

»» Reprocessing



2011 Summit

*Priority Issues from the AAMI/FDA
Medical Device Reprocessing Summit*



A Clean Start

PRIORITY ISSUES FROM THE AAMI/FDA MEDICAL DEVICE REPROCESSING SUMMIT

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“No one group can do this alone, and the answer is not as simple as ‘more standards’ or ‘more regulations.’

A Call to Action



Dear Colleagues,

We all share the common bond of being passionate about patient safety and improving patient outcomes, and that passion was evident in your high engagement at the AAMI/FDA Medical Device Reprocessing Summit on October 11–12, 2011. Thank you.

We also all share the perspective that reusable medical devices, such as endoscopes, are major advancements in supporting improved patient outcomes. It's important for all of us to celebrate advances in technology as we address the challenges with reprocessing reusable medical devices.

This publication captures the essence of the summit. It will help all of us who attended to remember the priorities that we set together and see a clear path forward. It will help those who were unable to attend to understand the issues discussed and priorities set. It will also serve as inspiration for everyone to use the list of priorities and follow-up actions identified during the summit to do just that: follow up and take action.

Several attendees mentioned that the healthcare community has been talking about reprocessing issues and the challenge of following complex reprocessing instructions for almost 40 years. While we have made significant progress along the way, some of the frustrations and issues raised at the summit were obviously longstanding. We commend the willingness of healthcare and industry professionals to come together to address these important issues.

Healthcare organizations which have experienced challenges associated with reusable medical devices, including the Veterans Administration, Tulane Medical Center, and Victoria General Hospital, join countless other hospitals and surgical centers in our recommitment to solving these old frustrations and issues because of their desire to prevent future patient events. On a more personal level, the countless patients who have been potentially or actually exposed to contaminated instruments resulting from inadequate reprocessing would fervently urge us to do something now.

To do something now is exactly why we co-convened this important event. AAMI standards committees already are making plans and setting priorities on what can be addressed now and by whom. The FDA continues to seek out and capitalize on opportunities to improve the reprocessing of reusable medical devices through regulatory science. Working together, AAMI and the FDA will facilitate collaboration with other organizations, companies, and individuals to take the lead on different areas of the reprocessing challenge. No one group can do this alone, and the answer is not as simple as "more standards" or "more regulations."

We all look forward to updating you in 2012 and beyond on the progress that is being made.

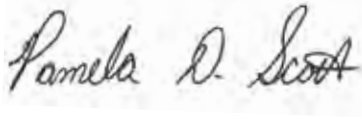
We encourage you to use this post-summit publication in your own organizations, professional associations, standards committees, task force meetings, and the like. This is not an AAMI or FDA "to do" list. It is a multi-stakeholder "to do" list, and every organization and person that impacts reprocessing has an important role in the follow-up activities. We all want to look back with pride in five years and collectively say, "Working together, we made a difference."

Thank you again for your engagement in these important issues. We look forward to hearing your stories of progress as we move forward together.

Sincerely,



Mary Logan
AAMI President



Pamela D. Scott
Senior Science Advisor for Reprocessing of
Reusable Medical Devices
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Executive Summary

“The Medical Device Reprocessing Summit proved to be an opportunity for a renewed emphasis on performing all the necessary steps in reprocessing reusable medical devices—to ensure clean and disinfected or sterilized devices—not just in the universe of regulations, standards, and best practices, but also in the harried clinical environments and diverse sterile processing centers that are ground zero for reprocessing.”

Every patient undergoing a medical procedure has a basic expectation that the environment and instruments of care will be clean and safe.

In recent years, that expectation has been shaken by reports of patients put at risk of serious infection from reusable medical devices that were inadequately cleaned, sterilized, or disinfected—the domain known as reprocessing.

Virtually every stakeholder organization is keenly aware of the heightened patient safety concerns surrounding reprocessed medical devices. The U.S. Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and The Joint Commission have issued warnings, guidance, and new reprocessing requirements. The Association for the Advancement of Medical Instrumentation (AAMI) and other standards developing organizations have established or updated industry-recognized standards for reprocessing. Manufacturers and service providers have created new products and tools. Professional organizations have published guidance and recommended practices for healthcare staff, on the various aspects of reprocessing.

Yet, reprocessing remains a significant and tenacious concern. ECRI Institute cited cross-contamination from improperly reprocessed flexible endoscopes on its Top Ten Health Technology Hazards list for 2012 (ECRI, 2011), where it has appeared for several years.

In October 2011, more than 275 participants convened at the FDA headquarters in Silver


Spring, MD, for a multidisciplinary AAMI/FDA Medical Device Reprocessing Summit. For some, the summit actually was a reconvening. The summit built on an FDA public workshop on reprocessing in June 2011. For all participants, the summit proved to be an opportunity for a renewed emphasis on performing all the necessary steps in reprocessing reusable medical devices to ensure clean and disinfected or sterilized devices—not just in the universe of regulations, standards, and best practices, but also in the harried clinical environments and diverse sterile processing centers that are ground zero for reprocessing.

The summit crystallized a compendium of challenges and priority actions for delivering on patients’ basic expectation of cleanliness for



reusable medical devices. Indeed, this “patient safety first” focus—with the ideal of ensuring that reprocessing is done correctly every time—was a recurring message from summit participants. So, too, was the overarching challenge for all stakeholders to deepen knowledge and eliminate confusion about reprocessing requirements, to increase communication and collaboration, and to pay closer attention to human and environmental challenges.

The clarion themes that emerged from the summit should serve as a call to action for all stakeholders with roles to play in improving patient safety in reprocessing reusable medical devices.



“The FDA, industry, and health care facilities share the responsibility of making sure that reprocessing procedures work and are properly implemented. Through efforts such as this summit and our continued work with the AAMI Sterilization Standards Committees, we will be able to address each of our responsibilities and improve public health care.”

— Pamela D. Scott, Senior Science Advisor, Center for Devices and Radiological Health, FDA

Seven Clarion Themes

1. Gain consensus on “how clean is clean” and on adequate cleaning validation protocols for reprocessing reusable medical devices.
2. Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.
3. Pay early, iterative, and comprehensive attention to reprocessing requirements throughout the device design process.
4. Make human factors and work environment factors priorities when developing reprocessing requirements.
5. Improve information collection and sharing to broaden the use of best practices in reprocessing.
6. Improve reprocessing competencies by strengthening training, education, and certification.
7. Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing.

About This Report

An important disclaimer: This publication reports on the clarion themes, challenges, and priority actions developed by consensus at the summit. The report summarizes summit presentations and provides additional context from experts. The clarion themes, challenges, and priority actions have not been endorsed by AAMI, the FDA, or any of the summit sponsors or supporting organizations. The views expressed by individuals in summit presentations and expert perspectives should not be construed to represent these organizations’ views.

More Summit Information on AAMI Website

The summit agenda, PowerPoint presentations of summit speakers, reference materials, and updates are available on the AAMI website.
www.aami.org/reprocessing

10 Things Your Organization Can Do Now to Improve Reprocessing

This top 10 list emerged from the presentations, audience discussions, and follow-up input to AAMI. It is intended to be inspiring, and serve as a refresher on some of the basics. It does not take the place of standards, regulations, or internal policies, nor is it intended to suggest a standard of care. While some priority items from the summit will take time to address, we want everyone to know that there are at least 10 things that an organization can begin to do immediately, without waiting for other actions, such as long-term standards and research.

