Raising the Bar: New Standards for IFU Development

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LEARNING OBJECTIVES

1. Understand the implications and expectations for medical device manufacturers as a result of the newly published standards for instructions for use
2. Review the significant requirements in ANSI/AAMI/ISO 17664:2017
3. Review the significant provisions in ISO 17664-2:2021
4. Review the significant guidance and other innovations in AAMI TIR12:2020

Developing and validating the instructions for use (IFU) for processing (cleaning, disinfecting and/or sterilizing) medical devices by a healthcare facility is a significant responsibility of medical device manufacturers (MDMs). The U.S. Food and Drug Administration (FDA) requires that these instructions be validated—not just for efficacy but also so the healthcare facility can practically implement the instructions. This latter requirement includes human factor considerations as well as consideration of the equipment and tools the healthcare facility is likely to have in order to carry out the IFU. While this has been a requirement of the FDA, with much greater emphasis since its guidance document was updated in 2015, the reality is implementing IFU remains a significant challenge for healthcare facilities.

Objective 1: Understand the implications and expectations for medical device manufacturers due to the newly published standards for instructions for use

The result of developing and validating robust processing IFU is complex, for the following reasons:

- Many devices, particularly the latest and most innovative, are complex designs that provide physical challenges to cleaning and visual inspection.
- The sheer diversity of devices of many different designs, material construction, etc., further challenges the practicality of implementing IFU as written for each device.
- While medical devices cleared by the FDA since 2015 have had to meet the higher standard for IFU, the fact is there are literally thousands of medical devices in use that were cleared prior to 2015. MDMs are

(generally) under no obligation to update their IFU to meet the requirements established in 2015.
- Finally, the human factor—staff training and having the correct IFU readily available for staff—is a significant challenge. Technology has helped; however, it remains a considerable challenge.

While industry standards and standards writing bodies such as the Association for the Advancement of Medical Instrumentation (AAMI) and the International Standards Organization (ISO) cannot wave a magic wand and make everything better, they can—through updates to their standards—raise the bar and raise expectations for the industry. In the past couple years, the publication of ANSI/AAMI/ISO 17664: 2017, ISO 17664-2:2021, and AAMI TIR12:2020 have done just that.

Objective 2: Review the significant requirements in ANSI/AAMI/ISO 17664:2017

Although ANSI/AAMI/ISO 17664:2017 was published four years ago, it is nonetheless essential to understand how the latest version changes impacted the other two documents addressed in this lesson. ANSI/AAMI/ISO 17664:2017, *Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices,* is the ISO document that lays out for MDMs the information they are required (if they are to comply with this voluntary standard) to provide the healthcare facility as to how to make ready their device for use on the next patient. The 2017 version delivered a significant revision to the previous version published in 2004 (the 2004 version was titled *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices).* Among the fundamental changes include:

- The 2017 version is 29 pages versus 18 for the 2004 published version; the scope has been widened to include devices for which the final step is high-level disinfection (including flexible endoscopes).
- As the new title suggests, the 2017 version goes into much greater depth regarding each step in processing a medical device, including the cleaning process.
- Single-use devices that are to be processed by the healthcare facility prior to clinical use are included in the 2017 document's scope.
- The 2017 version excludes non-critical medical devices not intended for direct patient contact, and textile devices used in patient draping systems or surgical clothing.

After publication, AAMI ST/WG12 agreed to recommend adopting ISO 17664 as a U.S. national standard. First, the AAMI Standards Board and the American National Standards Institute (ANSI) accepted that recommendation, and 17664 became a U.S. standard. Following that adoption, the FDA added 17664:2017 as a recognized consensus standard.

Objective 3: Review the significant provisions in ISO 17664-2:2021

The ISO TC198/WG12 authored—and ISO has now published—ISO 17664-2:2021, *Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices.* As the title suggests, this document is for medical devices classified as non-critical. The actual scope of this document applies to non-critical medical devices that are not intended to be sterilized. This is a subtle but essential distinction. As part of adopting 17664-2, WG12 also modified the scope of 17664:2017 to include non-critical devices that are intended to be sterilized. Soon, 17664:2017 will be republished with this revised scope and with a document number of ISO 17664-1.

