10 Things Your Organization Can Do Now To Improve Reprocessing

This list emerged from the presentations, audience discussions, and follow-up input to the 2011 AAMI/FDA Medical Device Reprocessing Summit. It is intended to be inspiring, and serve as a refresher on some of the basics. It does not take the place of standards, regulations, or internal policies, nor is it intended to suggest a standard of care. While some priority items from the summit will take time to address, here are 10 things that an organization can begin implementing immediately, without waiting for other actions, such as long-term standards and research.

1 The basics: Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes, and must be performed before each patient use, according to the device manufacturer’s written instructions for use (IFU). For more information, go to www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm

2 The right tools: Have the IFU, as well as all cleaning implements and equipment required by the IFU, readily available in all reprocessing areas.

3 Create a multidisciplinary committee to review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: operating room, infection prevention and control, healthcare technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management.

4 Share lessons learned: Remind senior management and safety officers that it costs much less to “do it right the first time.” Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.

5 Written procedures: Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA’s MedWatch program.

6 Standards matter: Know the current standards, recommended practices, and IFU.

7 Purchasing: Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility’s existing resources.

8 Separate and standardize functions and locations: Separate central service (warehouse, stocking, etc.) from reprocessing; and create standardized job descriptions and functions.

9 Training: Train, train, and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaned or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.

10 Assessment: Conduct an audit of compliance with standards and regulations, using any number of available tools and resources. For more information, go to: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm.