

ACCE News

Newsletter of the American College of Clinical Engineering

November-December 2016

Volume 26 Issue 6



Call for Nominations! Clinical Engineering Hall of Fame Class of 2017

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President's Message



I find it hard to believe that two months have passed since I wrote my last President's message to you. Time truly is relative, and for me it is accelerating at an alarming rate. Much has happened in the past two months, some of which I will write about below and some that you can read in other articles in this newsletter.

I want to take a few moments to reflect on the importance of professional relationships in the workplace. I recently left my job of 20 years with the Winnipeg Regional Health Authority to join a provincial (read as "state" in the US) healthcare delivery organization responsible for all urban and rural public medical laboratory services and rural diagnostic imaging services. My new role is Chief Operating Officer, and I oversee our clinical operations in partnership with our Chief Medical,

Financial and Information Officers. Working daily in this arena has really confirmed for me that professional relationships are a key component to success. Failure to recognize the importance of relationships limits how far a clinical engineering service/department can go or how far an individual can go in their career.

As a young engineer, I focused much of my energy on learning the technical side of my work and how it applied to various clinical environments. As I look back on those early days of my career, I realize now that the time I spent physically in the operating room, critical care unit, emergency department or inpatient unit interacting with physicians, nurses, RTs, and others, was foundational to forming relationships with those staff. In those days, I was focused on providing a valuable technical service, but in so doing, I was forming relationships that paid dividends beyond the immediate work that was being done. I learned to speak their language and truly understand the work they did for their patients. It was not clear to me then, but it is now, that it was the relationships formed that had lasting value. As I reflect on the subsequent years I spent growing my clinical engineering department to include responsibility for support of areas not previously supported, success was frequently, if not always, based on having formed a relationship with a key decision maker prior to making a formal proposal to provide support or to do work in their area of responsibility. It was not the business case document written, or the countless emails sent that tipped the proposal or initiative into success, it was the relationship between me and the other person that made the difference. For many of us who see our work first through a technical lens, appreciating the psychosocial aspects of the work can be challenging. I encourage you to keep a part of your conscious mind turned to the question of how each piece of work or project you are doing is nurturing personal relationships with your subordinates, colleagues and your superiors (direct or indirect). Be strategic in developing relationships and over the course of time, those relationships will open many doors.

Strong relationships are important for individuals and for organizations. One of my goals for ACCE is for it to foster productive relationships with other organizations that have substantial influence on the work that clinical engineering professionals do in the places of work. We are an organization of volunteers with very busy day jobs, and this makes it important for each member of ACCE to contribute. On October 27th and 28th, four of your colleagues – Malcolm Ridgway, Barbara Maguire, Alan Lipschultz and Mark Bruley attended the FDA Public Workshop on "Refurbishing,

(Continued on page 2)

President's Message (Continued)

(Continued from page 1)

Reconditioning, Rebuilding, Remarketing, Remanufacturing and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers". They attended as official representatives of the ACCE, and they deserve your gratitude. ACCE actively petitioned the FDA for the opportunity to speak during the opening half-day plenary session. Only a small number of "entities" were granted this opportunity and ACCE was one of them. This speaks well for our professional organization. I can attest to the tremendous amount of work that our delegation did to prepare presentations and other materials for the 2-day workshop, which included the plenary session and several panel discussions. Many hours were spent by them formulating the key messages that would be communicated. Thank you, Malcolm, for providing overall leadership to the group as it prepared for the Workshop and for your content expertise. Thank you, Barbara, for stepping up and delivering the plenary presentation. Thank you, Alan and Mark, for your substantial contributions to the overall content and your parts in the panel discussions. And another thanks to Mark for the analytical work he did to support the key messages. Looking ahead, the work is not done on this file, either at the federal or state level. Many opportunities exist for ACCE members to be involved in coming months and years. I hope you will contribute when the next call goes out. Who knows, you could create a relationship that pays dividends in unexpected ways.

On October 21st, 2016, the ACCE participated in the first ever Global CE

Day. This event was largely conceived by Yadin David and Tom Judd. Much work went into making the event a truly global celebration of all the tremendously important work done by the clinical engineering community around the world. The day-long live web broadcast of contributions from clinical engineering groups around the world included features from China, India, Australia, the United Kingdom, Ethiopia, Italy and Albania, Brazil, the United States, Peru and Mexico. The ACCE contributed two separate live sessions; the first at noon Eastern time and the second at noon Pacific time. I acted as narrator and Tom Judd as producer. We showed recorded presentations from Antonio Hernandez about the ACCE International Committee, Pippin White about the Healthcare Technology Certification Commission, Jennifer DeFrancesco and Rodney Nolan about the ACCE Education Committee, Elliot Sloane about the CE-IT Committee, and a personal success story from Tracy Rausch. Thank you to all who gave of their time to make the presentations and for those who tuned into the event. Overall the event was a great success. If you missed it, you can view the content by visiting <http://global.icehtmc.com/>.

