



1275 K Street, NW, Suite 1000  
Washington, DC 20005-4006  
Phone: 202/789-1890  
Fax: 202/789-1899  
[apicinfo@apic.org](mailto:apicinfo@apic.org)  
[www.apic.org](http://www.apic.org)

May 9, 2016

Leslie Kux  
Associate Commissioner for Policy  
U.S. Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

***Re: Docket No. FDA-2016-N-0436; Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers: Request for Comments.***

Dear Ms. Kux:

The Association for Professionals in Infection Control and Epidemiology (APIC) appreciates the opportunity to provide information and comments on *Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers*. APIC is a nonprofit, multidisciplinary organization representing over 15,000 infection preventionists whose mission is to create a safer world through prevention of infection. Our members are charged with the prevention of healthcare-associated infections and providing guidance and recommendations to individuals in our facilities regarding third party reprocessing. In order to protect patients from harm, APIC welcomes the opportunity to work with the Food and Drug Administration (FDA) to ensure that devices and equipment used for necessary medical procedures and care are as safe as possible and do not cause increased risk to patients. What follows are our comments on the issues for consideration.

### **Proposed Definitions of Third-Party and OEM Activities**

APIC agrees with the definitions proposed by the FDA. We also suggest adding the term “reprocess”, which generally refers to all operations performed (e.g. to cleaning, disinfecting, sterilizing, and validation) to render a used reusable or single-use device patient-ready or to allow an unused product that has been opened to be made patient ready. APIC recommends that this term be defined as, “the treatment of medical devices or equipment using validated technology and/or methods described by the original equipment manufacturer (OEM) in order to make them safe for reuse.”

### **Evaluation of Risk Associated With These Third-Party and OEM Activities**

#### **1. Who are the different stakeholders involved with the medical device activities listed previously? What are their respective roles?**

APIC identifies the following as stakeholders in the medical device activities listed previously:

- **Patients:** Patients often do not completely understand that an item once thought to be single use can be safely restored or refurbished to the OEM’s original specifications. Additionally, for



reusable patient care equipment, patients often do not understand the complexity of the processes required to adequately clean, disinfect, and/or sterilize reusable patient care equipment. Patients expect to be cared for safely and trust that healthcare providers and manufacturers take steps to ensure safety and quality of devices and procedures utilized to provide care. Education of patients and the concerned general public regarding the definitions listed previously and the safety and efficacy of reprocessing is important in order to support patient-centered healthcare decisions.

- **Licensed Independent Practitioners:** Fit and function of the refurbished, reprocessed, or reconditioned device (such as a surgical instrument or reusable device) is an important concern for direct patient care stakeholders involved in these activities. Ensuring that reprocessed, refurbished, or reconditioned devices are returned to the OEM's original specifications is important to physicians. Concerns regarding perceived inferior quality of reprocessed, refurbished, or reconditioned devices are often voiced by physicians to other stakeholders during efforts to evaluate implementation of reprocessing initiatives in hospitals and other healthcare settings. Additionally, device availability and its impact on operating room or clinic turn-around time are important concerns for physician stakeholders involved in these medical device activities.
- **Infection prevention and control:** Patient safety and mitigation of the risk of transferring an infection from one patient to another patient via contaminated device(s) is of utmost concern for the infection preventionist stakeholder. Infection preventionists work to ensure that manufacturer instructions for use regarding care and cleaning of reusable patient devices and equipment are followed. Infection preventionists also work to ensure healthcare settings that contract with third parties or OEMs to reprocess, refurbish, repair, or remanufacture devices do so only if the FDA guidance (including required 510K clearances) for safety and efficacy are met.
- **Sterile processing:** As stakeholders, sterile processing professionals must follow all manufacturer instructions for use regarding care and cleaning of reusable patient care devices. Additionally, when devices demonstrate wear and tear, fail quality assurance testing, or are identified by users as demonstrating the need for repair, sterile processing staff are most commonly tasked with the responsibility for sending the device out for repair or refurbishing and returning the item into circulation once repair or refurbishing has been completed. Unlike nurses and physicians, certification and/or standardized education requirements for sterile processing professionals are not required in all states.

Other stakeholder groups involved that are important to note include:

- Biomedical engineering
- Risk management and legal professionals affiliated with hospitals and health care settings
- Perioperative services
- Hospital Administrators and operational leadership



- Manufacturers
- Third party reprocessing companies
- Instrument and equipment repair companies

**2. What evidence exists regarding actual problems with the safety and/or performance of devices that result from these activities? Specific examples should be submitted.**

Many are already aware of the redesign of the endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes which affected the ability of end users to effectively clean the scopes, resulting in outbreaks at several institutions.

Recent epidemiological evidence linked non-tuberculous mycobacterium infections and deaths due to the use of heater-cooler units during cardiac surgery in the United States and Europe. The mechanism of spread was proven by Sommerstein et al.<sup>1</sup> to be airborne transmission in the operating room.

