Making HTM a Family Affair

For the general public, healthcare technology management (HTM) tends to be an obscure profession. For a happy few with family members in the same profession, HTM is a family affair that forges deep bonds.

Diane Geddes, president and CEO of RepairMED, began her long career as an X-ray and ultrasound technologist working in hospitals and later for companies managing medical equipment. Seven years ago, after a company divestiture eliminated her division, she launched her own company, which is based in Naples, FL. “The company got busy and I needed help,” she said.

Geddes found the talent she needed in her own family. Both of her daughters and her niece now work for RepairMED handling customer support, marketing, sales, and accounting. Her eldest daughter Lacey McArn, who lives in Biloxi, MS, was the first to join the company five years ago. A cosmetologist and aesthetician by trade, the opportunity came at the right time for her. “I had my second child and reality set in that it was hard to be able to work in a spa and salon with two children,” she said.

How did McArn learn about the medical device repair business?

“Brute force,” she said, wryly. She started in customer service, researched the equipment, and shadowed her mother at trade shows. But she wasn’t entirely new to the business. “I’ve been around this my whole life,” she said. “I remember as a little girl when my mom—

Continued on page 14

AAMI Foundation Awards
2020 Research Grants

The AAMI Foundation has named the 2020 recipients of the Mary K. Logan Research Award Program. Two grants, worth a total of more than $119,000, will support research initiatives that focus on improving patient safety and eliminating morbidity and mortality associated with the use of healthcare technology.

“The AAMI Foundation is pleased to support these important research initiatives this year, and looks forward to sharing the results of the researchers’ work with the entire healthcare community,” said Steve Campbell, executive director of the AAMI Foundation. “Competition for this year’s research funding was strong, but these two grant submissions stood out because of the depth and importance of the topics and the impressive proposals put forth by the researchers.”

The awards program, which was named in honor of AAMI’s former president and CEO, was established in 2016 with a gift from the association’s Board of Directors. This year, it supports research from the School of Engineering and Applied Science at George

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FDA Delays UDI Enforcement in Midst of COVID-19

To enable industry to focus on responding to COVID-19 public health needs, the Food and Drug Administration (FDA) has pushed back compliance dates for its universal device identification (UDI) system for Class I and unclassified devices—other than implantable, life-supporting, or life-sustaining devices.

The updated UDI policy, issued last month via an immediately-in-effect guidance, “presents a less burdensome policy that is consistent with public health,” according to the FDA.

The guidance document, Unique Device Identification: Policy Regarding Compliance Dates for Class I and Unclassified Devices and Certain Devices Requiring Direct Marketing, establishes that in addition to UDI labeling, standard date formatting and submission of device information to the FDA database for Class I and unclassified devices won’t be enforced before Sept. 24, 2022, nor will compliance with the additional direct marking requirement for reprocessed and reusable devices. The new dates are in effect regardless of when a device was manufactured and labeled.

The new date change, according to the FDA, is the result of the agency continuing to work on questions from higher-risk device manufacturers on UDI implementation, but also noted new demands on manufacturers as a result of the novel coronavirus.

“For those labelers that have not already implemented UDI requirements for Class I and unclassified devices, preparing to implement UDI requirements while addressing the challenges related to [COVID-19] could be very difficult and could divert resources from COVID-19 response efforts,” the agency wrote. “To the extent this policy helps labelers remain focused on public health needs related to COVID-19, we believe the policy is further consistent with the public health.”

The UDI system, established in a final rule released by the FDA in 2013, is designed to adequately identify devices through distribution and postmarket use. This is the second time the FDA has delayed enforcement of the original dates established for phased rollout of the system for Class I and unclassified devices. The compliance dates are:

- Sept. 24, 2018, for standard date formatting, labeling, and data submission to the Global Unique Identification Database (GUIDID); and
- Sept. 24, 2020, for direct mark requirements.

While the immediately-in-effect guidance was submitted without prior public comment, the FDA is accepting public comments at www.regulations.gov (docket FDA-2017-D-6841).
AAMI Foundation Establishes Kilmer Scholarship Fund Committee

The AAMI Foundation has created the new Kilmer Fund Committee to develop the scope and criteria for the new Kilmer Scholarship Award.

The Foundation launched this new scholarship program in September 2019 for students pursuing a career in sterility assurance. The Foundation teamed up with Johnson & Johnson to create the Kilmer Fund, which will award scholarships and grants to individuals and organizations in the field. Up to three scholarship awards or research grants will be given annually through a selection process by the committee. By July 2020, the Foundation had raised more than $130,000—about 65% of the $200,000 goal—for this award.

Named to the Kilmer Fund Committee are: Amanda Benedict, acting vice president of standards at AAMI; Jennifer Benolken, MDM and regulatory specialist at DuPont; Christophe Deneux, senior director of global sterility assurance at BD; Vu Le, manager of manufacturing engineering assurance on the sterility task force at Baxter; Michelle “Shelly” Luebke, research scientist at Baxter; Gerald McDonnell, senior director of microbiological quality and sterility assurance at Johnson & Johnson; Nicole McLees, sterility assurance specialist at 3M; Emily Mitzel, director of global cleaning and disinfection at GE Healthcare; and Whitney Tull, senior director of governmental affairs at STERIS.

The committee is expected to publicize the award criteria this fall and select this year’s winners by the end of this year. To contribute to the scholarship fund, contact Steve Campbell, executive director of the AAMI Foundation, at scampbell@aami.org.

Global Study Results in Tool to Prevent Respiratory Depression

A global, Medtronic-sponsored study, the largest of its kind, fills in knowledge gaps in the prevention of opioid-induced respiratory depression.

The PRODIGY (PRediction of Opioid-induced respiratory Depression in patients monitored by capnoGraphY) study’s primary objective was to develop an easy-to-use risk prediction tool to guide clinicians in identifying patients who would benefit most from continuous monitoring, including capnography and oximetry, on the general care floor. Respiratory compromise is common, costly, deadly, and preventable.

The prospective study, which analyzed data from 1,335 patients at 16 sites in the U.S., Europe, and Asia, found that 46% of patients experienced respiratory depression episodes, which show evidence of poorer outcomes. Patients with one or more such episodes were more likely to experience an adverse event that required action. Patients experiencing such episodes also showed increased costs and increased lengths of study. Preliminary results of the PRODIGY study were released in 2019; the final results were published in Anesthesia & Analgesia this year.

Based on the findings, the research team developed a risk prediction tool with scoring criteria for five risk factors: patient age, sex, previous opioid use, sleep-disordered breathing, and chronic heart failure.

Medtronic was an industry partner to the AAMI Foundation’s National Coalition to Promote Continuous Monitoring of Patients on Opioids.

AAMI Launches Online Summer Learning Series

Continuing live and on-demand all summer, AAMI is offering an interactive, online learning series that tackles many of the biggest topics facing health technology, sterilization, and regulations. There are 36 available sessions, with each custom track offering four to six sessions that can be watched live or streamed later.

