



ACCE News

Newsletter of the American College of Clinical Engineering

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President’s Message



Dear ACCE Community,

I trust each of you are healthy and having a productive first quarter! I am thrilled to share updates in this newsletter about ongoing activities and share appreciation for our members.

Our Education Committee has been making great strides in delivering quality content. A big shout out to Nader and Tony for paving the way. As the demands of their day job have increased, Nader and Tony are taking a step back to hand-over the Committee activities to Mike Powers and Juuso Leinonen as the new co-chairs. Mike and Juuso have been active members of the Education Committee and are engaged in several industry workgroups. This helps keep up with trends and incorporate the latest and greatest in our content delivery. Thank you Nader and Tony for all your efforts and Mike and Juuso for stepping in!

Our Membership Committee is hugely responsible for building a strong close-knit community and kudos to Juuso who has done a fantastic job at it! With his transition over to the Education Committee, I’m grateful to announce that Amy Klemm is taking over as the Membership Committee chair! Thank you Amy for stepping in and continuing to lead the efforts.

ACCE is going big with the CE-IT Symposium at HIMSS23 in Chicago, IL on April 17, 2023. This year’s theme and topics circle around securing IoMT proactively – which is a very relevant, much-needed, and timely topic. While most of us HTM/CE practitioners are well into cybersecurity efforts, there is still a long way to go so we can build our processes, mature our programs, and secure these devices proactively. The lineup of speakers is excellent and for the first-time, we even have a live tabletop exercise that focuses on communication, coordination, and collaboration in incident response and management.

June is not far away and we are all getting ready to go to the AAMI Exchange in sunny Long Beach, California! For those preparing for the CCE oral exam, an [oral exam review webinar](#) was organized so make use of it and continue to prep to ace it – I’m rooting for you! Our task force is planning several noteworthy events and if you are interested to participate in any, reach out to Mike Powers, Juuso Leinonen, or Suly Chi.

Saving the best for the last – On April 6th at 12p ET, two of my industry favorites, Matt Baretich and Carol Davis-Smith presented a joint AAMI-ACCE webinar on **‘Adopting the AAMI Failure Code White Paper’**. This session provided key ways to help you elevate the way you build and monitor maintenance activities and key metrics to showcase the value of your HTM program.

In closing, my sincere thanks to all of you for the efforts you put in to ensure safe delivery of healthcare technology. I am excited and look forward to seeing you at AAMI Exchange, if not sooner!

Priya Upendra, President

American College of Clinical Engineering

president@accenet.org

Pioneer, Leader, Mentor, Innovative Thinker, Humanitarian, and Dear Friend



Marvin Dale Shepherd passed away peacefully on April 13, 2023 in Walnut Creek, California, at the age of 90. Marvin is survived by his lovely wife, Patricia Ann Shepherd. Marvin began his career in the 1960s and is certainly one of the pioneers in clinical engineering. After graduating from a Fire Safety college program and becoming a professional engineer (P.E.) in California, he transitioned into the application of his newly gained knowledge to the bedside environment and to the prevention of failure modes of medical devices while being connected to patients.

Marvin is recognized as one of the first in our field to propose a methodology that described patient safety and risk management as a system that consists of elements to be identified and controlled. Around 2002, Mr. Shepherd joined the then named "ACCE-Health Technology Foundation" Board, with a focus to teach Patient Safety. In 2006, Marvin initiated through his personal financial contribution, the annual ACCE/HTF Shepherd Patient Safety Award. It "Bestowed the award on a single individual (per Marv's request) or one entity who has excelled in the "safety" area related to the CE field. Potential awardees could be a national investigator of accidents, an inventor of a safety device, or an author of books on medical device hazards" promoting excellence in this subject matter."

Based on his contributions for over 50 years, Marv is absolutely one of the most influential pioneers and industry leaders in our profession. He has had a substantial impact on its evolution since the profession's inception. He advocated by prolifically writing and speaking widely on topics related to a systems approach to medical device safety, fire safety, electrical safety, human factors engineering, and incident investigation.

Marv's innovations in safety, human factors engineering, and incident investigation led him to develop two of what would become the clinical engineering profession's most referenced tools. One is Shepherd's System for Medical Device Incident Investigation and Reporting (Quest Publishing, 1992) and the other is the Electrical Safety Manual: A Comprehensive Guide to Safety Standards for Healthcare Facilities (AAMI).

Marv was recently nominated and selected to be inducted into the ACCE Clinical Engineering Hall of Fame in 2023. That award will now be given posthumously.

For memories and words from Marv's friends and colleagues visit [MarvinShepherd \(accenet.org\)](http://MarvinShepherd.accenet.org)

We will all miss Marv's expertise and humanitarianism. Rest in Peace Marv!

ACCE News

ACCE News is the official newsletter of the American College of Clinical Engineering (ACCE).

Managing Editor

Ted Cohen
tedcohen@pacbell.net

Co-Editors

Ismael Cordero
icordero@ECRI.org

Sonja Markez

sonja.markez@uhn.ca

Circulation & Address Corrections

Suly Chi, ACCE Secretariat
Secretariat@accenet.org

Advertising

Dave Smith
advertising@accenet.org

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CCE Exam Prep

The CCE Prep column series provides sample questions and other information about preparation for the CCE examination. The sample questions are based on topics from the ACCE Body of Knowledge survey, the CCE Study Guide, version 1.1, and other sources. Answers and rationale for the answers are also provided. Note that the authors of this column do not have any affiliation with the CCE Board of Examiners and have no access to the actual exam questions. If you have specific topics you would like us to cover in this column, or if you are a CCE and you would like to write sample questions for this column, please contact the ACCE News editors.

1. Which one of the following tools or standards is not a Quality Improvement tool or standard?

- A. DMAIC
- B. ISO 13485
- C. FMEA
- D. ROI

Answer is 'D'.