The annual Healthcare Information and Management Systems Society (HIMSS) meeting will take place Feb 19-23, 2017 in Orlando. Historically, the ACCE has had a strong presence at the meeting particularly related to the CE-IT Community. We must work hard to maintain the relationship we have with AAMI and HIMSS as the tri-partite collaborative behind the CE-IT Community. In recent times, this initiative has not garnered the amount of attention it deserves, and new energy is needed in this critically important area of clinical

engineering work. At the HIMSS meeting, ACCE will be presenting the ACCE-HIMSS Excellence in CE-IT Synergies Award. The award recognizes individuals who have best demonstrated leadership in promoting or implementing significant synergies between the clinical engineering and the information technology professions.

Also at the HIMSS Conference and Exhibition, the ACCE is an official endorser of the HIMSS Interoperability Showcase. This is a great opportunity to volunteer and get involved. I suggest that you look at this opportunity not just as a chance to learn or to participate in the technical side of interoperability but also to see it as a great chance to build relationships. Visit "HIMSS Interoperability Showcase". I will be attending HIMSS and hope to see you there.

Petr Kresta, President, ACCE
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ACCE News

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View from the Penalty Box

I recently had the misfortune of spending 4 days in the penalty box, aka, inpatient at a hospital. While there was nothing major wrong, the bill will probably cover several car and tuition payments for the physicians involved.

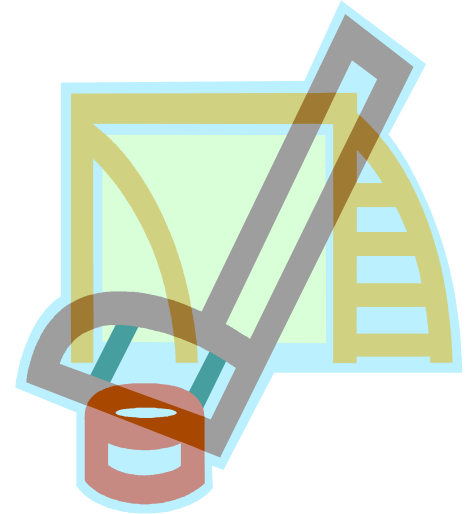
The total process was as frustrating as the recent election, as nothing seemed to make sense. I must ask why our election cycle was over 500 days for president and several billion dollars while Canada did theirs in less than 90 days for much less money. We never heard about it down here. Maybe that is why we never seem to get things done in holding down the costs in healthcare. We have too many groups establishing requirements for their specialties, such as AABB, CAP, CMS, ACC, to name just a few. These groups never seem to consider what other organizations have for requirements. On top of it all we cannot even agree on our own titles. While we talk about what to do, prices go up, names change, and we gain nothing. This name change bugs the hell out of me. I have been a clinical engineer since the early 70's. Before that, I was a biomedical engineer designing clinical equipment. Why the change to Healthcare Technology Manager? Does anyone have a job description for the Healthcare Technology Manager? One used for clinical engineers is short and simple - "the CE works to maintain the various medical devices so that the patient and user are safe and the results are accurate". That is what we started with. Over the years, the word count has grown, but the core statement is as true now as it was in the 60/70's - safety and accuracy for the patient and staff. From what I have seen, most of the new job descriptions do not

mention patients. Data and connectivity are the prime concerns. Have we lost sight of the patient? I sure hope not.

In 1990, I published a paper in the JCE on how devices would all be connected in 5 years. Now some 26 years later, we have a lot of data being collected, but it all seems to be for billing purposes not the care of the patient. Where have we gone wrong? Where is the problem in getting devices interconnected? Are we doing enough?

I am not sure how some of the present devices got approved, but there seems to be many out there in use that are of questionable value. The patient across the hall from me was old, not totally clear in the mind and tended to wander. They used a bed exit monitor on him. It had a loud and ugly sounding alarm that went off constantly. He discovered that when he needed to relieve gas pressure the alarm would go off as soon as he had one cheek slightly raised. The device was clearly in need of an adjustment on the alarm trigger point and delay. It's an example of a good product that turned out bad because it was too sensitive. That is an easy fix, but it will probably take years to get FDA approval.

As Clinical Engineers, we see and read about major breakthroughs in instrumentation or healthcare delivery only to learn that if you need that level of technology or care you might have to leave the US to get the service. Why is it that stem cells to combat dementia are created in San Diego but must be administered in Mexico? The same is true for a cure of diabetes that is made in the US but you must go to Canada or Europe to get the cure. To me, our gov-



ernment is limiting potential breakthroughs in treatments, and the benefits are not for the patients. They appear to be for the companies, agencies and physicians that push that product.

In my final meeting on the FDA's Good Manufacturing advisory panel, not known to be the one for me, I asked what I thought was a very simple question. The question was, "Why not use the ISO standards instead of creating another set of standards?"

I never got an answer. Maybe with an outsider becoming President we can modernize our systems.

Also, have a great Holiday Season.

Dave Harrington
Dave@sbtech.com

Journal of Clinical Engineering Call for Papers

The Journal of Clinical Engineering prints selections of the ACCE News in each issue and is interested in papers from you. If you have an urge to write, and good clinical engineering activities or ideas to share, please consider JCE as one of your outlets. One type of article not seen in a while is the Department Overview which presents how your department is structured and how it performs its functions. Shorter "Perspective" pieces are also welcome. You can discuss manuscript ideas with fellow member William Hyman, who is one of the editors of JCE. Contact: w-hyman@tamu.edu.

