CMS Clarifies Flash Sterilization Guidelines
Routine flashing for ASCs is OK if loads are wrapped or contained.

Routine flash sterilization of surgical instruments is acceptable in ambulatory surgery centers, says CMS, as long as loads are wrapped or contained and facilities follow manufacturers' guidelines for all devices involved. ASCs shouldn't be sterilizing instruments in uncontained loads, but may do so in emergency situations, such as when an instrument is dropped during a case, CMS wrote in an Oct. 9 revised memo to state survey agency directors.

The clarification comes in response to issues raised during CMS's first round of on-site infection control surveys, according to the memo. The survey checklist doesn't address flash sterilization specifically, but surveyors will check whether "items are appropriately contained and handled during the sterilization process to assure that sterility is not compromised (before) use."

While the memo says it's "crucial that everyone have a common understanding of what is meant by 'flash sterilization,'" the agency doesn't give a precise definition, suggesting that it will take an approach similar to the one the Joint Commission announced earlier this year, focusing on the entire process of sterilization. In its updated position on steam sterilization, published in June, the Joint Commission clarified that "instruments subjected to steam sterilization using methods other than full cycle sterilization may be transported in 'flash pans' or other devices specifically designed for the prevention of contamination during and after the steam process."

CMS's latest guidance similarly says loads must be wrapped or contained, for example, "in specialized metal containers, pouches or cassettes."

"The only time an open tray should be used is when the sterilizer is in the operating room or opens directly into the operating room," says Rose Seavey, RN, BS, MBA, CNOR, CRCST, president and CEO of Seavey Healthcare Consulting, which specializes in sterile processing and surgical services. "Otherwise it should be covered in a validated rigid container."

But what kind of container is acceptable? Wrapping instruments isn't practical for flash sterilization because it defeats the purpose of saving time. And even though CMS's memo lists "pouches" as potential containment devices for short-cycle loads, Ms. Seavey says she doesn't know of any pouches that are validated for flash sterilization.

Rigid containers are the best solution, says Ms. Seavey, although she warns that not all rigid containers are validated for use in a flash cycle. If you typically sterilize surgical instruments according to the Joint Commission's definition of flashing — steam sterilization for 3 minutes at 270°F and at 27 to 28 lbs. of pressure — the containment device must be labeled by its manufacturer for use in that cycle. The bottom line, says Ms. Seavey, is "you've got to follow manufacturers' written instructions for every product."
At a time when budgets are tight, many ASCs will be facing some tough decisions ahead as they seek to comply. "For everybody that does short-cycle sterilization in open pans, it's a bit disconcerting, because it's going to impact the cost," says Jody Looker, RN, CNOR, clinical director of the Winchester (Va.) Eye Surgery System. Ms. Looker says she's considering transitioning to flash pans designed for 10-minute sterilization loads, but the containers cost nearly $900 apiece. Another alternative would be to follow AORN's recommendations and scrap routine flashing altogether. But purchasing enough instrument sets to get through the day without flashing may not be a viable option for some facilities, particularly ophthalmology centers that rely on flashing to keep their daily case flow humming. "I can't imagine any small center that could afford to have 25 cataract sets," says Ms. Looker, who heads a 1-OR, single-specialty eye center. "There's no way I could afford to buy that much instrumentation to meet these guidelines, so I have to figure out a way around it." — Irene Tsikitas

How Will Surveyors Define “Proper” Flash Sterilization?

In its new guidance, CMS encourages surveyors to use the following questions to determine whether an ambulatory surgery center is properly flashing contained loads:

1. Is the sterilizer labeled for this cycle by the manufacturer?
2. What is the sterilizer manufacturer's recommended load for that cycle?
3. Is the containment device labeled by its manufacturer for use in that cycle?
4. For what load is the containment device recommended by its manufacturer?
5. Is the chemical indicator labeled for use in this cycle by its manufacturer?
6. If a biological indicator is used, is it labeled for use for this cycle by its manufacturer?
7. If the cycle is used frequently, is it checked regularly with a biological indicator?

For full memo, go to www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_55.pdf

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