Explanation: ROI is a financial metric with the acronym being defined as Return on Investment. DMAIC is a commonly used tool with the acronym defined as Define, Measure, Improve and Control. FMEA is another commonly used tool with that acronym being defined as Failure Mode and Effects Analysis. The ISO 13485 is a medical device quality management standard.

2. What is the maximum time frame that emergency electrical power should be available in the event of a power failure from the utility provided power based Joint Commission, NFPA, and CSA requirements?

- A. Within 5 seconds
- B. Within 10 seconds
- C. Less than 5 seconds
- D. Within 1 minute

The correct answer is 'B', within 10 seconds.

3. Which of the following are common metrics for calculating and justifying staffing levels in a Clinical Engineering Department (select two)

- A. Number of licensed beds per FTE
- B. Square footage of facility
- C. Number of medical devices per FTE
- D. Ratio of Nursing staff to CE FTE's

The best answers of the choices provided are 'A' and 'C'.

Explanation: There is no standard for calculating staffing levels for Clinical Engineering departments. Although Number of Beds and Number of Medical Devices are commonly used, these metrics do not sufficiently cover the varying complexity and cost of the devices in a modern healthcare facility. "One infusion pump is not the same workload as one MRI". Medical device Acquisition Cost is another metric that has been used within CE for justifying staffing levels.

Chris Riha, CCE

BOK Committee member

cdriha@crihaconsulting.com

Welcome New ACCE Members!

We welcome our newest members, approved by the Membership Committee, and supported by the Board of Directors:

| Name | Class | Job Title | Organization | Country |
|-----------------------------|--------------------------|--|---|-----------|
| Odey Al-Hilaly | Individual | Project Manager/Medical Equipment Consultant | Proton S.A. | Greece |
| Frank Paul Fries JR | Individual | Director, Biomed | US Med Equipment | TX/USA |
| Ken L. Mylar | Associate | System Director | SUMMA Health | OH/USA |
| Alice Casagrande Cesconetto | Associate | Regional Engineering Team Leader | Providence Health Care | BC/Canada |
| Scott Mazure | Associate | Imaging Service Engineering | TRIMEDX | MI/USA |
| Jean Ngoie | Institutional/Individual | Chief Clinical Engineering Officer and Regional Director | Children's Hospital of Eastern Ontario (CHEO) | ON/Canada |
| Kenny Downey Jr. | Institutional/Individual | Sr. Manager, Clinical Engineering/Technology Management | Banner Estrella Medical Center | AZ/USA |
| Mitchell Veltri | Institutional/Individual | Clinical Systems Engineer II | Lucile Packard Children's Hospital Stanford | CA/USA |
| Jon T. Kocurek | Institutional/Individual | Director of Medical Equipment Maintenance | Northern Light Health | ME/USA |
| Stephen Sin | Institutional/Individual | Clinical Systems Engineer | Lucile Packard Children's Hospital Stanford | CA/USA |
| Jerold Abel | Institutional/Associate | Senior Systems Engineer | Lucile Packard Children's Hospital Stanford | CA/USA |
| Aimee Co | Institutional/Associate | Clinical Engineer | Northern Light Health | ME/USA |
| Justin Ricketts | Institutional/Associate | Senior Manager | Banner Health | AZ/USA |
| Keith Ostrowski | Institutional/Associate | Biomedical Engineer | West Palm Beach VA Healthcare System | FL/USA |
| Randell Beralde | Institutional/Associate | Systems Engineer II | Lucile Packard Children's Hospital Stanford | CA/USA |
| Harsh Purani | Institutional/Associate | Clinical Engineer | University of Vermont | VT/USA |
| Kwame Ochir | Institutional/Associate | Biomedical Tech II | UI Health | IL/USA |
| Bill Handy | Institutional/Associate | Manager, Clinical Engineering | SUNY Upstate Medical University Hospital | NY/USA |
| Keith Roach | Institutional/Associate | Director, Clinical Engineering | SUNY Upstate Medical University Hospital | NY/USA |
| Ishtar Al-Tahir, MSE | Institutional/Associate | Clinical Engineer in Training | Children's Hospital of Eastern Ontario (CHEO) | ON/Canada |

Amy Klemm, MS, CCE
 Membership Committee Chair
Amy.s.klemm@gmail.com

ECRI Perspectives

Hello from ECRI!

We're seeing signs of spring (and winter) here in scenic Plymouth Meeting this Patient Safety Week and getting the word out about patient safety, environmental cleaning and disinfection, and a slippery situation concerning floor mats,

[Top 10 Patient Safety Concerns for 2023.](#)

More than 20 years after the publication of the landmark report, *To Err Is Human: Building a Safer Health System*, the *Institute of Medicine (2000)*, more than 100,000 patients continue to die from preventable medical errors each year. To improve health equity and patient safety, leaders are going to have to engage the entire organization in a total systems approach. That is why we took a different approach with this year's list of patient safety concerns. We tied each of our concerns to the four pillars essential to achieving total systems safety: 1) Culture, leaders, and governance; 2) Patient and family engagement; 3) Workforce safety; and 4) Learning systems.

[Environmental Cleaning and Disinfection:](#)

[Break the Chain of Infection.](#) Watch the recording of ECRI's engineers and infection, prevention and control experts from the Lab Webcast held on March 22 for a discussion about recommendations for effective environmental cleaning and disinfection procedures. We discussed actionable recommendations on how to enhance your cleaning and disinfection processes. Why focus on environmental cleaning this month? Over the course of the last three years, infection prevention and healthcare technology management leaders needed to rapidly adjust to prevent the spread of SARS-CoV-2. Now, with the concurrent spread of multiple viruses, as well as bacteria and fungi, effective environmental cleaning and disinfection procedures can help

eliminate pathogen reservoirs, thus breaking the chain of infection.

