Extended sterilization cycles. Different cycles for implants and instruments in the same tray. Vague instructions that say “follow your usual procedure.” These are issues central service (CS) professionals say they’re having with some device manufacturers.

“It can be almost impossible to get the manufacturers to provide sufficient instructions,” says Anne Cofiell of Cofiell Consulting Services, a CS consultant.

In an informal online survey last year, the International Association of Healthcare Central Service Materiel Management (IAHCSMM) found lack of reprocessing instructions was the chief complaint.

Some manufacturers specify extended cycles beyond those that health care facilities typically use. For example, instructions for devices made in Europe where variant Creutzfeldt-Jakob disease (vCJD) is a concern may require a prevacuum cycle of 134 C (274 F) for 18 minutes, intended to inactivate prions, without other options.

Orthopedic companies and some other manufacturers call for prolonged prevacuum cycles of 8, 10, or 20 minutes or longer. The cycles are based on testing that shows a set such as a big orthopedic tray needs a longer cycle to demonstrate sterility assurance.

Difficulties for CS

These situations create difficulties for CS departments. They may choose to ignore the instructions and use their routine cycles, risking sterilization failure. Or they may reprogram their sterilizers to match the extended cycle but then use the sterilization indicators intended for routine cycles.

“Errors are possible if a sterilizer has to be reset or reprogrammed,” says Natalie Lind, CRST, CHL, education director for IAHCSMM. Plus, an extended cycle can tie up a sterilizer. “If you have only 2 or 3 sterilizers, and you have 2 sets needing extended cycles, everything else has to wait,” she says.

Nonstandard cycles pose a potential risk to patients because there are not appropriate process monitors, including biological and chemical indicators and challenge packs for the cycles, notes a user alert from Canada.

The alert recommends that users require detailed information from manufacturers before acquiring any devices—including those loaned or leased. For existing sets, the alert suggests conducting limited testing by placing biological indicators in various locations in the set before it is used for the first time to ensure steam penetration is achieved. If any biological indicators (BIs) fail (ie, show growth), break down the tray into smaller sets and retest. If BI failure still occurs, remove the set from use and file a report with the manufacturer, the alert suggests.

FDA requires instructions

The Food and Drug Administration (FDA) requires manufacturers to include reprocessing instructions when they submit device applications for review. An FDA guidance states: “Manufacturers are responsible for supporting the claim of reuse with adequate labeling; the labeling must provide sufficient instructions on how to prepare the device for the next patient, and the manufacturer is responsible for the documentation of tests which show the instructions are adequate and can be reasonably executed by the user.” (Labeling Reusable Medical Devices for Reprocessing in Healthcare Facilities, April 1996. www.fda.gov/cdrh/ode/198.pdf)

The Association for the Advancement of Medical Instrumentation (AAMI) has 2 documents that can help device companies develop instructions that are feasible in health care facilities:
• AAMI TIR12:2004 gives guidance on performing validation studies for reprocessing instruments.


How OR managers can help

OR managers and directors can assist by insisting that manufacturers provide instructions hospitals can follow. Here are ways to help:

• Use buying power. Insist on adequate cleaning and reprocessing instructions when making the decision to purchase a new device, Lind advises. Include adequate instructions as a criterion on the product evaluation form. Develop a checklist for evaluating the instructions. Ask how any extended cycle should be monitored to assure sterility. AAMI TIR12 and ST81 provide guidance on what to look for.

• Insist on receiving reprocessing instructions from sales reps. “Don’t let them tell you the company doesn’t have instructions—they do. It’s required by the FDA,” says Lind.

• If instructions aren’t adequate, file a report with the FDA’s MedWatch program, using Form 3500 at https://www.accessdata.fda.gov/scripts/medwatch/. MedWatch is the way the FDA learns about device-related problems. It takes a volume of reports to make the agency aware of the magnitude of the issue, says Lind. IAHCSMM is in contact with the FDA, and FDA representatives have participated in discussions at its annual conference.

• Urge companies to post cleaning and reprocessing instructions on their web sites. Says Lind: “If instructions were on the Internet, and I got a loaner set in at 5 pm, I could go to the web site and get the instructions. Then I could review them for my own peace of mind.”

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