“The entire health technology community has been impacted by COVID-19, including the cancellation of in-person educational opportunities, such as the AAMI Exchange. The AAMI Summer Learning Series pulls together key speakers and topic areas to ensure professionals from all areas of health technology can get quality education and training from the comfort and
“Pent-up Demand” for Elective Surgeries Postponed by COVID-19

Japanese medical device manufacturer Olympus is seeing signs that hospitals that canceled tens of millions of surgeries due to COVID-19 are beginning to reschedule them, according to an article in *Financial Times*. This could be a signal that will help revive the global medical equipment industry.

Olympus makes gastrointestinal and surgical endoscopes used in procedures such as colonoscopies, which were put on hold as hospitals focused on the response to the pandemic and on minimizing risk of infection.

“A study published in the *British Journal of Surgery* in May estimated that 28m [million] elective surgeries would be cancelled or postponed globally during the peak 12 weeks of a country’s COVID-19 outbreak,” according to the *Financial Times*. Even if surgical volume rose by 20 percent after the pandemic, the backlog would take about a year to clear, according to the study.

Healthcare facilities worldwide have a backlog of millions of elective surgeries.
Reliability and Resiliency: Vital to Dealing with Incredibly Complex, Fragile Healthcare Supply Chains

Philip Settimi, MSE, MD, is president and chief executive officer of PartsSource in Aurora, OH. Previously, Settimi was the chief marketing officer, senior vice president of global marketing and corporate development, and company officer at Hill-Rom and has held various commercial, strategy, mergers and acquisitions, and product leadership roles at Hospira and GE Healthcare.

Q What common challenges do healthcare facilities face in terms of supply chain, health technology procurement, and vendor management, and what are the benefits of streamlining these processes?

The COVID-19 crisis has highlighted a known but under-addressed fact: Healthcare supply chains are global, incredibly complex, increasingly lean, and very fragile. When I joined PartsSource in 2014, we pivoted the company in a new direction to improve the reliability and resiliency and, along the way, the cost, quality, and team productivity of the medical devices supply chain.

I found PartsSource hospital clients who waited weeks for a manager or purchase order approval and, all the while, a procedural room was offline or a critical asset was clinically unavailable. We observed supplier stockouts, logistical failures, abnormal dead-on-arrival rates, poor master data management, little use of clinical evidence, no decision support, and highly manual workflows.

Having spent the previous 10 years building electronic medical records, decision-support systems, and connected devices, this was shocking to me. The financial and operational impact to hospitals by not addressing this opportunity in healthcare technology management (HTM) and the medical devices supply chain was profound.

In 2015, we began building a software platform dedicated to clinical resource management. It was purpose-built for the specialized workflow and procurement needs of the medical devices supply chain. With patented evidence-based decision support to ensure that the highest-quality, lowest-cost, and most reliable supply options are selected across products and services, we have digitally transformed the workflow, massively improved team productivity, and provided enterprise analytics to more than 1,200 hospitals.

With the support of our people, process, and technology, clients are able to reduce vendor management from 800 to 1,000 down to one, visualize key performance indicators on all of their medical device suppliers, leverage our data science to predict and avoid stockouts, actively identify and institutionalize lower-cost supply alternatives, ensure all their staff work at the top of their professional license, and, most critically, maximize the clinical availability of their medical device fleet to best support caregivers and patients.

Q The criticality of 100% uptime in hospitals has been underlined by the coronavirus pandemic. What focus points surrounding uptime do you emphasize?

We believe that to achieve maximal clinical availability of mission-critical medical assets, an HTM organization must address the people, process, and technology associated with the procure-to-pay (or sourcing-to-reconciliation) experience for products or services. We often find that limitations and obstacles in the medical devices supply chain exist in these categories: poor data management, ineffective or incomplete use of computerized maintenance management system and enterprise resource planning integrations, little use of electronic data interchange, and lack of an enterprise purchasing policy, real-time order updates, legacy technology, or workflow and approval systems.

Q What are your observations about client behavior, market trends, and unmet needs?

Broadly, we see two major forces occurring in the U.S. acute care healthcare landscape. First is the significant and continued consolidation of health systems. Second is the continued focus on the cost side of healthcare as revenue growth becomes difficult with worsening demographics, case mix, and payor mix. We are focused on the nonclinical labor aspect of spend, which implicates the supply chain and purchased services (where HTM sits). Both are leading to the same outcome, with more and more organizations bringing HTM in-house and many seeking to reduce long-term service agreement obligations with original equipment manufacturers. Many also recognize that substantial in-house programs create the most intimate possible partnership to support clinical caregivers, along with the ability to deliver a safe and effective patient experience.

This Q&A is adapted from an article in the July/August issue of AAMI’s journal, Biomedical Instrumentation & Technology. Visit www.aami.org/BIT.
Medical Equipment Service Guide Helps Ensure Safety and Efficiency

How do you choose a service model for your medical equipment inventory? How do you manage medical equipment service when a service model is in place? Who does what—and how is performance measured?

AAMI’s newly published Medical Equipment Servicing Guide: Managing Compliance, Quality, and Cost has answers. The purpose of the guide is to make sure that medical devices used by patient care providers are safe and effective—and economical in the use of resources. The guide covers:

- Key components of medical equipment service
- Roles and responsibilities for healthcare technology management (HTM) professionals and organizational leaders
- Recommendations for maintaining compliance, gauging quality, and calculating costs
- A proactive process and decision matrix for evaluating service model options
- Ongoing performance monitoring of compliance, quality, and cost

Matthew F. Baretich, president of Baretich Engineering in Fort Collins, CO, is the author of the guide. He has written many other AAMI special publications, including AEM Program Guide: Alternative PM for Patient Safety, Computerized Maintenance Management Systems for Healthcare Technology Management, 3rd edition (with Ted Cohen), and Electrical Safety Manual.

“Medical equipment service is a core function of HTM,” Baretich said. “The guide is a way of thinking about how to choose an HTM service model and how to manage the one you have chosen.”

To order this guide, visit the AAMI Store.

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Device Servicing Collaborative Community Moves Forward

The Medical Device Servicing Collaborative Community (MDSCC) is moving forward with plans to support the safe and effective servicing of medical devices. The interdisciplinary group—initially envisioned by the Food and Drug Administration (FDA)—first convened an exploratory meeting in April 2019.

The group comprises various stakeholders that have an interest in device servicing, such as in-house HTM departments, independent service organizations, device manufacturers, and regulatory/accrediting bodies. The mission of the MDSCC is to bring together the community of stakeholders to advance the safety, effectiveness, and quality of medical device servicing.

According to the working charter drafted by the MDSCC, “the medical device servicing industry currently lacks a shared understanding of how to define safety and quality and the associated responsibilities.” The document also notes that the community supports the FDA’s goals “to achieve common outcomes, solve shared challenges, and leverage collective opportunities.”