- 1 The basics:** Cleaning and disinfection/sterilization of reusable devices are separate, equally important processes and must be performed before each patient use according to the device manufacturer's written instructions for use (IFU). For more information go to www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm.
- 2 The right tools:** Have the IFU as well as all cleaning implements and equipment required by the IFU readily available in all the reprocessing areas.
- 3 Create a multidisciplinary committee** to review the priority issues and set a plan for solving them throughout the organization. The following areas should be represented: OR, infection prevention and control, healthcare technology management (biomed), endoscopy, risk management, quality, safety, education, and materials management.
- 4 Share lessons learned:** Remind senior management and safety officers that it costs a lot less to "do it right the first time." Share lessons learned from other healthcare organizations that have had to inform patients of exposure to inadequately reprocessed reusable devices.
- 5 Written procedures:** Establish a formal program for reprocessing, including written standardized policies and procedures that include a chain of accountability. Expert guidance can be obtained from industry experts in order to resolve conflicts between the IFU and facility policies. Written procedures should also be developed and implemented for central sterile processing reporting of inadequate instructions, equipment problems, and in-service issues to the manufacturer and, when applicable, to the FDA's MedWatch program.
- 6 Standards matter:** Know the current standards, recommended practices, and IFU.
- 7 Purchasing:** Central sterile processing should be included in purchasing decisions for medical devices, to provide input on whether the device can be reprocessed appropriately and with the facility's existing resources.
- 8 Separate and standardize functions and locations:** Separate central service (warehouse, stocking, etc.) from reprocessing; create standardized job descriptions and functions.
- 9 Training:** Train, train, and retrain. Ideas include: assess staff competencies; negotiate for training budget with cost/benefit analysis to prove value; partner with vendors for education; create a list of available continuing education units (CEUs) for easy access by staff; work with human resources to create career ladders for certification and promotion; promote the importance of certification. Note: In-service for loaner or new instruments should include reprocessing in-service areas that are separate from (or in) central sterile processing.
- 10 Assessment:** Conduct an audit of compliance with standards and regulations, using any number of available tools and resources. See References and go to: www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofReusableMedicalDevices/ucm252941.htm.

Clarion Themes, Challenges, and Priority Actions



“As a patient, I want every reprocessed device to be in the same condition as when it was new, so there is no possibility of adverse effects.”

—A summit participant

“We’re obsessed in medicine with having great components—the best drugs, the best devices, the best specialists—but pay little attention to how to make them fit together well.”

—Atul Gawande

The AAMI/FDA Medical Device Reprocessing Summit explored a range of challenges in many domains: complex semantics, science, technology, and device design; regulations, standards, and instructions; human knowledge, skills and cognition; and organizational processes, assets, and leadership.

The risk to patient safety underlies every challenge and priority action. The CDC and Centers for Medicare & Medicaid Services (CMS) have begun to quantify that risk. In a study by CDC and CMS conducted in three states, more than one in four (28 percent) ambulatory surgery centers had infection control deficiencies associated with device reprocessing (Schaefer et al., 2010).

The two agencies developed an infection control worksheet, using a CDC checklist and guidelines for infection prevention. The worksheet, which was piloted in 67 facilities in Maryland, North Carolina, and Oklahoma, has now been used in more than 1,500 CMS surveys of ambulatory care facilities, according to summit presenter Daniel Schwartz, chief medical officer of the CMS Survey and Certification Group.

CMS, which oversees Medicare and Medicaid certification in many types of facilities, has developed a 16-page audit tool for assessing

facilities for compliance with infection control (CMS, 2010). The tool, which is available on the AAMI website, includes observations, interviews, and patient tracking methodology. For reprocessing of reusable medical instruments, areas of emphasis include:

- Compliance with nationally recognized standards and guidelines
- Formal training in areas of infection control and sterilization
- Adherence to facility cleaning, sterilization, and monitoring policy and procedures
- Established criteria for immediate-use steam sterilization

“We worked with CDC because of reports of ‘never events’—serious outbreaks of infection in healthcare facilities that should never happen,” Schwartz said. The real possibility of “never events” was the real driver of the urgency for action.

With that concern, Schwartz said, CMS plans to analyze the 1,500 worksheets already completed by facilities as well as finish, pilot, and implement a new hospital tool. CMS will continue to collaborate with the FDA, CDC, professional associations, and other organizations to optimize device reprocessing and surveying for better results. In addition, CMS plans to work with the Partnership for Patients:

Better Care, Lower Costs, a public-private partnership aimed at improving the quality, safety, and affordability of healthcare for all Americans. The Partnership for Patients brings together leaders of major hospitals, employers, physicians, nurses, and patient advocates along with state and federal governments in a shared effort to make hospital care safer, more reliable, and less costly. CMS will work with this partnership to gather data and assess results.

The Joint Commission also expanded its survey of all of the critical steps and the integrity of the medical device cleaning, disinfection, and sterilization processes, according to summit presenter Chuck Hughes, general manager, SPSmedical Supply Corp. In 2011, The Joint Commission encouraged accredited organizations that perform sterilization or high-level disinfection to review their processes in detail. The Accreditation Association for Ambulatory Health Care (AAAHC) added a new chapter, "Infection Control and Prevention and Safety," to its standards handbook in 2010 (AAAHC, 2010).

Hughes hailed these stricter audits, while acknowledging some of the challenges that emerged at the summit. "Strict compliance with manufacturer's validated reprocessing

instructions for use (IFU) is a critical aspect of patient safety," he said. "While each of us here today knows and respects that statement, it is important to recognize that many healthcare facilities may not have the resources to comply with complex cleaning instructions for use. Add to this challenge a lack of cleaning verification, and it is easy to conclude that patient safety is a real concern."

"In addition to co-hosting this summit, the FDA is already taking steps that will help manufacturers produce safer reusable devices. We have issued a draft guidance for manufacturers of reusable devices that provides greater clarity on how to scientifically validate the reprocessing instructions that are part of the device labeling, and we are working with our partners in the development of standards, guides and other reports that update processes, materials, test methods, design, and acceptance criteria for cleaning reusable medical devices."

— William H. Maisel, Deputy Center Director for Science and Chief Scientist, Center for Devices and Radiological Health, FDA.

Brief Overview of Three Critical Steps of Reprocessing

- **Cleaning and decontamination.** All soil must be removed prior to sterilization because steam and other sterilants cannot penetrate most soil, particularly organic matter. Soil retained on an instrument can protect microbes from removal and killing, which can result in device-related infection. Improper cleaning also can result in instrument malfunction. Manufacturers' instructions should be available for all instruments, including directions for the cleaning and decontamination processes. Some smooth metal instruments may be more easily cleaned, while complex devices may be more difficult to clean and require additional steps and precaution.
- **Sterilization.** Most sterilization is accomplished via steam, but other methods are also available. Steam sterilization must meet multiple parameters (time, temperature, and pressure) specified by the manufac-

turer of the sterilizer, the maker of the sterilization packaging system, and the manufacturer of the device being sterilized. In addition to these instructions, physical, chemical, and biological controls must be used as designed and directed by manufacturers in concert with sterilization standards.

- **Storage or return to the sterile field.** Each sterilized instrument must be carefully protected to ensure that it is not re-contaminated. For terminal sterilization, instruments are packaged and sealed. Instruments sterilized, unwrapped, and intended for immediate use must be aseptically transported promptly to the point of use.

Source: Chuck Hughes, "Cleaning Reusable Medical Devices." Oct. 11, 2011. Presentation at the AAMI/FDA Medical Device Reprocessing Summit, from The Joint Commission.

Clarion Theme 1: Gain consensus on “how clean is clean” and on adequate cleaning validation protocols for reprocessing reusable medical devices.



“As an end user, I’m just so confused about what is clean.”
—A summit participant

Challenge	Priority Action	Accountability
Lack of understanding and lack of a consistent definition for the meaning of “clean” for reprocessed medical devices	Research the essential factors to be considered when defining “clean” for handling and reprocessing medical devices. Develop a common definition or explanation of “clean” for reprocessed medical devices.	Researchers Regulators CDC Professional societies Manufacturers
Lack of specific criteria and endpoints for measuring whether a device is clean	Define acceptance criteria and analytical endpoints for determining “how clean is clean enough” for specific clinical uses of medical devices.	Researchers Regulators AAMI and other standards developing organizations (SDOs)
Lack of standardization of clinically relevant test soils for validating the effectiveness of reprocessing methods	Standardize test soils for validating the reprocessing of specific types of medical devices.	Regulators Researchers AAMI and other SDOs

Understanding the Issues: Defining, Specifying Criteria and Endpoints, and Validating “Clean”

When is a device “clean”? How clean is clean? And how do you know you’ve reached the ultimate destination of returning used devices to clinical use in the same clean condition as brand new devices—a stated expectation?

Merriam-Webster defines “clean” as “free from contamination or disease,” according to summit

presenter Chuck Hughes, general manager, SPSmedical Supply Corp. While this definition fits well with how the healthcare community defines cleaning of reusable medical devices, standards developing organizations have refined the definition of clean in inconsistent ways. This assertion struck a chord for summit participants, as detailed on page 12 (see Terms of Art, Terms of Confusion.)