Send manuscripts to William or Michael Leven-Epstein at: michael.levinepstein@gmail.com

AAMI Update

AAMI Updates Core Competencies for Entry-Level HTM Professionals

AAMI has released an updated guide to the functional and personal competencies—and related academic topics—that healthcare technology management (HTM) students need to master to be fully prepared for their eventual jobs. These competencies were compiled by a committee of experts from a range of backgrounds, including academia, healthcare delivery organizations, independent service organizations, the medical device industry, the U.S. Department of Defense, and the U.S. Veterans Administration.

According to Barbara Christe, healthcare engineering technology management program director and associated professor at Indiana University–Purdue University Indianapolis, the major difference between the two editions is the specificity of the competencies. The new version offers more details to make the guide easier to use.

“We worked to more narrowly define the competencies and topics to provide greater clarity. For example, instead of listing ‘information technology concepts’ as an educational topic, the second edition talks about communication protocols, address schemes, and microprocessor fundamentals like memory and registers,” Christe explained.

The primary objective of the core competencies is to provide academic institutions with the information necessary to develop and validate their curricula; however, students can use the guide to ensure they have everything employers expect in entry-level employees, said Steve Yelton, an HTM professor at Cincinnati State Technical and Community College.

“Students can use this information to make sure they have the tools and skills that employers are looking for,” Yelton, who also contributed to the guide, said. “They may find that there are areas where they are lacking and may choose to take additional coursework while they are still in college. This is very valuable information that would

be hard for them to obtain on their own.”

Because the technology associated with healthcare is constantly changing, the committee expects to continue to update the guide. “Competencies will shift and evolve, as in every technology-based discipline. As a result, the document will continue to be updated in order to remain relevant and useful,” Christe said.

The guide is available as a free PDF at www.aami.org/corecompetencies.

AAMI Certification Programs Receive ANSI Accreditation

In a major acknowledgment of the quality of AAMI’s certification programs, three of them have been accredited by the American National Standards Institute (ANSI). The association’s certifications for biomedical equipment technicians (CBET), laboratory equipment specialists (CLES), and radiology equipment specialists (CRES) were recognized by this widely respected standards body.

There are more than 3,000 people who hold CBET, CLES, and CRES credentials, demonstrating their commitment to the profession, mastery of skills, and experience in core competencies. These certifications also help highlight a professional’s ability to provide quality and trustworthy service, which ultimately leads to a safer, more reliable healthcare environment.

“Earning ANSI accreditation is a major milestone for the AAMI Credentials Institute (ACI),” said ACI Board Member George Mills, director of engineering at The Joint Commission and member of the AAMI Board of Directors. “The value of being recognized as a CBET, CLES, or CRES is enhanced with this recognition and shows the significant benefits these professionals bring to their organizations.”

ANSI accreditation is based on an international standard that ensures the use of best practices and involves an application process and onsite assessment.

“I am delighted by the ANSI accreditation of the AAMI Credentials Institute’s certifications. Adding the credibility and capability of the ANSI organization to AAMI’s reputation serves to further solidify how meaningful the CBET, CRES, and CLES certifications are to the industry,” said ACI Board Chair Larry Hertzler, vice president of technical operations at Aramark in Charlotte, NC.

“We are so proud of this achievement,” said Sherrie Schulte, senior director of certification and the annual conference at AAMI. “It is a testament to the contributions of our volunteers who work to ensure that ACI-certified professionals represent the best in their field.”

AAMI Publication Probes Coexistence of Healthcare and Wireless

The availability of wireless technology in the healthcare environment is expanding rapidly, but its implementation can be complicated. Navigating the challenges of wireless technology in healthcare is the focus of the newly released issue of AAMI’s award-winning journal supplement *Horizons*. The articles and commentaries featured in the fall 2016 edition include:

- A roundtable discussion in which leading experts weigh in on questions such as: What lessons have the wireless community taken away from recent high-profile cybersecurity incidents? What are the opportunities and challenges associated with wireless medical devices moving healthcare in people’s homes? What will changes in the FCC spectrum open up for patients and industry, and what new risks do they introduce?
- Advice for healthcare delivery organizations and medical device manufacturers for improving the state of wireless.
- An explanation of an experimental method for evaluating wireless coexistence of Wi-Fi medical devices.

(Continued on page 5)

Update to IHE Commercially Available PCD Devices and Systems List

Clinical Engineers writing specifications for the acquisition or upgrade of integrated systems need a convenient, reliable way of specifying a level of compliance to standards sufficient to achieve truly efficient interoperability. The purpose of the Integrating the Healthcare Enterprise (IHE) initiative is to meet that need.

IHE Profiles provide a common language for purchasers and vendors to discuss the integration needs of healthcare sites and the integration capabilities of healthcare IT products. They offer developers and healthcare organizations a clear implementation path for communication standards supported by industry partners and carefully documented, reviewed and tested. They give purchasers a tool that reduces the complexity, cost and anxiety of implementing interoperable systems. See ftp://ftp.ihe.net/Patient_Care_Devices/Deployment/Commercially_Available_PCD_Systems/PCD%20Commercially%20Available%20Devices%20and%20Systems%202016%20November.pdf for a current list of commercially available IHE Patient Care Devices (PCD) systems and which IHE PCD profiles they meet.

