Routine sterilization of unwrapped or uncontained loads is inappropriate and should be cited as a violation of the government’s infection control requirements for ambulatory surgery centers (ASCs). But an ASC that properly uses short sterilization cycles for wrapped/contained loads should not be cited, the Centers for Medicare and Medicaid Services (CMS) clarified in a memo to state surveyors September 4, 2009.

The memo spells out how CMS intends for surveyors to distinguish appropriate from inappropriate use of flash sterilization during ASC infection control surveys.

The memo says flash sterilization of unwrapped or uncontained items should be used only when there is an urgent or unexpected need for a device, such as when an instrument is dropped.

**Follow manufacturers’ instructions**

The crux of compliance is to follow all manufacturers’ instructions—for the sterilizer, container or wrap, chemical and biological indicators, and sterilizer testing. Manufacturers’ instructions have to be validated by the manufacturer and cleared by the Food and Drug Administration (FDA).

If a facility isn’t following the manufacturer’s instructions,” CMS says, “the outcome of the sterilization cycle is guesswork,” and the ASC should be cited.

Following the instructions is critical, especially for short cycles, the agency notes. The reason is that it takes time for steam to penetrate a sterilizer load to achieve an acceptable sterility assurance level (SAL), usually $10^{-6}$. Many variables affect the outcome, including the weight and complexity of items in the load, the type of wrap or container, and whether there are lumens. If loads don’t comply with instructions—for example, are too heavy or complex—sterility can’t be assured.

Cleaning is another area CMS says surveyors should look at. Failure to clean devices adequately can lead to sterilization failure. A major concern about flash sterilization has been that facilities will not take time to do cleaning properly.

**Instructions for short cycles not common**

Following manufacturers’ instructions is a familiar refrain, emphasized in professional recommendations from AORN and the Association for the Advancement of Medical Instrumentation as well as in the Joint Commission’s statement on sterilization in June 2009.

Be aware that manufacturers’ instructions for short cycles aren’t common,
cautions sterilization expert Martha Young, BS, MS, CSPDT, of SAVVY Sterilization Solutions, Woodbury, Minnesota.

“You need to obtain written, up-to-date manufacturers’ instructions for use for any purchased or loaner sets to ensure you are running the correct sterilization cycle,” she advises. Examples are instructions for gravity or dynamic-air-removal cycles, the sterilization temperature and time, such as 270°F (132°C) for 4 minutes, and dry time.

“Some medical device manufacturers may require a sterilization cycle longer than the cycle validated and recommended by the sterilizer manufacturer. These are called extended cycles,” Young notes. An example is 270°F (132°C) in a dynamic-air-removal sterilizer.

“Many manufacturers of complex medical devices do not provide 270°F (132°C) gravity flash sterilization parameters because the cycle time is too long to be practical and because implants are not to be flash sterilized,” she continues. “Make sure you follow the packaging instructions from the medical device manufacturer, because if you remove instruments from their original packaging, the sterilization parameters are no longer valid.

“Too many surgeries are being performed with instrumentation that has not been sterilized for a long enough time for the product to be safe for patient use.”

When surveyors see that manufacturer’s instructions for use for short cycles aren’t common, that will create a new challenge for facilities—and a possible new hook for surveyors, Young says.

CMS says it decided to clarify the surveyor instructions after reviewing surveyors’ infection control worksheets from states that voluntarily participated in the new survey process. The worksheet is at the end of the CMS interpretive guidelines for the revised ASC Medicare conditions for coverage (CfCs) which were effective May 15, 2009.

Though the worksheet doesn’t specifically mention flash sterilization, CMS says some surveyors made comments about flash sterilization.

CMS notes that it is important for everyone to have a common understanding of the term “flash sterilization.” The term used to refer mainly to sterilization of single items in unwrapped trays. Now there are sterilizers programmed for short cycles as well as specialized containers. For these reasons, CMS says a “more nuanced understanding” of the term is needed.

The big challenge for facilities—collecting and managing all of the instructions and making sure the staff are always educated on the latest versions.

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*The CMS memo (S & C-09-55) is available at www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_55.pdf*