Watch your step! Engineering Director Chris Lavanchy is investigating an interesting issue that was reported by an ECRI member. The issue concerns floor mats that are used to help mitigate the risk of injury when a patient fall occurs. In this case, the member found that the use of mats was leading to more potential injury because the mats slipped across the floor when wet (e.g., after the floor had been mopped but not yet dried, or if fluids spilled onto the floor). Specialized mats are widely used next to patient beds in a variety of patient care settings, including long-term care. When we measured the frictional forces of several mats, we found one model with a significant reduction of the frictional forces when it is wet. Chris describes it as "becoming startlingly more slippery when wet." In this case, a safety precaution can result in an increase in the risk of injury.

[Is this isolation gown really isolating?](#) In our latest ECRI Now video, we spoke to Karen Haberland, Senior Project Officer, about testing of disposable isolation gowns to ensure they protect the healthcare workers wearing them. A deceptively simple piece of equipment can be the difference between an exposure and a safely protected staff member, and we're getting to the bottom of how real clinical use can sometimes differ from widely adopted testing standards. Check out how we assess the function, durability, permeability, usability, and human factors of these critical items of personal protective equipment, as well as how to find a reputable supplier.



ECRI

[Are you getting involved with value analysis?](#) Our members are feeling the pinch when it comes to supply chain. Costs for providers have been rising, due in part to higher labor costs, driven by demand. Labor expenses, which typically make up approximately 50% of a health system's budget, will continue to intensify in 2023. Vendors, on the other hand, who historically would negotiate on price to win or keep business, are now reluctant to do so amid tighter profit margins, leaving providers facing over-extended budgets. A few providers have even reported that some vendors were no longer willing to honor previously negotiated terms or were relying on vague contract language to rewrite terms. Check out our white paper for strategies around identifying product substitutes, assessing utilization data, and looking to the clinical evidence for the best approaches.

If you're ever in the neighborhood, we'd love to show you around our gorgeous new laboratory space. But, in the meantime, wash your hands, keep on excelling, and, as always, tell us what you're seeing.

Erin Sparnon,
Senior Engineering Manager,
Device Evaluation, ECRI
esparnon@ecri.org

2023 ACCE Awards

ACCE 2023 Professional Achievement in Management/Managerial Excellence Award

Angela Bennett, CHTM



The award recipient this year is Angela Bennett, for her distinguish contribution in putting together a CHTM study group and study materials that are being incorporated into AAMI's CHTM study course.

Angela started out in the HTM field as a 68A BMET in the United States Army. Her first civilian HTM job was a BMET I for TRIMEDX at Ascension

Borgess in Kalamazoo, Mi. She is now a Sr. Site Manager with TRIMEDX/Clinical Engineering Director for FMOL Our Lady of the Lake in Baton Rouge as well as an active member in AAMI as she has held the chair position in the Healthcare Technology Leadership Committee (HTLC) under 35 for the last few years. Angela was the founder and former president of the West Michigan Biomed Society. She then joined the ACCE education committee.

Angela has written several articles for HTM magazines, and has been a guest on a few podcasts. She has presented a few educational webinars for ACCE as well as being a guest speaker at the 2022 AAMI exchange with ACCE.

ACCE 2023 Professional Achievement in Technology Award

Joan Brown EdD, MBA, CCE

This year's recipient is Joan Brown EdD, MBA, CCE for her work in advancing the medical community's knowledge in multi-site data collection and health information exchange.

Dr. Brown serves as the Associate Administrator of Care Transformation for the USC Healthcare System and an Adjunct Assistant Professor of Clinical

Surgery at the Keck School of Medicine. Prior to this role, she served as the Chief Data Officer for both the Department of Surgery in the Keck School of Medicine of USC, and the Critical Care Institute at Keck Medical Center. Dr. Brown was also the

Administrative Director for Discovery Program for Emergency Preparedness (PREP), which fosters investigator-initiated hypothesis testing and strategic planning at the national level for research public health emergencies. Her academic focus is on design and implementation of innovative and systematic processes that integrate robust engagement with data analytics, patient care, quality improvement, and research.

Dr. Brown has previously worked as the Director of Telehealth and Program Technology at Orbis International where she formed and led a team to develop and implement a comprehensive strategy for technology programs worldwide. She was awarded the 2014 International Agency for the Prevention of Blindness (IAPB) Eye Health Leaders Award for Innovation in Eye Health, commending the important work she brought to a global scale.

In her role within the Discovery Program for Emergency Preparedness (PREP) of the Society of Critical Care Medicine (SCCM), Dr. Brown led the team's technical work to explore better ways to collect and share data across the nation. She used her foundational skills as a clinical engineer to work with various stakeholders to understand workflow and design and test technical solutions that would meet the needs of our country during expected (influenza) and unexpected (COVID-19) public health emergencies. The effort helped the medical community to further understand multi-site electronic data capture approaches and provided a foundation for continued advancement in the healthcare technology field. The work was an example of how clinical engineering knowledge and principles can be applied to further health information technology. Two manuscripts were published in peer reviewed manuscripts describing the team's effort.

ACCE 2023 Lifetime Achievement Award

Mario Alberto Castañeda Peña, MBA

This year's Life Time Achievement Award is presented to Mario Alberto Castañeda Peña, MBA (Posthumous Recipient) - a Clinical Engineer, Leader, Humanitarian, Mentor and past ACCE President (2010 – 2012).