Ted Cohen
IHE Liaison

Open Position: HTCC Secretariat

The Healthcare Technology Certification Commission (HTCC) is looking for a new Secretariat. The HTCC Secretariat is responsible for the administrative duties related to processing exam applications, notification of and processing renewals; organizing the annual BOE/Commission meeting; generating and distributing certifications; and answering questions regarding the exam process, appeals and renewals.

- 30 hrs/month (estimated)
- Administrative duties related to processing exam applications and renewals
- Organizing the annual BOE/Commission meeting
- Answering questions regarding the exam process, appeals and renewals
- Attending monthly HTCC and BOE Meetings

Skills Required

IT Literacy including knowledge of

- MS Word
 - Email
 - Online/cloud documentation storage
 - Time management and organizational skills
- Ability to work with minimal supervision
- Customer service and conflict management skills



If you are interested, or know someone that would be willing to help the Commission, please contact Pippa White, CCE at: certificationchair@accenet.org

AAMI Update (Continued)

(Continued from page 4)

- A case study on deploying real-time location system in a hospital.
- Evidence to dispel common wireless technology myths and steps for success.
- An approach to assessing the operational reliability of a wireless device and/or system.
- An evaluation of the potential impact of changes in the Wireless Medical Telemetry Service bandwidth.

A perspective on combining unique device identifiers with link-layer discovery protocol to secure networked medical devices.

Horizons is a peer-reviewed supplement to AAMI's journal *BI&T (Biomedical Instrumentation & Technology)* and is a benefit of AAMI membership. More information about *Horizons* is available at www.aami.org/horizons.

AAMI Staff



We wish you all a

Happy Holidays and Happy New Year!

Jim Keller, Ted Cohen, Jarek Rockman

The ACCE News editorial team

Closed Loop Systems: FDA holds workshop on Closed-Loop Controlled Devices

Closed loop systems are everywhere in our environment. From the thermostat, you have in your house or apartment to the cruise control in your car, they have become a regular part of our everyday experience. Recently, closed loop innovations are bringing us self-parking cars and cars that put the brakes on in the case of a pending collision. Factories and the airline industry have used closed loop systems for years to improve safety and lower costs.

The healthcare industry, especially in the USA, has been slow to adopt closed loop systems. An FDA workshop on Physiological Closed-Loop Controlled Device in the fall of 2015 offered insight into some of the thinking of key opinion leaders and the FDA on this important topic. More information from this workshop can be found on the FDA's website: <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm457581.htm>

In September of 2016, the FDA gave approval to an Artificial Pancreas Device System from Medtronic. This system is a full closed loop system, an automated insulin delivery system. The industry is watching very closely to see how well this does and

what types of guidance is available going forward.

There are a lot of products/systems in development that offer closed loop control to support pain medicine, anesthesia, sedation, dialysis and blood pressure control – to name a few.

Closed loop systems use a measurement of some kind coupled with a control system to administer the appropriate therapy based on the measurement and an algorithm. In your house, the thermostat measures the temperature and then increases or decreases the heat or air-conditioning to maintain the desired temperature. It is simple, sort of. The thermostat has no idea your teenage son left the porch door open. As the furnace tries to heat the whole outdoors it has no way to say, "We seem to be using a lot more heat than usual". Closed loop systems will need sophisticated algorithms to know when things are running off the rails.

One of the things the FDA worries about is what happens in a failure. You can imagine all the things that can go wrong and what could happen. If the blood glucose

sensor fails, becomes disconnected or the battery runs down, how does the system respond? This is a sophisticated system, and how it all works needs careful testing and demonstration to the FDA as to its safety and function.

The early systems will in many cases be open loop systems, where the system tells the clinician what to do, but does not take any steps on its own. A semi-closed loop system can take its own actions while alerting the clinician to what it is doing. A fully closed loop system is designed to run autonomously.

The military is looking at these systems to help provide care on the battlefield and during transport. A lot must happen before this is available, but it's on the horizon.

So, watch for more to change in this very exciting area, and be prepared. If we can have self-driving cars it will not be too long before the infusion pumps truly have a mind of their own.

Paul Cross, RN
President, The HTF
coss.paul@gmail.com

Update on ACCE Bylaws

All five of the recent proposed amendments to the [ACCE Bylaws](#) have been passed by the membership. ACCE currently has 305 eligible voting members. As per the bylaws change we passed in the spring of 2016, "An amendment shall be adopted only if at least 1/3 of members (quorum) respond; and 2/3 of the members responding to the ballot by the deadline vote to approve the amendment."

For these amendments, 132 members (43%) voted (3 members submitted blank ballots which are not in vote totals below). The vote for each individual amendment was as follows:

- Amendment #1 (121 approve, 6 do not approve, 2 abstain)
- Amendment #2 (127 approve, 2 do not approve, 0 abstain)
- Amendment #3 (128 approve, 0 do not approve, 1 abstain)
- Amendment #4 (126 approve, 2 do not approve, 1 abstain)
- Amendment #5 (127 approve, 2 do not approve, 0 abstain)

I communicated directly with those members who submitted comments associated with negative votes; or forwarded comments on membership issues to Jim Wear, Chair of the Membership Committee.