While 17664-2 in many ways mirrors 17664-1, there are some significant differences. The first and most significant is related to validating and conducting cleaning/disinfection procedures. For many non-critical devices, a pre-moistened wipe and/or a spray and wipe are used to clean and disinfect the device's surface in one step. In these instances, the surface is wiped (as directed by the IFU). The act of wiping is the cleaning step. The solution released from the wipe is allowed to stand for a period of time (as directed by the IFU) to allow the disinfectant to kill organisms on the surface. This step may be followed with another wiping step to remove the residual process chemical and/or dry the device's surface; however, this is not always the case. The following note from Clause 6.2.1 best explains this:

"NOTE 2 The requirements for cleaning and disinfection are stated as separate clauses in this document. However, when the steps are concurrent, the requirements of both stages can be considered as one. In such cases, removal of soil, a reduction in microorganisms, and inactivation of viable microorganisms can be achieved as a result of the combination of applying the disinfecting agent and a physical action."

This contrasts considerably with the requirements of 17664-1, which directs the MDM to conduct and validate cleaning and disinfection separately.

Another difference is the recognition that the processing steps for these devices are often not conducted by Sterile Processing (SP) personnel and not conducted in an SP area. Instead, often the processing steps are conducted by healthcare providers at the point of use. Instructions need to reflect this. Special consideration needs to be given to facilitate the delivery of the instructions to the end user.

Objective 4: Review the significant guidance and other innovations in AAMI TIR12:2020

AAMI TIR12:2020, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers,* was approved by the AAMI Standards Board in late 2020 and was published in early 2021. It represents a significant rewrite of the previous version that was published in 2010. The primary purpose of the major rewrite was the significant update of two other documents (including ANSI/AAMI/ISO 17764).

The other purpose was to update the FDA's guidance on device reprocessing, *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff* (March 2015, updated June 2017). As was true with 17664, the update to the FDA guidance document put a great deal more emphasis on cleaning and cleaning instructions than did the 1996 version. Before these updates, TIR12 was the document that had rich detail and suggested requirements about cleaning validation and IFU and disinfection and sterilization instructions.

An AAMI TIR (technical information report) is not a standard but, as the name implies, is intended to provide information to the reader. In practicality, an AAMI TIR falls into one of three categories:

- Purely informational on a topic of interest/concern to the industry;
- Acts as a guidance document to support compliance with an AAMI standard or other standards;
- A quasi-standard. In the case involving new technology, new practices or new industry structure (to list a few situations), the industry may not be ready for a standard that sets requirements for complying with the standard. Instead, a TIR is authored. TIRs of this nature often have the structure of a standard. They often are worded like a standard by suggesting requirements (using words such as "shall" and "should"). By definition, a TIR cannot be normative, so any clauses that have "shalls" and "shoulds" do not set requirements, as they do in a standard.

The 2010 version was most like the "quasi-standard," particularly as it applied to cleaning medical devices. This was because the normative documents provided little guidance when it came to cleaning. The updates of 17664 and the FDA guidance document changed that. For that reason, TIR12 was recast into the second kind of TIR, a guidance document to support compliance with 17664 and the FDA reprocessing document.

ANSI/AAMI/ISO 17664 is obviously an AAMI document; therefore, TIR12 sections now mirror the sections of 17664. First and foremost, the document's guidance is meant to help MDMs comply with the requirements of 17664. Secondarily, since TIR12 is a U.S. document, it also guides how to comply with the FDA reprocessing document. Including extensive references to the FDA document only makes sense. In the opinion of this author, at least 17664 and the FDA guidance align very closely. As a result, giving guidance within TIR12 that aligns with both documents was very achievable.

