# Updating and Upgrading Device Reprocessing: AAMI/FDA Summit

By Ralph Basile

In 2011, there were two events at the Food and Drug Administration (FDA) headquarters where the key issues of medical device reprocessing were raised and discussed. The first event was put on by FDA staff, with an assist from the Association for the Advancement of Medical Instrumentation (AAMI). During this two-day meeting in June, a parade of industry experts presented their research and experience to describe the key challenges facing the healthcare industry when it comes to effective device reprocessing. Representatives from industry, academia, the FDA and experts from other industries that have faced similar challenges (for instance the food industry) shared their diverse views.

In November, AAMI — in cooperation with the FDA — hosted a follow-up two-day meeting. While the first meeting featured expert speakers, the second meeting sought to draw out the expertise of the attendees. During those two days, key issues in reprocessing were raised in succession by a panel of experts, followed by extended discussion by those in attendance. Again, a broad cross-section of the industry was well represented: industry, the FDA, academia, legal community and a diversity of healthcare professionals from sterile processing, surgery, infection prevention and control, endoscopy and outpatient facilities, amongst others. The result of that effort was a list of key issues for the industry to tackle, with the objective that the state of the art in device reprocessing will be raised.

It is axiomatic in sterile processing: if it is not clean, it is not sterile. The goal of device reprocessing is to remove and/or destroy all contaminants that may pose a danger to the next patient and also to the healthcare personnel handling those instruments. This is a much broader objective than sterilization, as residuals other than microorganisms also pose a risk to patients. One of the great difficulties in the industry, however, is defining "clean" — in other words, how clean is clean enough? This is the first topic the industry must tackle.

Defining clean is more complex than at first blush. In simplest terms, "perfectly clean" would be the complete absence of any foreign substance, organic or inorganic, on the surface of a medical device. Of course, we live in the real world and "perfect" is often not achievable. Further, while we can theoretically discuss a completely clean surface, we cannot actually measure it with economically viable methods. Methods of detection have a limit or sensitivity level, below which they can not detect the presence of a given contaminant. Further, to be as sensitive as possible, methods are specific to a target residue. But the specificity is also a limiting factor — as another residue may be on the device — one not tested for. Finally, surgical instruments are of radically different design and material compositions. Not only do they differ in design, but in "cleanability." Typically, the more complex the instrument, the more difficult it is to clean and the more difficult it is to determine if it is clean. In our perfect world, we would be able to test all areas of the instrument, but in particular the areas that present the greatest challenge to cleaning.

In a less-than-perfect world, judgments must be made about what to test for, what to test with and where on the instrument to test. When we make these judgments, we will have a definition of "what is clean."

With "clean" defined, the challenge comes to design surgical instruments that can be cleaned in the real world of sterile processing departments. Much of the second summit was focused on this issue, as healthcare providers stressed the challenges they face in the fast-paced, high-pressure environment of a healthcare facility; and device manufacturers described the challenges they face in designing instruments that accomplish their clinical objectives and also can be effectively reprocessed.

I think it was this divide that presents the greatest challenge but also the greatest opportunity to improve device reprocessing. Spend an afternoon in a busy CSSD when typically the case carts start to arrive en masse from the OR. The sinks, sonics, washers and sterilizer are all going at full capacity and you will understand what the challenge is for the healthcare provider. The issues facing device manufacturers are not so easy to observe, but they are just as real. Can these conflicting challenges be made to create a harmonious opportunity for improvement?

Well, in fact, there are three initiatives at AAMI to do just that:

1. Standardized IFUs

As part of their FDA submission, device manufacturers must include validated instructions for use (IFUs) for device reprocessing. This includes instructions for cleaning as well as terminal sterilization (or high-level disinfection). While there are standard cycles for sterilization, there really are not for cleaning. Of course, given the great diversity of surgical instruments in materials, design and function, cleaning will never be as uniform as sterilization. It is the consensus of AAMI Workgroup 12, however, that it is possible to develop some standardized processes that similar devices could be validated to. A standard "recipe" for cleaning could greatly assist device manufacturers in developing their instructions, and also greatly assist CSSDs in implementing those instructions effectively.

2. Human Factors in Reprocessing Instructions

A growing science in the last few decades, human factors engineering, will come to IFUs for device reprocessing. The basic goal of human factors engineering is to reduce mistakes by engineering out the sources of error that come from the inherent limitations of human beings. A simple example is font size: rather than print instructions with six-point type, human factors engineering would specify that a larger, minimum-size type face. For humans that have weakening vision (like yours truly) this is a natural benefit, helping us do our jobs better. The new workgroup taking up this challenge will develop principles and guidelines for IFUs to insure a high degree of usability (i.e., illustrations, demonstration videos, etc.).

3. Flexible Endoscope Reprocessing

An oft-repeated example of challenging devices at the Summits was flexible endoscopes. Use and uses of flexible endoscopes is increasing every day. These marvels of modern technology, however, pose a serious challenge to effective cleaning. Various groups, formal and informal, have developed recommended practices for proper reprocessing. But the challenge remains to develop a "best practices" document that merges the best of what is and can be done when it comes to flexible endoscope reprocessing. The new AAMI workgroup will bring together the best in the industry to share their expertise and knowledge in a Technical Information Resource (TIR) document that will summarize those best practices.

Four days in 2011 when the industry came together to discuss the key issues of device reprocessing has sprouted opportunities for change. Of course, it remains for members of the industry, including the AAMI workgroups, to nurture those sprouts to fruits of improved practices.

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