



# ACCE News

Newsletter of the American College of Clinical Engineering

July - August 2016

Volume 26 Issue 4

## 2016 ACCE Officer and Board Election Results

[See Page 5](#)

## ACCE Congratulates 2016 Class of CCEs

[See Page 11](#)

In this Issue:

View from the Penalty Box	<a href="#">2</a>
AAMI Update	<a href="#">3</a>
2016 Officer/Board Election Results	<a href="#">5</a>
HTF News	<a href="#">6</a>
Perspectives from ECRI	<a href="#">7</a>
CE Development in Albania and Balkan Region	<a href="#">8</a>
AAMI HTM Certification	<a href="#">9</a>
ACCE Bylaws Update	<a href="#">10</a>
Welcome New Members	<a href="#">11</a>
2016 Class of CCEs	<a href="#">12</a>

## President's Message



Wow, this is it. By the time you read this, I will have completed my terms as President of ACCE. That means this is my last President's Message, so I'm going to get a bit philosophical.

It all started with a call from Jennifer Jackson about four years ago. She knew I was retiring from the VA; when Jennifer called, she said she didn't want me to be bored in my retirement. Then she made me "an offer I couldn't refuse" – run for President-Elect. And this is where I ended up.

I've been a member of organizations that look beyond self-interest, to serving the public good most of my life. Starting with my military duty – which was the highest commitment; a willingness to sacrifice everything, including my life to protect others. After that, I've been a member of veterans' organizations and later, professional organizations. All are willing to donate time and resources to help leave this place better than we found it.

This has been a great run, it's been an honor to serve as your President for the last two years. It's a bit strange to me, I've never seen myself as a leader. My career path wasn't traditional. I joined this field in 1989, at the tender age of 33, after a disability ended my career as a field service electronics tech. At a Manny meeting, a new CE asked me for career advice. I've heard from others I highly respect that their advice was "to make their boss look good". Excellent advice, if your career is your primary focus. Mine hasn't been – I came into this profession focused on helping ensure my fellow veterans received the best care possible. That was my driving force while at the VA. If that helped my boss look good, then great. If given the choice between making my boss look good to help my career vs. ensuring we did the best by the patients, I chose the patients. For most of my time, that worked. When I felt I couldn't do that anymore, it was time to do something else.

That something else is Integrating the Healthcare Enterprise (IHE). I realize that this is a logical extension of my career philosophy. And ACCE has a lot to do with it.

My introduction to ACCE was at an AAMI meeting in Anaheim, CA. I had a poster session that year which was my first presentation. While at my poster, two older gents came up to discuss my poster with me. When I saw them, I was pretty intimidated. They quickly made the feeling go away and were incredibly supportive and kind. Those two were George Johnston and Marv Shepherd. A great intro to ACCE. A few years later, George called to ask me to start a Professional Practices Committee for ACCE. I did, and that decision led me down this path. It also put me in contact with Manny Furst, who I got to know fairly well via the Manny Meetings. When it was time to move on from the VA, Manny was ready to wind down from his IHE duties and was looking for a replacement.

Next, I'd like to highlight a few of our activities while I've been President.

One of my goals was to 'de-grey' ACCE leadership. Taking on this role at 58 (literally, I took over on my birthday), I was concerned that we didn't have enough participation from younger members. I'm quite pleased to see that we now have several younger members taking on major ACCE roles.

*(Continued on page 2)*

# President's Message (Continued)

(Continued from page 1)

I'm incredibly confident of our future thanks to all of you.

I believe we've accomplished and started quite a few things during the last two years. We've integrated HTCC, started our first ever financial audit, are in the process of becoming an official Non-Government Organization with WHO, advanced our relationship with AIMBE, and are currently updating our bylaws. We also submitted formal comments to the FDA on their proposed Rule regarding 3rd party service. By the time you read this article, we will have a volunteer to represent us at their conference in October. As you can see,

some of this is not 'sexy' work, but it's necessary as we mature as an organization.