Mario served as the National Clinical



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2023 ACCE Awards (continued)

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Technology Executive Director for Kaiser Permanente and as Northern California Biomedical Engineering Manager for Hospital Corporation of America. He was instrumental in developing and advancing Kaiser's Clinical Technology program. As the national leader for Kaiser Permanente's Clinical Technology, Mario led a highly matrixed organization of over 300 employees and 400,000 medical devices across 8 regions and Washington, D.C. Mario ushered in many new technologies, devices and methodologies through difficult times and challenging economic conditions. He helped establish the National Product Council in Kaiser and created different technology committees which fostered partnership and communication between clinicians and engineers. His efforts to lead locally and partner globally helped put both Clinical Technology and Kaiser Permanente on the map. As a result of his work with Kaiser, he also advanced the clinical engineering profession in the US and throughout the world. Throughout his clinical engineering career, which spanned over 50 years, Mario kept contributing to the clinical engineering profession by sharing information, leading by example, and serving with American College of Clinical Engineering and other professional organizations. He dedicated a lot of time to advancing clinical engineering worldwide, and he did this by participating in many Advanced Clinical Engineering Workshops, sharing his knowledge, and helping where and how he could. He leveraged a lifetime of experience in the health industry in 2010, serving a two-year term as President of The American College of Clinical Engineering (ACCE). Mario's tenure as ACCE President helped entrench a tradition of bringing AAMI and ACCE members together to share education and valuable industry knowledge. In addition, he strengthened the collaboration with national associations, such as HIMSS & AAMI & IHE, AIMBE, as well as internationally with IFMBE, CORAL, and many more.



2023 Antonio Hernandez International Clinical Engineering Award

Dr. Ernesto Antonio Ibarra Ramirez

The award recipient this year is Dr. Ernesto Antonio Ibarra Ramirez, for his extraordinary leadership in pro-

moting Clinical Engineering in Panamá and the Caribbean Region, and advancing healthcare safety in the Latin America Region through his collaboration work.

Dr. Ramirez served as the inaugural President of the IEEE ULATINA Student Branch in 2006, where he spearheaded the coordination of the first national and international academic and professional activities of biomedical engineering in Panama. Since then, his active participation and significant contributions to the fields of academia, research, and professional practice in biomedical engineering have motivated hundreds of individuals and greatly advanced the development of biomedical engineering in Panama and the Latin America Region.

Among his notable achievements, Dr. Ramirez has contributed to the preparation of Resolution No. 788 of the Engineering and Architecture Technical Board, which establishes the functions of the Biomedical Engineer in Panama (2008). In 2009, he founded the IEEE Engineering in Medicine & Biology (EMB) Chapter of Panama and held the position of President for two terms (2009-2010; 2017-2018). Additionally, he formed the Scientific Committee of the IEEE EMB of Panama, which comprises IEEE senior members with a PhD degree. This committee has provided national and international support for the review of scientific articles on biomedical engineering.

Dr. Ramirez has made significant contributions as a project manager in the field of biomedical science and technology in Panama, particularly in the development of telemedicine systems from 2014 to 2022. He has also held various academic positions in the discipline of biomedical engineering, including that of professor, researcher, and academic coordinator, and has been instrumental in the training of professionals in Panama. Furthermore, he has represented the IEEE EMB Chapter in numerous conferences and workshops across several countries, including Panama, Colombia, El Salvador, Ecuador, Peru, Costa Rica, and Mexico.

Since 2010, Dr. Ibarra has been actively engaged in biomedical engineering research, with a focus on Wireless Body Area Networks, Human Energy Harvesting, and Radiation and Human Health. Notably, in 2020, he played a crucial role in providing protection to healthcare professionals against COVID-19, through the design and construction of acrylic protective barriers, face shields, acrylic boxes for intubation of COVID-19 patients, and contributed to the design and development of biomedical equipment. These contributions were particularly vital in the early stages of the pandemic.

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2023 ACCE Awards (continued)

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In 2020, Dr. Ibarra was elected as President of the Panamanian Association of Biomedical Engineering (APIB), where he has achieved several significant milestones during his tenure. Notably, he coordinated the vaccination of over 100 biomedical engineers from the private sector who were working in high-risk areas for COVID-19 contagion, in collaboration with the Ministry of Health of Panama in 2021. As President of the APIB, he has also emphasized the crucial role played by biomedical engineers in the health sector both nationally and internationally.

Under his leadership, Panama has established important relationships with esteemed organizations such as the Regional Council of Biomedical Engineering for Latin America (CORAL), the IEEE EMB R9, ACCE, and the International Federation of Medical and Biological Engineering (IFMBE). These collaborations have strengthened the position of Panama in the global biomedical engineering community and have contributed to the growth and development of the discipline.

2023 ACCE/HTF International Organization Award



**Associação Brasileira
de Engenharia Clínica -
ABEClin**

The award recipient this

year is the Brazilian Association of Clinical Engineering (ABEClin). Founded in 2003, ABEClin was established with the objectives of promoting clinical engineering, integrating and qualifying CE professionals, and providing input to the development of a code of ethics, and development and improvement of medical devices used in Brazil. Currently, ABEClin has 800 active members. In addition to having a national board of directors, ABEClin has already established 10 regional boards and a few others in formation, to cover the vast territory of Brazil. Each one of the regional boards has its own Technical Committees and promotes their regional activities for all members in that region.

During the COVID-19 pandemic and thereafter, ABEClin contributed actively to manage the impact of the pandemic including interactions with other organizations like ACCE, IFMBE, PAHO, and AIIC. ABEClin helped lead the use of anesthesia equipment as ventilators and splitting ventilators for multiple patients. ABEClin also helped the Ministries of Health and Education in the project +Ventilators that recovered more than 2,400 inoperative ventilators in public hospitals. In addition, ABEClin contributed to develop and organize numerous webinars, monthly live chats and a few in-person workshops.

Finally, ABEClin has also contributed to the creation of the certification program for CE outsourcing companies from the National Accreditation Organization of Brazil (ONA) and is actively working with the Brazilian Federal Council of Engineering and Agriculture (CONFEA) to register clinical engineers as professional engineers in Brazil.

