AAMI TIR12 and the Future of Device Processing Instructions

The technical information report (TIR) AAMI TIR12, which has a rich history of providing leading-edge guidance for medical device manufacturers (MDMs) in the area of processing instructions for use (IFUs) for reusable medical devices, is undergoing a significant rewrite.

One major change to TIR12 is that it will be recast more clearly as a guidance document in support of ISO 17664. Closer to the pure role of a TIR, TIR12 will provide a deeper dive into processes used in healthcare facilities. This information is intended to help MDMs author processing IFUs that healthcare facilities will find more useful and easier to follow and comply with. A crucial aspect of that objective is—for the first time ever in the United States—the establishment of standard cleaning protocols.

A History of Innovation

Members of the AAMI Instructions for Reusable Device Reprocessing Working Group (AAMI ST/WG 12), which is under the auspices of the AAMI Sterilization Standards Committee, have used the increased freedom offered by a TIR (compared with a standard) to recommend improved industry practices via TIR12. In contrast to standards and Food and Drug Administration (FDA) guidance available at the time, the most recent (2010) version of TIR12 placed particular emphasis on cleaning. As a result, it helped pave the way for processing-related standards to place greater emphasis on cleaning and enhanced requirements for MDMs, providing them with increased specificity and detail in devising validated processing IFUs.

An illustration of TIR12’s influence was seen in 2015, when the FDA published an update to its 1996 guidance. The FDA document was again updated in 2017, providing additional guidance related to complex devices identified as particularly difficult to clean—and thus requiring even more detail in validated IFUs.

Also in 2017, the International Organization for Standardization (ISO) Sterilization Standards Committee, TC198, published a major update to ISO 17764. Similar to the update to the FDA document, one of the most significant changes to 17664 was greatly expanded requirements for cleaning IFUs that accompany medical devices.

As part of this increased focus on cleaning, the AAMI Sterilization Standards Committee also made the decision to “upgrade” TIR30 into a standard for cleaning validations: AAMI ST98, *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices*. Although ST98 is still in early draft phase, it represents a substantial step forward in requirements for validation of cleaning IFUs.

If nothing was left to be accomplished in the area of validation of cleaning IFUs, then perhaps the role of TIR12 would come to an end. But, alas, that is not the case. Opportunities for improvement remain, and as a TIR, TIR12 remains an important vehicle for driving progress.

Standardized Cleaning Protocols

Why is the establishment of standard cleaning protocols such an important step forward? Visit the sterile processing department in any healthcare facility and ask them to show you all the IFUs they need to follow. If they plan to show the IFUs in print, then step back, because you are about to be flooded by paper!

The reality is that the sheer diversity of IFUs makes complying with any of them almost impossible. In part, the diversity of IFUs comes from the complexity of modern medical devices. The complexity is two
dimensional: One dimension is that the devices are becoming more complex, while the other is related to the diversity of devices. Therefore, even if each device was designed as simple to clean, the sheer diversity of devices—both in terms of their designs and IFUs—complicates things for sterile processing.

AAMI ST/WG 12 focused particularly on addressing the latter dimension. With the active and helpful contribution of global MDMs, the latest draft of TIR12 defines four cleaning protocols that are believed to encompass the vast majority of medical devices. These protocols are detailed in two informative annexes. The purpose of presenting these protocols is to encourage MDMs to validate one or more of them as appropriate method(s) for cleaning their devices. By doing this, the hope is that the diversity of IFUs will shrink dramatically over time. In turn, this will make it easier for healthcare facilities to actually follow IFUs.

WG 12 believes this approach will work for two reasons. First, currently, each MDM authors and validates the IFU for its own devices—in other words, MDMs are working in siloes. They are authoring IFUs in a vacuum without any specific guidance as to what are common or acceptable cleaning protocols.

A comparison with steam sterilization is useful here, as there are two cleared cycles in the United States (and, globally, very similar cycles in the vast majority of markets). MDMs are encouraged and seek to validate sterilization of their device using one or both of these cleared cycles. When it comes to cleaning, no such corollary exists. These four protocols are intended to provide, or at least get us on the path to achieving, those corollaries.

Second, as mentioned previously, these four protocols resulted, very importantly, from the experience and input of major, global MDMs. Independently, each of these companies was working to simplify the IFUs they provide. As
WG 12 began working on the cleaning protocols, the MDMs were gracious enough to share their work. Through further discussion, including the active involvement of sterile processing professionals and independent testing labs, the four cleaning protocols were devised. Because these major MDMs already have been able to use one or more of these protocols to validate their own broad and diverse population of devices, it is reasonable to believe that they will prove valuable for many other MDMs and their devices as well.

**What's Next?**

At its October 2018 meeting, WG 12 agreed to put the next draft of TIR12 out as a committee draft for vote, meaning the document will go out for working group ballot. The comments received will be taken up during the next WG 12 meeting in March. With the assumption that we will receive many comments and TIR12 will undergo significant technical changes, it would not be surprising if we end up with another committee draft for vote. But when it comes to standards writing, making predictions is a hazardous activity—so forget I said anything.

No matter what happens during this round of commenting and balloting, the version of TIR12 that is eventually published will stay true to its mission: paving the way to greater improvements in the processing of medical devices and the IFUs that accompany them.

**References**


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