Finally, I'd like to thank all of you for your support and trust the last two years. This has been an honor and your faith in me, the other Board members and our Committee Chairs is humbling.

In particular, I'd like to thank Jennifer Jackson for asking me to give this a try, and Petr Kresta, who agreed to do just that as ACCE's next president. And, of course, a huge thanks to the rest of the Board and Committee members who do all the hard footwork. Finally – thanks Suly; you keep this show running. I'm incredibly confident that ACCE is in great hands.

While I'm at it, I'll hopefully plant a seed – I plan on remaining the IHE-PCD Technical Program Manager for a while longer. However, I've been working to put food on the table since I was 14; 46 years is quite a while to work. I'll retire completely before too much longer and will look to pass this opportunity on to another. As for ACCE: I'm not quite gone yet – as Immediate Past President, I'm head of the Nominations Committee. What that means, is that in the next year, I'll approach some of you, just as Jennifer approached me. At that time, please consider the opportunity: "Give it a try".

Paul Sherman  
[president@accenet.org](mailto:president@accenet.org)

## View from the Penalty Box

Here we are past the mid-point of the 2016 year and not much seems to have changed. We have a winner of the Stanley Cup. Pittsburgh has a very good team and should repeat. Cleveland has had its first winner in a major sport in 50 years, they probably will not repeat. Recently we lost several hockey players, most my age or older, like Gordie Howe, but some too young. Every time I look into a mirror I can see the results of a "discussion" that I had with Gordie Howe. Off the ice he was the nicest, most gentlemanly person you would ever want to meet, but once on the ice, stay clear or you were going to hurt.

In several published articles the authors all pointed to the fact that here in the US the average cost of healthcare for a person is \$10,000.00 per year. Yet we are not in the top 10% in life expectancy, or wellness, or general health levels. Are we providing too much healthcare or just the wrong healthcare for that 10 grand? Then we see reports of the billions that will have to be spent on the EMR—or is it the EHR or just the black hole that money is getting poured into. Most of the hospitals that I have information on say that it will be 2 to 3 years before everything is in place. What I have not seen is

what the benefits of these systems will be to the patients. Are they just another way to suck money from our pockets, in the name of better healthcare? What is not going anywhere is the politics which are so nasty and divisive. If things don't change, the US is in from some tough times. All the politicians seem to do is point fingers rather than find solutions to solve some of our problems.

Remember all the promises made on how all the data collection on medical device testing and repairs was going to reduce costs? Has anyone seen any publications or presentations where it is shown that the data collected did impact healthcare costs? If so, please share it with the world. One problem that no one doing this digging thought about is that by the time the data was collected over a few years, worked on and published, most of the equipment was probably replaced often by newer equipment with the same problems. As a profession, we need to get better control over what comes into our hospitals, ensuring that it advances patient care and is not just "something new" with the same problems as whatever it's replacing.

(Continued on page 3)

## ACCE News

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

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# View from the Penalty Box (Continued)

(Continued from page 2)

In another published “research paper”, the statement was made that 250,000 people, here in the US, die every year because of medical errors. Not mentioned was the type of errors, what corrective actions were taken, and who got punished for the errors. Part of being a good clinical engineering group is looking into “unexplained deaths”, to determine if technology contributed to the death or could have prevented it. As a profession, we have to look beyond alarms, leakage and useless data searches. Instead, look for and implement better technology to prevent these deaths, if in fact the data is true.

At a recent regional meeting of Biomed and Clinical Engineers the conversations over a “treated” glass or bottle of water, or 2 or 3, were almost always the best source of good and useful information.

Too many of us are reluctant to do formal presentations or write articles for publication on what we have found to be true and helpful. Please share your findings in a formal way not just over “treated” water. Also at this meeting was a lack of young people just getting started. As managers it is important to get the young ones exposed to colleagues at other institutions most of whom probably are very willing to share thoughts on what they have encountered and what actions it took to make the situation better and the patient safer.

