Have you taken steps to avoid the abuse of IUSS?

I have heard the following statement from OR personnel: “We use rigid sterilization containers and run a 270-275°F (132-135°C) prevacuum steam sterilization process in our OR. So we no longer use IUSS.”

Is that an IUSS cycle?

IUSS, or immediate-use steam sterilization, was formerly known as flash sterilization.

This article discusses the what, when, and how of IUSS along with risks, the Joint Commission perspective, and how to minimize use of IUSS.

What is IUSS?

The Multi-society Immediate-Use Steam Sterilization statement issued in 2011 broadly defines “immediate use” as the shortest possible time between a sterilized item’s removal from the sterilizer and its aseptic transfer to the sterile field. The sterilized item is:

• used during the procedure for which it was sterilized
• used in a manner that minimizes its exposure to air and other environmental contaminants
• not stored for future use
• not held from one case to another.

The standard, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities (ST79) from the Association for the Advancement of Medical Instrumentation (AAMI), in section 2.61 defines IUSS as a “process designed for the cleaning, steam sterilization, and delivery of patient care items for immediate use.”

AAMI ST79 also states, “Since drying time is not usually part of a preprogrammed cycle for immediate-use, the items processed are assumed to be wet at the conclusion of the cycle.”

IUSS cycles

An IUSS cycle can be either a gravity or dynamic-air removal (eg, prevacuum or steam-flush pressure-pulse) cycle run at 270-275°F (132-135°C) for the time recommended by the device manufacturer’s written instructions for use (IFU). This includes extended cycles if required. What makes IUSS different from terminal sterilization is that there is no dry time. That is why items must be used immediately.

AAMI and AORN recommend using rigid containers intended for IUSS cycles to protect instruments during aseptic transfer to the sterile field. Processing unwrapped items is not recommended, because they are wet and could become contaminated during the transfer process.

So the answer to the question, “Is processing instruments in a rigid sterilization container at 270-275°F (132-135°C) in a prevacuum steam sterilization process considered IUSS?,” is yes, if there is no dry time, and the items are wet at the end of the cycle.
When to use IUSS
AORN states IUSS “should be used only when there is insufficient time to process by the preferred wrapped or containerized method intended for terminal sterilization.” IUSS “should not be used as a substitute for sufficient instrument inventory.”

AORN, AAMI, and the Centers for Disease Control and Prevention agree that IUSS should not be used to sterilize implants.

How to use IUSS
Here are the steps to keep in mind:
• Medical devices processed by IUSS should be cleaned, packaged, and sterilized according to the manufacturer’s IFU.
• Cleaning should be performed in an area that has the equipment (eg, sinks and mechanical and/or ultrasonic washers), cleaning agents, tools (eg, brushes), and water quality needed to follow the medical device manufacturer’s IFU.
• If the OR processing area does not have the appropriate setup, devices should be sent to the sterile processing department (SPD) for cleaning, packaging, and sterilization.
• Packaging material should be that recommended by the device manufacturer’s IFU and should provide protection for aseptic presentation. Unwrapped trays are not recommended.
• The sterilization cycle, exposure time, temperature, and drying times (if recommended) should be followed. It is no longer acceptable to run a 3- or 10-minute 270-275°F (132-135°C) gravity cycle for IUSS unless those cycles are recommended by the device manufacturer’s IFU.
• The same sterilization cycle and parameters used in SPD need to be used in the OR. This may require the use of an extended cycle, eg, 270-275°F (132-135°C) gravity cycle for 30 minutes, or a 270-275°F (132-135°C) dynamic-air removal cycle for 10 minutes.
• The sterilization cycle should be documented with physical monitors and chemical and biologic indicators (BIs) and the results documented along with the name of the patient.

AORN states that because these devices are hot and wet, care should be taken to transport the devices to the point of use “in a manner that minimizes the risk of contamination of the item and injury to personnel.”

Take care to document
A recent study by Zuckerman et al, conducted in Vanderbilt University Hospital’s main OR, identified potential lapses in practice related to IUSS, including incomplete documentation of:
• use of chemical and BIs (ie, used in each load)
• peak temperature
• cycle time
• description of specific instruments sterilized.

The authors encourage “institutions to strictly assess the rationale for IUSS and documentation of core IUSS components. Only through sound documentation can practices be monitored and quality improved.”

Joint Commission perspective
John Rosing discussed observations about IUSS from Joint Commission surveys in the October 2012 OR Manager. He noted: “Joint Commission surveyors won’t cite an
organization for sterilizing instruments for immediate use. Rather, they will check that data is being collected on instances when immediate-use sterilization is used and then check to see if action is being taken based on the data. If surveyors don’t find that, they may cite the organization under the performance improvement standards.”

Data to collect routinely and to aggregate monthly, Rosing advises, includes:

- the number of IUSS episodes attributed to lack of instruments
- the evaluation completed by OR leadership and submitted to the infection control committee for its evaluation.

The committee should present its data on the number of IUSS episodes that were due to a lack of instruments to the hospital’s finance department to justify the need to buy more instruments.

**Traceable to the patient**

At the 2011 meeting of the International Association of Healthcare Central Service Materiel Management (IAHCSMM), a Joint Commission surveyor said that the Joint Commission is also interested to see that any devices, including implants, processed by IUSS be traceable to the patients on which they are used or implanted.

AAMI ST79 Section 10.3 states: “IUSS of implantable devices is not recommended; however, if it is unavoidable, full traceability to the patient should be maintained.” Traceability is important because of the serious consequences of infections related to implants.

**Releasing implants**

AAMI ST79 also states that “releasing implants before the BI results are known is unacceptable and should be the exception, not the rule.” AAMI ST79 has 2 forms in Annex L that can be used to track documentation of premature release of implants. One is an Implantable Devices Load Record, and the other is an Exception Form for Premature Release of Implantable Device/Tray that includes documenting why premature release of the implant was needed and what could have prevented this premature release.

Joint Commission surveyors will check these forms to see how many implants are released before the BI is available. They will expect to see a Department of Surgery policy that includes multidisciplinary input to address who can authorize early release of implants. The Joint Commission suggests this be a surgeon.

**How to minimize IUSS**

Be sure you and your superiors are aware of the Joint Commission’s National Patient Safety Goal 07.05.01, in particular EP 4, which states: “As part of the effort to reduce surgical site infections, conduct periodic risk assessments for surgical site infections in a time frame determined by the hospital.” This could be interpreted to apply to IUSS. Conduct a risk assessment to determine why the facility is using IUSS and determine how to eliminate all reasons except for intraoperative contamination.

The data collected, as suggested above, will assist in this risk assessment.

**Policy on loaners**

As a result of the risk assessment, your facility may determine that the policy and procedure for loaner instruments needs to be updated and/or enforced.

Communication is key. When loaner sets are used, the correct instrumenta-
tion needs to arrive at least 2 business days before the scheduled case to facilitate proper cleaning, sterilization, and quarantine of implants until the BI results are negative. The IAHCSMM position paper and sample policy are invaluable tools to use in this process.

Management teams from the OR, sterile processing, infection prevention, and risk management need to work together to develop policies and procedures to ensure IUSS is not performed for convenience. Abuse of IUSS has the potential to increase risk for development of SSI.

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