Regulators are trying to respond to the

confusion. In May 2011, the FDA issued *Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*. The draft guidance updates and clarifies recommendations for labeling instructions for reprocessing reusable devices, according to Victoria Hitchins, senior research scientist at the FDA's Center for Devices and Radiological Health (CDRH). The draft guidance also provides more details about the FDA's recommendations for the validation of processes intended to support reprocessing.

Still, manufacturers, service providers, and healthcare organizations said that they need greater specificity in acceptance criteria and analytical endpoints for determining “how clean is clean enough” for specific clinical uses of medical devices. In the words of summit participants:

- “For validation, part of the issue we find is that experiments are not designed to have negative controls to know what the baseline is.”
- “We don't know what the measured numbers mean.”
- “We need performance-based measurements and benchmarks.”
- “There is a lack of clear standards.”
- “We don't know what the expectation is.”

Others cited the burden to validating reprocessing methods in “worst-case scenarios”—but many summit participants said that these worst-case scenarios are, in fact, typical in healthcare settings, so should be addressed.

Validation and Verification, Test Soils, and Biomarkers

Validation by the device manufacturer and verification by the end user are processes required to measure the effectiveness of reprocessing methods. Summit presenter Trabue D. Bryans, vice president and general manager at WuXi AppTec, a contract research firm, explained the distinction between the two processes:

- **Validation of the efficacy of reprocessing**—“If I clean the device this way, will it be acceptable for use?”
- **End-user verification**—“Did I clean the device to the acceptable level?”

“What the testing lab does is different than what end users do,” Bryans said. “Validation of efficacy does *not* have to be user-friendly, quick,

or easy.” Validation *does* have to be sensitive (able to be measured to a specific level) and thorough (able to be correlated to complete recovery of soil).

The general procedure for validation (measuring cleaning efficacy) can be described as including the following steps:

- Soil the device
- Allow soil to simulate worst-case conditions (e.g., allow soil to penetrate lumens, allow soil to dry)
- Clean the device according to the manufacturer's IFU
- Extract the cleaned device with elution fluid or other solvents, or measure soil directly on the device (i.e., the radionuclide method for cleaning validation)
- Test the extracted fluid for residual soil

Determining the appropriate soils that represent the soils from actual use is a continuing question for validation studies, just as determining the appropriate verification assays is a struggle for end-user verification, according to Bryans and two other summit presenters, Emily F. Mitzel, laboratory manager at Nelson Laboratories, Inc., and Ralph J. Basile, vice president, Healthmark Industries Company, Inc.

According to the *Draft Guidance for Industry and FDA Staff: Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling*, which is not for implementation, the FDA recommends the use of a quantitative test method capable of measuring meaningful levels of clinically relevant soil to meet a related, predetermined cleaning endpoint. When choosing a test method, consideration should be given to the chemical constituents that the device is expected to come in contact with during actual clinical use, which should be adequately represented in the artificial soil. The FDA generally requests that at least two quantitatively measured components of soil be assayed as part of cleaning validation protocols.

As noted in the draft guidance document, the FDA does not recommend the use of spore log reduction testing as a method to determine the effectiveness of the cleaning methodology. According to the FDA, it is unclear whether or not the removal of bacterial spores directly correlates to the removal of clinical organic soil from the devices. Such testing only indicates

“If you don't know where you are going, chances are you will probably end up somewhere else.”

—Yogi Berra

Summit participants identified many reprocessing terms as confusing or lacking in specificity for clinical and reprocessing staff.

how well a process reduces spore count, and provides no information on any other component of organic soil.

“Do microbial markers need to be eliminated completely or should their use be continued *in conjunction with other markers* to allow correlation of results?” Bryans asked. Bryans also noted that definitive biomarker guidance is needed to:

- Establish which markers are actually appropriate
- Ensure that the markers selected are measurable to appropriate levels
- Ensure test results are reliable and reproducible
- Standardize testing (e.g., soil) for categories of devices
- Standardize test criteria across laboratories

In addition, none of the markers have specific endpoints to define what is clean, Bryans said. Scientific data is needed to determine the levels of a marker that are considered clean, the lower limits of detection and variability of markers, and the cost of marker assays versus the value of the data.

Several participants commented on the type of research needed to establish cleaning endpoints. The suggestions included determining the residual soil levels on clinically used devices and using those levels as endpoints, or determining the levels of soil that prevent subsequent sterilization or high level disinfection and using those levels as an endpoint for cleaning. Reaching consensus on the type of scientific information needed is a critical first step in establishing endpoints for cleaning.

Mitzel, in her presentation, echoed the need for clarification on simulated test soils used for validation of reprocessing procedures. Simulated test soils are formulations designed to substitute for clinical soil or debris found on used devices. “There are probably hundreds of simulated test soils,” she said. “If they use simulated soils for validation, manufacturers must justify why the specific soil is used and make sure the test soil is appropriate for all the markers to be measured. One single test soil cannot be used for all medical devices. There have to be multiple, or at least a few, test soils that can mimic what an instrument will be exposed to.”

The test soils need to be “clinically relevant.” For example, devices that will be soiled with blood in a clinical setting should be soiled with a

test soil that incorporates blood or blood components. She adds that standardization is needed, based on each device type, in these areas:

- Simulated soil type
- Reasonable and appropriate residual markers
- Specific acceptance criteria
- Specific device numbers to test

The FDA’s Steven Turtill, biologist in the Division of Surgical, Orthopedic, and Restorative Devices, said the agency is well aware of the validation and verification challenges. “We’ve tried to identify, for ourselves, what is clean,” he said. “The core issue is direct measurement of clinically relevant soil.”

Turtill also expressed the FDA’s interest in exploring more standardized methods for validation of cleaning instructions.

Challenges of End-User Verification

As described by Basile and other summit participants, end-user verification of reprocessing effectiveness in clinical settings presents an equally great challenge. Instruments that have been used on patients might be soiled with blood, carbohydrates, synovial fluids, lipids, bones, tissue, sodium, endotoxins, or other soils, Bryans and Basile said. Protein,



adenosine triphosphate (ATP), and other organic carbon compounds are among the common markers presently evaluated for devices. There are some rapid test methods available to healthcare facilities to detect all of these markers, including multiparameter test strips; but each has disadvantages, Basile said.

Verification of the adequacy of reprocessing by testing for the presence of more specific soils or markers, such as hemoglobin, for specific instruments could be another option. “For some device manufacturers, the best alternative solution may be to provide or recommend a surrogate test device rather than specify the soil and methods for testing,” Basile explained. The surrogate test device would have the “right soil” for the target device, which would take the burden of determining the appropriate test soil

away from healthcare facilities, and could produce a simple pass/fail result. But this solution would work only for automated processes, not for manual cleaning. End users also need to know how frequently they should verify reprocessing procedures, he said.

“Any method is superior to doing nothing,” Basile said. “But is there one soil marker that could be used as a universal? Or should the marker change with the device? Are there soils or markers that can be practically tested in a non-lab setting?”

“Cleaning is a basic initial step in medical device reprocessing procedures. Yet, the importance of proper cleaning to ensure the effectiveness of downstream reprocessing steps such as sterilization/disinfection has been underappreciated. This summit is an important effort to help us change that.”

— Geetha C. Jayan, Senior Science Advisor, Center for Devices and Radiological Health, FDA



Clarion Theme 2: Create standardized, clear instructions and repeatable steps for reprocessing whenever possible.



“Right now, it is impossible to follow manufacturers’ instructions for use.”

— Linda Condon, educator, Central Sterile Processing Department,
The Johns Hopkins Hospital

Challenge	Priority Action	Accountability
Complicated reprocessing instructions—and many different sets of instructions for many medical devices—for clinical and reprocessing staff with a wide variety of skills	Take clinical and reprocessing staff into account when developing reprocessing instructions and obtain their input. Conduct usability testing. Keep instructions clear. Write reprocessing instructions for clinical and reprocessing staff, not engineers or regulators. Consider using visuals and symbols to communicate more effectively. Consider making instructions available electronically for reprocessing sites with access to computer technology. Select a few of the most commonly used and current reprocessing practices and validate to all of these practices, so reprocessing steps are repeatable.	Manufacturers Regulators SDOs Clinical staff Reprocessing staff
Obtaining instructions	Make instructions readily available on websites—and keep them current.	Manufacturers
Uncertainty about device life spans Tracking uses of devices is burdensome	Establish the number of reprocessing cycles devices can undergo, if relevant, and define how to track cycles. Explain in the IFU how to identify the end of product life by visual inspection.	Manufacturers Clinical staff Reprocessing staff

Understanding the Issues: Reprocessing Staff Overwhelmed by Instructions

The single purpose of reprocessing—rendering reusable medical devices safe for the next patient—is often obfuscated by manufacturers’ IFU. The IFU at times add confusion and conflict with standard processing methods, summit participants said.