In closing, I would like to thank all of our officers and committee members for your time and efforts to make patient care better, safer and less costly. We might not have hit all the goals, but at least we are trying, which is more than we can say for the politicians who seem to be more interested in doing nothing, collecting very good salaries and fantastic benefits. I keep going back to an old great lie “I am from the gov-



ernment and I am here to help”, so sad but so true.

Stay cool this summer.

Dave Harrington  
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## AAMI Update

### Interviews for New AAMI CEO Set to Begin

The first round of interviews for AAMI’s new president and CEO began in early August, signaling the start of the next phase of the association’s executive search. The search is being led by Korn Ferry, with the assistance from members of AAMI’s Executive Search Committee.

Mary Logan, only the second AAMI president and CEO in AAMI’s 48-year history, will be retiring at the end of 2016. Her departure will come almost eight years after she took the helm of the association.

“Mary has done a remarkable job of leading AAMI since 2009. She brought new life and energy into AAMI and has helped position the association for a strong future. Now it’s up to all of us to find that perfect person who embodies the spirit, energy, and skills needed to lead AAMI through this next phase into the future,” Phil Cogdill, who chairs both the AAMI Board of Directors and the search committee, wrote in

### AAMI News.

The search for AAMI’s next president has generated considerable interest in trade publications that cover the healthcare technology and association industries. Reporters and other interested parties are making calls, trying to determine who is in the running.

With input from AAMI staff, the Board of Directors, and other volunteers, Korn Ferry and the search committee developed a leadership profile earlier this summer that outlined the qualifications and qualities the next CEO of AAMI needs to help the association grow and thrive at a time of incredible change for healthcare technology and healthcare in general.

Cogdill described this person in his essay as “someone who is a proven strategic thinker, capable of anticipating challenges and trends, a credible executive with stature and presence, and a ‘servant leader’ who will gracefully navigate the unique dynamics of working with a diverse membership,

volunteer board, and staff.” This person will also have proven business and financial acumen, strong negotiation skills, a sense of diplomacy, and a track record of recruiting, developing, motivating, and retaining staff.

Fitting this profile is more important than having experience in any specific field or industry, according to Cogdill. “AAMI’s new president could come from any number of career paths with experience as a hospital senior executive, industry senior executive, seasoned association executive, or someone from a unique sector that aligns well with AAMI’s core businesses,” he added.

The second round of interviews with the finalists is scheduled for mid-September, and the committee plans to have a new CEO firmly on board before the end of the year. Ideally, search committee members would like to have some overlap between the start of the new president’s tenure and the end of Logan’s.

(Continued on page 4)

# AAMI Update (Continued)

(Continued from page 3)

## New Video Takes Charge of Device Battery Management

The batteries used to power medical devices are increasing in variety and complexity. AAMI surveys of healthcare technology management (HTM) professionals consistently show that the management of batteries is a top medical device challenge. A failure in battery management can result in a loss of power, leakage, overheating, fires, or explosions.

To help HTM professionals better understand and manage batteries, AAMI has released an instructional video, *Battery Management and Medical Devices*. The video, released in June, covers the most commonly used battery technologies, the benefits and drawbacks of different battery types, how to develop a battery management plan, as well as procurement, testing, and safety.

“Each hospital should have at least one person who really knows what’s going on and can be used as an in-house resource,” said David Marlow, CBET, a senior biomedical technician for the University of Michigan Health System in Ann Arbor and a consultant for the video. “People need to realize that all batteries are perishable items. They’re going to die. How you treat them determines how long they’ll live.”

According to a small survey by the Food and Drug Administration (FDA), up to half of service calls in hospitals are related to battery issues, as detailed in the March/April 2014 cover story of BI&T.

In an interview with AAMI, Alan Lipschultz, president of HealthCare Technology Consulting, said that keeping batteries working requires a defined plan and staff education.