International Committee Report

ACCE-DMBIUBIH Webinars:

The ACCE delivered two webinars to the Bosnia and Herzegovina Medical and Biological Engineering Society (DMBIUBIH):

“Introduction to Project Management” was presented by Jonathan Gaev on 23 Feb 2023.

“Evidence-based maintenance” was presented by Binseng Wang on 9 March 2023.

ACCE has a collaboration agreement with DMBIUBIH which was signed in October 2021.

We have one more webinar to present. “Building a case for medical device cybersecurity” will be delivered later on this year (the webinar was rescheduled, the date for the presentation has not yet been determined).

Jonathan Gaev, Member ACCE International Committee

jgaev@yahoo.com

AAMI Update

FDA Recognizes First AI-Focused Document, AAMI CR34971:2022, in List of Consensus Standards

The U.S. Food and Drug Administration (FDA) recognized [AAMI CR34971:2022, *Guidance on the Application of ISO 14971 to Artificial Intelligence and Machine Learning*](#), as a guidance document “appropriate for meeting requirements for medical devices under the Federal Food, Drug, and Cosmetic Act.” Additionally, ten other new or updated AAMI documents were [added to the federal regulator’s list](#) of recognized consensus standards.

AAMI’s Joe Lewelling, vice president for Industry, noted that “not only is the FDA recognition a critical endorsement of what we hope will soon be an AAMI technical information report (TIR) and a British National Standard, it is also the first AI-focused document that the FDA has recognized.”

According to Lewelling, AAMI CR34971:2022 responds to an urgent, immediate need. Existing standards for regulated medical devices do not yet adequately address the potential risks of emerging AI and ML applications, which “could jeopardize patient health and safety, increase inequalities and inefficiencies, undermine trust in healthcare, and adversely impact the management of healthcare,” the CR states.

Seen as equally disruptive as it is promising, U.S. FDA experts are paying close attention to AI-driven medical devices. In early 2021, the FDA released its [Artificial Intelligence/Machine Learning \(AI/ML\)-Based Software as a Medical Device \(SaMD\) Action Plan](#). The action plan describes a “multipronged approach to advance the agency’s oversight of AI/ML-based medical software.”

As part of the agency’s action plan, FDA liaisons participate in the standardization efforts of the [AAMI AI Committee](#) to address the risk management of AI-driven medical devices, including the development of AAMI CR34971:2022, which is the first AAMI CR to be recognized by the FDA.

A First-of-Its-Kind Document

AAMI CR34971 is a relatively new kind of guidance document from AAMI called a consensus report (CR). A CR is not subject to the formal years-long process as a standard, and while similar in nature to a TIR, a CR is based on the collective knowledge and experience of a select group of stakeholders. These documents are developed to provide prompt, concise, and practical guidance on narrowly focused topics of high importance, where limited data exists, where there is variation in practice, or where there is confusion among stakeholders.

“The development of standards/TIRs can take a significant amount of time, and for quickly evolving topics [such as AI], we can’t wait,” said Pat Baird, co-chair of the AAMI AI Committee and senior regulatory specialist at Philips. “A CR doesn’t have all of the details that a standard or TIR has, but it does offer good advice on the safety and efficacy of medical devices.”

Baird is part of the small task force of the AAMI AI Committee that developed CR34971, which was reviewed by the full committee and by risk analysis experts at BSI. The committee then approved the consensus-driven report.

“For this CR, we have further reaching plans,” noted AAMI Principal Director of Standards Hae Choe. “AAMI CR34971 will be the basis for a technical information report and then, possibly, AAMI will propose it as an international document. FDA recognition will definitely aid in this plan.”

The AAMI AI committee now hopes to publish its important next step, designated as TIR34971, within 2023.

Promising Recognition for AAMI Standards

Other standards newly-recognized by the FDA include the new [ANSI/AAMI ST98:2022, *Cleaning validation of health care products—Requirements for development and validation of a cleaning process for medical devices*](#) and the AAMI/UL 2800 Series.

ANSI/AAMI ST98 is a new standard which normalizes requirements for cleaning validation methods. It not only advances understanding of and conformance with cleaning best practices but has the potential to have an [impact on the design and development](#) of medical devices.

The document is “revolutionary in the sense that it is really the first document, globally... that gives requirements for device manufacturers as far as what they need to do to validate their cleaning [and ensure] their cleaning instructions actually produce a clean device,” said Ralph J. Basile, vice president of Marketing and Regulatory Affairs for Healthmark Industries.

[The ANSI/AAMI/UL 2800 series](#) is the result of a years-long collaboration between AAMI and UL Standards & Engagement. FDA representative Shawn Forrest of the Digital Health Center of Excellence (DHCoE), Office of Strategic Partnerships and Technology Innovation (OST), and Sandy Weininger, a senior electrical/biomedical engineer at the FDA and JC member, explained the importance of this work in a joint statement.

“Medical device interoperability is an essential objective to enable more efficient patient care, more robust science, and improved insights into device performance across diverse populations,” they said. “ANSI/AAMI/UL 2800-1 is a valuable resource to support stakeholders in developing and implementing safe and secure interoperable medical devices by providing a detailed framework to coordinate these processes.”

The AAMI Team

Renew your 2023 CCE Certification by June 30, 2023



Clinical Engineering Certification Program

Renew your 2023 CCE Certification by June 30, 2023

All active certified individuals with a *Renewal Expiration Date* of June 30, 2023, must complete the 2023 CCE Renewal Application form and submit it electronically to the HTCC via email at certification@accenet.org.

The three year renewal fee is \$150 if paid by June 30, late renewals will be accepted through September 30th for an additional \$150 late fee. For more information, please reference the 2023 CCE Renewal Handbook posted on ACCE website.

