Adequate Staffing, Comprehensive Education Needed in Sterilization and Reprocessing

Joe Sheffer  How would you describe the current state of the sterilization and reprocessing field?

Betty McGinty  The reality is that medical instruments are not 100% patient ready, despite reprocessing to remove their harboring bacteria. I say this because of the news reports, published articles, and research that demonstrate that assessment. We have professional guidelines and standards, such as those from the Society of Gastroenterology Nurses and Associates, Association of periOperative Registered Nurses, and AAMI, as well as regulatory and other agency guidelines and tools. Coupled with numerous hands-on and didactic educational opportunities, these resources have helped to elevate and standardize reprocessing practice. So, regarding the level of support, we’ve come a long way.

Jenny Crnkovich  There is opportunity to address discrepancies regarding following the instructions for use (IFUs). I have experienced this as an employee and as a consultant. Matching up the IFU with the sterilization or high-level disinfection (HLD) modality that is recommended for the medical device is a key element. This is a gap in the industry.

Trabue Bryans  I deal with both industrial sterilization and hospital sterilization. In terms of the current state of sterilization, you have to make a distinction between the two. Each of these disciplines is very different, and it seems to me that we’re making progress on the clinical side—hospital sterilization. We’re progressing toward better practices and controls. Awareness also is improving, but I’m not sure if the solutions are there yet. In industrial sterilization, there’s quite a bit going on with sterility assurance levels and novel processes.

Joe Sheffer  What do you see as the greatest need for sterilization and reprocessing professionals at this time?

Betty McGinty  The need for adequate staffing is the greatest. We need truly adequate staffing to support meticulous reprocessing and cleaning verifications.

Jenny Crnkovich  With experience on both the manufacturing and the end user sides, the greatest need is for more robust and comprehensive education. We want people to be engaged, receive the education they need to be competent, and repeatedly perform the duties as directed in the IFUs.

Trabue Bryans  I agree that both staffing and training are very important. The third one on my list would be respect for the sterile processing job itself—for the demand and expectations of the profession. I’ve dealt with this in the past with another type of job that involves sterility testing, and I believe that leadership needs to do a better job of elevating the pay and respect for these positions.

Joe Sheffer  An AAMI committee is developing a standard that focuses on “end-to-end sterility assurance.” What value do you see in linking individual sterilization activities into a broader framework? What specific gaps or challenges might such a framework help alleviate?

Betty McGinty  My main focus is HLD, but of course, we march hand-in-hand with anything that can be sterilized. We want to get to the point where we’re linking HLD and sterilization, and I believe that’s where we’re going with our scopes. The gaps or challenges that I would see, broadly speaking, would be in getting the buy-in and support of the various facilities to allow for all of the validation testing that needs to occur.
**Jenny Crnkovich** Addressing some of the process challenges that we are experiencing to achieve end-to-end sterility assurance in the healthcare setting will add value and close gaps. With this new standard, I’d like to see a focus on sharing the responsibilities and accountability similar to what takes place in industrial sterilization. In the healthcare setting, we have “batch” records (sterilization), quality control methodologies, and other safety measures we could use to correlate and assist with end-to-end sterility assurance. We can bridge these measures so they’re interconnected, which would support a large framework. Using a standard, such as ANSI/AAMI/ISO 13485:2016 or ANSI/AAMI/ISO 17665-1:2006, we can reimagine how end users need to address challenges. This can be completed by incorporating an uninterrupted sterilization process to reduce mistakes, build a stronger team, improve quality and consistency, and add value and safety every step of the way.

**Trabue Bryans** I was involved with drafting the new work item proposal for the new standard on end-to-end sterility assurance. It's really important to understand that sterility assurance encompasses everything—every piece. And a lot of companies haven't recognized all the pieces of the puzzle—research and development (R&D), sourcing, environmental, packaging, distribution—you name it. Sterilization is just a small piece of that overall picture, and reprocessing, as a subset of sterilization, is an even smaller piece. There are so many things, but they're all linked together. The key is getting everyone to see that no matter how small the contribution is that they make to the overall picture, it still makes a difference.

**Jenny Crnkovich** In the clinical setting, environmental monitoring related to sterility assurance and production areas could help integrate the standard. We have sterility assurance supported by a human process from beginning to end that typically falls back on the department performing the reprocessing. Many times, the end user department handling it passes off accountability for compromising the sterility. We then look to the leadership team, the robustness of their relationship with infection control, and how well they keep abreast of and integrate the standards. With that comes risk and liability, which often is ignored until a surveyor shows up to audit the facility. Instituting a process that documents the quality of goods received can help identify process and quality breakdowns to increase compliance and internally support the framework.