“There is a much greater variety of batteries available than in the past, and their chemistries and characteristics vary widely. Your staff needs to understand the differences between the battery types and how each type should be stored, charged, and disposed of,” he said.

Battery managers can use the video to select the right batteries for their devices and keep them working properly. That’s especially important when these devices are used outside of a clinical environment, such as in a patient’s home.

Jake Kyprianou, senior science health advisor for the FDA, who contributed to the script, said, “We’re excited that AAMI has taken the initiative to provide what we see as a service to the healthcare community, and we want to thank AAMI for raising awareness of this issue.”

*Battery Management and Medical Devices* is available from [www.aami.org/store](http://www.aami.org/store) or by calling 1-877-249-8226.

## Guide Shows HTM Departments How to Move ‘Beyond the Basics’

Healthcare technology management (HTM) departments should strive to provide added value to healthcare delivery organizations—moving beyond compliance with regulatory requirements to help blaze new trails for the effective and safe stewardship of medical devices and enhancing patient care in the process, according to the authors of an updated version of AAMI’s *HTM Levels Guide*.

“Just doing the regulatory basics is one thing. That’s important. But we’ve also found examples of HTM programs doing very innovative things that provide a lot more support to clinicians,” said Matt Baretich, CPPS, president of Baretich Engineering and co-author of the updated guide. “We wanted to emphasize that the target for every agency or program is level two—established. You’re not just meeting basic requirements—you’re providing a lot more value to the organization.”

The guide—which was developed based on feedback from clinical engineers, consultants, AAMI staff, AAMI’s Technology Management Council, and others—provides guidance to help HTM departments progress through three levels, defined as:

- **Fundamental:** Programs that provide a basic level of technology services and

compliance with applicable standards and regulations. The authors describe the minimum level as suitable for new HTM programs and those in very small healthcare organizations.

- **Established:** Programs that have moved beyond the basics to provide additional services, with a focus on cost-effectiveness. This is the level that all HTM programs should work to achieve, according to the authors.
- **Advanced:** Programs that are on the leading edge, demonstrating the full range of potential for HTM contributions to patient care. While very few programs achieve this level of performance across the board, the authors believe that every HTM program can find opportunities for improvement at this level.

The second edition includes updated regulatory requirements, references, and an emphasis on continuous improvement beyond the basics. For example, a HTM department operating at the “fundamental” level would have some involvement in equipment planning. At the “established level,” HTM is regularly involved, while the most “advanced” HTM department takes the lead in the equipment planning process.

The guide also includes a pull-out HTM program checklist poster to help departments visualize what they have accomplished and where they are headed.

“The *HTM Levels Guide* is easy to use, read, and makes it easy to make decisions on what to implement,” said Patrick Bernat, director of HTM at AAMI. “Certainly, a manager or director of a department would use the guide for planning. But anybody in the field could read and understand it, to learn where the field is headed.”

The second edition of the *HTM Levels Guide* is available to download for free. Printed copies can be ordered from the AAMI Store using product code HTMLEVEL. Printed copies cost \$50 or \$30 for AAMI members.

AAMI Staff

# 2016 ACCE Officer and Board Election Results

Thank you for participating in the 2016 ACCE Officer and Board Election and casting your important vote. The election for ACCE's new Board for the year 2016 has been finalized and the Board has approved the results.

The election ballot was emailed to 284 eligible members, who include Individual, Fellow and Emeritus members in good standing. Institutional/Corporate Fellow and Individual members also participate in elections. Of the 284 members, 109 votes were received between July 1 and July 17, 2016

The new Board of Directors will take office as the governance body for ACCE on August 26, 2016. We are pleased to announce the 2016-2017 team and, as always, we look forward to serving you and your needs.

