The Centers for Medicare & Medicaid Services (CMS) has replaced the term “flash sterilization” with “immediate use steam sterilization” (IUSS) in surgical settings.

The change in terminology, which applies to Medicare-participating hospitals, critical access hospitals, and ambulatory surgical centers that are subject to Conditions of Participation or Conditions of Coverage, also comes with updates for CMS to use when surveying facilities.

In an August 29, 2014, Survey and Certification (S&C) Memorandum (14-44), CMS said the change was recommended by organizations with expertise in infection prevention and instrument sterilization because the term “flash sterilization” is outmoded.

CMS noted that practices associated with IUSS have been implicated in surgical site infections and pose an increased risk of complications because of incomplete reprocessing steps. IUSS also entails an increased risk of inadvertent contamination during transfer to the sterile field and damage to the instruments as well as risks related to wet instruments and the potential for burns.

Therefore, CMS says, use of IUSS, even when all steps are performed properly, should be limited to situations in which there is an urgent need and insufficient time to process sterilization & infection prevention

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Survey questions for IUSS

- Is immediate use steam sterilization (IUSS) reserved for immediate use needs when an instrument has been contaminated and there is no sterile replacement available, or for an item that cannot be packaged, sterilized, and stored before use?
- Is there a process in place to ensure IUSS is not used for implants, instruments used on patients with known or suspected Creutzfeldt-Jakob Disease or similar disorders, devices or loads not validated with the specific cycle, and single-use devices?
- Are instruments to undergo IUSS first cleaned and disinfected following the manufacturer's instructions for use (IFU)?
- Is there evidence that all personnel who perform IUSS:
  - have the necessary time, equipment, supplies, and facilities readily available
  - have been trained and are able to correctly follow the manufacturer’s IFU with respect to each instrument, sterilizer, container, and cleaning supplies
  - have had their competency verified before they undertake IUSS and periodically thereafter?
- Can personnel provide evidence that the sterilizer cycle being used for IUSS is indicated in the device manufacturer’s IFU?
- Are physical monitors documented that cycle parameters are met for each load?
- Is there evidence that the sterilizer is being maintained as required by the IFU?
- Is the rigid sterilization container, packaging, or tray used consistent with how it is labeled by the manufacturer?
- Is the rigid sterilization container consistent with the manufacturer’s recommendations (eg, load weight, configuration of instruments)?
- Are chemical indicators (CIs) used labeled for IUSS by the manufacturer?
- Is a Class 1 CI placed outside each sterilization container/package unless the internal Class 4, 5, or 6 CI used inside each package is visible?
- Is a Class 4, 5, or 6 CI placed in each container?
- If a biological indicator (BI) is used, is it labeled for IUSS by its manufacturer?
- If IUSS must be used on an implantable device, is the load checked with a BI and a Class 5 CI?
- Are all monitoring (physical, chemical, and biological) results evaluated by trained personnel at the conclusion of the IUSS process before the instrument or device is used?
- Are instruments sterilized using IUSS aseptically transported and cooled prior to use?
- Is there evidence that the healthcare provider or supplier is monitoring personnel for adherence to policy and procedures for IUSS?

— Adapted from Centers for Medicare & Medicaid Services’ Change in Terminology and Update of Survey and Certification (S&C) Memorandum 09-55 Regarding Immediate Use Steam Sterilization (IUSS) in Surgical Settings.
an instrument by using terminal sterilization. In addition, CMS says, IUSS is not considered an appropriate substitute for maintaining a sufficient inventory of instruments.

The memorandum also reiterates and updates information on nationally recognized infection prevention guidelines and professionally acceptable standards of practice with respect to IUSS, and it supersedes S&C Memorandum 09-55, which was issued September 4, 2009.

More detailed questions

The 2009 memorandum (09-55) was built around ambulatory surgery centers and had only seven questions for surveyors to use to assess the appropriateness of the flash sterilization cycle:

- Is the sterilizer labeled for this cycle by the manufacturer?
- What is the sterilizer manufacturer recommended load for that cycle?
- Is the containment device labeled by its manufacturer for use in that cycle?
- For what load is the containment device recommended by its manufacturer?
- Is the chemical indicator labeled for use in this cycle by its manufacturer?
- If a biological indicator is used, is it labeled for this cycle by its manufacturer?
- If the cycle is used frequently, is it checked regularly with a biological indicator?