Inadequately reprocessed reusable medical devices are the unintended consequence of the

demand to reprocess thousands of medical devices, with many distinct and complicated requirements set forth in lengthy IFU that may be inaccessible. Some IFU recommend specific cleaning, disinfection, or sterilization parameters that cannot be followed, are not consistent with AAMI standards, or are unintelligible to reprocessing staff.

The Johns Hopkins Hospital, for example, reprocesses approximately 37,000 instruments

"So may a thousand actions, once afoot, end in one purpose, and be all well borne without defeat."

— William Shakespeare

every day, including 500 instrument sets (with about 75 instruments per set), and 200 individual instruments. The total hospital inventory of different instruments requiring reprocessing tallies about 14,000, according to summit presenter Linda Condon, educator, Central Sterile Processing Department, The Johns Hopkins Hospital.

"Right now, it is impossible to follow manufacturers' instructions for use," she said, citing a lack of standardized cleaning processes as the major culprit. "There are like instruments with different instructions, processes, and tools. There are complicated instructions with too many steps that are unreasonable, with too many variables. There is minimal repetition of tasks. Device IFU do not specify the brush size needed to clean specific devices. Staff have to work from memory or 'hearsay.' IFU expect people to read an awful lot, in an environment that is not conducive to do such. Nobody reads. It is easier to ask a neighbor or see what someone else is using."

Condon said standardization is needed for:

- Soaking time
- Brushing (until clean vs. one, two, or three times?)
- Rinsing
- Ultrasonic cleaning

"Cleaning instructions should be simple, concise, and repeatable," Condon said. "Mechanical cleaning instructions should be specific, but broad enough to be used with any FDA-cleared washer."

"There are multiple IFU for all products, [including instructions] for inspecting, cleaning, function testing, and protective packaging," said summit presenter Sue Klacik, central sterile supply manager at Humility of Mary Health Partners and the AAMI representative

for the International Association of Healthcare Central Service Materiel Management (IAHCSMM). "For

every instrument, you have to consult a different IFU." She compared nine IFU for general instruments, as shown in Table 1, which provides a snapshot of the variability in IFU that reprocessing staff face. "Reprocessing of nine devices would take about an eight-hour

day," she said. "But there is absolutely no consistency in the IFU."

Klacik also pointed out inconsistencies between IFU and AAMI standards, including ANSI/AAMI ST 79:2010 and A1: 2010, *Comprehensive guide to steam sterilization and sterility assurance in health care facilities* and AAMI TIR12:2010, *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers*. Of 22 different manufacturers' IFU for stainless steel, non-lumened, hand-held devices that she reviewed, 41 percent omitted the use of a washer-disinfector, 50 percent omitted the process of using a sonic cleaning method, and 86 percent omitted the use of a lubricant.

"These are standardized processes, discussed in AAMI documents, but omitted in IFU," she said. "IFU don't meet standards."

Klacik and other summit participants recommended that IFU use visuals, posters, videos, and step-by-step instructions on websites, because many people are visual learners. Others countered that visuals can oversimplify reprocessing procedures, confuse people about what takes priority, and clutter reprocessing work areas with visual noise. A combination of both written and visual instructions that are accessible electronically, could be an innovative solution. (See Lead User Profile: Center for Evaluation of Human Factors in Reprocessing Safety, Phoenix VA Health System, on page 18.)

The difficulty reading and executing IFU is not the only problem—healthcare personnel often face difficulty even obtaining IFU. Standards require reprocessing staff to follow the manufacturers' written instructions, and manufacturers are responsible for providing them to users. That is easier said than done, according to summit presenter Rose Seavey, president of Seavey Healthcare Consulting, LLC®.

In a consulting project with a healthcare facility, Seavey sent repeated e-mails and spent 23 days trying to get specific cleaning and sterilization IFU from a manufacturer for one difficult-to-clean device. The company repeatedly sent her generic instructions, stated that the "burden" of reprocessing is on hospitals, and ultimately sent her only "extended recommendations" that were outdated. She escalated the issue by threatening to report to MedWatch, the FDA's safety information and adverse event reporting system.

"Read the directions and directly you will be directed in the right direction."

— The Doorknob in Lewis Carroll's *Alice in Wonderland*

Manufacturer	Wash				Rinse		
	Time	Temperature	Detergent	Sonic	Time	Temperature	Water Quality
1	15		Detergent		1		
2	2	Hot	Enzyme				XX
3	> 3	< 95		X			XX
4	5		Enzyme	X			
5	> 40	Warm	Enzyme	X			
6	5	109	Enzyme	X	1	113	
7	> 20		Renu-Klenz				XX
8	5		Neutral pH enzyme		2		XX
9	30		Neutral pH 6.0–8.0 detergent				XX

Table 1. Multiple IFU for General Instrumentation

Note: “X” and “XX” indicates that IFU provided information.

Source: Sue Klacik. Oct. 11, 2011. “Human Factors and Considerations in Reprocessing Procedures and Instructions.” Presentation at the AAMI/FDA Medical Device Reprocessing Summit.

“Would the technician who was working at that facility have done that? Probably not. MedWatch is a little intimidating,” Seavey said. She recommended these requirements for IFU:

- IFU need to be readily available, clear and specific to the device (especially for complicated devices), and cover categories of instruments
- Design considerations, FDA labeling, and “like categories” should be standardized
- Healthcare professionals and reprocessing staff should be notified of updates or modifications to IFU in a consistent and timely manner
- Vendor representatives should be knowledgeable about current, published standards and provide accurate information; they should also provide specific IFU in writing
- Healthcare professionals should make an effort to obtain the specific IFU that they need—and use MedWatch to report any obstacles

Seavey also recommended that The Joint Commission, CDC, and CMS reference AAMI and Association of periOperative Nurses (AORN) standards for reprocessing in their guidance documents. These are the documents that clinical and reprocessing staff follow—and they are specific, comprehensive, and evidence-based.

Finally, Klacik voiced a concern shared by many summit participants: uncertainty about device life expectancies. IFU do not always specify how long devices can endure the rigors

of decontamination and sterilization processes, and record keeping is difficult and time consuming for sterile processing staff.

“A CSSD [central sterile supply department] should not be required to track uses unless absolutely necessary,” she said. “Using wording in an IFU to identify end-of-product life by visual inspection or other means is more feasible.”

Where Do the IFU Go?

Stryker’s Rod Parker offered a manufacturer’s perspective of the missing-in-action IFU: “Reusable products get one set of the IFU sent with the product. The IFU must get through receiving, through transport, to the central sterile supply department, to the central sterile manager, then to the decontamination personnel after training. Unfortunately, most go out with the trash at receiving.

“One point is that, possibly, there are too many instructions. Paper is shipped with every product, including disposables. Often, the only line of communication is the sales representative, and it depends on their knowledge of the issue or the contact name of who does have the IFU at their company.”

Lead User Profile

Center for Evaluation of Human Factors in Reprocessing Safety, Phoenix VA (Veterans Administration) Health Care System

"We need instructions not just for use, but for users."

— Emily Hildebrand, director of the Center for Evaluation of Human Factors in Reprocessing Safety

A research group within the Phoenix VA Health Care System spent two years studying IFU—and confirming many of the problems summit participants identified.

"OEM [original equipment manufacturer] instructions are not easy to use," said Emily Hildebrand, a human factors and cognitive science researcher and director of the Center for Evaluation of Human Factors in Reprocessing Safety (CEHFRS), which is based at the Phoenix VA Health System. "Humans have specific abilities and limits, and current IFU designs do not match end user's needs."