Title	Name	Votes received
President	Petr Kresta, MS, P.Eng.	102
President Elect	Arif Subhan, MS, CCE, FACCE	101
Vice President	Alan Lipschultz, PE, CSP, CCE, FACCE	103
Secretary	Elena Simoncini, MS, CCE	105
Member at Large	Joan Brown, MBA, CCE	103
Member at Large	Shelly Crisler, MS, CCE	103
Member at Large	Samantha Jacques, PhD	103
Member at Large	Ilir Kullolli, MS	103

The following Board member will be continuing the second year of his term:

Title	Name
Treasurer	James Panella

The following Board member will automatically become Immediate Past President when the new President takes office:

Title	Name
Immediate Past President	Paul Sherman, CCE, FACCE

*Elena Simoncini*  
ACCE Secretary  
[secretary@accenet.org](mailto:secretary@accenet.org)

## 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 [LWV.com](http://LWV.com) to enter code.





# Healthcare Technology Foundation News

## HTF Alarms Group Update

The HTF Alarms group has been very active since the AAMI 2016 conference. Tobey Clark presented the preliminary results from the 2016 survey during the conference and now the group is completing a comparison review from previous surveys. The group is focusing on what have we learned since the first survey.

HTF is also partnering with AARC to look specifically at the data as it applies to the respiratory therapist world.

Many alarm group members participated in the AAMI Alarm Coalition group held on July 20th. Those who did participate with help guide HTF in their continued partnership with AAMI in the alarms endeavor. Marge Funk presented at the coalition meeting on the AAMI survey: *Use of Monitor Watchers and led the panel discussion: Are We Over Monitoring?*

The group also released a **Guide to Clinical Alarms** brochure that can be used by clinical facilities to educate patients and visitors. The brochure was also published in Spanish. Both can be found at

<http://www.thehtf.org/publications.asp>.

Karen Giuliano will be presenting at the AAMI Hot Topics in Clinical Care meeting on September 28th. She is the first presenter to the National Coalition for Infusion Therapy Safety group.



HTF Board members Yadin David and Jim Wear and ACCE Past-Advocacy Committee Chairman Tom Judd at Chinese Technology Management Congress

The second annual China Clinical Engineering and Health Technology Management Congress took place in Suzhou, south of Shanghai, China. Suzhou is known for its beautiful gardens, culinary dishes (see the Dragon fish photo above), and large lake. The organizing committee hosts were very kind and made sure that the HTF team had time to enjoy the gardens in spite of the extreme heat that influenced the region.



Improve healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies.



In addition to the keynote presentation by Yadin David, Jim Wear, Tom Judd and Yadin presented lectures on the CE-IT technology management topics.

A new part of the Congress program this year were English presentations by Chinese Clinical Engineers with Tom and Jim serving as judges ranking the best presentation and the runner ups. Jim also received an award for traveling to China many years and helping the Chinese CE society to evolve. Tom, Jim and Yadin also conducted a clinical engineering certification prep workshop and conducted the written and oral examination. This program successfully produced over 250 CCEs out of 900 candidates over the past nine years!

Be sure to visit the HTF website, [www.thehtf.org](http://www.thehtf.org) to see our programs and resources. While you are there, feel free to hit the DONATE NOW button. We will accept them anytime and they are always tax deductible!

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# Perspectives from ECRI Institute

As I write this article, I am wrapping up my tenth and last year as a member of ACCE's Board. I was first recruited to serve as a Member-at-Large. I served for two terms, for one year under Elliot Sloane's leadership, then for two years with Ray Zambuto as president, and then under Izabella Gieras as she took over from Ray. All three were great leaders for ACCE and did an excellent job of helping me to serve the members of our great organization. I then took a break from the Board to focus more on my ECRI Institute responsibilities. Five years later Steve Grimes, who was Immediate Past-President at the time, called and asked (twisted my arm) if I'd be willing to serve as President-Elect. It was a tough decision, given my continuing busy workload with ECRI Institute, but I said yes and am very happy that I did. I was President-Elect under Mario Castaneda, served as President for two years, and have been happy to support current President Paul Sherman for the last two years as Immediate-Past President.