Alan Lipschultz, CCE, PE, CSP, CPPS
Chair of ACCE Bylaws Task Force
alan@hctc.pro

FDA Workshop: October 27-28, 2016

Opening remarks

The FDA held a workshop on October 27-28 in Silver Spring, MD to obtain input from stakeholders regarding the risks associated with servicing medical devices. The workshop, titled “Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing (5R), and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers” was well attended by clinical engineers, representatives of the OEMs and third-party servicers.

History of FDA Involvement

In 1993 the FDA introduced the Quality System Regulation (QSR), but exempted third-party servicers of medical equipment. In October 1997, the scope of the QSR was reviewed, and it was concluded that only OEMs and remanufacturers would be required to register with the FDA. Note that for this workshop, the FDA has combined in-house and independent service organizations (ISOs) into one group of ‘third-party’ service providers and was not making any distinction between the two groups.

Stakeholder presentations

The workshop was kicked off by presentations from several stakeholder groups. Peter Weems from Medical Imaging and Technology Alliance (MITA) spoke on behalf of the OEMs, who were also represented by Tara Federici of Advamed and Mark Leahey of the Medical Device Manufacturers Association (MDMA). Their main points were:

- Patients should have the assurance that no matter who services their medical equipment - the same quality standards are in place.
- The low percentage of reported incidents is due to lack of reporting, not lack of a problem.
- Manufacturers want data from other servicers on all problems, not just those that result in a patient incident, so that they can

trend and make corrections.

- Providing all documentation and parts could force the manufacturers to share trade secrets and also force them to share with some unqualified partners.

The ACCE stakeholder presentation was developed by Barbara Maguire, Vice President of Quality & Geisinger Clinical Engineering, Alan Lipschultz, Healthcare Technology Consulting, Malcolm Ridgeway, Acting Director, Maintenance Practices Task Force and Mark Bruley, Vice President, Accident and Forensic Investigation, ECRI Institute. Ms. Maguire presented the talk which highlighted the following points:

- Hospitals are already subject to many regulations from CMS which overlap the QSR requirements.
- Many third parties are already certified through ISO 13485 so additional certification is not necessary.
- Manufacturers should improve the resources provided to third parties so they can safely service their own equipment. This includes access to parts, documentation, training, updates, and technical resources on a par with what is provided for their own field service engineers.
- The FDA should not use its resources to regulate an industry where no patient safety problem exists. There is no credible evidence of a patient safety issue related to medical equipment service.

Representatives from independent service providers also weighed in. David Anbari from Mobile Instrument Service and Repair, Rob Kerwin from IAMERS and Tim McGeath from Trimedx strengthened the point that they do not see evidence of safety issues from service performed by third-parties. They discussed the policies already in place at their respective organizations to ensure quality and encouraged the FDA to take steps to require the OEMs to provide equal access to parts, training and documentation.

Mary Logan, President of AAMI, provided

several examples of how standards could provide a framework for consistent definitions and quality policies. Kate Ambrogli of the Federal Trade Commission (FTC) explained that the FTC encourages competition to improve safety, choice and quality in the marketplace.

The stakeholder presentations were followed by three panel discussions, each on a specific aspect of service chosen by the FDA. Panel #1 focused on the ‘Benefits and Risks associated with... Servicing Activities’. ACCE representative Mark Bruley from ECRI presented an analysis of data which showed a decrease in service related events since 1998.

“In the current analysis, we searched more than 3,622,000 combined records of MAUDE, Health Devices Alerts Tracker, and ECRI’s accident investigation cases files. Of those, 2,115,523 related to capital equipment. Based on searching for possible relevance, thousands of potentially relevant reports were then read. We found a total of 96 relevant reports out of the 2,115,523 records. That is a miniscule incidence of 0.005%. That incidence of problems—related to the theme of this workshop—is now two orders of magnitude **smaller** than it was in 1998.” Bruley, ECRI, FDA Workshop October 27, 2016.

This very useful and comprehensive study was cited by many other speakers as evidence that further regulation was not warranted.

During panel #2, several positive aspects of ‘Characteristics Good 5R and Servicing’ were highlighted. Salvatore Tatta, CCE Director of Clinical Engineering at the James J. Peters VA, Bronx, NY, provided a compelling summary of the valuable attributes of in-house clinical engineers, which could be curtailed if regulation imposed added costs.

Scot Mackeil, ACCE member and Senior Anesthesia Biomedical Technician from Massachusetts General Hospital (MGH) made several excellent and impassioned points expressing the view of the front-line

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FDA Workshop: October 27-28, 2016 (Continued)

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biomed during panel #3. The subject was 'Challenges Stakeholders Face in Performing High Quality 5R and Servicing Activities'. He demonstrated how proper information and parts from the OEMs could make patients safer by making the role of a biomedical technician more effective.

Malcolm Ridgway presented as part of the panel on "Current Best Practices and Recommendations" and outlined HTM community initiatives which improve the service of medical equipment, such as the use of benchmarking tools for identifying areas of improvement, development of interoperability standards and increased use of reliability centered maintenance (RCM).

He advocated for these types of cooperative activities between manufacturers and servicers as a way of improving patient safety, rather than additional regulation.