**Trabue Bryans** Even though the standard on end-to-end sterility assurance is focused more on the bigger picture of R&D and distribution—that type of thing—you actually could look at reprocessing itself as a mini end-to-end process. You could apply an end-to-end framework for any of these factors. Hopefully the new work item will provide guidance on the various subprocesses, after which we are able to look at everything in the same context.

**Joe Sheffer** It has been noted that industry needs “better input from users related to the gaps and needs that they struggle

---

**Background on End-to-End Sterility Assurance**

In May, a draft new work item proposal for a new standard on end-to-end sterility assurance was circulated to the AAMI Assurance of Sterility Work Group (AAMI ST/WG 15) and the AAMI Sterilization Standards Committee (AAMI ST). The purpose/justification for the project was stated as follows: "Currently, the AAMI standards associated with assurance of sterility are documents addressing individual topics, such as a specific sterilization modality (e.g., radiation, ethylene oxide, moist heat), manufacturing monitoring requirements to demonstrate maintenance of sterilization validation (e.g., environment monitoring, bioburden), or maintenance of sterility (e.g., packaging). This document would provide a framework for the integration of the individual topics to demonstrate how they are linked to provide assurance of sterility.”

Further, the proposed outline for the standard states the following: "With the increasing speed for change, and the need to develop personnel, we as an industry need to understand how these activities" (e.g., individual components of sterilization validation and periodic and routine testing) "are linked together, and assist in the implementation of these concepts within our organizations. The End-to-End Sterility Assurance framework will be defined around the steps of the supply chain from both a manufacturing and healthcare standpoint.”

The work has been approved by the AAMI Standards Board to move forward. If the proposed work progresses successfully through the Project Initiation Notification System period via the American National Standards Institute, the standard will be developed by ST/WG 15.
with.** What is being done—or what more needs to happen—so that device manufacturers are incorporating feedback from sterilization professionals into, for example, product designs and the development of IFUs?

**Jenny Crnkovich** It would be very beneficial to have a critical partnership panel with a required feedback loop, where the manufacturers (quality, R&D, and regulatory) seek our expertise to help them. This panel would help manufacturers write IFUs in a more comprehensive manner by providing critical feedback versus calling medical device companies or the Food and Drug Administration to get them. Our industry received new (AAMI) standards last fall, and hopefully we’re all incorporating those into our current practices. If you haven’t done this yet, it’s important for people to begin reaching out and just have conversations, ask questions, and discuss the changes they’ve made. It’s important for medical device companies to take a look at those standards and update their IFUs.

**Betty McGinty** Although there are some companies that will seek some input from end users, I think there needs to be something a little more formalized, because really, they could benefit from getting that input.

**Trabue Bryans** I’ve worked with IFUs all the time in the testing arena. Of course, in a lab, it’s very easy: You have the time, you have the means, and you’re getting paid to follow the IFU and run a validation, so to speak. However, in the healthcare setting, it’s bridging that disconnect of what should be done and what can be done—that is, and always has been, the biggest issue.

**Jenny Crnkovich** Instructions related to sterilization and reprocessing are crucial to end users. Working on the medical device side, those instructions were among the smallest areas of concern when trying to get a 510(k) submission approved.

**Trabue Bryans** I always say, ‘Everyone who graduates from high school needs to go work for a year before they go to college.’ Each of the medical device companies should send somebody to central processing for a week—that would change everything.

**Joe Sheffer** AAMI WG84, the workgroup responsible for ANSI/AAMI ST91:2015, Flexible and semi-rigid endoscope processing in health care facilities, has been considering more stringent guidelines for processing endoscopes, moving away from HLD and toward sterilization.** What benefits could this change provide? What are some of the real-world challenges to implementation?**

**Betty McGinty** With my focus being on HLD, I have a huge vested interest in this. However, the benefit would be that sterilization would of course kill all of the microorganisms versus the survival of various levels of spores with HLD. The real-world challenges are related to the time and expense of sterilization, as well as the cost related to additional scopes and sterilizers with the correct capabilities. But even with all of those measures, the bottom line is that cleaning still may be inadequate. Of course, we all know we can't sterilize or high-level disinfect an item has hasn't already been cleaned appropriately. I’ve worked with scopes for most of my practice, and seeing all the challenges involved, I do think we'll be moving toward either a disposable-type environment or to sterilization.

