If you work at an ambulatory surgery center (ASC), make sure your instrument sterilization policies are consistent, clear, and follow manufacturers’ guidelines.

That’s because a host of regulatory organizations—ranging from The Joint Commission to the Centers for Medicare and Medicaid Services (CMS)—are taking a closer look at instrument sterilization, particularly at ASCs.

Plus, a study published online in June in *JAMA*, which reported that 67.6% of ASCs included in the study had at least one lapse in infection control, has garnered national media attention. One of three common infection control lapses cited in the study includes not adhering to recommended practices regarding reprocessing of equipment (28.4%).

Here’s some background on when and why the spotlight on instrument sterilization began to shine, why regulators continue to talk about the issue, and what ASCs need to do to stay current.

**The Joint Commission Clarification**

The Joint Commission, which accredits hospitals and ASCs (among other healthcare facilities) via regular surveys, typically reviews instrument sterilization during surveys. However, some cleaning and sterilization practices that are standard for other specialties are not necessarily appropriate for eye surgery, said David F. Chang, MD, clinical professor of ophthalmology, University of California, San Francisco.

“Instrument size and the degree of contamination are very different for eye surgery versus abdominal or orthopedic surgery,” he said. “Therefore, what would be necessary to clean and sterilize general surgical instruments may not be necessary for ophthalmic instruments, which are simply exposed to aqueous or lens material.” Additionally, instrument-cleaning protocols used in other surgical specialties may be problematic in eye surgery, Dr. Chang said. For example, traces of detergent within the lumens of intraocular instruments can cause toxic anterior segment syndrome (TASS), while that same tiny amount of detergent would be inconsequential during abdominal surgery, he said.

Because of these concerns regarding differences in instrument handling and sterilization, particularly with sterilization involving steam, representatives led by ASCRS and including the American Academy of Ophthalmology (AAO) and the Outpatient Ophthalmic Surgical Society met with The Joint Commission regarding sterilization in ophthalmic facilities. Those concerns led leaders at The Joint Commission to clarify their interpre-

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**For more information on instrument sterilization**

“Recommended practices for cleaning and sterilizing intraocular surgical instruments” (published in the *Journal of Cataract & Refractive Surgery*, March 2007; from ASCRS and the American Society of Ophthalmic Registered Nurses. Web link also contains a related ASCRS press release)


“Steam sterilization: Update on The Joint Commission’s Position”

[www.jointcommission.org/Library/WhatsNew/steam_sterilization.htm](http://www.jointcommission.org/Library/WhatsNew/steam_sterilization.htm)


“Infection control assessment of ambulatory surgical centers” (abstract of *JAMA* article published online in June 2010)

[jama.ama-assn.org/cgi/content/short/303/22/2273](http://jama.ama-assn.org/cgi/content/short/303/22/2273)
tation of standards regarding steam sterilization.

In its June 2009 clarification (see attached supplement), The Joint Commission addressed cleaning/decontamination, sterilization, and storage during instrument sterilization.

Among the guidance provided in The Joint Commission clarification:

1. For cleaning/decontamination, all visible soil must be removed before sterilization as steam cannot penetrate soil. Those who clean instruments must be careful to follow manufacturers’ instructions.
2. Sterilization itself can take place with steam, although other methods are acceptable. “Steam sterilization of all types ... should meet parameters (time, temperature, and pressure) specified by both the manufacturer of the sterilizer, the maker of any wrapping or packaging, and the manufacturer of the surgical instrument,” the clarification states.

The clarification frowns upon the use of the older term “flash sterilization,” as sterilization processes have improved in the past few decades and do not always follow the process to which that term originally referred. In fact, whether defending sterilization processes to a regulatory agency or for internal medical director, Charles T. Laboratory, University of Pittsburgh School of Medicine, Pittsburgh, recommended using any once-common terms to summarize it, as these terms may not have the same universal definition. Dr. Mah has been involved with the ASCRS group that is reviewing sterilization processes—these members are part of the ASCRS Task Force on Ophthalmic Sterilization.

Those who sterilize instruments must be careful that the instrument is not recontaminated. “Instruments subject 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,” according to The Joint Commission clarification.