Examples of efforts underway within the group include the establishment of key performance indicators (metrics that define what constitutes safe, effective, and high-quality servicing); identification of best practices for designing a training program for servicing; educating the various stakeholder groups about the challenges and requirements each stakeholder group faces; and defining key aspects of quality management.

In 2018, the FDA published a report of its findings regarding the safety of device servicing, noting that there was insufficient evidence available to determine whether significant problems with device servicing exist in the current healthcare landscape. And while the FDA did not find justification to impose new regulations regarding servicing, the agency recommended the establishment of the Collaborative Community to bring stakeholders together to explore service-related issues more closely.

The FDA made it clear that it would not take ownership of the community, but that it would participate in it as an equal partner.

AAMI—which has participated in the group since its inception—hosted the initial face-to-face meeting in April 2019.

During the COVID-19 pandemic this year, the Collaborative Community paused its activities for several months. In June, however, the group reconvened and recommitted to accomplishing its goals. During the coronavirus-induced break, some Collaborative Community participants chose not to resume their participation. But other groups elected to resume activities under the banner of the Medical Device Servicing Collaborative Community.

Outcomes and deliverables emanating from the MDSCC are intended to be helpful and informative consensus documents and resources, rather than new legislation or regulation.

### AAMI Standards Monitor Digest

**Highlights for the standards community**

**New Work**

- **AAMI/CN, Small Bore Connectors Committee** is working on the revision of AAMI/ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications—Part 7: Connectors for intravascular or hypodermic applications*. Contact Colleen Elliott at celliott@aami.org.

- **AAMI EQ, Medical Equipment Management Committee**. The committee is working on the development of AAMI EQ110/Ed.1, *Guidance for health care technology management education programs*. This standard seeks to provide a recommended framework for new or established education programs in health care technology management (HTM). Contact: Patrick Bernat at pbernat@aami.org

To get updates on the latest standards activities, including calls for comments and notices about meetings, subscribe to AAMI’s free monthly Standards Monitor Online newsletter at [www.aami.org/standardsmonitor](http://www.aami.org/standardsmonitor).

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CMS, FCC Push for Permanent Telehealth Expansions

Actions by both the Federal Communications Commission (FCC) and the Centers for Medicare & Medicaid Services (CMS) are on track to establish telemedicine as a permanent fixture of the U.S. healthcare system during and after the COVID-19 pandemic.

Under a proposed rule, CMS would permanently allow as administrative costs the expenses related to telehealth for over 11,000 home health agencies that are registered with Medicare for patient care.

To be eligible under the proposed rule, the telehealth visit must be outlined in a care plan, be part of a treatment goal, and be related to skilled services being provided such as physical or occupational therapy.

Writing in the journal Health Affairs, CMS administrator Seema Verma detailed the growth of telemedicine since the pandemic began. “Before the public health emergency, approximately 13,000 beneficiaries in fee-for-service Medicare received telemedicine in a week … in total 9 million beneficiaries have received a telehealth service during the public health emergency, mid-March through mid-June.”

Under Medicare and many private insurers, telemedicine services include phone-only visits and patient/provider interactions by email.

The FCC announced it has given out its full allotment of $200 million under its COVID-19 Telehealth Program to support more than 500 healthcare providers across the country who have expanded telehealth. Much of the FCC funding covered the costs of laptop computers, tablets, video monitors, and network upgrades at hospitals and community centers.

Other FCC telehealth initiatives include:

- The FCC waived gift rules in the Rural Health Care programs to allow healthcare providers to accept improved capacity, Wi-Fi hotspots, networking gear, or other equipment or services to support doctors and patients during the coronavirus outbreak.
- Increased funding of $42.19 million for the Rural Health Care Program to promote telehealth solutions for patients during this outbreak.
- A waiver for GE Healthcare to expedite medical equipment such as wearable patient monitors, diagnostic testing systems, and portable X-rays from new suppliers during the pandemic, and one for MIT for certification and marketing of its WiTrack system for remote patient monitoring.

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ATS2015 is a useful tool for:
- Independent testing labs conducting validation studies of reprocessing instructions for cleaning, disinfection and sterilization.
- Medical device manufacturers conducting their own validation testing, or for use during the design phase to assist in developing devices which are “reprocessing friendly.”
- 3rd party reprocessors to validate their cleaning and reprocessing methods for single-use devices.

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HTM Educators, Students Adapt to Displacement in a COVID-19 World

As COVID-19 swept across the world, uncertainty about the spring semester, the school year, graduations, and internships spread even faster among healthcare technology management (HTM) educators and students. Rescuing education programs has become a new kind of gauntlet for them. In a field where keeping pace with ever-changing, life-saving technologies is the norm, AAMI members and educators have been up to the task.

The Lucky Ones
For James Linton, professor of biomedical engineering technology (BET) at Saint Clair College, Ontario, a gut feeling allowed him to save some students’ semester.

“On a Wednesday, just before spring break, there were talks about shutting down [the college] and I started getting this vibe that, no, we weren’t coming back,” he said. Fearing the worst, he sent an email to his students, urging them to finish a semester’s worth of HTM labs while the machines they needed were still available to them. They had three days before shutdown.

“They dug in their heels for long, 10-hour days,” said Linton. “It was grueling, but I’d say that at least 75% of them got it all done. I had really dedicated students, so it worked out.”

With their studies complete and enough knowledge to entice employers, these students were even able to find work and volunteer opportunities at Canadian hospitals bracing for the inevitable first wave of ventilator maintenance.

Trouble with a Hands-Free World
You could say that Linton’s students were the lucky ones. For HTM, hands-on experience is an invaluable resource. “If you remove that hands-on aspect, it’s going to be hard,” said Danielle McGeary, vice president of HTM at AAMI. “You can watch a video a million times and someone can talk you through it, but until you’ve actually opened up that device, you can’t really understand all the components.”

A lot of people are under the misconception that healthcare was unscathed during this pandemic, when in reality they’re one of the hardest hit.”

—TRAVIS AHLQUIST, DAKOTA COUNTY TECHNICAL COLLEGE, MN

One way that HTM professionals gain that experience is through internships and part-time positions at hospitals. During a pandemic, those opportunities become sparse. “A lot of people are under the misconception that healthcare was unscathed during this pandemic, when in reality they’re one of the hardest hit,” said Travis Ahlquist, a BET instructor at Dakota County Technical College, MN. “Things that actually bring a lot of money into the healthcare system like elective surgeries and routine care got put on hold,” he said, “and because they got hit so hard, hospitals have gone into hiring freezes.”

Because the danger of exposing untrained students to a pandemic situation is so great, many internship programs are similarly on hold, which leaves recent and soon-to-be grads with nowhere to go.

Finding a New Edge
This worries Ahlquist, who acknowledges that employers often hunt for real-world experience in a résumé. To help his students, he’s making calls. “I worked with Danielle at AAMI, and together we found a lot of HTM professionals willing to have a phone or video interview with displaced students,” he said. Students can get tips on résumé building and ask questions, vicariously absorbing what they can from working HTMs.