It's been very gratifying to help lead a continued steady growth in ACCE's membership and to support the amazing activities of our committees. Many of us were recently at the AAMI conference in Tampa, Florida where the Education Committee ran an excellent clinical engineering symposium with record-breaking attendance. Each time I have gotten together with our International Committee, I have been im-

pressed by its energy and the commitment of Antonio Hernandez as chair and his fellow committee members. The Advanced Clinical Engineering Workshops have enriched the professional lives of so many clinical engineering and other healthcare professionals around the world. And, I suspect that the programs have been at least as enriching for the faculty members as the program attendees.

During my presidency ACCE took on the ownership of the Healthcare Technology Certification Commission which runs Clinical Engineering Certification. You may remember that HTCC was previously part of the Healthcare Technology Foundation (HTF). HTF's board had decided that the certification program was not part of its future plans and sought another organization to take it on. I was very proud that the HTF Board had the confidence and trust in ACCE to select us as the new steward of such an important program and service for the clinical engineering community.

The transition of HTCC from HTF to ACCE was a tremendous amount of work. It involved extensive contract review and negotiation, management of new financial responsibilities, and communications with current and prospective certified clinical engineers and the rest of the clinical engineering-related community. I'd like to thank past HTF President Tobey Clark and

the HTF Board, the members of the HTCC under the leadership at the time of now incoming ACCE President, Petr Kresta, ACCE's Board, and ACCE Secretariat Suly Chi for all of their help and support with this effort. I'm pleased that we put in place a strong and thriving certification program. In fact, on one of the many trips I've been taking in my new international role at ECRI I met a colleague from Hong Kong who traveled to AAMI this year to take the oral exam for CCE. It's great to see how far reaching our program has become.

I'd like to wish the incoming ACCE Board the best of luck as they take on the stewardship of our fine organization. Congratulations on your new roles and responsibilities. I know that we will be in good hands. I'm looking forward to supporting you in my role as a now regular member of ACCE. I'll also be continuing my longtime support of our newsletter as managing editor.

Finally, I'd like to give a big thank you to our 2015-2016 Board, especially our President, Paul Sherman. Paul, you did a great job and you and the rest of the Board were great to work with. ACCE should be very proud to have such excellent and dedicated leadership.

*Jim Keller, Vice President for International Market Development, ECRI*  
[jkeller@ecri.org](mailto:jkeller@ecri.org)

## Just Released: A complete CCE study guide, V6.0—August 2016

ACCE would like to thank the volunteers who contributed over the past 20 years (1996-2016) to update the CCE Study Guide, which is today a complete guide.

Order your copy [here!](#)

Recent and previous contributors include:

V6.0 (August 2016): Matthew Baretich; Tobey Clark.

V5.0 (May 2016): Austin Hampton

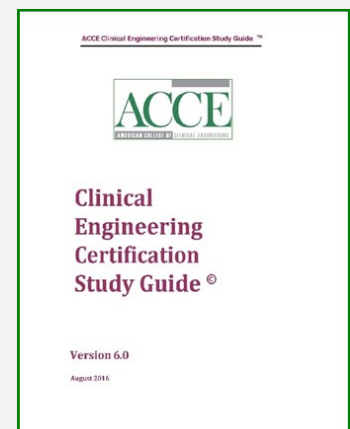
V4.0 (July 2014): Jacob Johnson, Jennifer DeFrancesco

V3.0 (August 2012): Ilir Kullolli, Kindall Druker, Frank Painter

V2.0 (July 2007): Arif Subhan, Ismael Cordero, Evelyn Fan, Robyn Frick, Jennifer Jackson, Jeff May, Frank Painter, Bokang Rapoo

V1.0 (1996): Stephen L. Grimes, Jerry Anderson, Salil Balar, Ted Cohen, Vinnie DeFrancesco, Izabella Gieras, Frank Painter, Christine Ruther, Marv Shepherd

\* Prepared by Individuals not involved in the preparation of the CCE Exam.