Written instructions are "extremely long and complex," typically exceeding 75 pages in length, and are overly wordy, according to Hildebrand. They have inconsistent formatting and sectioning, and multiple cross-references. Physical documents don't stand up to the environmental conditions in reprocessing facilities. Visual images do not facilitate comprehension.

Visual instructions oversimplify processes, do not contain all the information necessary to reprocess a device, and provide information that conflicts with written IFU.

Many medical facilities recreate instructions

into "usable documents." In the process, however, content can be compromised, time is wasted, and patient safety can be put at risk.

In collaboration with the Cognitive Science and Engineering Program at Arizona State University, CEHFRS developed a prototype for an electronic IFU that addresses human factors issues for reprocessing staff. They conducted observations, site visits, task analyses, expert interviews, and heuristic evaluations of reprocessing then developed the prototype and conducted usability testing. The electronic IFU addressed the following human factors issues:

High memory demands

- Highly complex process (e.g., 200+ subtasks for reprocessing a colonoscope; an average of 20 procedures a day in the Veterans Health Administration)
- Technical jargon
- Too many similarly named items (e.g., an IFU for a single endoscope lists the following parts and tools: suction machine, suction canister, suction port, suction connector, suction tube, suction cylinder, suction cleaning adapter, suction valve)
- Pictures not oriented correctly

Poor visibility

- Complex equipment designs not supported with pictures
- Low-fidelity pictures make it difficult to discriminate information

Inconsistent feedback

- Lack of perception cues leave users unsure of progress in tasks

IFU developers need to design instructions for all end users, and accommodate different levels of users, including beginners, infrequent users, and experts. The CEHFRS electronic model builds in search features to make it easy for users to find information, provides clear content and pictures to aid comprehension, and facilitates correct application of instructions as users switch between instructions and cleaning tasks. This search–comprehend–apply framework for instructions for users is shown in Figure 1.

The model has proven effective in testing, Hildebrand said. Successful completion of reprocessing tasks increased from 44 percent to 87 percent with instructions developed using human factors design principles.

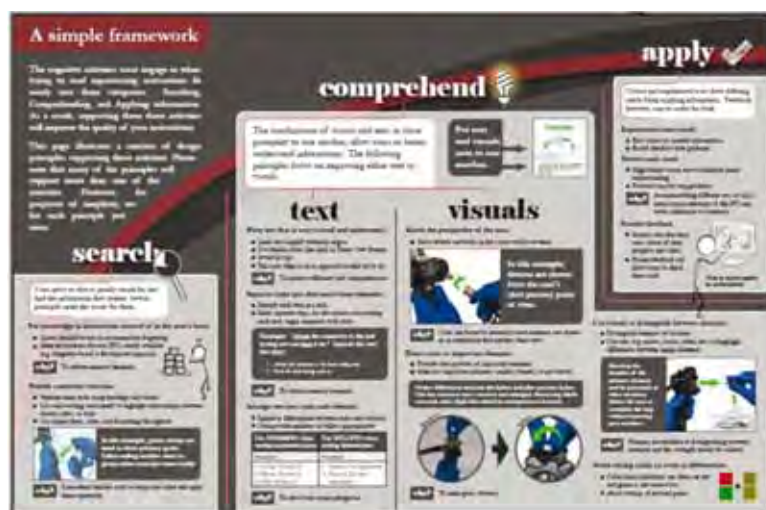


Figure 1. CEHFRS Instructional Design Guide

Source: Emily Hildebrand. (Oct. 11, 2011). "Developing Instructions for Use(rs)." AAMI/FDA Medical Device Reprocessing Summit.

THE CHALLENGE FOR STANDARDS: KEEPING UP WITH THE STATE OF THE ART

A number of summit presenters and participants called for new standards, and greater implementation of existing standards, to address challenges in reprocessing.

AAMI is on the case, according to AAMI's Joe Lewelling, vice president, standards development. Lewelling delivered a presentation prepared by Michael Scholla, global regulatory director, DuPont, and co-chair of the AAMI Sterilization Standards Committee.

AAMI, which is accredited by the American National Standards Institute (ANSI) to develop American national standards, has been at the forefront as a standards developing organization for 40 years, working closely with other organizations in the United States and some 50 other countries. AAMI administers technical committees of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) and administers technical advisory groups (TAGs) for ISO and IEC. AAMI also develops U.S. standards, recommended practices, and technical information reports.

Keeping up with the state of the art in reprocessing, as in other medical device issues, is a challenge in developing standards and guidance. "Every time we solve problems, new ones pop up, primarily because of new technologies," Lewelling said. "Standards capture the state of the art, they're not pushing the state of the art. Standards alone don't solve problems—people have to use the standards."

When they are used, standards and guidance do help elevate the state of processes and practices. AAMI's sterilization standards program, launched in 1974, today addresses issues ranging from steam sterilization to endoscopes to human factors. A case in point: ANSI/AAMI ST 79:2010/A2:2011, *Comprehensive guide to*

steam sterilization and sterility assurance in health care facilities, is a landmark document that responds to unclear guidance and uneven practices in the field. This recommended practice is helping healthcare institutions and accrediting organizations put quality practices into place.

Now, AAMI's standards development team is addressing changes in technology and a number of issues that are relevant to reprocessing:

- More attention to device design, including materials and construction
- Better instructions for reprocessing
- Immediate-use steam sterilization
- Ambulatory surgery centers
- Robotics
- Minimally invasive surgery
- Hospital-acquired infections
- More complex instruments, such as endoscopes

New AAMI sterilization working groups are addressing endoscope reprocessing and human factors for medical device reprocessing. AAMI has received three new work-item proposals for standards and guidance related to reprocessing:

- Standardized IFU
- Low- and intermediate-level disinfection
- Management of loaner instruments

To participate in the development of AAMI standards and guidance, e-mail standards@aami.org.

Clarion Theme 3. Pay early, iterative, and comprehensive attention to reprocessing requirements throughout the device design process.



“Devices aren’t designed to be cleaned from the very beginning of the device design process.”

— A summit participant

“Work hard to make it simple. That has been one of my mantras—focus and simplicity. Simple can be harder than complex; you have to work hard to get your thinking clean to make it simple. But it’s worth it in the end, because once you get there, you can move mountains.”

— Steve Jobs, interview with *Business Week*, 1998



Challenge	Priority Action	Accountability
Reprocessing is often an afterthought in device design	<p>Make effective reprocessing a priority from the very beginning of device design development</p> <p>When possible, minimize features such as lumens, channels, articulated surfaces, and/or finishes and materials that are difficult to clean.</p> <p>Take into account the reprocessing capacity of healthcare facilities and the reprocessing staff who will conduct reprocessing.</p> <p>- Validate cleaning methods for the most difficult to clean areas, taking into consideration all potential soil types, locations and surfaces on devices. If a device cannot be cleaned effectively, redesign it.</p>	<p>Manufacturers</p> <p>Regulators</p> <p>AAMI and other SDOs</p>
Lack of guidance for medical devices that must be disassembled and reassembled for reprocessing	<p>- Design devices to minimize the need to disassemble and reassemble them for reprocessing.</p> <p>- If disassembly and reassembly are needed for reprocessing, provide clear instructions, with guidance on when in the process the device should be disassembled and reassembled (i.e., before or after cleaning and disinfection/sterilization).</p>	<p>Manufacturers</p> <p>Regulators</p> <p>AAMI and other SDOs</p>

Understanding the Issues: Memo to Designers: Think About Reprocessing

The superior clinical outcomes that result from advanced medical technologies are often accompanied by the need for careful attention to cleaning and reprocessing. A number of factors add up to tremendous challenges for reprocessing, such as increasing device complexity, smaller and more delicate components, and articulating surfaces with different materials and finishes.

Some summit participants felt that, too often, reprocessing is an afterthought in the device design process—if it is considered at all. Summit presenter Thomas Gilmore, senior manager of product development for cleaning, disinfection, and sterilization at Olympus America, Inc., highlighted the design challenges that make one type of device, flexible endoscopes, difficult to clean:

- Long, narrow interconnected channels and lumens
- Sophisticated materials (e.g., polymers, metals, adhesives, and resins)
- Advanced electronics and optics that are densely packed for size reduction
- Differences in coefficients of thermal expansion for different materials, which can result in material stress, fracture, or failure of seals if different materials are rigidly joined together

Reprocessing is equally problematic with other surgical instruments, according to Linda Condon, educator, Central Sterile Processing Department, The Johns Hopkins Hospital. Figure 2 shows her example of one set of surgical instruments that requires three different cleaning processes. Klacik noted that components of a single device can require multiple disinfection levels. And Seavey said that many similar-looking devices have very different reprocessing requirements. Summit participants indicated that for many devices with small parts or long lumens, it is impossible to do a visual inspection to determine whether devices are clean.