Ahlquist admits that these calls don’t replace an internship, but they do provide and edge to students. “It could be very valuable in the future and we’re considering weaving them into an internship program or a class even after COVID-19,” he said.

Joie Marhefka, BET program coordinator at Penn State New Kensington, is taking a similar approach with her students. “We’re trying to help them create contacts that they’d otherwise be unable to make because they’re not in the hospitals,” she said. “Between that and online classes, there’s a lot of troubleshooting.”

One benefit of the pandemic is that it’s inspiring educators to invent new learning experiences. Marhefka recently asked her students to try to solve problems with a piece of equipment that’s not in front of them—a difficult proposition that tests their knowledge and ability to visualize.

Meanwhile, Linton is challenging Saint Clair College with a new five-year plan to have at least 33% of BET courses fully online and at least 40% of courses with some aspect of virtual reality learning. “We’re going to build out these supplemental strategies so that, should we ever be stuck at home again, we can flip a switch and classes are still in session,” he said.

McGeary has served as the bridge that’s getting AAMI knowledge into the hands of these educators as they explore new teaching avenues. “Our members are forced to adapt and overcome, and this pandemic is no different. They’re not just surviving, they’re adapting.”
Potential International HTM Standard Emerges

A Malaysian standard addressing the maintenance and management of medical devices was recently approved to be utilized as the basis for development into an international standard. The creators of the standard, which has been a requirement in Malaysia since 2008, are interested in evolving their local standard into an international one for the benefit of the international medical device community.

This standard specifies requirements of what Malaysia refers to as “good maintenance management of active medical devices.” It applies to any active medical devices in any healthcare or other facility that require maintenance. The developers of the Malaysian standard have formally proposed that it be considered internationally to ensure that medical devices are managed in healthcare facilities so that they function in their intended manner; they are safe for the patient and user; and their interruptions of use are minimized.

Although the standard has been a formal requirement in Malaysia, that would not be the case internationally. Once published, it would join the collection of international voluntary consensus standards. It would be up to industry and each regulatory jurisdiction to determine how to use it.

AAMI has an active healthcare technology management (HTM) standards development program and will provide feedback and expertise to contribute the U.S. perspective to the international effort. The participants of AAMI’s HTM-related standards efforts will likely see value in supporting the international promulgation of the Malaysian standard for the good of the international community.

“It’s an exciting opportunity to discuss device maintenance issues on an international level,” said AAMI Director of HTM Standards Patrick Bernat.

Standards Malaysia, the Malaysian national standards body, proposed the standard project to ISO/TC 210, Quality management and corresponding general aspects for medical devices—an international technical committee focused on general aspects of quality and performance of medical devices. “The commitment and dedication of the Malaysian experts to share this standard with the world has been rather inspiring,” said Wil Vargas, senior director of standards at AAMI and committee manager of ISO/TC210.

Anyone interested in participating in AAMI’s HTM standards program should contact Patrick Bernat at pbernat@aami.org. Those interested in participating in this international activity should contact Wil Vargas at wvargas@aami.org.
In Memoriam: Sérgio Santos Mühlen

Professor Sérgio Santos Mühlen, president of the Regional Council of Biomedical Engineering for Latin America (CORAL), passed away suddenly on June 27, 2020. He is survived by his wife Renata Guimarães, son Luis Sérgio Mühlen, and grandsons Thomas and Benjamin.

Professor Mühlen was considered an excellent teacher who helped educate a very large number of biomedical and clinical engineers in Brazil and Latin America. In addition, he held several leadership positions in the Brazilian Society of Biomedical Engineering, serving as its president in 2015–16, and was also a founder of the Brazilian Association of Clinical Engineering.

He was vice president of CORAL in 2017–20 and became its president early this year. In these roles, he was considered by all as a truly charismatic, inclusive, conciliatory, and friendly person, always willing to listen to different opinions and while building consensus among different stakeholders.

I had the privilege of guiding Professor Mühlen early in his career, serving as his master’s thesis advisor in 1984–85, and hired him in 1990 for the Department of Biomedical Engineering of the State University of Campinas (UNICAMP) in Brazil after he earned his doctoral degree from the Institut National Polytechnique de Lorraine, France. After starting graduate studies, he dedicated himself to learning and research. He always asked tough questions, wanting to know why things worked the way they did, and becoming fascinated when he found the right answer.

At UNICAMP, Sérgio devoted his academic career to biomedical and clinical engineering. Besides the usual teaching and student mentoring, he also served in 1994–98 as the director of the Center for Biomedical Engineering, founded to conduct research and provide clinical engineering services to the university hospitals.

He retired in 2017 but continued to teach occasionally and was an active participant in many professional activities in Brazil and worldwide. I last saw him last October at the Latin American Congress of Biomedical Engineering in Mexico. We had several long chats and a wonderful dinner with him and his lovely wife. I will cherish all the wonderful memories of him and miss him tremendously as a true friend.

Binseng Wang is vice president of program management at Sodexo Clinical Technology Management in Brentwood, TN.
AAMI Partners with Amplifire to Bring Cognitive Science, Analytics to Training

How well do doctors, nurses, sterile processors, and other users of healthcare technology and equipment really know about the devices they use every day? How much clinical, regulatory, and reputational risk do industry and hospitals face because of misinformation and knowledge gaps that are prevalent among users?

Amplifire, a leading eLearning and performance platform, can answer such questions. A case in point: About 30 million Foley catheters are inserted each year, leading to nearly 1 million catheter-associated urinary tract infections, according to an Amplifire case study. Yet as many as 50% of urinary catheterizations are unnecessary—and even properly ordered catheters can cause infections if guidelines are not strictly followed. A major U.S. health system used Amplifier training to learn what nurses knew and didn’t know about managing urinary catheters. The findings: 49,572 instances of confidently held misinformation and uncertainty. After completing the training, 100% of nurses were confident and correct on every topic.

AAMI has now formed a strategic partnership with the Boulder, CO–based company. “We’ve invested heavily in upgrading our education offerings—overhauling core components of our curriculum, investing in new courses and certifications, and launching our state-of-the-art AAMI Center for Excellence to support classroom-based and live-streamed training,” noted Rob Jensen, president and CEO of AAMI. “Now, we’re turning our attention to transforming the delivery of online education. To that end, we are delighted to announce a strategic partnership with Amplifire, the leader in leveraging cognitive science to radically improve training outcomes.”

As a part of the strategic partnership, AAMI has joined the Amplifire Healthcare Alliance and will leverage AAMI content and subject-matter expertise to add medical device and health technology courses to the Alliance network. In addition, AAMI will work directly with medical device manufacturers, independent service organizations, and healthcare delivery organizations to develop custom solutions using the Amplifire platform. AAMI’s industrial sterilization course is expected to be ready in October.

“AAMI is the de facto world leader driving the safe and effective use of medical devices,” said Bob Burgin, CEO of Amplifire.

