Two new documents from the Association for the Advancement of Medical Instrumentation (AAMI) should help device companies develop clear reprocessing instructions that can be applied in health care facilities. They can also assist OR and Central Service managers evaluate instructions they receive from companies.

The first document, TIR12: 2004, gives guidance to manufacturers on how to perform validation studies for their reprocessing instructions. It also provides advice on choosing protocols that are feasible for facilities to perform.

The second, ST81: 2004, is a voluntary standard to guide manufacturers in labeling their devices and providing reprocessing instructions. Importantly, ST81 calls on manufacturers to validate each step in the cleaning, disinfection, and sterilization process, says Sandra Lee, RN, BS, a sterile reprocessing consultant and educator who co-chaired the working group that developed the documents.

For example, on cleaning, the standard says the manufacturer shall give a validated manual method for cleaning plus at least one validated automated process unless the device can't withstand an automated method.

Both documents can help users when they are considering purchasing a device, Lee says. TIR12 can assist them in understanding the kind of information manufacturers should provide so they can ask the right questions. In addition, ST81 lets them know what standard manufacturers should be expected to meet for reprocessing instructions.

“In the past, it has been difficult to get meaningful, specific information,” says Nancy Chobin, RN, CSPDM, Lee’s co-chair and educator at St Barnabas Healthcare System, Livingston, NJ. “There are many manufacturers that have provided detailed instructions to end users. However, there are just as many that do not.”

Meeting real-world needs

One challenge manufacturers face is making sure their reprocessing requirements match the real world, Lee notes.

Device manufacturers know what processes are compatible with the materials in their devices. But they also need to make sure methods they recommend are achievable and can be carried out safely, she adds. For example, is the manufacturer recommending a sterilization cycle that is used in industry but is not commonly used in health care facilities?

Lee urges manufacturers to partner with health care facilities to learn more about their processes so the information they provide is achievable.

“I would love to see manufacturers provide this information on their web pages so health care personnel could have access to instructions 24/7. This would be a great customer service feature,” she says.

AAMI notes that the FDA used the first edition of TIR12 published in 1994 in preparing its guidance on designing, testing, and labeling reusable medical devices. ST81 is consistent with Euro-pan and ISO standards, with some differences for application in the US.

For more information or to order the documents, go to www.aami.org or phone 800/332-2264 ext 217.
**AAMI documents**


ANSI/AAMI ST81:2004. Sterilization of medical devices—information to be provided by the manufacturer for the processing of resterilizable medical devices. *List price $80; member discount price $40.*