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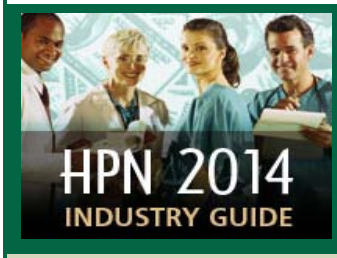
October Cover Story

Hand hygiene's delicate balance



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CS Solutions

Questions can be sent to:vdimond@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.

Sterilizing stuffed animals, missing IFU's, HLD safety

by Ray Taurasi

Q I am the nurse manager of Sterile Processing Services at a large Women and Infants Hospital. Very often we are asked to sterilize foam-filled stuffed animals that parents bring in to place in their preemie's incubators and bassinettes. I have been sterilizing these items in our gas sterilizer because I figured steam moisture and heat would damage the cute little critters. One of my techs also works at another hospital and she said her manager suggested we should not be sterilizing stuffed animals because we don't have any instructions for use (IFU). I don't see any harm in what I am doing since the stuffed animals aren't medical devices. Do you see any reason why I should not do this?

A I do not feel it is wise to sterilize foam-filled stuffed animals in your gas sterilizer because it may be dangerous and unsafe. Here are my concerns:

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1. Since you have no idea what the material composition of the stuffed animal's fabrics and fillers are, there is no way of knowing if this is causing a chemical reactivity with the ethylene oxide (EO), which could be hazardous to staff, patients and/or the environment
2. You cannot be certain that you are using adequate aeration time to fully remove all residual EO. Foam and other stuffing material are likely dense and will absorb and hold the gas residuals, presenting an exposure risk to staff and the babies. This is especially concerning in cases where the stuffed animals are being placed and contained inside incubators and making very close contact with the babies.
3. It is unlikely that the toy manufacturers will be able to provide you with any documentation relative to the effective and safe sterilization of the stuffed animals. Just like anything else that is processed in Sterile Processing, one should never reprocess or sterilize items without the manufacturer's documentation and instructions.

Q In addition to my many responsibilities as the CS educator, I am also required to make certain that all of the items we reprocess have manufacturer's IFUs, including cleaning and sterilization directions. We reprocess many different products and medical devices in our department and I have found that far too many items are without IFUs. The IFUs we do have vary in content, format, clarity and are ambiguous. I am feeling quite overwhelmed. Would you please explain the specific information that should be included in an IFU?

A I understand how challenging it can be to gather all of the required documentation and then get it all into a format that is user friendly — an arduous but essential task. The following list includes some information that should be contained in an IFU, although it may not be applicable to every product or device.

- Heading to include manufacturer's name, location, and contact information
- Brand and generic names of product
- Product identification or code numbers
- Areas of product application (e.g., areas where used)
- Product specification and parts (key components)
- Material composition and compatibility
- Shipping conditions and requirements
- Storage requirements
- Packaging conditions
- Shelf life
- Instructions for using the item
- The product's intended use
- Diagrams and pictures with steps related to use
- Interpretation of inspection/testing results
- Checks, inspections and any contraindications
- Special warnings, hazards, and precautions
- Disposal
- Preparation for decontamination, pre-cleaning
- Instructions for disassembly and reassembly, when applicable
- Manual cleaning instructions, including required cleaning tools, chemical agents and aids
- Automated cleaning instructions, specific processing equipment and cycle times, and parameters, including generic cleaning agents
- Disinfection methods and process, including chemistries
- Drying instructions
- Inspection and testing for cleaning efficacy, functionality, etc.

- Packaging requirements
- Sterilization guidelines and instruction, compatible processes and parameters
- Sterile storage requirements
- Other product support documentation and how to access
- Document date and identification
- Reference documents
- Customer service contact information

Many hospitals benefit by subscribing to an online service that provides a link to virtually thousands of manufacturer's IFUs and related documents. These user-friendly services provide a standardized format and are maintained and continuously updated with the latest information. Having this information readily available fulfills the requirements and guidelines for regulatory and professional entities.

Q We have not used glutaraldehyde in some time but recently our case volume has increased significantly and our procedures have changed, causing us to use much more high level disinfectant (HLD). My staff and I are concerned about safety and possible exposure to this toxic chemical. What safety measures should we implement?

A There are several measures you can implement to ensure personnel safety when working with glutaraldehyde. First and foremost you want to obtain and follow the manufacturer's IFUs. Exposure can be limited by the use of proper personal protective equipment (PPE), including gloves that are impervious to glutaraldehyde, splash proof goggles, impervious gowns, aprons, masks, face shields and head coverings. Glutaraldehyde should also be stored in closed, labeled, air tight containers, placed and used in a restricted area with adequate ventilation (minimum of 10 air exchanges per hour with a dedicated exhaust system), and only be accessible to trained personnel. Emergency procedures should be in place, including those for accidental skin and eye exposure, as well as a readily-accessible eyewash station and employee shower. 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.