“Their standards are used worldwide in manufacturing, servicing, and healthcare delivery; their education programs set the bar for quality; and AAMI members, like members of our own Science Board, are thought-leaders in their field. We can’t wait to see what they can do with the Amplifire platform at their disposal.”

“Amplifire’s results across multiple industries have been astounding,” said Robert Burroughs, senior vice president of education at AAMI. “They’ve proven they can drive significantly improved outcomes while reducing training time. Even better, Amplifire has made the invisible visible, and it’s now possible to get an accurate snapshot of your workforce’s competency before and after training.

“I’ve been focused on organizational effectiveness for 20 years and this is the first time I’ve felt we have the power to really do something radically different and better than we could before the advent of online learning,” Burroughs added. “This isn’t just about using online learning to drive down the cost curve or facilitate distribution, it’s about leveraging science to do something we couldn’t even imagine doing 20 years ago—in the classroom or online.”

How Amplifire Training Works

Amplifier developed its platform with a literal brain trust—leading neuroscience and cognition experts. The platform incorporates seven research-based “triggers” that switch on learning and memory in the brain, according to an Amplifier paper, 7 Ways to Build a High Performing Workforce in Your Organization:

1. **Adaptivity** provides each employee exactly what they need when they need it.
2. **Evaluating confidence** keeps employees focused and improves their memory.
3. **Delayed feedback** to correct an error makes the correction more powerful.
4. **Gamification** keeps dopamine levels optimal so employees keep learning.
5. **Priming** by asking questions prepares the brain to learn—even if the material is brand new.
6. **Retrieval** of information from memory is the best way to strengthen knowledge.
7. **Spacing** between learning sessions makes the learning far more durable.

“Under the hood, this platform has algorithms that are paying attention to your every move,” said Brad Schoener, vice president of innovation at AAMI. “How long you take to answer questions, what sort of answers you try, how much struggle is involved in finding the answer.”

The platform usually asks two things: What’s the answer, and how confident are you that the answer is correct? That confidence index gets at the emotional aspect of learning and identifies where your confidently held misbeliefs are, Schoener said. Then, the learning platform adapts the content to every single learner.
Making HTM a Family Affair
Continued from page 1

Diane—had been in hospitals, she would come home and be on the phone with customers. I instinctively call her mom, because she’s been my mom for 37 years. I’ve had to train myself to call her Diane.”

Geddes’ niece Ashley Proctor and daughter Jessica Wortman joined the company shortly thereafter. Both had just graduated from college. Proctor with a degree in exercise physiology, Wortman with a degree in animal science. “When I started, I had no idea that this would be my career path,” said Proctor, who lives in California. “I love interacting with people in the industry. Everybody is really nice, super helpful. I wouldn’t want to work anywhere else now. I love it so much.”

“I became interested in the field by growing up watching my mother work in the industry for my entire life,” said Wortman, who lives in Huntsville, AL. “It always seemed to connect her with interesting places and people.”

How do the women navigate working in the same field and company? “We all live in different states and work remotely,” Geddes said. “It’s given us a reason to talk every day. It’s made us closer. I’ve seen all of these girls grow in their wonderful careers and personally. At the end of the day we’re family. We respect each other and know each other’s personalities. There are definitely days that it’s challenging to wear the hat of being a mom or aunt and being the owner of a company. Sometimes Lacey, especially, will call and say, ‘I just want to talk to my mom.’”

“This is a family business,” McArn said. “It’s not like working for another company. It’s more than a job here. It’s mom’s baby. This is something that she created and that we want to continue to nurture and grow and baby and not let anything happen to it.”

“Working with family is first and foremost a blessing,” Wortman said. “But it is also important to keep work and family matters separate. I try not to discuss personal matters on the same phone call as work matters.”

Brothers Take Different Routes to HTM
Neither Jonathan McNamara nor his brother Peter McNamara set their sights on HTM early in their careers. Jonathan, a biomedical equipment program specialist at Indian Health Services in Portland, OR, spent four years in the Navy working on fighter jets before earning a bachelor’s degree in electronics engineering technology from the Oregon Institute of Technology. After graduating, he worked for an architectural and engineering firm. “I actually found it terribly boring,” he said. “It was all cubicle work. It was just about knowing the electrical codes, applying the codes, rinse and repeat. I found it uninspiring.”

He hightailed it to a job fair, eager to find another job quickly. He did, as a biomedical equipment technician (BMET) at Providence health system in Portland. “I had been a technician in the Navy,” Jonathan said. “I really enjoyed the work. I excelled in it. It was a very comfortable place to go”—although he didn’t know if he would stay in the HTM field. Spoiler alert, readers: He did.

Peter took a decidedly different path to an HTM career. He earned a degree at Western Culinary Institute in Portland. “I really like working with my hands,” he said. “After five or six years of doing that, I realized I needed to get out because this was no way to make a living and actually have a personal life.”

He landed a job as a transporter at Providence, mainly moving patients to and from the diagnostic imaging department. “From there, I got to know a lot of techs and a lot of different modalities,” Peter said. He considered and even applied for an X-ray technician program, but then moved in a different direction. “Every once in a while, Jon would be on site. We’d have lunch and I’d hang out with the other biomeds. And they seemed like a pretty cool crew.” The manager of the in-house biomed shop let him job shadow technicians for a day. “I just ran around with those guys. With it being working with your hands all day and troubleshooting and problem-solving, I was sold after that.”

While continuing to work as a transporter, Peter advanced his skills in a two-year electrical engineering technician program at Portland Community College. Whenever he had an electronics question, Jon was his go-to resource. As soon as Peter earned his degree, he landed a position as a BMET at Providence.

“I had taken my CBET (certified biomedical equipment technician) exam and earned the certification,” Jonathan said. “I really encouraged Pete to do this too.” Peter responded, “And I was like, ‘Yeah, I know I just got out of school but I’m going to go home and study for another 15 minutes a night to just get this knocked out.’” Like his brother, he is now a CBET, working on the surgery team. He jumps at the chance to take on special projects, such as designing and 3D-printing plastic cases for patient tracker badges.

Jonathan and Peter worked together at Providence for two years in different shops before Jonathan moved to managing programs in Oregon, Washington, and Idaho for Indian Health Services. Because of their three-year age difference, they never developed a sense of competition with each other. And they still talk shop when they get together (virtually, these days).
New Collaboration Between AAMI, Archimedes Center Promises Greater Innovation in Medical Device Security

AAMI and the Archimedes Center for Medical Device Security in Ann Arbor, MI, have announced a new collaboration to advance the practice of cybersecurity. The two organizations will work together to connect their networks of medical device and health technology professionals across the country.

“Cybersecurity is a major area of concern for medical device safety, and it’s an area where AAMI has been active and will be even more active in the future,” said Robert Burroughs, AAMI senior vice president of education. “Our collaboration with Archimedes will expand the reach of some of the world’s leading experts in the area of cybersecurity and lead to new education offerings and resources that will drive patient safety. We welcome them as members to the AAMI community.”