**3. What are the potential risks (patients/users) and failure modes (devices) introduced as a result of performing the previously defined activities on medical devices? Please speak to issues common to all devices as well as specific risks with specific devices.**

Failures involving reprocessing, reconditioning, or remanufacturing reusable patient care devices can result in catastrophic patient outcomes. Recent infections involving Carbapenem-resistant Enterobacteriaceae (CRE) transmitted by Olympus TJF-180V (ERCP) duodenoscopes highlight this. Changes made by the OEM to the scope resulted in hard to reach crevices that increased difficulty in cleaning. The reprocessing of reusable patient care devices is a complex process with many steps. This is especially true in the case of duodenoscopes and endoscopic ultrasound scopes, which are highly complicated devices that are exceedingly difficult to clean effectively. In a prospective multisite study it was noted that all steps in manual high level disinfection are completed only 1.4% of the time.<sup>2</sup> The same study reflected that all steps in high level disinfection with an automated endoscope reprocessor (AER) are completed only 75.4% of the time.<sup>2</sup> For these reasons, accepting a manufacturer's high level disinfection process that assumes 100% compliance with the process does not reflect the reality in the field, and an assumption that it will be followed puts patients at risk.

**4. These activities are performed by OEMs and various third-party entities, including hospitals and humanitarian organizations. Are the risks different depending on who performs the previously mentioned activities?**

Key to risk mitigation is education of the individuals performing the tasks. They must have a clear understanding of the importance to detail in following the OEM guidance and raising concerns if they encounter difficulty complying with that guidance. Risk mitigation needs to occur with whoever is performing these activities, but a vulnerability for third-party entities is that to perform activities outside the OEMs guidelines may in some unpredictable manner alter the intended use and performance.

**5. We are interested in knowing if these activities are more difficult or riskier to perform on certain devices versus others. Please cite specific examples in your response, along with an explanation of the source of this particular complexity.**



Devices that must be high level disinfected pose a greater risk due to the complexity of the task. Endoscopes are classified as semi-critical items because they come into contact with an intact mucosal barrier that is naturally colonized with microorganisms and therefore not considered to be sterile. However this same exposure makes endoscopes far more likely to incur higher levels of contamination than items that are typically considered critical and require sterilization.

In addition, devices which use water baths or water reservoirs pose a unique challenge as organisms known to contaminate water may become pathogens in the right environment and with the right host. Medical devices are becoming more and more complex and manufacturer instructions for cleaning are likewise more complex and often impractical or inadequate in the clinical setting. Manufacturers also test a limited number of products to clean and disinfect their devices, thereby posing challenges for end users. Using a different hospital-approved disinfectant can nullify the product warranty, requiring institutions to have several different cleaning products in stock, more complicated training for staff, and thereby challenges with staff compliance.

**6. What information do third-party entities need in order to perform these activities in a way that results in safe and effective operation of the medical device? Please provide specific examples.**

Collaboration with manufacturers is essential to determine the appropriate guidelines. A validation approach is necessary to determine when the process has been successful at eliminating the risk of transmission of microorganisms and/or infection. The approach should take into consideration both the financial and resource cost to the institution. As an example, routine microbiological surveillance to ensure equipment is not contaminated can incur a significant cost to an institution that does not have the capability to do environmental sampling in-house.

Manufacturers' reprocessing instructions should state specific timetables for the reprocessing steps and avoid imprecise words such as "immediate". For devices that have a defined number of times it can be reprocessed, simple mechanisms that clearly delineate to users and reprocessors when the limit is reached is necessary.

Instructions for scopes should also include data to show what process timeframes resulted in successful reprocessing. In addition, manufacturers need to validate the total number of complete reprocessing cycles a scope should be expected to tolerate during its usable lifespan.

For low level disinfection, manufacturers need to provide simple cleaning instructions with a broader range of cleaning products, including new technologies such as hydrogen peroxide. It may be helpful to understand which chemicals are compatible with a device instead of brand names of products.

APIC appreciates the opportunity to share our views with the FDA, and we look forward to working with manufacturers, and third party reprocessors to ensure the safest possible care for patients.

Sincerely,

A handwritten signature in cursive script that reads "Susan Dolan".

Susan Dolan, RN, MS, CIC  
2016 APIC President

---

<sup>1</sup> Sommerstein R, Rüegg C, Kohler P, Bloemberg G, Kuster SP, Sax H. Transmission of *Mycobacterium chimaera* from heater–cooler units during cardiac surgery despite an ultraclean air ventilation system. Emerg Infect Dis. 2016 Jun Available at: [http://wwwnc.cdc.gov/eid/article/22/6/16-0045\\_article](http://wwwnc.cdc.gov/eid/article/22/6/16-0045_article). Accessed March 29, 2016.

<sup>2</sup> Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. Gastroenterol Nurs 2010 Jul-Aug;33(4):304-11.