At the conclusion of the workshop, Captain Sean Boyd, Deputy Director for Regulatory Affairs, Office of Compliance, CDRH provided a summation on behalf of the FDA. He reiterated that the FDA had no predetermined conclusions and would not make a decision before reviewing all viewpoints thoroughly. Throughout the workshop, it was clear that the researchers from the FDA truly wanted to understand the situation better and to hear more from those on the front lines of this issue. Possible next steps which were proposed by participants were to set up work groups to encourage further cooperation between

servicers and OEM, develop standardized reporting of service data, define what the manufacturers should provide to third parties and recommending voluntary compliance with ISO 13485.

Further details on the workshop are available through the FDA website <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm511411.htm>, as well as through the [ACCE website, http://accenet.org/publications/Pages/Presentations.aspx](http://accenet.org/publications/Pages/Presentations.aspx).

Barbara Maguire, CCE MBA
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On behalf of the ACCE Board, the ACCE Advocacy Committee is pleased to note the [following awards and past winners](#). The 2017 ACCE Award Reception will be on Monday, February 20, 2017 at the HIMSS17: CE-IT/ACCE Awards reception in Orlando, FL and on Saturday, June 10, 2017 at the AAMI/ACCE meeting in Austin, TX.

Please take time to nominate worthy colleagues today or contact students to submit their papers. Just email [Nomination Form](#) with recommended individual(s), justification(s), and or papers to awards@accenet.org by December 30th, 2016.

Thank you,
Alan Lipschultz
ACCE Vice President

Welcome New Members

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

Name	Class	Job Title	Organization	Country
Calvin Wong Chi Hung	Individual	Assistant Biomedical	St. Paul's Hospital	Hong Kong
Shane Waltsak	Candidate	Graduate Student/Clinical Engineer Intern	UCONN/Brigham Women's Hospital	MA/USA
Brandon C. Low	Candidate	Graduate Student/Clinical Engineer Intern	UCONN/VA Los Angeles	CA/USA
Eric Aring	Institutional-Associate	Director of Business Development	Stanford Children's Hospital	CA/USA
Mawuli Hilarion Amedzekor	Associate	Biomedical Engineer	ENGISYS Limited	Ghana
Rodrigo Taborda Bonilla	Associate	Sales & Technical Support Director	DeLeC Cientifica Uruguaya SA	Uruguay
Michael Cauthen	Individual	Biomedical Engineer		MO/USA
Brittany Pack	Candidate	Graduate Student/Clinical Engineer Intern	UCONN	CT/USA
Benjamin Ford	Candidate	Graduate Student/Clinical Engineer Intern	UCONN/UMASS Memorial Hospital	CT/USA
Nithya Kubendran	Institutional-Associate	Clinical Systems Specialist I	Cedars-Sinai Health System	CA/USA
Angela Greene	Institutional-Associate	Sr EIS Project Manager	Cedars-Sinai Health System	CA/USA



We congratulate Jim Keller who was inducted to ACCE Fellow status:

James P. Keller, Jr., M.S., FACCE

Vice President, International Market Development, ECRI Institute

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 \$265). You must [login](#) to the ACCE website to view the code. Then visit [LWWW.com](#) to enter code.



VII Latin American Congress in Biomedical Engineering

The seventh Latin American Congress in BME was held on October 26th -28th in the beautiful city of Bucaramanga, Colombia. The city is noted for its superb and plentiful parks, the cleanliness of the public areas, ecological sites such as Juan Curi waterfalls and Chicamocha National Park, and the pleasant climate. Universidad Aut6noma de Bucaramanga was the site for the congress hosted by the Regional Council of Biomedical Engineering for Latin America known as CORAL. The American College of Clinical Engineering, International Federation for Engineering in Medicine and Biology (IFMBE), IEEE Engineering in Medicine and Biology (EMBS) and other BME organizations supported the conference.



Juan Curi Falls



Rainbow over Bucaramanga, Colombia

The keynote presentations from IFMBE included James Goh, President, Shankar Krishnan, President-Elect, Ratko Magjarevic, Past President, Marc Nyssen, Treasurer, and Luis Kun, Editor in Chief – Journal of Health & Technology, IUPESM. Dr. Kun's presentation was highly impactful to all, taking the congress from the focused areas of biomedical research to the big picture, such as resources for water and energy; climate change and related consequences; population growth areas; disaster preparedness; and security, ranging from terrorism to cybersecurity.

Clinical engineering topics were led by Renato Garcia (Brazil), Luis Vilcahuaman and Rossana Rivas (Peru), and Andrea Garcia, Jesus Soto and Antonio Miguel Cruz (Colombia). I was invited to present at the conference for Antonio Hernandez because he was unable to attend due to a family issue. Antonio's presentation on The Challenge of Interoperability in Health Technology was done virtually. His absence along with that of Adriana Velasquez from WHO were the only disappointments related to this outstanding congress. Antonio asked me to present on clinical alarm hazards which is becoming a concern in Latin America. Mario Castaneda with his close ties to congress leaders and Colombia attended the event also representing the ACE International Committee. I made a second presentation with Rossana Rivas and Jesus Soto on the ten year clinical engineering internship program conducted by the University of Vermont in partnership with Pontificia Universidad Cat6lica del Peru PUCP (Lima) and Universidad EIA/CES (Medellin). A video showing the 31 clinical engineering interns trained based on this partnership is found [here](#).

