The Joint Commission announced in June it will look beyond flash sterilization to take a broader view of sterilization. Surveyors will scrutinize the entire process rather than just focusing on which sterilization method is selected.

“If a complete and effective process of sterilization is used, it will be considered an effective sterilization method,” the commission said in a June 15 update.

According to the update, surveyors will review the critical steps of disinfection and sterilization, including:
1. cleaning and decontamination
2. sterilization
3. storage or return to sterile field.

One theme—manufacturers’ instructions. The Joint Commission says surveyors will ask the staff for manufacturers’ instructions for cleaning and decontamination and will ask how the staff is following the instructions. They will want to see that steam sterilization of all types, including flash, meets the parameters set by the manufacturers of the sterilizers, of wrap or packaging, and of instruments themselves.

Applause, and some confusion
Sterilization experts say they’re pleased the Joint Commission plans to look at all steps in sterilization but find some aspects of the update confusing. One issue is the description of flash sterilization as a cycle of “3 minutes at 270°F at 27 to 28 lbs of pressure.”

The description doesn’t refer to dry time, differentiate between gravity and prevacuum cycles, nor mention that flash-sterilized items are intended for immediate use, says Rose Seavey, RN, MBA, CNOR, CRCST, CSPDT, an independent consultant and former director of sterile processing.

Reconciling instructions
Reconciling manufacturers’ instructions is another concern. It’s not always possible to reconcile instructions for sets that require extended cycles, which have become increasingly common, says Cynthia Spry, RN, MA, MSN, CNOR, an independent consultant who chaired the working group that developed the comprehensive steam sterilization standard for the Association for the Advancement of Medical Instrumentation (AAMI).

Sterilizer manufacturers can’t provide instructions for some extended cycles because they fall outside the range of those that can be cleared by the Food and Drug Administration (FDA).

“What’s a user to do when it’s impossible to meet these requirements?” Spry asks.
AAMI recommends performing product testing for these sets, but many facilities aren’t familiar with that, she notes.

Reconciling instructions will be a “horrendous job,” agrees David Narance, RN, BSN, CRCST, manager of sterile processing for MedCentral Health System in Mansfield, Ohio.

He makes sure to keep binders with instructions on hand for the staff—and makes sure they get used. He expects surveyors will ask about some of the more complex equipment, such as power drills and back retractors.

**AORN comments**

AORN “applauds and supports” the Joint Commission’s effort to begin reviewing the whole sterilization process, Ramona Conner, RN, MSN, CNOR, AORN’s manager of standards and recommended practices, told OR Manager.

She added that AORN is “considering how we can open a conversation and talk further about how to clarify the statement.” This would include terms used and how surveyors plan to implement the update.

She said AORN had discussed sterilization issues with the Joint Commission last year but was not asked to review or comment on the update before it was released.

**Need to educate staff**

The broader focus means OR managers “will have to educate everyone in the OR and ensure all of the critical steps are met,” Seavey says.

They will need to make sure sterilizers located in the OR are subject to biological monitoring weekly and preferably daily, as recommended by AAMI.

“The sterilizers in the OR will need to be capable of running multiple types of cycles. Every type of cycle used in each sterilizer will have to be challenged with a BI and with a Bowie-Dick type indicator for dynamic air-removal sterilizers,” she says.

**Possible questions from surveyors**

Managers will need to prepare the staff to respond to questions from surveyors. Spry says possible examples are:

- “Show me the manufacturer’s instructions for processing these instruments. How are you following them?”
- “How do you know the parameters for this sterilization cycle were met?”
  - The staff should be able to show the surveyor the printout or display from the sterilizer and explain how the parameters are documented.
- “How did you verify and document the biological and chemical monitoring for this instrument set?”

Seavey urges managers to be well versed in the AORN and AAMI standards and recommended practices. The Joint Commission refers to the *Guideline for Disinfection and Sterilization in Healthcare Facilities* from the Centers for Disease Control and Prevention (CDC) and Healthcare Infection Control Practices Advisory Committee (HICPAC).

*The Joint Commission update is at* www.jointcommission.org/Library/WhatsNew/steam_sterilization.htm

**Resources**

Association for the Advancement of Medical Instrumentation.
Specific activities surveyors will observe

The Joint Commission says surveyors, among other activities, will:

- Observe instruments from the time they leave one operating room to when they are returned to the next.
- Ask health care workers to provide manufacturers’ instructions for instrument sterilization and to describe and demonstrate how instruments are being cleaned and decontaminated according to those written instructions.
- Observe cleaning of instruments. “Rinsing is rarely enough to properly remove soil from instruments; meticulous cleaning is needed,” the commission says.
- Verify staff are wearing appropriate personal protective equipment.
- Observe the sterilization process, including asking for manufacturers’ instructions for the sterilizer, wrapping or packaging, and instruments.
- Review sterilization logs, asking about parametric, chemical, and biological indicators.
- Observe return of instruments to the sterile field and verify they are being protected from recontamination.