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FDA Issues Final Guidance on Reprocessing of Medical Devices

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The US ***Food and Drug Administration (FDA***) issued a final guidance document on March 12 titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." Although the final guidance was expected to issue soon, given that the draft was released in 2011, the FDA expedited its issuance in response to recent cases of carbapenem-resistant enterobacteriaceae infections associated with duodenoscopes at the Ronald Reagan UCLA Medical Center. This facility reported seven serious infections and two deaths as a result of duodenoscope contamination in patients who underwent endoscopic retrograde cholangiopancreatography (ERCP). Duodenoscopes, and especially ERCP duodenocopes, are known to be difficult to sterilize completely because the devices have narrow, miniscule interior channels that are hard to reach and brush or clean. FDA issued a safety notice on February 19, 2015 (updated on February 23 and March 4) in response to these infection reports.

In issuing the final guidance, FDA officials noted that, despite the recent reports, the risk of acquiring an infection from a reprocessed medical device is low and that the final reprocessing guidance is intended to enhance the safety margin by outlining steps that manufacturers should follow to ensure that their reprocessing instructions are effective. Pursuant to FDA's authority to require adequate directions for use (21 C.F.R. § 801.109), the final reprocessing guidance requires that manufacturers validate their cleaning and disinfection or sterilization processes to ensure that they are consistently effective, ready for the next lay use, and safe for use by healthcare practitioners.

The final guidance recommends that manufacturers address the following six criteria in their reprocessing instructions:

Labeling should reflect the device's intended use.

Instructions should advise users to thoroughly clean the device.

Instructions should indicate the appropriate microbicidal process for the device.

Reprocessing instructions should be technically feasible and include only legally marketed

devices and accessories.

Reprocessing instructions should be comprehensive.

Reprocessing instructions should be understandable.

Although no specific recommendations are made, the final guidance also states that, at the earliest stages of a reusable device's design, manufacturers should consider designs that will facilitate effective reprocessing. This might involve, for example, replacing features that are difficult to reprocess with single-use ports, and specification and provision of dedicated cleaning accessories. For those manufacturers that develop new reusable devices, it will be important, therefore, to have complete design control documentation that describes how companies addressed risks associated with their devices.

Additionally, the final guidance instructs that manufacturers of reusable devices should ensure that they have validated the cleaning process using worst-case testing and that they have validated the disinfection processes and instructions or the sterilization cycle specifications. Specific information is provided on selection and use of artificial soil, inoculation sites, simulated use, and cleaning validation protocols. The final guidance also specifies the documentation required to be submitted to the FDA for its review of reprocessing instructions.

Finally, the FDA has scheduled a public meeting of the Gastroenterology and Urology Devices Panel for May 14–15, 2015 to discuss the recent reports of transmission of infections associated with use of duodenoscopes in ERCP procedures. Interested persons may submit comments to the FDA prior to the meeting.

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