Archimedes was the first of its kind to bring together the different stakeholders from the medical devices industry—including healthcare providers, medical device manufacturers, security researchers, and regulators—for the purpose of solving security challenges. Housed at the University of Michigan’s Computer Science and Engineering department, the unique center is funded by 17 institutional members to support graduate students and train healthcare professionals to better integrate security engineering into medical device design, procurement, and operation.

AAMI staff cited a growing focus on security across the medical devices industry as a major motivation behind the collaboration.

“There are a few things happening in the future that are really crucial for medical devices,” Burroughs said. “In an Internet-of-Things world, cybersecurity is already here today as an issue and it’s only going to grow in importance.”

The two organizations intend to connect their membership and stakeholder networks to work on advancing security practices for these life-saving devices. Potential outcomes of this initiative include a standardized healthcare and medical device security curriculum for manufacturers and healthcare delivery organizations.

Introducing a New Risk Management Resource

ANSI/AAMI/ISO 14971, Medical devices—Application of risk management to medical devices

This American National Standard specifies a process by which a manufacturer can identify the hazards associated with medical devices. This standard is now available in the AAMI Store.

Product Code: 149712019PDF

For more information, please visit www.aami.org/store.
As a thank-you for participating in HTM Week, AAMI sent healthcare technology management professionals #IamHTM face masks, including the team at Morton Plant North Bay Hospital in Clearwater, FL. Left to right: Nick Grecco (AAMI & GE Healthcare’s BMET of the Year), Joe Moscato, Dennis Stewart, and Colin O’Connell.

AAMI eSubscription
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An eSubscription allows multiple individuals across your enterprise to easily access standards. Whether you need a particular set of standards—such as sterilization—or a wide range, you can choose a plan that meets your organization’s needs.

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App coming soon! For complete details, visit www.aami.org/eSubscription.
Let’s Collaborate to Create a Health Technology ‘Dream Team’

Matt Dummert is the healthcare technology management director for Froedtert & the Medical College of Wisconsin; an adjunct online instructor for Indiana University–Purdue University Indiana and Marquette University; creator of the ParadigmHTM podcast; and a member of the Biomedical Instrumentation & Technology (BI&T) Editorial Board.

We live in a polarized world, which implies opposing viewpoints and little collaboration and compromise, often expressed by people taking sides on “teams.” Unfortunately, polarization also occurs in the medical device industry. We choose a team, and place our loyalty behind it, while resisting the reality that we are in an infinite game where there are no “winners.”

Sports offers a good analogy. We sports fans obsessively arrange our schedules around our favorite teams’ broadcasts; wear authentic, authorized jerseys; and sometimes cover ourselves in body paint and ridiculous hats. Many of us choose our teams based on where we live, where we went to school, or through a family tradition.

I was born, raised, and still reside in Wisconsin, so I could go on about how the Green Bay Packers are the greatest sports team on the planet. But if I’m honest, the primary driver of my loyalty is that I am from the place the Packers also call home. I will seek out evidence to support my view of their greatness. If I am presented with evidence that opposes my view, I will simply put more weight into factors that support my perspective and downplay the relevance of negative evidence. For sports, this is “team loyalty.”

In the medical device servicing industry, many of us identify with one of three teams: original equipment manufacturers (OEMs), independent service organizations (ISOs), and hospital-based programs. We can find evidence to support how exceptional our team is—and evidence for why the other teams are not so exceptional. This biased loyalty is exaggerated by our abundant access to quick references that we can cherry pick, detailed data sets we can filter in just the right way, and, in some cases, confusion over inaccurate or misleading information.

Loyalty is just “supporting your team” and taking pride in the great work you all do, right? But if we are not careful, this can turn from rooting for your team to rooting against the other teams. Since I’m a Packers fan, you might assume that I hate the Chicago Bears, who have battled my team for decades. Actually, this is not the case! I want the Packers to be successful in an exceptional division of worthy opponents, including the Bears.

Strong opponents make us stronger. They push us to new limits, force us to innovate, and inspire us to elevate our game. OEMs, ISOs, and hospital-based programs are all teams playing in the same division. We all need to be strong to elevate the industry. We need to focus our energy on becoming better versions of ourselves while rooting for and supporting our worthy “opponents.”

Sometimes, that support requires direct collaboration. Patients who rely on our technology don’t see three distinct teams. They just assume someone is taking care of the medical devices. That “someone” is the healthcare technology management (HTM) industry. HTM is more than hospital-based programs. It’s all of us working together:

- OEMs offer design and engineering, which can bring the wildest dreams of technology to life. They can develop resources to enable servicers to keep technology safe and effective.
- ISOs bring an economy of scale and large datasets that drive standardization. They can share that experience to help the industry be more efficient and more coordinated.
- Hospital-based HTM programs bring the practical application of technology service within diverse and dynamic healthcare environments and cultures. They manage the entire ecosystem where the physical, financial, and political environments influence the technology.

Imagine what we could accomplish together if we all brought our strengths into a culture of collaboration—a health technology Dream Team.
AAMI Foundation Awards 2020 Research Grants

Continued from page 1

Washington University and the Regenstrief Center for Healthcare Engineering at Purdue University.

Developing Utilization-Driven Management of Connected Medical Equipment

The AAMI Foundation awarded $69,565 to a research team at George Washington University, led by Ekundayo Shittu, assistant professor of Engineering Management and Systems Engineering. The group will explore the potential impact of utilization-based alternative equipment maintenance (AEM) programs.

“In recent years, AEM programs have gained traction in the healthcare technology management (HTM) field, but their full potential remains untapped as available data has been limited to maintenance records and risk assessments,” Shittu said. “Fortunately, this is rapidly changing with the rise of connected medical devices that wirelessly report their status and utilization. HTM professionals will be able to schedule planned maintenance based on equipment usage, or by using more advanced techniques that take into account when, where, and how equipment is used.”

With the funding received by the AAMI Foundation, Shittu and his team are developing a software tool that will enable others in the HTM community to evaluate the effect their AEM programs have on patient safety, equipment availability, and cost reduction.

Shittu hopes that the research will revolutionize the field of HTM. “This project aims to catalyze an industry-wide paradigm shift towards utilization-based AEM. By showing that such an approach is both effective and attainable in this new era of connected devices, this project will provide a foundation upon which other HTM innovators can build and will signal to stakeholders across the industry an opportunity for additional research and investment.”

An Informatics-Driven Dashboard for Infusion Safety Advancement

Poching DeLaurentis’ research at Purdue University focuses on collecting data from smart infusion pumps in collaboration with clinicians who use them daily. She has noticed the drawbacks of not having a uniform system that analyzes detailed infusion data.

“We live in an age of digital data—we generate and can receive or collect lots of data from various sources. However, not everyone is equipped or has time to extract meaningful information out of the abundance of data,” DeLaurentis said. “I see opportunities in extracting data from smart infusion pumps and using advanced analytics and algorithms as tools to present meaningful information so clinicians can prioritize their actions in maintaining and improving patient safety practices.”