It's also worth noting that patients often times think that a sterilized endoscope is being used or that the scope has never been used on anyone else.

**Jenny Crnkovich** Betty, you make a really great point in addressing not only the increased number of scopes but also the cleaning challenges. To increase the quality of cleaning the scope, it could be run through an automatic endoscope reprocessor after initial precleaning and cleaning versus solely relying on what sometimes is a completely manual process. I know that seems like a long and expensive process, but every year, if you can put in for capital and build up your capabilities and portfolio, it's within reach. Basically, it's a way to ensure that safety is increased, especially for
difficult-to-clean scopes. Borescopes certainly help with visualizing lumens. In a future state, a recommendation that certain scopes are to be sterilized can be very beneficial.

**Trabue Bryans** They have some very, very small ones too, where you can really get down in the tiny lumens.

**Betty McGinty** I purchased one of those, and I use it in my quality assurance program. I look for moisture and damage in endoscopes following HLD. They are great diagnostic devices.

**Jenny Crnkovich** WG84 may consider adding them as a requirement. Relying on the manual process is one thing, but when we have these tools, we should take it one step further for quality checks, like Betty is describing.

**Trabue Bryans** It definitely could be added, because manual visual inspection is already a step. Using borescopes for visual inspection could be an option for clinical places that can afford them. But also, for the reprocessing validation done at labs, you could add that as a requirement—actual observation as opposed to relying on subjective data.

**Betty McGinty** We already expect that for cleaning verification. ATP testing is expected to be done on every flexible scope at my organization before the devices make it out of the manual cleaning phase and into HLD. Scopes with high ATP are the ones that I target for visualization and additional testing.

**Jenny Crnkovich** This sheds light on potentially incorporating standards for the type of enzymatic solution effective enough to get the job done.

**Betty McGinty** There are different schools of thought. Some say it should be a detergent without an enzymatic. Finding reliable information is difficult, and you can’t necessarily look to your IFUs for help with enzymatic solutions. Some of them will simply say, “low foaming, low sudsing, easy to rinse, neutral pH”—information that isn’t sufficiently detailed.

**Joe Sheffer** In addition to what we’ve already discussed, what other aspects of sterilization and reprocessing need to be more explicitly addressed through standards development?

**Jenny Crnkovich** The use of perfumes, colognes, body sprays, and unapproved lotions could be addressed because they can atomize and aerosolize. Sterilization does not remove these products.

**Betty McGinty** I would like to see more standards work that addresses stricter handling of ultrasound probes and appropriate use of probe covers. Probes are everywhere in the organization, and guidance is needed on the appropriateness of following the Spaulding classification in their use. APIC now has a toolkit that offers guidance to measure current guideline compliance.

Dilators, particularly gastrointestinal dilators, also are an issue because standards don’t address the time frame for when they should be reprocessed if they haven’t been used.

**Trabue Bryans** I’m usually a relatively big picture person. I would like to see standards and guidelines that delve more deeply into real-world experience. The focus generally is on compliance and not as focused on science. It would be nice to see science tempered with real-world experience. I believe that approach would actually drive compliance, unlike some documents, which are either too detailed or based on the idea of someone who has never actually seen what things are really like. I really would like to see that tempering with real-world experience come into play a lot more.

**Joe Sheffer** Any closing thoughts? Are there any major themes or challenges that we have not addressed?
Jenny Crnkovich  The importance of connecting the dots among IFUs is worth emphasizing. For example, say we have a scope that is approved for one type of hydrogen peroxide low-temperature sterilization. However, when you look in the sterilizer manufacturer’s IFU, it says you can’t sterilize that type of scope in there. Then, you have some other company coming out with the matrix, saying that it’s for a low-temperature or ozone sterilizer, that they’ve done the validation studies, and that everything is compatible. There can be a lot of uncertainty with trying to follow guidelines; there’s too much reading between the lines to try to figure out what you’re supposed to do. Best practice would be for these companies to work together more effectively and communicate what they’ve validated. That would provide the greatest benefit to patients.

Betty McGinty  I’d say ditto on HLD chemicals. You’ll have one company say that you can use a chemical to reprocess certain instruments, whereas the company who made the instrument will say, “No, you can’t.”

References

“There can be a lot of uncertainty with trying to follow guidelines; there’s too much reading between the lines to try to figure out what you’re supposed to do.”
—Jenny Crnkovich, corporate assistant director and educator in the Department of Sterile Processing at NorthShore University HealthSystem in Evanston, IL