Any active CCEs with a renewal expiration date of June 30, 2023, who wishes to change their certification status to Retired or Emeritus, must submit the 2023 application by 06/30. Please refer to the Retired and Emeritus Status Change handbook for additional details.

2023 CCE Renewals:

All active certified clinical engineers with a June 30, 2023 renewal date must complete the [2023 CCE Renewal Application form](#) and submit it electronically to the HTCC via email at certification@accenet.org. The three-year renewal fee is \$150 if paid via [PayPal](#) by June 30, late renewals will be accepted through September 30th for an additional \$150 late fee.

For more information, please reference the [2023 CCE Renewal Handbook](#)

Retired and Emeritus Status Changes:

Any active CCE with a Renewal expiration date of June 30, 2023, that wishes to change their certification status to Retired or Emeritus Status, must submit the 2023 application by 6/30/2023. Please refer to the [Retired and Emeritus Status Change Handbook](#) for additional details.

To check your CCE expiration date:

The list of all certified clinical engineers and associated expiration dates is posted on the [ACCE website](#). To check the expiration date on your CCE status, please [click here](#).

[Click here for the list of CCEs with expiration date of June 2023](#)

Julia Mazzoleni, HTCC Secretariat
Sudhakar Nagavalli, HTCC Chair
certification@accenet.org

Appreciation to Outgoing and Congratulations to Incoming Chairs

Join us to thank our outgoing Education Committee co-chairs:

In great appreciation to Tony Cody for his leadership and dedicated support as Education Committee co-chair
May 2021 - February 2023
Thank you, Tony!

In great appreciation to Nader Hammoud for his leadership and dedicated support as Education Committee co-chair
May 2021 - February 2023
Thank you, Nader!

ACCE welcomes Juuso Leinonen & Mike Powers, as the Education Committee co-chairs:



Juuso Leinonen

Juuso Leinonen is Principal Project Engineer at the Health Devices group at ECRI, where he performs comparative medical device evaluations and investigates medical device related problems. He also conducts accident investigations and advises hospitals on large scale equipment purchasing and selection projects. His current subject matter expertise includes medical device cybersecurity, infusion technology, pharmacy technologies, and telehealth. He came to ECRI with a background in clinical engineering from St George's Hospital London, United Kingdom, and holds a bachelor's degree in biomedical engineering from City University London, United Kingdom.



Mike Powers, MBA, AAMIF, CHTM, CDP

Mike Powers is the System Director for Field Service in the Healthcare Technology Management Department at Intermountain Health, headquartered in Salt Lake City, Utah.
He co-leads a task group for the Health Sector Coordinating Council on Legacy Medical Device Cybersecurity. He is a vice chair of the AAMI Healthcare Technology Leadership Committee. Prior to Intermountain, he was the Clinical Engineering Quality Manager at ChristianaCare Health System. He has an MBA in Healthcare Administration from Wilmington University and is a Certified Diversity Professional.

ACCE thanks our outgoing Membership Committee Chair:

In great appreciation to Juuso Leinonen for his Leadership and Dedicated Support as Membership Committee Chair August 2019- February 2023

ACCE welcomes our new Membership Committee Chair:



Amy Klemm, MS, CCE

Amy Klemm is a Clinical Engineering Area Director for TRIMEDX. She has held multiple roles throughout her career at TRIMEDX including Site Manager, Senior Site Manager, System Director and currently Area Director. Her experience prior to TRIMEDX includes working for Sodexo Healthcare Technology Management as a Senior Manager and a Regional Safety Coordinator. Amy graduated from Vanderbilt University with a Bachelor of Engineering (BE) and a Master of Science (MS) both in Biomedical Engineering, and she is a Certified Clinical Engineer (CCE).

Amy has been an active member of the Membership Committee since April 2018.

ACCE at AAMI eXchange2023 – Long Beach, CA



Join ACCE at AAMI eXchange 2023
Member discount available!
Connect with our team at booth # 660



ACCE is a **Contributing Organization** for AAMI eXchange 2023. ACCE members are eligible to register for the conference at AAMI members discounted rate. Just complete this **[registration form](#)**.

Attend these co-sponsored can't miss events at AAMI Exchange:

Clinical Engineering Symposium – Presented by ACCE

Title: Wearables and IoT - The Emerging Healthcare Technology Support Challenge

Date: Saturday, June 17, 2023, 7:30AM-10:15AM

Location: Long Beach Convention Center

Theme:

The use of wearables and IoT devices in healthcare organizations is rapidly expanding. This technology shift is providing interesting new opportunities, but also presents a number of practical technology management and support challenges. Healthcare facilities are increasingly faced with the use of patient owned wearables. Many clinicians are leveraging bring your own device (BYOD) policies and utilizing their own medical devices and IoT to deliver care. The home use of medical devices is also rapidly ramping up with the expansion of telehealth. Many of these wearables and IoT medical devices are also network connected, exchange patient data, and utilize various cloud services. How do we stay on top of managing these new clinical use cases and expanding fleets of wearable and IoT devices? What are the related roles and responsibilities of HTM departments? How do we ensure these systems are used safely and the associated security risks are controlled?

Join this ACCE symposium to hear about the latest trends and best practices regarding the use, management, and support of wearables and IoT in healthcare. During this symposium we will discuss the common use cases for wearables and IoT in the healthcare setting and review the best practices in managing them. Learn the latest from the leading industry experts in panel discussions and hear education sessions from healthcare organizations about their successes and challenges in adopting wearables and IoT.