What follows is the type of guidance AAMI TIR12:2020 provides:

- Both 17664 and the FDA document stress that the instructions within the IFU should be able to be practically carried out by the healthcare facility. Still, SP professionals can attest that isn't always the case. The complex matrix of healthcare providers and each one's uniqueness as they try to deliver the best outcomes is a challenge. TIR12 informs MDMs of the most common practices (and some less common) so that the MDM creates IFU that can practically be implemented.
- Both documents stress that the IFU be validated—that the MDM proves, through scientific study, that the steps they recommend will result in a clean, disinfected, and/or sterile device that is ready to use on the next patient. TIR12 does not provide requirements for validation testing (other AAMI documents do that), but it does provide some guidance as to how to comply with those other AAMI documents. More importantly, it provides guidance to MDMs on how they are to put those validated steps into an easy-to-follow and easy-to-understand IFU.
- Human factors are another key consideration when developing and authoring IFU. TIR12 provides guidance in that area as well. AAMI TIR55 goes into much greater detail, but TIR12 focuses on those aspects necessary to meet the requirements of 17664 and the FDA reprocessing document, while also referencing relevant sections of TIR55.
- The medical device's design has a great deal to do with the ability to clean it.

This is emphasized in 17664 and is an even great point of emphasis in the FDA document. In fact, the 2017 update to the FDA document includes an annex dedicated to particularly challenging device designs. TIR12 helps to guide in this area as well.

- While an increasing emphasis is being placed on the cleaning process, getting a device properly disinfected and/or sterilized, needless to say, is also critical. Since the 2010 version of the document was published, there are new and novel methods for disinfection and sterilization. Again, requirements for those methods can be found in other AAMI documents. TIR12 does provide guidance as to how to meet those requirements. Historically, non-critical medical devices have not received the attention in standards that critical and semi-critical devices have; however, that is changing. Recent standards such as ISO 17664-2, and soon-to-be-published standards do address non-critical devices. TIR12:2020 reflects this and provides guidance for meeting those requirements.

In one very important way, TIR12:2020 opens the door to a new approach to help lead to IFU that healthcare facilities will be better able to implement. Today's reality is that healthcare facilities struggle to follow all IFU as written because of the complexity described in the Introduction section of this lesson.

To help address this complexity, TIR12:2020 lays out, in the informative annexes, four processes for cleaning medical devices. These summarize four common "programs" for cleaning a medical device:

- Medical devices that can be cleaned manually or by a washer-disinfector without manual cleaning (other than rinsing off gross debris). This applies to devices of simple design, such as an osteotome.
- Medical devices that require brushing or other manual processes before being placed in a washer-disinfector. An example would be shavers and other devices with lumens, and other hidden areas, presenting a physical challenge to the cleaning solution reaching those areas in a washer-disinfector.
- Medical devices that require sonication as part of the cleaning process. These may be a medical device that will be placed in a washer-disinfector after sonication, as well as those that cannot be run in a washer-disinfector (e.g., thermal labile).
- Medical devices that are classified as non-critical. These are medical devices intended not to come in contact with patients or only with intact skin. Often, these medical devices are cleaned and disinfected with premoistened wipes (e.g., consoles).

The concept is that an MDM could author (and validate) the cleaning instructions for their device to one or more of these four processes. In doing so, the hope is the sheer diversity of IFU will be reduced. Devices of similar construction would, therefore, have the same basic IFU, simplifying the ability of healthcare facilities to comply with IFU—and do so more efficiently and effectively.

Conclusion

Standards development is a long-term process. As ISO 17664 documents and TIR12 demonstrate, there has been real progress in raising the bar for medical device processing IFU, and more is to come (in fact, AAMI ST/WG93 is busy authoring ST98, *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices).* While the documents reviewed in this lesson are about the information that MDMs should provide healthcare facilities for cleaning, disinfection and sterilization, ST98 will provide requirements for the validation testing done to demonstrate that the IFU will indeed result in a clean device.

It is important to note that ST98 and TIR12 were not each developed in a vacuum. Many of the same people deeply involved in the development of TIR12 are also closely involved in the development of ST98. TIR12 was written very much to be compatible and complementary to ST98 and vice versa—and other related standards are also coming.