# Clinical Engineering Development in Albania and the Balkan Region

By Ledina Picari, MS



On February 22, 2016, I was honoured to receive the “ACCE 2016 Antonio Hernandez International Clinical Engineering Award” from American College of Clinical Engineering (ACCE) for the leadership in promoting and advancing Global Collaboration of Clinical Engineering to enhance Healthcare.

I have been working for Ministry of Health (MoH) Albania since 2004. I am head of the Medical Devices and Systems Unit at Ministry of Health of Albania, responsible for the overall supervision and monitoring of medical devices in the healthcare sector aiming to increase patient and user safety through design of laws, sub-laws, policies, recommendations and guidelines for the use, as well as management and maintenance of medical devices. One of my priorities is trying to introduce and expand the role of clinical engineering in my country and the Balkans region.

Receiving this Award from a prestigious institution like ACCE was a fantastic surprise to me. It motivates and helps me to continue working hard in the clinical engineering area. Before meeting Antonio for the first time in Denver, June 2015, during a seminar organised by ACCE, I knew him only virtually from his great contribution in the field. I would have never imagined that we were going to be connected in such a special way.

The international recognition is a great encouragement for me on realizing my project for the development of clinical engineering in Albania; further strengthening of the unit for medical system in Ministry of Health, legislation design and implementation etc., through a detailed plan of action for the next years.

As a focal point for medical devices, I have a long collaboration with WHO participating in the First Global Forum on medical devices and other important events. As a member of ACCE, I am in contact with a lot of experienced people in the field and have more access to resources. This helps me to expand the role of clinical engineering in my country, to further develop MoH CE and CE-IT structure, CE training, Health Technology (HT) maintenance strategies, and HT legislation.

The next step toward legislation implementation is the process of registration of medical devices, which we are finalizing soon. The process is done in collaboration with the law department at Ministry of Health, the Agency for drugs and medical devices. My Unit has a leading role in this process by collaborating with public and private stakeholders to realize this process with no artificial barriers for the medical devices operators but to guaranty safety for the devices in our market.

One of my main duties is the preparation of the legislation. Albania has started the process of integration in the European Community so the legislation design is based on the approximation of legislation for medical devices with European directives.

On July 17th, 2014, Albanian Parliament approved the first legislative framework on medical devices: the Law 89/2014 “For Medical Devices.”

The law regulates the circulation of medical devices in Albanian market and improves the safety for the patients and users. The law defines and enables the regulation of:

- Drugs and Medical Devices Agency for registration, inspection, and adverse event report.
- The registration of medical devices and registration of persons responsible for putting medical devices in the market.
- The essential technical requirements that medical devices, in vitro medical devices, and implantable medical devices must meet.

- Conformity assessment procedures for medical devices.
- Authorization criteria for conformity assessment bodies for medical devices.
- Documentary requirements needed to be submitted to the competent authorities before putting on the market and/or using of medical devices.
- Vigilance system and market surveillance procedures.

To make the law applicable, we design three sub-laws: The Decision of Council of Ministers (DCM) “On Essential Requirements, conformity evaluation, classification and CE marking of medical devices” that transposes the Directive 93/42/EEC dated 14 June 1993 for Medical Devices, DCM Nr. 508 date 10.06.2015, “On Essential Requirements, conformity evaluation and CE marking of active implantable medical devices” that transposes the Directive 90/385/EEC dated 20 June 1990 on “Active implantable medical devices” and DCM Nr. 189 date 09.03.2016, “On Essential Requirements, conformity evaluation, CE marking of in vitro medical devices” that transposes the Directive 98/79/EEC dated of 27 October 1998 for In vitro Medical Devices.