Click here to register (<https://www.surveymonkey.com/r/2023CE-Symposium>)

(Continued on page 13)

ACCE at AAMI eXchange2023 (continued)

(Continued from page 12)

Education Sessions, presented by ACCE: Focusing on What's Important – Leadership Evolution in HTM/CE

Date: Sunday, June 18, 2023

Time: 8:00 AM – 9:00 AM

Location: Long Beach Convention Center

Speakers: Tony Cody, Nader Hammoud, Mike Powers



Description:

In the early 20th century, leaders were taught to manage their team so that the individual contributors performed essentially as robots taking inspiration from the introduction of the assembly line. As generations have come and gone, leadership has stagnated and not leveraged many changes in culture or work style. AAMI proposed that between 2020 and 2025 75% of the leaders in HTM would retire / be replaced. With such an influx of new talent, there is an opportunity to share Leadership Techniques for the 21st century, where people are appreciated for both who they are today and who they can be tomorrow. Join us in this round-table discussion as we share the foundations of successful leadership of our HTM/CE teams.

33rd Members Meeting/Awards Reception Saturday, June 17, 2023,



7:30PM-10PM
Hyatt Regency Long Beach
200 South Pine Avenue
Long Beach, CA 90802

You are invited! [RSVP here](#)

Join us for an evening of networking with your peers and to congratulate the 2023 Advocacy Awards recipients, the 2023 ACCE Fellows and the 2023 Clinical Engineering Hall of Fame inductees.

ACCE at AAMI eXchange2023 (continued)



2023 CCE Oral Exam

June 15 - 16, 2023

Location: Hyatt Regency Long Beach

Please confirm your exam schedule with HTCC Secretariat at certification@accenet.org

Stop by ACCE Booth at Exhibit Floor, [Booth # 660](#)

Learn about new webinar series

Learn about the CCE exam

Learn about the membership programs

Learn about ACCE activities

Connect with old and new friends

Check/update your membership status

[Registration](#) and [Housing](#) are Open!

[eXchange23 Schedule at a Glance](#)



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- Risk Simulation
- Device Utilization



CE Week with the UCONN Clinical Engineering Interns

The first full week of February was marked by our spring semester CE Week. The agenda included presentations by each intern highlighting their projects at their host hospitals along with a resume workshop and a CE Internship alumni panel discussion. The interns also found time to network and have some fun during lunches and after hours.

Our 2nd Year interns will graduate in May 2023 and are exploring job opportunities across the country. I encourage you to reach out to all of these about-to-be graduates on LinkedIn to congratulate them, get to know them, and share your experience and expertise with them. If you have an open clinical engineer position on your team, I'd be happy to make an email introduction!

Thank you for all you do every day. Be well.



*Carol Davis-Smith, MS CCE FACCE AAMIF
Program Director – UCONN BME Clinical
Engineering Internship Program
Carol.Davis-Smith@uconn.edu*

| May 2023 Graduates | |
|---------------------|---------------------------|
| Sarah Basenese | Heather Heidenreich |
| Shawn Byrne | Camila Leyva |
| Stefani Chiarelli | Zachary (Zach) Newman |
| Erin Coon | Abigail (Abby) O'Sullivan |
| Charlotte Cooperman | Tehya Pavelka |
| Molly Donahue | Matthew Vinacco |
| Jacob Girard | |

ACCE Website **Job Postings**

For posting job opportunities,
please contact Dave Smith at

advertising@accenet.org

Education Committee Report

In this edition of the ACCE News, the Education Committee would like to take some time to thank our 2022-2023 webinar panelists for sessions 6 and 7: Mr. Herman McKenzie & Nader Hammoud, Angela Bennett, Tony Cody. And we thank again our co-sponsors for your continuous support to the ACCE community and supporting the profession, your generous sponsorship allows us to bring the most updated education to our community at no charge helping our members and collaborators to advance the Clinical Engineering profession. – THANK YOU!



2022-2023 Educational Webinar Series

KPI - Above and Beyond the Compliance

Thursday, April 27, 2023; 12 pm - 1pm (EDT)

Panelists

FREE
for
MEMBERS

Dean Skillicorn
Medical Images Services Manager
St. Luke's Health System

Perry Kirwan
VP, Technology Management
Banner Health

Samantha Jacques
VP, Clinical Engineering
McLaren Health Care

Courtney Nanney
National Quality Manager, CE
Catholic Health Initiatives

The 2022-2023 Educational Webinar Series will continue with session #8 on April 27, 2023, with Dean Skillicorn, Perry Kirwan, Samantha Jacques and Courtney Nanney to discuss “KPI – Above and Beyond the Compliance”.

2022-2023 Educational Webinar Series

Lessons learned: 2023 CE-IT Symposium: Securing IoMT Proactively

Thursday, May 11, 2023; 12 pm - 1pm (EDT)

Panelists

FREE
for
MEMBERS

Philip Englert
Director of Medical Device Security
Health-ISAC

Shawn Anderson
Manager, Cybersecurity Architecture
Intermountain Health

Chris Falkner
Sr. Director of HTM Digital Strategy
SODEXO HTM

Jim Panella
Director of CE/IT
UI Health

Session # 9 on May 11, 2023, “Lessons Learned: 2023 CE-IT Symposium: Securing IoMT Proactively”, with Phil Englert, Shawn Anderson, Chris Falkner, and Jim Panella. Moderator: Juuso Leinonen.

(Continued on page 17)

Education Committee Report (continued)

(Continued from page 16)

Unable to attend the ACCE CE-IT Symposium Securing IoMT Proactively - Collaboration Between Information Technology and Clinical Engineering Professionals in person at HIMSS23? No worries! We are bringing the key insights from the event to you through our webinar panel discussion.

Join our panel discussion, which will recap the essential takeaways from the CE-IT Symposium, and listen to a panel of industry experts as they delve into the key challenges and opportunities associated with the rapidly expanding IoMT landscape.

These sessions will be followed by one more session (10 total) that will dig deeper into topics that Clinical Engineering Departments experience globally. Register today for sessions #8, and #9 and stay tuned as we have a great line-up of speakers this year building on the previous years' successes.