DeLaurentis and her team aim to design and implement an infusion safety dashboard on the community-supported Regenstrief National Center for Medical Device Informatics (REMEDI) web portal (CatalyzeCare.org). It will be powered by computational algorithms that evaluate infusion data from smart infusion pumps. They were awarded $50,000 by the AAMI Foundation to aid in this project.

DeLaurentis expects that the research will influence future smart pump management as well as device design and requirements. “The safe infusion dashboard will provide a set of concise, easy-to-understand metrics of selected infusion safety measures as outlined by ISMP (Institute for Safe Medication Practices), and therefore serve as a guide for clinicians to reach those specific best practices,” she said.

New Dialysis Standards Available Now

Dialysis fluid quality plays a critical role in providing safe and effective hemodialysis. The NEW 23500 series of standards provides health professionals and manufacturers with guidance for handling water and concentrates and for the production and quality oversight of dialysis fluid.

Product Code: 23500
For more information, please visit www.aami.orgstore.
Looking for a Job or a Candidate?
AAMI Career Center Can Help

In these unprecedented times, searching for a job can be more overwhelming and stressful than ever. The AAMI Career Center is a valuable resource to help health technology professionals navigate your next career move or find the ideal candidate for your organization. Whether you graduated this year in a virtual ceremony, are adapting your skills in this constantly changing environment, or are hiring to cover a surging need in your hospital, we are here to support you throughout your search.

The Career Center provides 24-hour access to job openings in the health technology field, attracting thousands of professionals every week and new postings daily, as well as a wealth of helpful resources for AAMI members.

For Job Seekers
- **Searching for your next position?** While many organizations are figuring out their next move, now is the time to polish up your résumé and be considered as a top candidate when they are ready to hire.

  The Career Center allows you to upload your résumé, or you can create one online. There are a number of articles and tips on résumé writing, from things you may have forgotten to include to how to make your writing sound more professional. Additionally, make sure to increase your confidence in your résumé by taking advantage of our complimentary service to receive expert review and feedback on this important document. Once you’ve perfected it, you can include your résumé anonymously in our bank for companies to review.

- **Interested in jobs with a certain title, or in a certain location?** The Career Center allows you to create custom job alerts tailored to what you are looking for. You can easily set up alerts on your account to be notified when positions are posted that match your criteria. This is a helpful tool to use when you don’t have time to check the job boards every day, and instead the best matched postings are sent straight to you at a frequency of your choosing.

- **Need some advice?** Not only does the Career Center allow you to search for jobs and post your résumé, but you can visit the resource area of the site for practical tips and tricks to help you successfully advance in your career. Topics like interview preparation and follow-up, networking, and using social media to your advantage are all covered.

We also have guidance on tough subjects like making an industry change, searching for a job in a new city, and negotiating salary expectations. We even offer one-on-one customized career coaching for an additional fee, where career experts and job seekers work together toward specific professional goals.

For Organizations Seeking to Fill Positions
- **Recruiting to fill a role at your organization?** The Career Center empowers you, too! Choose from a variety of posting packages, ranging from one post for 30 days, to bundles that you can use over the course of a year. You can boost it by posting on additional job boards to highlight your position in emails sent to job seekers.

  You also can search the résumé bank to find the best candidate for your position and contact them via the site, inviting them to interview. The user-friendly interface makes it easy for you to keep track of your postings, interested candidates, and résumés. As a member, you receive significant savings on any available packages.

While this is a more trying time than most to search for new opportunities, the AAMI Career Center has ample resources to help you every step of the way. Utilizing job alerts, making sure your résumé is up to date, and brushing up on interview skills might just lead to your dream job!

**Visit the Career Center at www.aami.org/CareerCenter. For questions or suggestions, contact MaryJane Thomas, AAMI director of membership development, at mthomas@aami.org.**
Q What are priorities of the AAMI Board of Directors for the next year or two?
AAMI is about to embark on an ambitious two-year extension of our strategic plan, so the Board will play a significant role in helping to monitor and guide those initiatives. For example, the plan calls for projects that would strengthen AAMI’s outreach globally, modernize all of our information technology (IT) platforms to ensure they are state-of-the-art and easy to access, and better target the products and services that we offer our members and customers.

In addition, we will continue to make strides in advancing the interests of the HTM profession, which is near and dear to me. For example, we are pushing forward with an HTM apprenticeship program and a major rewrite of the HTM Levels Guide to help HTM departments around the country.

On top of that, we are tasked with “the new normal” with respect to COVID-19.

Q Has the COVID-19 pandemic had any impact on the Board’s plans?
COVID-19 has had a significant impact on the Board’s plans, forcing us all to re-examine priorities for the near future.

The Board is here to support AAMI staff in whatever they need to serve the membership as effectively as possible. AAMI has made significant upgrades to the IT infrastructure to help improve remote learning and support “work from home” and remote meetings of standards committees and other groups. Changes like this and changes that will be made in the future will all help AAMI to be agile and responsive to new needs of the next few years.

Q You’ve retired as a full-time professor, but you continue to teach. Did you switch to remote learning in the spring semester? If so, how did you manage that? How did students respond?
I did switch to total remote learning about halfway through the spring semester. My HTM courses are already hybrid, which means that we meet partially live and partially virtual. This was done many years ago to accommodate students since we are a cooperative education college and we have some students working every semester. This enabled them to work with employers to be able to attend classes even when they are working. We also have students traveling longer distances to class to get HTM courses. The hybrid approach also helps them.

The main challenge for me was establishing quality laboratory experiences. We used YouTube videos and the AAMI CBET (Certified Biomedical Equipment Technician) review course to help with this. We are planning to be totally virtual in the fall 2020 semester.

Q Is the future of HTM education online?
I feel that the future of HTM education is going to be partially online as it often is now. I think it’s important for students to be comfortable with remote and computer-based learning. Lots of training is conducted online even after graduation from college because of funding of travel and so on. Most of our employers want graduates with experience in online course work.

I truly believe that HTM education must also include live, hands-on experiences. A live laboratory experience as well as an internship or cooperative education experience is crucial to a quality educational program. I also prefer some face-to-face time with students for discussion and answering questions.

Q What are you doing in your spare time, now that the golfing, traveling, and sporting events you enjoy are curtailed?
I have to say that my garage is as clean as it has ever been. When the shutdown first started, we worked on a lot of home projects that we had been putting off. My wife and I have really missed traveling and sporting events. These things have been a big part of our lives this time of year. Now, I am playing a little more golf, although not that much. Golf is a sport where it is a little easier to socially distance.
Mary Ann Drosnock has been promoted to director of clinical affairs at Healthmark Industries in Allentown, PA.

Rick Edwards is now IT program manager at the University of Maryland Medical System in Linthicum Heights, MD.

Edward Reyes has started a new position as biomedical equipment support specialist at the U.S. Department of Veterans Affairs in Orlando, FL.

Bianca Wyman has started a new position as a clinical engineer at Lifespan in Providence, RI.