The clarification also refers those who work regularly with instrument sterilization to the Center for Disease Control and Prevention’s (CDC) Guidelines for Disinfection and Sterilization in Healthcare Facilities, a document that parallels and expands on some of The Joint Commission’s clarifications. Another protocol that many ASCs use for infection control and sterilization guidance comes from the Association of periOperative Registered Nurses (AORN), Dr. Chang said.

Because of this clarification, The Joint Commission’s surveyors now pay closer attention to the sterilization process as a whole versus only the sterilization cycle. Noncompliance could lead to a requirement for improvement, said Elizabeth Zhani, media relations manager, The Joint Commission.

“Examples of survey findings would be a high percentage of steam sterilization using less than a full sterilization cycle or the exclusive use of this process for certain types of instruments,” according to a July 2009 article from The Joint Commission Perspectives. Surveyors will look for evidence of proper sterilization by observing instruments when they leave one OR and are brought to another OR, asking healthcare workers for copies of manufacturers’ instructions regarding sterilization, and reviewing sterilization logs, among other actions, according to The Joint Commission Perspectives article.

Turning Attention to Sterilization Again

While The Joint Commission’s clarifications have continued to influence ophthalmic ASC surveys over the past year, discussions of steam sterilization—both what it is called and how it is done—have continued.

As part of the American Recovery and Reinvestment Act of 2009, the CMS is surveying a number of ASCs with a special focus on reducing infections. In states like California, unannounced surveyors could eventually inspect every ASC, Dr. Chang said. A CMS press release from July 2009 indicated that more than 125 ASCs in 12 states were to be surveyed by the end of September 2009. The CMS inspections relate to ASCs’ licensure to treat Medicare patients.

Because these inspections focus on infection control, once again, questions regarding flash steam sterilization have arisen, said Nick Mamalis, MD, professor of ophthalmology, John A. Moran Eye Center, department of ophthalmology & visual sciences, University of Utah, Salt Lake City. Dr. Mamalis is part of the ASCRS Task Force on Ophthalmic Sterilization.

In September of last year, the CMS published a letter to clarify flash steam sterilization guidelines for its ASC surveyors, as a result of The Joint Commissions’ amended policy. The letter addresses the ambiguity of the term “flash sterilization” and, like The Joint Commission clarification, recommends that ASCs follow manufacturers’ guidelines regarding sterilization. Discussions with Medicare have since revealed that ASCs may use instrument cleaning and sterilization protocols written by their subspecialty societies, Dr. Chang said. This is a positive step because ASCRS developed ophthalmology-specific instrument han-
The guidelines in 2007 to focus on avoiding the spread of TASS, he said. Those guidelines were published in the March 2007 issue of the *Journal of Cataract & Refractive Surgery*.

Additionally, representatives from various specialty societies (including Dr. Mah, who represented ASCRS as well as the AAO) met with leaders at the Association for the Advancement of Medical Instrumentation in April to try to clarify when short steam sterilization would and would not be acceptable, Dr. Mah said. Although no conclusions have yet been reached, the group plans to talk again at some point this summer, Dr. Mah said.

Dr. Mah does not anticipate the group making any major changes to how ophthalmic instruments are sterilized, but he said that the group will hopefully better define the sterilization process and when certain kinds of sterilization are most appropriate.

**The Bottom Line**

So what does all of this mean for instrument sterilization at ophthalmic ASCs?

First, this would be an opportune time to review your instrument cleaning and sterilization protocols, Dr. Chang recommended. “Hopefully [staff] has been monitoring their ASC’s instrument handling all along, but now, with all of the increased regulatory scrutiny, it is especially important to make sure that proper protocols are in place,” he said.

The operating room staff should review the ASCRS guidelines for cleaning and sterilizing ophthalmic surgical instruments, which are specific to eye surgery, unlike the general CDC or AORN guidelines, he added.

Reviewing The Joint Commission’s clarification is also recommended.

And, although most ASCs are likely following manufacturers’ guidelines for sterilization practices, this is an ideal time to confirm your facility is indeed doing just that, Dr. Mah said.

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