ACCE Members (in good standing),

[Click here to register for session # 8](#) and [Click here to register for session # 9](#)

If you have not renewed your 2023 membership yet, please renew it via PayPal [here](#), or contact us at secretariat@accenet.org to request an e-invoice.

If you are not an ACCE member yet, please join us today! Just complete the [membership application form](#) and submit it to secretariat@accenet.org. Or if you prefer to register as a non-member, please complete registration for this session [here](#).

Juuso Leinonen & Mike Powers

Education Committee co-chairs

educationchair@accenet.org

Suly Chi

Webinar coordinator

Secretariat@accenet.org



The graphic features a light blue background with four gold stars in the corners. On the left is a gold award ribbon with a red ribbon, reading "2023 Student Paper Competition Winners" and the ACCE logo. To the right are two columns. The first column is titled "Master Division" and features a portrait of Simin Nazeri with her name and paper title: "Strategic Budget Planning for Complex Medical Devices: A Case Study on Surgical Microscopes" from the University of Ottawa. The second column is titled "Doctorate Division" and features a portrait of Kordell Mitchell Tan with his name and paper title: "Development of a Vein Detection Imaging System" from the University of North Dakota.

IFMBE–CED Update- Clinical Engineering is ready for Entrepreneurship

Clinical engineering and entrepreneurship are two fields that may not have much in common at first glance. Clinical engineering is a specialized area that applies engineering principles and techniques to the design, development, and maintenance of medical devices and equipment. Entrepreneurship is starting and managing a new business venture.

Clinical engineers with an entrepreneurial spirit may be at the forefront of developing innovative medical technologies that can significantly improve patient outcomes and reduce healthcare costs. Although it has not been a frequent case, the conditions are in place for this clinical engineer profile to be replicated worldwide.

Designing and developing an innovative medical device requires a unique set of skills beyond technical expertise. Clinical engineering and entrepreneurship, intersect in many ways, and one of the most significant is the development of new medical devices and equipment. Successful entrepreneurs in this field must be able to identify market needs, secure funding, navigate regulatory processes, and develop business plans. Clinical engineers with entrepreneurial skills are well-equipped to handle these challenges. They possess the technical knowledge needed to create the technology and can acquire the business acumen to bring it to market.

The growing trend of clinical engineers transitioning into the role of medical device entrepreneurs is becoming a reality. By applying their engineering, clinical medicine, and healthcare management expertise, these individuals can be well-positioned to launch successful medical device startups. The constant contact with reality in daily activity allows them to raise awareness of health problems from different perspectives. The eye of the clinical engineer enables the integration of elements that lead to the identification of opportunities in the form of practical solutions.

One of the most significant advantages of clinical engineers in entrepreneurship is their ability to identify and assess medical device risks. They are trained to identify potential hazards and work to mitigate them before they become an



IFMBE
Clinical Engineering Division

issue. This is particularly important in medical device development, as a faulty or poorly designed device can seriously harm patient safety. This entrepreneurial spirit in clinical engineering also drives the development of digital health technologies: telemedicine, mobile health apps, and wearables can improve patient outcomes, reduce costs, and increase access to care. Clinical engineers are uniquely positioned to develop and implement these technologies as they possess the technical knowledge to design and develop them.

An emerging field that clinical engineers are embracing is creating new business models. As the healthcare industry continues to shift toward value-based care, there is a growing need for innovative business models that can improve patient outcomes while reducing costs. Clinical engineers with an entrepreneurial mindset can be well-positioned to develop and implement these new business models. They may use their skills to design and optimize healthcare workflows, create new tools for data analysis and visualization, or develop software and other technologies to support clinical decision-making. Entrepreneurs may see the potential for these innovations to be scaled up and commercialized or used to create new healthcare delivery and management models.

As the healthcare industry evolves, clinical engineers with an entrepreneurial mindset will play a critical role in driving innovation and improving patient care.

Fabiola Martínez, Board Chair
IFMBE Clinical Engineering Division (CED)
fmartinez@ci3m.mx

Journal of Clinical Engineering Subscriptions for ACCE Members

The Journal of Clinical Engineering is a compilation of articles, papers, and extensive manuscripts relevant to clinical/biomedical engineering or biomedical technology. Subject matter directly relates to the engineering or technology involved in patient care and treatment or technology in the broad field of health care delivery.

ACCE members receive a discounted subscription to the [Journal of Clinical Engineering](#) for only \$99! (Originally \$366). You must [login](#) to the ACCE website to view the code. Then visit [LWW.com](#) to enter code.



ACCE CALENDAR

<https://accenet.org/NewsEvents/Pages/Calendar.aspx>

27 April 2023 12:00 PM-1:00 PM Educational Webinar session # 8: KPI - Above and Beyond Regulatory Compliance

11 May 2023 12:00 PM-1:00 PM Educational Webinar session # 9: Lessons Learned from ACCE CE-IT Symposium @HIMSS 23

14 May 2023-20 May 2023 2023 HTM Week Join the HTM/CE community to promote awareness of - and appreciation for - the critical work of professionals who manage and maintain the vast assortment of health technology found in healthcare delivery organizations.

16 May 2023-18 May 2023 CCE-CA Oral Exam @CMBEC45

08 June 2023 12:00 PM-1:00 PM 2022-2023 Educational webinar series, session 10: CMMS Standardization and implementation - best practices and lessons learned

15 June 2023-16 June 2023 2023 CCE Oral Exam

16 June 2023-19 June 2023 AAMI eXchange

17 June 2023 7:30 AM-10:00 AM Clinical Engineering Symposium by ACCE @ AAMI eXchange23: Wearables and IoT - The Emerging Healthcare Technology Support Challenge

30 June 2023: Last day to renew your 2023 CCE Certification.

ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING

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