing Director. This would ensure the standardization of proper reprocessing protocols throughout the organization. **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.