Condon also pointed out that the sizes of brushes and tools needed for reprocessing often are not specified, which means that reprocessing staff have to use a trial-and-error process to select the right equipment.

Another design-related issue that resonated with participants is disassembly and reassem-



Figure 2. One Set of Surgical Instruments, Three Different Cleaning Processes

This set of surgical instruments requires three different cleaning processes: hand wash, no sonication; pre-soak, flush, followed with mechanical rinse; and mechanical wash, according to summit presenter Linda Condon.

Source: Linda Condon. (Oct. 11, 2011). "Human Factors Associated with Reprocessing Reusable Instrumentation in the Decontamination Area." Presentation at the AAMI/FDA Medical Device Reprocessing Summit.

"The need to conform to and meet challenges that physicians present us results in highly complex devices. The very same design requirements that make these devices so remarkably effective in clinical outcome require careful attention to cleaning and reprocessing."

— Thomas Gilmore, senior manager of product development for cleaning, disinfection, and sterilization, Olympus America, Inc.

Improving Designs of Devices, Equipment, and Cleaning Agents

Device designers have made improvements to devices that make them easier to clean, Gilmore said, and more changes are on the horizon. For example, a single-channel flexible bronchoscope that is resistant to heat and pressure and can withstand steam sterilization was introduced in 2006.

Changes in device materials can also improve durability against oxidizing agents. Improved design geometry can eliminate stepped surfaces, sharp corners, and abrupt surface changes, which are particularly problematic in internal spaces. Devices should also be designed to avoid dead-end cavities that are hard to clean.

Improvements to automated reprocessing equipment, and recent and significant advances in chemistry, are reducing reprocessing time and the need for contact with chemicals, increasing efficacy, and providing more environmentally friendly cleaning products. "Chemistry plays a fundamental role in the cleaning and reprocessing of reusable medical devices," Gilmore said. "The two fundamental design criteria for chemistry are efficacy and material compatibility."


bly of devices for reprocessing. Many devices are not labeled with any indication of whether disassembly and reassembly is required. Condon advocated for a universal symbol to indicate whether disassembly is required.

In general, for medical devices, the FDA does not recognize symbols unless there is accompanying explanatory English text. There are exceptions to this as it relates to use of selected symbols on labels and in labeling of in vitro diagnostic devices intended for professional use (U.S. Food and Drug Administration, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research. (2004). *Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use*. In addition, the FDA's Center for Devices and Radiological Health (CDRH), in its enforcement discretion, does not object to the use of the statement "Rx only" (U.S. Food and Drug Administration, Center for Devices and Radiological Health. (2000). *Alternative to Certain Prescription Device Labeling Requirements*.

Some devices do not require disassembly (in the IFU), but reprocessing staff notice moisture or debris and take them apart for cleaning anyway. Michael Wiklund, co-founder and president, Wiklund Research & Design, said that some instruments that are not designed to be dissembled can be taken apart—and that's a design flaw.

"Instructions for use don't necessarily tell us to [take devices apart for cleaning], but we're doing it anyway," said summit presenter Mark Duro, manager of the New England Baptist Hospital Central Sterile Processing Department. "Central sterile managers might make up their own way of doing things," he said, if devices are designed in ways that make them difficult to clean.

Problems abound with devices that do require disassembly and reassembly as well. "When you take a device apart, you don't know how many parts there are," said Condon. "There are no pictures or tools to help staff identify parts. When you take a screw out and it ends up down the drain, I can't purchase that screw. That's a \$5,000 device, with no ID number on the screw, no parts associated with the device. I can't purchase that screw." She advocated for standards calling for all instruments, and all components of instruments, to have catalog numbers.



"A lot of times, manufacturing representatives will come in and talk to surgeons and nurses. Quite often they forget to talk to central sterile. Sometimes, new medical devices just show up in central sterile—and guess what, the doctor needs it now. Representatives need to teach us how to reprocess these devices. We feel we are a vital link in patient care. Each time a clinician uses an instrument, our goal is to make sure it performs flawlessly."

— Sue Klacik, central sterile supply manager at Humility of Mary Health Partners and AAMI representative for the International Association of Healthcare Central Service Materiel Management (IAHCSMM)

Clarion Theme 4: Make human factors and work environment factors priorities when developing reprocessing requirements.



"If designers made completely unrealistic assumptions about the physical world when designing technology, then we would blame them ... Yet when they make ... unrealistic assumptions about human nature ... we blame the unfortunate people who are just trying to do what the design requires."

— Kim Vincente, *The Human Factor*

Challenge	Priority Action	Accountability
Lack of understanding about the human factors that affect reusable medical device reprocessing	Validate that responsible staff can reprocess medical devices effectively, taking into consideration personal characteristics and professional conditions, such as demanding workloads.	Manufacturers Clinical staff Reprocessing staff Regulators Professional societies Healthcare organizations AAMI and other SDOs
Lack of understanding about the work environment factors that affect reusable medical device reprocessing	Validate that medical devices can be reprocessed effectively in the real-life conditions of reprocessing facilities.	Manufacturers Clinical staff Reprocessing staff Regulators Professional societies Healthcare organizations AAMI and other SDOs
Lack of understanding of the time constraints for reprocessing reusable medical devices	Consider the clinical demands for reusable medical devices in reprocessing instructions. Too often, the time to complete the reprocessing steps according to the instructions exceeds the time constraints of clinical need for reprocessed reusable devices.	Manufacturers Clinical staff Reprocessing staff Healthcare organizations AAMI and other SDOs

Understanding the Issues: A Disconnect Between Reprocessing Requirements and Realities

There is a gaping chasm between laboratory validation of reprocessing procedures and the clinical realities of putting validated procedures into practice. Keeping up with the sheer volume, sophistication, and diversity of

reusable devices that require reprocessing is, in a word, mindboggling.

In addition to the lack of standardized cleaning processes discussed above, a number of human and work environment factors affect reprocessing, according to summit presenters

Condon, Klacik, and Wiklund, as well as summit participants:

- People have different cognitive and physical capabilities and limitations, knowledge and skills, and preferences.
- Personal protective equipment (PPE) can be bulky and hot, limit dexterity and fine motor skills, and decrease vision due to fogging. Different PPE may be required in different parts of the facility (e.g., PPE is required in decontamination areas but not in sterilization areas). In some facilities, PPE is used intermittently or improperly.
- The reprocessing environment can be isolated, noisy, humid, and poorly lit.

- The workflow can be complex, with high volumes, peak periods, rush jobs, and constant interruptions.
- Time for adequate reprocessing can be limited by clinical demands, workforce availability, or equipment cycles.
- Facilities have different, and often limited, resources.

These human and work environment factors can make it hard to concentrate. Most people have limitations in how much they can remember, especially when detailed, complex information is presented to them without visual aids, Wiklund said. In addition, human and work environment factors can contribute to serious potential use errors, such as skipping steps in reprocessing or using wrong equipment or cleaning agents. Use errors can range from 3 percent to 30 percent across all tasks in reprocessing a device, he said.

Variability in reprocessing facilities is a factor as well, according to summit presenter Ramona Conner, manager of standards and recommended practices at AORN. “In hospitals, central sterile processing looks like a manufacturing facility,” she said. “Thirty years ago, only the most rudimentary procedures were done in ambulatory care facilities. Today, 70 percent of all surgeries—ranging from laparoscopies to total joint replacements—are done in ambulatory care. They’re using the same instruments as hospitals use—and doing almost all of the reprocessing by hand.”

“I’ve been in central sterile departments with three sinks; one for rinsing, one for inspecting, one for cleaning,” said Eileen Young, clinical nurse educator, Olympus America. “Others have one small sink that may be totally insufficient for what they need to do.” And work environment conditions mean that, despite IFU, medical devices and instruments are allowed to dry, causing caked-on matter that is more difficult to remove during reprocessing.