Have you changed organizations, been promoted, or won an award? Contact us at publications@aami.org so you can be featured in an upcoming issue.

Members on the Move

Mary Ann Drosnock

Rick Edwards

Edward Reyes

Bianca Wyman

AAMI All-Star

SAMANTHA JACQUES, PHD, FACHE
Vice president, clinical engineering at McLaren Health Care in Grand Blanc, MI

AAMI activities: Vice chair of the Healthcare Technology Leadership Committee (HTLC), member of several standards committees, and a member of the AAMI Foundation’s former National Coalition for Alarm Management Safety

Most enjoyable part about volunteering: “I enjoy working with AAMI’s diverse group of stakeholders. The varied membership lets me learn about other perspectives on a variety of topics related to healthcare technology management (HTM). There isn’t another association where I can work on standards one day, write an article for BI&T the next day, and help set direction on the HTLC the day after. The diversity of people I work with and breadth of topics we affect makes you feel like you’re making a real difference.”

Something people might not know about me: “HTM is a second career for me. I started my career in academia teaching in undergraduate biomedical engineering programs and conducting research. I continue to use those skills to champion continuing education in my staff. I plan to go back to teaching upon my retirement as I believe we need to continue to educate the next generation of HTM leaders.”

New Member Organizations

ADVOCATE AURORA HEALTH
Oak Brook, WI
www.advocateaurorahealth.org

AMERICAN GASTROENTEROLOGICAL ASSOCIATION
Bethesda, MD
www.gastro.org

BOSTON SYSTEMS CONSULTING LLC
Boston, MA
www.bostonsystemsconsulting.com

LOMPOC VALLEY MEDICAL CENTER
Lompoc, CA
www.lompocvmc.com

ORCHESTRA BIOMED INC.
New Hope, PA
www.orchestrabiomed.com

PRONK TECHNOLOGIES INC.
Sun Valley, CA
www.pronktech.com

AAMI Virtual Training

Ethylene Oxide Sterilization for Medical Devices

August 25 - 28 | Virtual

Participants experienced in working with an established ethylene oxide sterilization process come together to examine new challenges to ensure continued effectiveness.

aami.org/training/E-O-S
"Must-Have" TIR24971 Complements Risk Management Standard

A long-awaited technical information report (TIR) that provides state-of-the-art guidance on applying a fundamental risk management standard has just been published.

Already, AAMI/ISO TIR24971:2020, Medical devices—Guidance on the application of ISO 14971, has been a hot seller as a draft document. The TIR offers guidance on management responsibilities, components of a risk management plan, and the risk analysis and evaluation process. It is a companion piece intended to be used and applied together with the standard, ANSI/AAMI/ISO 14971:2019, Medical devices—Application of risk management to medical devices, which establishes a process for medical device manufacturers to identify, evaluate, and manage risk.

The standard and TIR were developed by ISO TC210—Quality management and corresponding general aspects for medical devices, JWG1—Application of risk management to medical devices.

“TIR24971 is the document that industry has been waiting for to apply risk management,” said Mark Swanson, president of H&M Consulting Group, LLC, and a member of the joint working group. “It is a must-have for anyone in the medical device industry to fully understand the concepts and intent as they look to apply risk management to meet ISO 14971 and the applicable regulatory requirements.”

“Risk management as a topic is only becoming more important to the medical device industry as devices are becoming more technically complex and manufacturers push innovation,” said Wil Vargas, senior director of standards at AAMI. “The revised guidance helps to ensure all are understanding and applying the principles of risk management in a harmonized, repeatable way, which will ultimately improve the safety and efficacy of medical devices.”

What’s New in TIR24971?

TIR24971 is the result of three years of intensive effort by the joint working group to align the guidance with the revised ISO 14971 standard, according to Edwin Bills, a consultant and a member of the group.

“The revision intends to bring the standard fully in line with regulatory expectations, so that it is fit for the next decade,” said Jos van Vroonhoven, senior manager of standardization for Global Regulation & Standards at Philips and convener of ISO/TC 210—IEC/SC 62A JWG1. “The revision of both the risk management standard and the TIR reflect changes in regulatory requirements, not only the Medical Device Regulations (MDR) in the European Union, but also with more focus on benefits and risks in several other jurisdictions.”

“This guidance has gone beyond the previous version of the TIR and the standard to answer all the questions that organizations had about how to implement life-cycle risk management within their organization,” said Tina Krenc, principal consultant for KTA Compliance Consulting, lead instructor for AAMI’s industry training course on Integrating Risk Management into the Product Life Cycle, and a member of the joint working group. “These two documents are considered state-of-the-art in medical device risk management.” Krenc cited specific areas that address questions or misunderstandings:

- The difference between the policy for determining risk acceptability criteria and actually defining criteria for risk acceptability
- Using criteria for risk acceptability in evaluating individual risks and overall residual risk
- Using the standard for products that were not initially developed using a risk management process
- Risk management and medical device security

"TIR24971 is the document that industry has been waiting for to apply risk management.”

—MARK SWANSON, H&M CONSULTING GROUP, LLC

“A large revision in the standard covers the production and post-production portion of the life cycle of the devices,” Bills said. “It requires a more active process to understand device performance in the field. Hopefully, manufacturers will form a closer relationship with the users to get data on the performance of the current devices to create new devices and correct more quickly any issues that appear in the field.”

In addition, healthcare delivery organizations could benefit from the revised TIR, Vargas said. “The risk management process can be part of a quality management system—for example, one that is based on ISO 13485:2016, Medical devices—Quality management systems—Requirements for regulatory purposes. But this is not required by ISO 14971:2019. Some requirements in ISO 13485:2016 (Clause 7 on product realization and 8.2.1 on feedback during monitoring and measurement) are related to risk management and can be fulfilled by applying ISO 14971:2019.” The handbook on ISO 13485:2016, Medical devices—A practical guide, is also useful for this purpose.

For more information, visit the AAMI Store.
NEW COURSE!

Lead Auditor for Management Systems and Processes – Principles & Practices

September 15 & 16 | Virtual

A Lead Auditor is responsible for leading an audit team in an organization—preparing the audit plan, delivering meetings and submitting audit reports. AAMI’s 2-day Lead Auditor course teaches participants the requirements of and how to utilize ANSI/AAMI/ISO 13485. Join us to gain understanding of best practices of auditing quality managements systems as defined in ANSI/ISO 19011.

For more information, visit aami.org/training/lead-auditor
Focus on Service and Repairs, Pages 6–11

Upcoming Events

- HTMLive!: Understanding the Stages of ACI Certification
  August 11  Online
- Integrating Risk Management into the Product Life Course
  August 18–20  Online
- AAMI Summer Learning Series: IoT Track
  August 20–September 11  Online
- Ethylene Oxide Sterilization for Medical Devices Course
  August 25–28  Online
- AAMI/CQT Solutions Quality System Course
  September 7–11  Online
- HTMLive!: Protecting & Maintaining Medical Devices
  September 8  Online

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