A site visit was made to Hospital Internacional de Colombia (HIC). This 900 bed Joint Commission International accredited hospital is considered the most advanced in the country with a focus on cardiac, neurological and cancer care. The most surprising aspect of the hospital system Fundacion Cardiovascular de Colombia which oversees HIC is that they also have an entity

which designs and manufactures medical



Physiological Monitor Developed by HIC



PUCP/UPCH Biomedical Engineering Students at the HIC Medical Device Innovation Center

devices with many approved by INVIMA, Colombia's FDA.

The group which I traveled with to the hospital was a 15 member contingent from the joint BME program from PUCP and UPCH – the best know engineering and medical schools respectively in Peru. Herbert Voight at Boston Univ. and I have been supporting Luis Vilcahuaman and Rossana Rivas throughout the development of this new BME program.

Lastly, in the spirit and culture of Latin America, there was a wonderfully arranged awards dinner at a traditional Colombian restaurant in the historic section of Giron. Professor Isnardo Torres, President of the Colombian Biomedical Engineering Society ABIOIN, was the primary organizer of the congress and received praise for his work

(Continued on page 11)

Clinical Engineering Graduate Education at UConn

This year UCONN had twenty-one students in their clinical engineering internship program. Ten of these students will be graduating in the spring with an MS BME degree and almost two years of clinical engineering experience. Resumes of the ten graduates can be found on www.ceeducation.org. Most of the cooperating hospitals who take these students are in southern New England, but we also have two students in Los Angeles at the VA medical Center. Next year three new hospitals will be taking student interns, one in Boston, one in Denver and one in San Francisco. This will bring the total number of students in the program to 25.

The program is a two year academic program with seven of the eight required courses focused on clinical engineering. The students pay no tuition and receive a graduate student stipend for 20 months of work as a clinical engineer in their sponsoring hospital. More information on the program can be found at www.bme.uconn.edu.



Clinical Engineering Distance Learning at UCONN Starting in Fall 2017

UConn will start a distance learning graduate level MEng BME degree focusing on clinical engineering. This program will not require the student to come to campus and will take three years to complete, taking one course per semester. There will be a prerequisite of three years of clinical engineering experience to apply to the program, so the program will not be for those looking to get into the field, but will be an advanced program for those who are currently practicing. Contact frpainter@engr.uconn.edu for more information.

*Frank Painter
Adjunct Professor & Clinical Engineering Program Director
University of Connecticut*

VII Latin American Congress in Biomedical Engineering (Continued)

(Continued from page 10)

along with the rest of the ABIOIN team. The entertainment finale of the event was a performance by professional tango dancers with congress participants from Argentina and Uruguay joining in.



Awards presentation and praise for the organizers



Professional tango dancers pictured with Toby Clark

*Tobey Clark, CCE FACCE
University of Vermont
ACCE International Committee Member*

Transcript of the International Committee Presentation during the Global Clinical Engineering Day on Oct. 21, 2016

View the recorded session [here](#).

Greetings to the Clinical Engineering community worldwide on October 21st, the day that we globally celebrate CE day.

My Name is Antonio Hernandez and I am the Chair of the International Committee (IC) of the American College of Clinical Engineering – ACCE.

The IC wants to be part of this celebration that recognizes the contributions and work of Clinical Engineers on improving the quality and safety of the healthcare delivery services worldwide, while also keeping pace and contributing to the evolution of the health technology field in the areas of deployment and managing new systems and devices.

ACCE has been operating for more than 25 years. Since the beginning, one of the objectives and priorities was to advance and promote Clinical Engineering and Health Technology Management, not only in the US, but worldwide.

The IC was the body within ACCE assigned with the purpose and responsibility to coordinate and facilitate the international relations and activities under the guidance and supervision of the ACCE's board and president.

The mission of the IC is to collaborate and work with Clinical Engineers and Health Technology partners and colleagues worldwide to facilitate further development and implementation of Clinical Engineering and Health Technology Management programs and services.

The main objectives of the International Committee are:

- Sharing Clinical Engineering and Health Technology Management knowledge and best practices through training and information exchange
- Advocate and promote Clinical Engineering and Health Technology Management
 - Coordinate and collaborate with international organizations:
 - International Federation for Medical and Biological Engineering; in particular, the Clinical Engineering Division – IFMBE/CED
 - World Health Organization - WHO
 - Pan-American Health Organization - PAHO
 - Institute of Electrical and Electronic Engineers; in particular, the Engineering in Medicine and Biology Society - IEEE/ EMBS
 - Latin American Regional Council on Biomedical Engineering - CORAL. This month, CORAL has the VII Latin American Congress in Biomedical Engineering

(VII CLAEB) in Bucaramanga, Colombia, on October 26-28.

One of the strategies and mechanisms implemented by ACCE to outreach the international community and share knowledge is through the “Advanced Clinical Engineering Workshops – ACEW.”

Since the beginning of the ACCE, and for the past 26 years, ACCE, in partnership with WHO, PAHO, and IFMBE, has implemented more than 50 workshops in more than 30 countries. Participants came from more than 64 countries for a total of more than 2,300 attendees.

The content of the ACEW is based on the body of knowledge developed by ACCE and the best practices documented by the members. Several of the health technology leaders can trace their beginnings back to being attendees of the ACEW.

