Inside the March Issue

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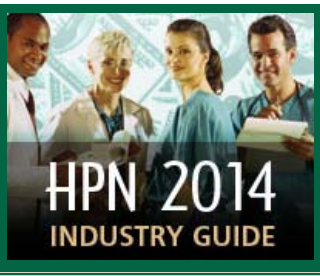
March Cover Story

Innovative surgical technology a boon in value-based care delivery



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INSIDE THE CURRENT ISSUE

March 2014

CS Solutions

Questions can be sent to:jakridge@hpnonline.com
called in to Jeannie Akridge at *HPN*:**(941) 927-9345 ext.202** or mailed to:
HPN CS Questions, 2477 Stickney Point Road, Suite 315B, Sarasota, FL 34231
Names and hospital identification will be withheld upon request.

Failed sterilizer recall; IUSS intended for immediate use; scrub attire in clean areas

by Ray Taurasi

Q I am the RN clinical administrator for a physician owned surgery center and responsible for all clinical operations of the center. We do not have a typical sterile processing department; all sterilization is done in the OR work room. The work room is staffed by one full time sterile processing technician who is assisted by OR staff on a rotating basis and between cases. For the first time ever one of our sterilizers failed the weekly biological test. We reran the test and it failed again. We put the machine out of service until the maintenance crew could repair the problem. Aside from re-sterilizing the sets in the load, what other measures, if any, should we have done? I would like to create a checklist for staff to use as a future reference.

A The Medical Devices Safety Act established in 1990, to ensure patient safety relating to failures of reusable medical devices, [MDR] regulations of 21 CFR 80, requires health care facilities to comply with reporting requirements. It is essential that you develop and implement policies and procedures to address failed Sterilizer biological tests including product recall and reporting procedures. A recall procedure is critical in order to expedite the retrieval of any processed instrument sets or supplies that are suspected to be non-sterile and to ensure adequate follow-up actions can be activated such as, quarantine of the sterilizer, notification of physicians and clinical areas, and the surveillance of patients that may have been exposed to the identified items. This is one reason why every package or item processed in a sterilizer must be traceable and every load run in a sterilizer must be recorded identifying the contents of the load. Each package should be labeled in a manner that will identify the sterilizer, load number, and date processed.

The following are some points to consider when developing your Written Recall

MARCH 2014

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Procedure:

- Identify circumstances to activate a recall of processed goods
- Identify the people who are authorized to declare a recall
- Identify the person(s) that will be responsible and their role in performing the recall
- Identify the person(s) responsible for preparing the final Recall Report
- Items to be recalled should include all items processed in the failed sterilizer since the last negative BI test was run
- Identify by the lot numbers a description of all items being recalled
- Manner of expedient communication to all potential user areas and to whom in each area communication should be directed
- Provide instruction to users on the disposition of all recall items such as: destruction, return to sterile processing, or required documentation
- Include the following in the Recall Report:
    - detail circumstances of why recall was initiated
    - actions taken to obviate a re-occurrence
    - identify the percentage or number of identified items that were actually retrieved
    - include documents of disposition of recalled items e.g. reprocessed, disposed of, etc.

Q Our hospital has a cataract surgical unit that runs on its own and is not a part of the main OR. The cataract center reprocesses and sterilizes all of their instruments and sets within the center, and I have no official authority over this area or how they process their goods. Once or twice a year, our Infection Control nurse invites me to go on rounds with him of ancillary departments, including the Cataract Center, to observe practices and offer feedback on my observations. On my last visit I observed that cataract sets were being processed via IUSS at the end of the day and held overnight for the morning cases. I questioned this practice and was told that they are using "Flash" containers approved for IUSS and that the container manufacturer stated the "Flash" container had been validated for sterility maintenance for up to 24 hours. To me this seems to conflict with what IUSS is. My infection control nurse seemed to feel this was ok. Am I wrong in my thinking?

A There is absolutely nothing wrong with your thinking (IUSS) Immediate Use Steam Sterilization is just what the name implies: "Sterilization of an item(s) intended for immediate use. In 2011, a Multi Society Statement on IUSS was published. The Multi Society consisted of seven professional organizations of which AAMI, AORN and IAHCSMM were a part. The Multi Society Statement defines IUSS as:

> "the shortest possible time between a sterilized item's removal from the sterilizer and its aseptic transfer to the sterile field. Immediacy implies that a sterilized item is used immediately on the procedure for which it was sterilized"

This principle has been incorporated and emphasized in both AORN and AAMI Recommendations.

The situation as you described it is totally inappropriate. There is certainly more than enough time to allow for these sets to be sterilized in a conventional terminal sterilization process. I would certainly consult with the "FLASH" container manufacturer as there very well could have been some misunderstanding between them and the end user. It could be that the manufacturer did a 24 hour sterility maintenance study to demonstrate the sterile integrity of their container. I am quite sure that if you consult their IFU it would confirm the intent is for immediate use.

Q I am a vendor and call on many ORs and Sterile Processing departments

quite often. I am required to put on a paper jump suit over my street clothes before entering the department. It is virtually impossible to don a jump suit without dragging it on the floor. I guess I don't see how the jump suit is any cleaner than my clothes after it has mopped the floor. I also find it puzzling when I am greeted by a worker who has just returned from a smoke break or from the food truck outside the hospital in the scrubs they are wearing and they don't change? Is there something magical about hospital attire that I am unaware of?

A What can I say other than two wrongs don't make a right? Both the OR and Sterile Processing have designated "clean" restricted areas. Measures are taken in these areas to protect the environments from any unnecessary contaminants and foreign matter that could become a source of cross infection. Most hospitals have very strict dress codes for these areas which prohibit wearing of street clothes and require scrub attire worn exclusively in the restricted areas and or that it is protected when leaving the restricted area. Healthcare workers must not become complacent and must practice what they preach. There is no magic in scrub attire. 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.