Like facilities around the country, you are probably considering alternatives to the Steris System 1 (SS1) for reprocessing your medical devices. The Food and Drug Administration (FDA) issued a notice in December 2009 stating that the SS1 as currently marketed had not been approved or cleared for its label claims, including claims that it sterilizes medical devices. The FDA advised users to transition away from SS1 “as soon as possible.” The FDA has since said it expects the transition to be complete within 18 months, or by August 2011.

One step in the decision-making process that may be overlooked is to make sure the manufacturers of your medical devices have provided you with up-to-date written instructions for use (IFUs) for each of their devices that describe how to reprocess each device. This includes processing methods validated by the device manufacturer for its devices.

Professional guidelines

Following manufacturers’ reprocessing instructions is a key part of sterilization and disinfection guidelines, including those of AORN, the Association for the Advancement of Medical Instrumentation (AAMI), and the Centers for Disease Control and Prevention (CDC). The Joint Commission and Centers for Medicare and Medicaid Services (CMS) also stress following manufacturers’ instructions.

This column outlines steps to consider to ensure alternative processing methods you select meet FDA requirements and professional standards and guidelines. In the context of this column, a processor is a piece of equipment used to reprocess medical devices with either a high-level disinfectant or a sterilant. Examples include automated endoscope reprocessors (AERs) and steam or low-temperature sterilizers.

What devices do you need to reprocess?

The first step is to determine what items you will need to process and what type of processing is needed for these items. A good place to start is with the familiar Spaulding classification, which classifies devices as critical, semi-critical, and noncritical, according to the risk of infection if the device is contaminated. The FDA recommendations are based on the Spaulding classification, as are the professional standards and guidelines.

There’s been some confusion about the term “liquid chemical sterilization.” A safety communication from the FDA, CDC, and the Department of Veterans Affairs (VA) on November 9, 2009, stated:

Sterilization with a liquid chemical sterilant may not convey the same sterility assurance as sterilization achieved using thermal or low temperature chemical gas/plasma/vapor sterilization methods. Liquid chemical
sterilants should be limited to reprocessing only critical devices that are heat-sensitive and incompatible with other sterilization methods.

Obtain manufacturers’ instructions for use

The next step is to obtain up-to-date written IFUs from the medical device manufacturer (MDM) for each device you reprocess that explain how to process the device. Then determine if you have a processor available that will enable you to reprocess the device according to the IFU.

This is not as easy as it sounds. Many MDMs recommend only one processing method in their IFU. If that method includes the SS1, that’s a problem. The FDA has said devices labeled for use with the SS1 are “misbranded” under section 502(f)(1) of the Federal Food, Drug, Cosmetic Act because they fail to bear adequate directions for use.

In a February 2010 letter, the FDA said MDMs must take immediate action to validate at least one reprocessing method using a legally marketed product. The MDMs should complete this testing and relabeling by February 2011.

Device makers need to provide instructions

Some facilities are depending on processor manufacturers to direct them to what processor to use. But the FDA is clear that the MDMs, not the reprocessor manufacturer, have the responsibility to provide you with a validated processing method. That’s because the processor manufacturer does not know when a device manufacturer changes the product material, and new testing is needed.

A good example of this situation is when Advanced Sterilization Products (ASP) in about 2000 provided a compatibility device list for products that could be processed in the Sterrad system. Then on November 13, 2007, ASP sent an “Urgent: Product Correction” letter to users stating:

Advanced Sterilization Products (ASP) would like to inform you that all brand- and model-specific compatibility lists and associated instrument assessments provided to STERRAD Sterilization System customers are now out-of-date. Information related to specific brands and models of medical devices, over time, can become outdated as manufacturers introduce new technologies and make materials, manufacturing and repair process changes.

To determine if a specific brand and model of device will remain functional following sterilization in your STERRAD System, please contact the MDM or refer to the Instructions for Use (IFU) for the device. Even if the MDM’s IFU references the STERRAD System, we recommend that you contact the MDM to ensure the IFU is up-to-date.

If recommendations from the device manufacturers seem to disagree with recommendations from the processor manufacturer, the FDA says to “follow the instructions from the manufacturer of the device to be processed.”

What if no instructions are available?

If your facility identifies critical medical devices for which no reprocessing information is available, notify the FDA to express your concerns using this website: www.fda.gov/Safety/Medwatch. The information may be lacking because the device was cleared for marketing before the reprocessing instructions were required and has been grandfathered into the FDA
system, or the MDM has not validated an alternative process to the SS1.

**Why one reprocessing method?**

Why do some MDMs recommend only one processing method? Because that is all the FDA requires and because it is expensive and time consuming to validate a processing method. For example, for sterilizers, FDA-required testing includes the following:

- Biocompatibility testing to determine that a material will not have toxic or injurious effects on the body.
- Materials compatibility testing to determine any material effects that may compromise use of a device.
- Device functionality testing to verify that the medical device meets specifications and is fit for use. The device manufacturer is responsible for validating functionality of a device after processing for a specified number of cycles in a specific process.
- Sterilizer efficacy testing to validate that reusable devices can be repetitively sterilized using the process defined in the IFU.

In addition, sterilizer manufacturers are required to test a range of materials and actual devices as part of the FDA 510(k) process. Their recommendations to users regarding device processing are based on this rigorous testing.

For liquid chemical disinfectants, for a manufacturer to make a high-level disinfection and/or sterilization claim, validation testing includes microbiological qualification testing, stability testing to show the high-level disinfectant is effective under its storage conditions and recommended use patterns, and material and device compatibility testing.

In some cases, a MDM may recommend only a particular processor it markets. That is because the company understands its processor and high-level disinfectant or chemical sterilant method and its effects on devices better than other systems.

When determining a reprocessing method, work with processor manufacturers that provide a broad list of medical devices, including lumen restrictions and medical device materials, which have been tested according to FDA validation requirements. If applicable, the testing should include compatible packaging materials along with FDA-cleared biological and chemical indicators and a process challenge device.

Determine if the processor manufacturer is willing to work with the MDM to assist in providing you with the written information you need to make a decision about the processor to use for the devices in question. Remember, the MDM has the responsibility to provide you with this information.

**Making future decisions**

In the future, when evaluating the purchase of new devices or processors, consider Recommendation 1 from the AORN Recommended Practices for Product Selection in Perioperative Practice Settings, which says “to select functional and reliable products that are safe, cost-effective, and environmentally conscious and that promote quality care and avoid duplication or rapid obsolescence.”

As part of the purchasing agreement for a device, you should expect the manufacturer to provide one or more validated processes (eg, high-level disinfection or sterilization) in addition to a validated cleaning process. If
those validated processes are not available within your system, you will
need to negotiate with the MDM to perform the validation testing for the
processes you use or work with the processor manufacturer, which may be
willing to perform the validation testing for the MDM. If neither is possible,
you may not want to purchase the device.

A lesson learned is not to put all your eggs in one basket but to use mul-
tiple types of processors that have been validated for the reprocessing of
individual endoscopes and other medical devices.

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