ACCE was instrumental in the creation and operation of INFRA-TECH, one of the oldest LISTSERV groups operating as a global forum to exchange information on Health Services Physical Infrastructure and Technology. Since the creation of the list in January 1999 by PAHO and WHO, ACCE has been the administrator of the list.

ACCE, through the International Committee, has a strong international outreach program for members. Currently, 18% of the members are internationals located in 42 countries. It is a strong worldwide network used to promote and expand Clinical Engineering and Health Technology Management.

Lastly, ACCE has two international awards to recognize professionals and organizations that have substantially contributed to the development of the field. The awards are:

- Antonio Hernandez International Clinical Engineering Award (personal)
- American College of Clinical Engineering & Health Technology Foundation International ACEW Award (institutional)

Finally, I want to thank you for joining me today during this Celebration.

Antonio Hernandez
internationalchair@ACCEnet.org

Attend these can't miss ACCE endorsed events at [HIMSS17](#)

Pre-conference symposia: Medical Device Security Information - Clarity for Action

Date: Sunday, February 19, 8:00 AM - 4:30 PM

Location: Orange County Convention Center

Registration required

Description: Medical device security is now recognized as a major public health problem. Examine the critical functions of the recently launched medical device Information Sharing and Analysis Organization (ISAO) initiative co-led by NHISAC and MDISS. Uncover the potential transformative impact of the open and collaborative ISAO on patient safety and privacy, health system and manufacturer cybersecurity operations, and opportunities for stakeholder participation. Key device cybersecurity updates will be provided.

Pre-conference symposia: Interoperability and HIE Symposium: Interoperability and Health Information Exchange – Making it Work

Date: Sunday, February 19, 8:00 AM - 4:30 PM

Location: Orange County Convention Center

Registration required

Description: Continued adoption of value-based payment models, implementation of a growing number of health IT applications across care settings, evolution of available technical standards, and attention from federal policymakers all underscore and align the need for semantic interoperability and exchange of data, information and knowledge across the health system. Explore the opportunities and challenges affecting diverse stakeholders stemming from a confluence of new policies, evolving standards and certification programs, applications, and coordination required to realize a learning health system that is patient-centered and improves population health.

HIMSS Spot: CE & IT: Past Achievement, Current Needs and Future Vision

(Joint session by ACCE, AAMI & HIMSS)

Speakers: Elliot Sloane, PhD, CCE, FHIMSS, FACCE & Steve Grimes, FHIMSS, FAIMBE, FACCE

Date: Tuesday, February 21, 3:00 PM – 3:45PM

Location: HIMSS Spot, Orange County Convention Center, West Hall C

Description: Clinical technology investments by healthcare organizations have skyrocketed in the past 10 years ... outpacing capital IT investments by more than a factor of 2. Clinical technologies are increasingly becoming integrated into the IT infrastructure. This session describes what has been accomplished and what still remains to be done by the IT and clinical engineering communities to achieve effective collaboration on the management of integrated support services.

HIMSS Interoperability Showcase - Redesigned

Location: Exhibit Floor, Hall F, Booth# 9000

HIMSS Interoperability Showcase: Where IT Connects Everything

Explore a health ecosystem where standards-based health IT enables individuals to securely access, contribute to and analyze their own health data. Start your interoperability journey at the HIMSS17 Interop Showcase February 20-22, 2017:

- Customize your interoperability experience with interactive learner stations to learn about the HIMSS Interoperability Story
- Engage in tours to see current health IT products in the market that deliver standards-based interoperability and health information exchange
- Learn about interoperability trailblazers, engage in peer-to-peer discussions, and meet key stakeholders in our Education Theater
- Visit kiosks and meeting place rooms in the Product Marketplace to learn more about the products being demonstrated
- Meet other attendees and interop experts to learn best practices during our networking events

[Click here for Schedule at a glance](#)

ACCE members to register at discounted Endorser Rate.

[Click here to REGISTER](#)

[Book your Room in the HIMSS Block](#)

Call for Nominations!

Clinical Engineering Hall of Fame Class of 2017



The American College of Clinical Engineering is seeking nominations of individuals who had made outstanding and notable contributions to and/or the evolution and advancement of Clinical Engineering.

Please submit your completed nomination form and supporting information to CE-HOF@accenet.org by February 28, 2017.

Induction - June 10, 2017 in Austin, TX.

[Eligibility Requirements](#)

[Nomination form](#)

[2016 & 2015 Inductees](#)

ACCE Calendar

January 12, 2017

ACCE Webinar: Clinical Engineering—Growing Competencies for Growing Responsibilities

[More Info](#)

February 10, 2017

ACCE Webinar: The Joint Commission Update

[More Info](#)

February 19-23, 2017

HIMSS17 Annual Conference & Exhibition

[More info on ACCE Activities](#)

February 28, 2017

Last day to submit nomination to CE Hall of Fame 2017

[Nomination Form](#)

March 9, 2017

ACCE Webinar: Translation Medicine—Moving Past Traditional Clinical Engineering Paradigms

[More Info](#)

March 19,-20 2017

2017 AIMBE Annual Event
Location: Washington, DC



AMERICAN COLLEGE OF CLINICAL ENGINEERING

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