It is incumbent upon all stakeholders to develop a use-related risk mitigation strategy to reduce potential errors, Wiklund said. This includes:

- Identifying potential use errors
 - Assessing risk levels
 - Mitigating unacceptable risks
 - Validating that mitigation strategies are effective
- Classic use-related mitigation strategies

“Walk a mile in these persons’ shoes. The environment is loud, noisy, very isolated. It’s like you have a contagion. Psychologically, it’s not real friendly.”

— Linda Condon, educator, Central Sterile Processing Department, The Johns Hopkins Hospital



include improving user interface design, and providing guards, warnings, instructions, checklists, and training. Validation with usability testing means that representative users should perform high-risk tasks in representative use environments. The FDA expects these tests to include 15 representatives of each distinct user group, Wiklund pointed out. This recommendation is included in the FDA's *Draft Guidance for Industry and Food and Drug Administration Staff—Applying Human Factors and Usability Engineering to Optimize Medical Device Design*, which is not for implementation. In the draft guidance document, the FDA recommends that human factors validation testing include 15 participants from each group of users that have distinct abilities or use roles.

Wiklund said that test administrators should document all use errors, close calls, and operational difficulties. Risk managers should determine if the residual risk level is acceptable.

“Usability testing should be the capstone to a comprehensive human factors engineering effort.”

— Michael Wiklund, co-founder and president,
Wiklund Research & Design



From Human Factors Theory to Practice

Researchers at Wayne State University in Detroit are applying human factors theory to develop a “desired future state” for reprocessing instructions.

Human factors theory brings together science, engineering, human capabilities and limitations, and the effects of the social and environmental context. It measures human and system performance, with overall goals of user-friendliness and usability, according to summit presenter R. Darin Ellis, associate professor of industrial and systems engineering and biomedical engineering at Wayne State University.

Ellis and his colleagues studied a reprocessing unit at a Veterans Administration hospital and discovered the kinds of problems identified throughout this summit. They have developed a prototype application, coded in SML and presented in HTML, that makes IFU accessible on “safe, wipeable” touchscreens that can withstand moisture and heat.

The team didn’t change the content of the IFU at all. Rather, they improved their accessibility, visibility, and usability. The application supports novices with links to more information and allows flexibility for experts to go through reprocessing steps quickly. It has on-screen, graphic “breadcrumbs” so that users know where they are in the procedures, even if they are interrupted or distracted. And it has a timer for users to keep track of timed processes.

“This is cognition in practice,” Ellis said. “Users rely on recognition memory of the screen format rather than recall memory. We were careful to keep tasks compact—breaking big tasks into subtasks, so people can finish what they’re doing on every single screen.”

Clarion Theme 5: Improve information collection and sharing to broaden the use of best practices in reprocessing.

Challenge	Priority Action	Accountability
A lack of documentation and data to analyze what works—and what doesn't work—in reprocessing	Create a registry that collects information about best practices and challenges in reprocessing in real clinical environments.	Manufacturers AAMI and other SDOs Clinical staff Reprocessing staff Professional societies Healthcare organizations
A lack of communication and sharing of best practices and challenges in reprocessing	Establish “feedback loops” to improve communication among reprocessing staff, clinical staff, manufacturers, and regulators about reprocessing experiences.	Manufacturers AAMI and other SDOs Clinical staff Reprocessing staff Professional societies Healthcare organizations
Difficulty bringing reprocessing issues to the attention of manufacturers	Develop a complaint procedure and make it easy to submit a complaint on a company website. Respond promptly to complaints.	Manufacturers Clinical staff Reprocessing staff Professional societies Healthcare organizations

Understanding the Issues: What Works? What Doesn't?

There is a considerable amount of anecdotal evidence about experiences with reprocessing, but little solid documentation and data to conduct meaningful analysis, summit participants said. Better ways to collect and share information, and learn from challenges and best practices, are needed.

At some facilities, part of the problem is that instrumentation is purchased without the input of central sterile managers. Only when it is sent for reprocessing and the IFU reviewed is it discovered that the necessary equipment is not available—and reprocessing staff are blamed when instrumentation, which can be very expensive, cannot be used.

“If there are challenges in the field, communi-

cation and feedback are very important to us,” one manufacturer’s representative said. “The mechanism is already in place to provide feedback information to the manufacturer. We train sales managers to feed back complaints; they report them to our regulatory affairs department.”

“We echo the frustration of manufacturers, whom we believe are trying to comply, and the frustration of hospitals,” an FDA employee said. “If you are not getting through to manufacturers, you always have an opportunity to submit a report to the FDA. Really, this is our only way to leverage information and provide guidance, if necessary, to authorize changes.” The FDA will provide help in completing the 3500A form [used for reporting adverse events and product problems]. “Give us a detailed clinical description. We can help fill in the forms.”

Clarion Theme 6: Improve reprocessing competencies by strengthening training, education, and certification.



“It’s important for facilities to understand and appreciate that even though CSSDs [central sterile supply departments] aren’t a true ‘revenue generator,’ they nonetheless fulfill a critical role—one that directly impacts other healthcare departments, particularly the revenue-generating OR. Having an adequate number of well-trained, certified CSSD technicians who can work efficiently—yet aren’t willing to rush the process and make potentially dangerous compromises—is absolutely critical to patient safety and the delivery of quality patient care. It’s also critical to the success of the healthcare organization, as a whole.”

— Betty Hanna, executive director, International Association of Healthcare Central Service Materiel Management (IAHCSMM)

Challenge	Priority Action	Accountability
Inadequate reprocessing knowledge among reprocessing staff and manufacturers	Provide thorough training to reprocessing staff.	Healthcare organizations Manufacturers Certifying organizations
	Adequately train manufacturers’ representatives in reprocessing processes and requirements.	Manufacturers Professional societies
	Ensure excellent training and educational materials.	Regulators Certifying organizations Manufacturers Healthcare organizations Professional societies SDOs
	Ensure that healthcare delivery organizations have appropriate competencies and instructional technologies to reprocess reusable medical devices.	Healthcare organizations Manufacturers
Uneven reprocessing competencies in the field	Encourage education of reprocessing staff at the national level through a two-year degree program.	State regulators Certifying organizations Accrediting organizations Educational institutions
High turnover and low pay for reprocessing staff	Encourage career ladders with increased compensation for additional education Compensate certified reprocessing staff with pay that reflects required competencies.	Healthcare organizations

Understanding the Issues: How to Skill Up Diverse Workforce

Many summit presenters and participants juxtaposed the increasing knowledge and skill demands placed on reprocessing staff with the uneven, and often inadequate, preparation for the job.

In many facilities, reprocessing is still treated as a low-skilled, low-wage job. Reprocessing centers can be staffed with people with low literacy, English language skills, and education levels. Turnover rates are high. There might be no education requirements for new central sterile technicians or even the managers.

AORN's Conner and IAHCSMM's Klacik joined summit presenters Marilyn Hanchett, senior director, research and clinical innovation at APIC, and Eileen Young, clinical nurse educator of Olympus America, in advocating for greater staff training and competencies. They also called for mandated certification for reprocessing staff. Resource limitations and personnel issues—including adequate education, pay, and responsibilities—are barriers to competencies. New Jersey is the only state that requires certification to work in a central sterile processing facility.

Pennsylvania and New York have active legislation under way to make this a requirement, and a handful of other states are planning and collecting data to begin certification processes. Mandated certification should provide:

- A consistent, baseline education in standard practices for reprocessing reusable medical devices
- Higher competency levels
- Required annual continuing education
- Critical thinking skills

"It is easy to say we need certification of central sterile professionals," Young said. "The obstacle is that at the state level, that is a three-to five-year process." Young called for a federal requirement for certification, but that is beyond the regulatory authority of the FDA, FDA personnel said. "It's not just certification," Young said, "but ensuring that they remain competent. There should be a minimum two-year degree requirement and a reward system. The demand is higher than the number of trained professionals—and there are not a lot of training programs available."

Even highly educated and trained clinicians know little about the reprocessing procedures for which they are responsible.

Nurses typically receive no education in reprocessing as part of basic R.N. programs. AORN offers post-graduate programs, films, and online modules for building reprocessing competencies among operating room nurses. A competency evaluation tool that includes reprocessing competencies for operating room nurses was in press at the time of the summit. These resources are available on the AORN website, www.aorn.org.

