Revamped guidance 'cleans up' medical device instructions for use

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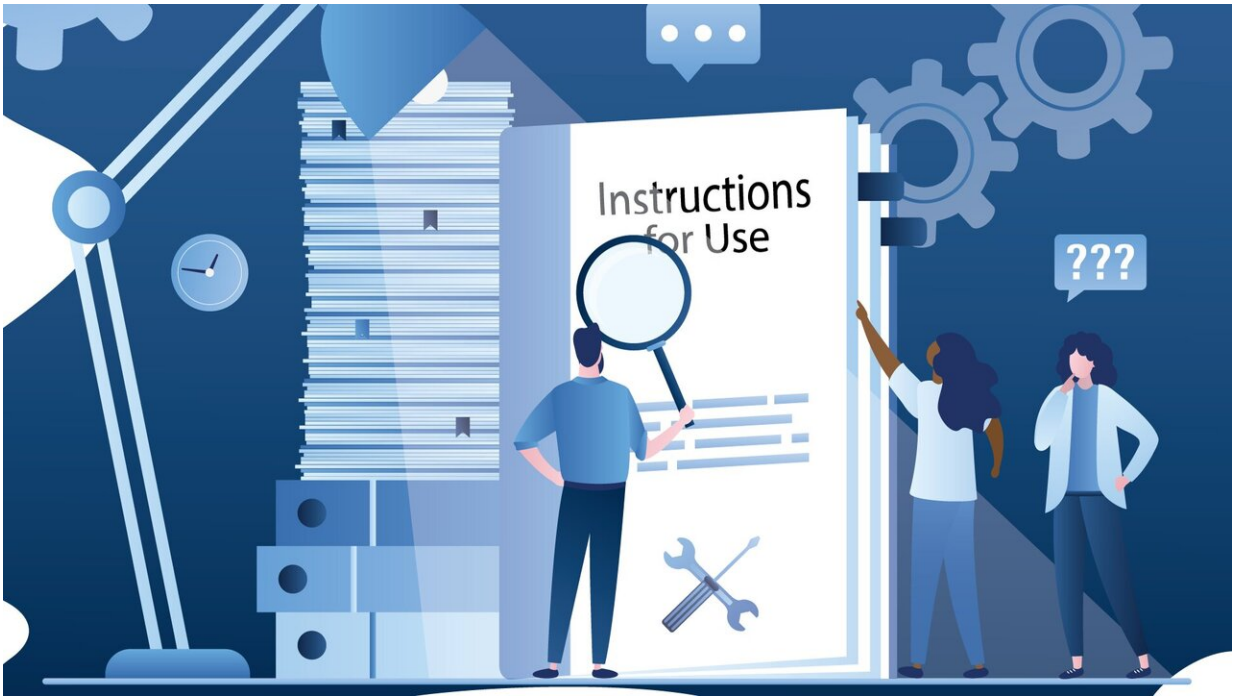

Credit: Association for the Advancement of Medical Instrumentation

Medical device manufacturers, regulators, and healthcare technology management (HTM) experts recently joined forces to solve a long-standing issue for medical device processing: confusing instructions for use (IFUs). These essential instructions explain how to properly clean, disinfect, sterilize and make the device ready for use on the next patient.

This updated technical information report, "TIR12:2020, Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers," standardizes manufacturer IFUs for the processing of clinically used medical devices and helps manufacturers understand how well the end users comprehend a device's instructions and labeling.

"Regulators have been pushing the message that end users need to follow manufacturer instructions, saying "Don't make it up yourself." But when users look at an IFU, it can be confusing or incomplete," explained Damien Berg, a regional manager of sterile processing at University of Colorado Health and past president of IAHCSMM.

Berg co-chaired the AAMI working group that completely revamped TIR12, creating its new 2020 version. The working group determined early on that even though manufacturers and test labs have been validating IFUs all along, the conditions and terminology that they have used were not always an "apples-to-apples" comparison to the rapidly changing environment that is the clinical setting.

To create more sensical instructions and labeling, manufacturers would need a way to reference the tools, terminology, and expectations of device users and regulators alike. This is where the new report comes in.

"It's a much cleaner and easier to read reference document for the manufacturers," Berg said. "In turn, the hope is that this will allow them to get their product through the FDA easier and quicker. Then I as an end user get to use their product with clear instructions. It all comes down to proactively reducing confusion for my staff."

Initially, sterile processing managers and device manufacturers worked at this problem from different directions, added AAMI working group co-chair Ralph Basile, vice president of marketing and regulatory affairs

for Healthmark Industries Company, Inc.

"A number of manufacturers were going through the process of rewriting their IFUs alone. They were saying, "If we can't figure this out, how are customers supposed to do it?" Around that time, the working group had turned its attention towards standardizing IFUs, so the manufacturers shared what they had," Basile said. "We got end-users, testing labs, and even the FDA involved and that really got this whole effort going."

An important milestone was the 2017 update of the standard "ANSI/AAMI/ISO 17664, Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices," which details what information must be provided to healthcare facilities (including instructions for pretreatment, cleaning, disinfection, drying, inspection, maintenance and functionality testing, and packaging). It also describes the validation testing that needs to be conducted to ensure each of these processes is suitable for the device.

Three years after ISO 17664 was published, TIR12 now ensures that manufacturers not only know what information they need to provide, but also how to provide it.

"This was an amazing collaboration of end users, manufacturers, and testing labs. At one point we were comparing hundreds of different IFUs, figuring out what the commonalities were and where the gaps were," said Berg. "Now, we're approaching a point where we all say, 'follow the manufacturer's instructions' with confidence."

Provided by Association for the Advancement of Medical Instrumentation