Sterile processing questions and answers

Answers to some of the questions asked at several recent annual meetings, notably AORN, APIC (Association for Professionals in Infection Control and Epidemiology), and IAHCSMM (International Association of Healthcare Central Service Materiel Management), are offered by sterilization expert Martha Young. Also included are questions from seminars and webinars she has presented.

Question: The OR staff opened a processed instrument set in the OR on the back table and the chemical indicator (CI) was missing. Do they have to tear down the entire room?

Answer: “No, only the area/items that may have contacted the suspect package need to be removed,” says Ramona Conner, MSN, RN, CNOR, manager of the standards and recommended practices for AORN. “The package with the missing CI should be considered unsterile, so any surfaces that came into contact with it should be considered unsterile.”

To avoid this situation, follow the recommendation VI.f.4. in the AORN Recommended Practices for Sterile Technique, which states: “Before the instruments are placed on the sterile field, the internal chemical indicator should be examined for the appropriate color change and the inside surface of the container inspected for debris, contamination, or damage.” By doing so, you can avoid the situation posed by the question above.

The recommended practices go on to say that when organic or inorganic material is remaining on a surgical instrument or when an instrument in a sterile set is found assembled or clamped closed, you should at a minimum remove from the sterile field the entire instrument set or any other instruments that came in contact with the contaminated instrument. In addition, any team member who may have touched the contaminated items should change gloves.

For more information, see Sections VI and VII of the AORN Recommended Practices for Sterile Technique.

Question: Our OR is using rigid containers in a dynamic air removal steam sterilizer for a 270°F/132°C, 4-minute cycle. Is this considered an immediate-use steam sterilization cycle (IUSS)?

Answer: Yes, it is considered an IUSS cycle because there is no dry time. Containerizing the instruments should be the standard of practice for IUSS. Containerizing the instruments reduces the risk of contamination during transportation, but staff should be careful because the contents are hot, wet, and possibly heavy.

The container should be transferred immediately to the sterile field using sterile technique and opened immediately so it is not stored for later use. Be sure to use a container cleared by the Food and Drug Administration (FDA) for use in IUSS.

In addition, all the processing steps in the medical device manufacturer’s instructions for use (IFU) (eg, cleaning, decontamination, rinsing, packaging, sterilization process, and cycle parameters) should be followed in the OR just as they are.
in sterile processing. No shortcuts can be taken. Remember to clean the containers after every use in the OR according to the container manufacturer’s IFU; do not just wipe them down with alcohol.

For more information on IUSS, see Section VII of the AORN Recommended Practices for Sterilization.

**Question:** Implants are processed in the OR using IUSS and a 10-minute, 270°F/132°C gravity-displacement cycle. Is that the correct cycle to use for processing implants?

**Answer:** It is correct only if the manufacturer’s IFU states that IUSS can be done at that time and temperature in a gravity-displacement steam sterilizer. That is not a recommendation I see in the manufacturer’s IFU for complex instrument trays or implants. The Association for the Advancement of Medical Instrumentation (AAMI) states that a dynamic air removal cycle should be used unless a gravity-displacement cycle is recommended.

AAMI, AORN, and the Centers for Disease Control and Prevention (CDC) also say that implants should not be processed by IUSS because of the risk to the patient if the implant is not properly processed and quarantined until the biological indicator (BI) result is negative. The exception is a documented emergency situation where no other option is available. IUSS “should not be used as a substitute for sufficient instrument inventory.”

For more information, see the IUSS section in the introduction in AAMI ST79 and Section 10.6.3 on the release criteria for implants. See also section VII of the AORN Recommended Practices for Sterilization.

**Question:** We run a 1-hour and a 3-hour rapid readout BI in loads containing implants so we can release the implant in 1 hour. Is that correct?

**Answer:** No, that is not correct because the 1- and 3-hour rapid readout BIs are FDA-cleared to be used in different cycles (eg, the 1-hour BI is for use in 270°F/132°C gravity steam cycles and the 3-hour BI is for use in 270°F/132°C vacuum-assisted or 250°F/121°C gravity steam cycles). I assume this is a vacuum-assisted cycle, so the 3-hour rapid readout BI should be used and the implant should not be released until the results are negative at 3 hours. This is an example of operator error, failure to use critical thinking skills, and failure to follow the BI IFU. The Joint Commission is citing health care facilities that do not use the correct BI for the loads they are processing. Be sure to follow the BI manufacturer’s IFU to determine which BI to use in which cycle.

**Question:** The BI process challenge device (BI PCD) used in the OR for routine sterilizer efficacy testing (eg, weekly, or preferably daily) of the IUSS cycle is an open perforated instrument tray that contains a BI and a Class 5 integrating CI. During the rest of the day, we use rigid containers for IUSS. Is this the correct BI PCD for routine efficacy testing?

**Answer:** No, it is not. The BI PCD does not represent the loads being processed and in fact is not as great a challenge to air removal and steam penetration as a rigid container. The BI may be killed in the open perforated instrument tray but not in a rigid container because the cycle time and temperature may not be correct for the container, the container is failing to remove air or allow steam penetration because
of a poorly functioning mechanical filter, or there are leaks caused by damaged gaskets.

The risk of not using the correct BI PCD that is representative of the loads being routinely run is that a sterilization process failure may go undetected.

In this example, the BI PCD to use should be the rigid container with a BI and a Class 5 CI inside the container in the area determined by the container manufacturer to be the greatest challenge. The BI PCD is placed on the rack, over the drain, in an empty sterilizer. Health care facilities are running BIs inside each container to ensure that sterilization process failures related to incorrect time and temperature, nonfunctioning mechanical filters, and damaged gaskets are detected. The Joint Commission is citing health care facilities that do not use the correct BI PCD for routine efficacy testing.

For more information, see AAMI ST79 Section 10.5.4 about PCDs, Section 10.7.4 about routine biological monitoring of IUSS cycles, and Section 10.7.6 about Bowie-Dick testing, along with the BI and BI PCD manufacturer’s IFU.

Question: We have 2 auto-readers, but we only run a positive control in 1 of them. Is that correct?

Answer: That is not correct. A positive control (ie, BI from box, not sterilized) should be incubated in each incubator or auto-reader each day a test vial is incubated. The positive control and test vial should be from the same lot number so they have experienced the same transportation and storage conditions. This is good science.

The purpose of the positive control is to verify that the test BI was placed into the correct incubator or auto-reader, the unit is functioning, the spores in the BI were still viable before they were sterilized, and the media will still promote growth of the spores.

Read and record the test and control results at the end of the incubation time. If the positive control is negative, the test BI results are invalid because the spores died in storage or the incubator temperature was not correct. The load should not be used, and the reason for the negative control should be investigated.

Read the BI manufacturer’s IFU for information on how to use a positive control. The Joint Commission is citing health care facilities that do not record the results of the positive control and test BI and if they are not from the same lot.

For more information about use of controls for IUSS cycles, see AAMI ST79 Section 10.7.4.3.

Question: Is it mandatory to have physical evidence of the routine sterilizer efficacy testing and sterilizer qualification testing for audit purposes, including the major or minor repairs during servicing of the steam sterilizers?

Answer: Yes. If you do not document this information there will be no proof that this required testing was done. AAMI ST79 states that each sterilizer cycle needs to be documented. See Section 10.3.2 for details on what information is recorded. Preventative maintenance and repair records should also be documented and retained so you can determine if the repair to the sterilizer was minor or major—which requires qualification testing of the sterilizer before it is placed into routine use. See Section 9.5.1 of AAMI ST79 for what maintenance information should be recorded.

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References