"We have to have critical thinking skills in central sterile processing."

— Sue Klacik, central sterile supply manager at Humility of Mary Health Partners and AAMI representative for the International Association of Healthcare Central Service Materiel Management (IAHCSMM)

"Certification and ongoing education is just as important today as it was some 50-plus years ago when the International Association of Healthcare Central Service Materiel Management (IAHCSMM) began. In fact, one could argue that certification and continuing education are even more important today because of technological advancements and resource constraints that plague many healthcare organizations.

It has always been IAHCSMM's goal to help Central Sterile Supply Department professionals become certified and stay on top of industry standards and proper processing-related practices, so they can do the right thing, each and every time."

— Betty Hanna, executive director, International Association of Healthcare Central Service Materiel Management (IAHCSMM)

Clarion Theme 7. Create a greater sense of urgency and understanding throughout the healthcare community about the consequences of inadequate reprocessing.



“We need to create a business case for infection prevention—the more you process people safely through the system, the more you will be reimbursed.”

— Eileen Young, clinical nurse educator of Olympus America

Challenge	Priority Action	Accountability
Lack of awareness about the potential patient safety risks from inadequately reprocessed medical devices	Educate all stakeholders about infection prevention.	Regulators Certifying organizations Manufacturers Healthcare organizations Professional societies SDOs Educational institutions
Inadequate resources to reprocess medical devices effectively	Ensure that healthcare organizations have appropriate time, facilities, and medical equipment to reprocess all medical devices in use.	Healthcare organizations Manufacturers Accrediting organizations

Understanding the Issues: The Fundamentals of Infection Control and Prevention

A root cause of many reprocessing challenges is “a lack of recognition of the importance of infection control across the industry,” Eileen Young, clinical nurse educator of Olympus America, asserted. “Infection prevention is everybody’s business.”

Clinicians and reprocessing staff will be more attentive to the procedural steps and details of reprocessing if they understand why they are important: Inadequate reprocessing can have adverse patient events.

An understanding of the fundamentals of infection control and prevention must begin with

top-level administrators and risk managers in healthcare organizations who can allocate resources to this challenge. “We need to create a business case for infection prevention—the more you process people safely through the system, the more you will be reimbursed,” Young said.

APIC is supporting this broad education effort with these resources:

- A new Infection Prevention Competency Module to be introduced in 2012
- Strategic planning to meet targeted and expanding infection prevention role requirements
- An online disinfection and sterilization course, which was introduced in 2011
- Archived webinars available on the APIC website, www.apic.org

Conclusion



“Change doesn’t happen from a leader announcing the plan. Change begins from deep inside a system, when a few people notice something they will no longer tolerate, or respond to a dream of what’s possible ... We don’t have to start with power, only with passion.”

— Margaret Wheatley

The October 2011 summit that AAMI co-convened with the FDA was a call for a clean start with medical device reprocessing to the entire healthcare community. The more than 275 cross-disciplinary summit participants heard the call and together developed seven clarion themes, 20 challenges, and 35 priority issues. This call for change came from deep within the system in all quarters: regulators, sterilization experts, industry experts, clinicians, central sterile processing staff, and infection preventionists—and the patients we all serve. It is our concern for patients that will enable us to keep the passion alive.

From a 30,000 foot perspective, the summit:

- Brought stakeholders together around a common goal: No patient should be harmed from devices that have been inadequately reprocessed, or devices that cannot be adequately reprocessed,
- Re-energized attendees to address vexing issues that have come up over and over again for decades,
- Created a setting for industry to truly “hear” the concerns and needs of clinical and reprocessing staff,
- Confirmed the importance of the FDA’s decision earlier this year to engage the stakeholders in taking action to reach a solution,
- Developed an important research agenda (see Research Appendix on page 31)
- Reminded all of us that there are basic things all healthcare organizations can start to work on now, without waiting for research, devices that are easier to clean, or longer-term solutions (see “Top 10” list on page 7)
- Proved once again that these complex technology-related safety issues are systems-based, and require a holistic approach to solutions that will require collaboration by the entire healthcare community.

What’s Next?

None of the seven clarion themes can be resolved by a single organization. These system-wide issues will require the whole healthcare community to continue to work together as a team. AAMI’s Sterilization Standards Committee leadership is committed to sustaining the momentum from the summit with an action plan for addressing the priorities. Like the summit itself, the action agenda will require multidisciplinary, collaborative efforts. No single group can do it alone.

At the November 2011 AAMI Sterilization Standards Committee meetings, three new technical information reports were discussed. Work on these reports will begin at task group meetings in February 2012:

- Endoscope reprocessing
- Standardized cleaning instructions for use
- Human factors for device reprocessing

In early 2012, AAMI will convene a small group of stakeholders to review the clarion themes and determine which organizations will take the lead on various issues that cannot be addressed with standards alone. For more information on these activities, contact standards@aami.org.

AAMI will stay in touch with the community that came together in October 2011 and will continue to collaborate with the FDA on these important issues. We ask that all of you stay in touch as well. Please share your own organization’s success stories, lessons learned, and progress made. And please share this publication with your colleagues internally and externally, so other who are passionate about these issues will feel supported and inspired to act.

Tackling the 35 priority issues will take all of us—and more—committed organizations and individuals who continue to say we cannot tolerate the status quo. Together, we will celebrate success, not for ourselves but for the patients we all serve.

[www.aami.org/
reprocessing](http://www.aami.org/reprocessing)

RESEARCH APPENDIX

1. Defining Clean

- a. Identify and characterize the soil(s) that a surgical instrument comes in contact with in clinical use.
- b. Develop a classification scheme for surgical instruments based upon the above analysis (e.g., instruments that are primarily soiled by blood might constitute one class; instruments coming in contact with GI tract another)
- c. Determine the best extraction method for a given device design.
 - i. Flush method may be necessary for a lumened device.
 - ii. Swabbing method may be best for a less complex instrument.
 - iii. The design of the instrument may also be suggestive of where and how to test; e.g., the box-lock area of a hinged instrument may represent the greatest challenge area for cleaning, so that would be the location where soiling and testing would occur.
- d. Based upon the above, determine the best method(s) for detecting residual soil(s) as described in a and b above.
- e. Set the threshold for “clean”
 - i. Level of detection of the method(s) used.
 - ii. Level of soil that would interfere with terminal sterilization or disinfection.
 - iii. Level of soil that poses a threat to the next patient.

2. Standardized Instructions for Use (IFU)

- a. Develop a classification scheme of medical devices from a reprocessing perspective.
 - i. Similarity in physical characteristics (e.g., simple, hinged, lumened, multi-part)
 - ii. The type of clinically relevant soil with which the class of instrument comes in contact
- b. For each class, determine the necessary steps for robust, effective cleaning. Have both a 100% manual cleaning process and a process using commonly available reprocessing equipment (e.g., sonic, washer-disinfector, pulse flow washer).
 - i. Testing needs to demonstrate that the recommended steps will get instruments in the given class clean.

3. More Research into the Science of Human Factors Engineering

- a. What tools are consistently the most helpful/useful
- b. What environmental conditions contribute to best performance
- c. What education and training leads to best performance
- d. What medical device design features lead to best results from a cleaning and instrument care perspective

4. Prion Activation Studies

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STANDARDS

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On the AAMI Website

DRAFT HOSPITAL INFECTION CONTROL SURVEY TOOL

A draft hospital infection control survey tool developed by the Centers for Medicare and Medicaid Services (CMS) Office of Clinical Standards and Quality Control (OCSQ), is available on AAMI's website.

The tool is being used in the "pretest" phase of the Partnership for Patients initiative with the U.S. Department of Health and Human Services. CMS has field-tested the tool in surveys and received feedback from the survey teams. The next iteration will be completed in January 2012 and, after further training, all 50 states will use it at least once before the end of Fiscal Year 2012.

With more feedback, the final tool will be completed in time for a possible Fiscal Year 2013 implementation into the CMS survey process. Thus far, the only change will be the removal of the final question in both sections.

The tool was presented to the Healthcare Infection Control Practices Advisory Committee (HICPAC) and to the Centers for Disease Control and Prevention (CDC) in June, as well as to liaison and accrediting organizations, for their comment and feedback.

www.aami.org/reprocessing/materials.html

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