The new 2014 memorandum, which includes 17 surveyor questions and subquestions, lays out precisely what surveyors must assess (sidebar). If the answer to any of the questions or subquestions is “no,” or if IUSS is used in a manner that places patients at risk for infection, CMS says a citation is warranted.

Also included in the 2014 memorandum (14-44) are 14 recommendations from a 2011 position paper adopted by the Association for the Advancement of Medical Instrumentation (AAMI), the Association for Professionals in Infection Control and Epidemiology (APIC), AORN, and four other professional organizations. That paper recommends replacing the term “flash” sterilization with IUSS.

“In the memorandum, the recommendations are formed into the surveyor questions, and that becomes the open book test, if you will, for the healthcare facility,” John R. Rosing, MHA, FACHE, vice president and principal, Patton Healthcare Consulting, told OR Manager.

Rosing cautioned that each of the 14 recommendations and 17 questions represents a deal breaker or a limiting factor. “If an organization wants to continue to use the process of IUSS, it will have to satisfactorily meet all of the recommendations and address and answer all of the questions,” he says.

Too many hurdles?

“The level of detail, such as the type of indicator to use and the parameters around exposure time, temperature, and drying time, creates a number of large hurdles for hospitals to jump over,” says Rosing.

In a session on survey preparation at the 2014 OR Manager Conference in Long Beach, California, Jennifer Cowel, MHSA, RN, vice president and principal, Patton Healthcare Consulting, noted that because of the requirements in the new memorandum, some OR managers are questioning whether they can do IUSS correctly in the OR.

One question that Cowel sees as an easy target for the surveyors to find noncompliance with is: “Are instruments that are sterilized using IUSS aseptically transported and cooled prior to use?”

This question comes from the recommendation: “The items are assumed to be wet and hot and need to be transported in a manner to minimize both exogenous contamination and injury to personnel. Sterile heat protective gloves (eg, potholders or towels) may be used to carry the containment device directly to the point of use.”

Cowel asked the attendees, “How many of you sterilize the mitts you use to trans-
port hot instrument containers?” No one raised their hands.
This is the kind of detail surveyors may be looking at, says Cowel. “If they see an unsterile mitt hanging next to the sterilizer, they can score you on it.”
This question and recommendation represents a new threshold, and staff will have to use sterile towels if the mitts aren’t sterile, she says.

Moving IUSS to SPD
Because of the prohibitive thresholds ORs must meet, some are suggesting IUSS should be done in the sterile processing department (SPD), notes Rosing. This might be especially beneficial in newer ORs that are built without substerile rooms and have mini SPDs next to the OR.
For example, he says, the second recommendation in the memorandum states: “The same multistep process used to prepare the instrument for terminal sterilization must be completed for IUSS. Cleaning must be performed in an area that has all of the equipment (eg, sinks and mechanical and/or ultrasonic washers), cleaning agents, tools (eg, brushes), water quality, and availability of information needed to follow the medical device manufacturer’s IFU [instructions for use] regarding both cleaning and IUSS.”
The corresponding surveyor question asks: “Are instrument(s) to undergo IUSS first cleaned and disinfected following the manufacturer’s IFU?”
This recommendation and question present multiple hurdles for performing the steps for IUSS in the OR, he says.
“Newly constructed OR suites don’t have substerile rooms, so there is no sink suitable for doing the decontamination and cleaning. Old ORs have a substerile room, but AORN has said for years that decontamination and cleaning of instruments should not be done in substerile room sinks because there is too great a risk of something flying through the air and contaminating surfaces.”
To do this step properly, it should be done in the decontamination area of the SPD, he says.
“When it comes right down to it,” says Rosing, “the only thing you should really use IUSS for is an instrument you’ve dropped on the floor, and you absolutely need it immediately. For everything else, regulations are making it too prohibitive to do IUSS in the OR.””

—Judith M. Mathias, MA, RN

References