In addition to my work in the MoH, I am also a supporter of clinical engineering at Polytechnic University of Tirana lecturing “Risk Management in hospital environment” at the Clinical Engineering Master Program. My teaching responsibilities include healthcare safety, EU directives and Albanian legislation on medical devices, the radiation protection in hospitals etc. I am the Head of the Technical Committee (TK 140) of the In-Vitro medical devices, General Directorate of the Standardization, a technical body responsible for the preparation and approval of the national standards of the in vitro medical devices.

I received my Bachelor’s Degree in Electronics at Polytechnic University of Tirana, and my Masters of Science Degree in Biomedical Engineering, University of Surrey, UK.

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# A Quick Look at the New AAMI Healthcare Technology Manager Certification

The certification exam for Healthcare Technology Managers (CHTM) was introduced in Spring 2016. Developed and managed under the AAMI Credentials Institute (ACI), the exam is intended to offer professionals across the healthcare technology field a certification pathway leading to management of healthcare technology operations and the management of personnel. The exam is open to technicians, clinical engineers, managers and other approved disciplines provided they meet the minimum work and management experience. Those who already hold a current CCE or an AAMI certification would need to demonstrate three years of supervisory or management experience within the last five years to be considered eligible. Refer to the ACI Certification Handbook for complete requirements and eligibility pathways.

The scope of the CHTM exam questions cover skills needed to provide leadership in the areas of operational management, strategic planning, business operations and employee relationships. The body of knowledge for the 100 question written exam is outlined in the ACI Certification Handbook and is broken down as follows.

	Recall	Application	Analysis	Total Questions
<b>Operations Management</b>	11	11	24	46
<b>Financial Management</b>	3	13	3	19
<b>Risk Management</b>	2	8	2	12
<b>Human Resources</b>	3	9	0	12
<b>Education and Training</b>	4	7	0	11
<b>Total</b>				<b>100</b>

The depth of knowledge for each topic ranges from general recall to analysis of more complex problems. With the majority of emphasis on operations management, one should be familiar with management of daily departmental operations, compliance with regulatory agencies, procurement, project management, disaster planning, and interdepartmental relationships. There is no oral exam. Recertification is required every three years. Starting 2017, one must document thirty (30) continuing education credits (CEU) with their renewal application.

Because a number of clinical engineers are currently working as managers and department directors, one obvious question may be whether there is overlap between the CHTM and the ACCE clinical engineering certification (CCE) programs.

Clinical engineering certification is intended to promote healthcare delivery improvement and assess competency of professionals who

apply engineering and management skills to advance patient care and support healthcare technology. Eligibility is open to candidates who hold a BS degree or higher in engineering, PE licensure or BSET in engineering technology and demonstrate the required work experience. A CCE is required to pass the written exam and demonstrate application of practical knowledge and problem solving through the oral exam. CE Certification also requires recertification every three years to include active participation within the clinical engineering field in the areas of employment, continuing education and professional activities.

The distribution of the 150 question CCE written exam is listed below and has an emphasis on analytical approaches to technology management. Some of the content includes device interoperability, upgrade planning, life cycle analysis, and interpretation of codes and standards. Refer to the ACCE Candidate Handbook for CE Certification.

	Qty Questions
<b>Technology Management</b>	48
<b>Service Delivery Management</b>	25
<b>General Management</b>	16
<b>Risk Management</b>	16
<b>Education of Others</b>	16
<b>IT/Telecom</b>	12
<b>Facilities Management</b>	7
<b>Product Development, Testing, Evaluation &amp; Modification</b>	7
<b>Other</b>	2
<b>Total</b>	<b>150</b>

The intent of both the CHTM and CCE programs is to demonstrate the knowledge and advancement within the disciplines of healthcare technology they cover. While they share common elements, their scope, eligibility requirements, and technical content are unique. For more information, visit the Professional Development and Certification sections of the AAMI website and the Certification section of the ACCE websites.

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# ACCE Bylaws Updates

As you may recall, in March 2016 all ACCE voting members received an email ballot to amend the amendment process within the ACCE Bylaws. At that time, the Bylaws Task Force indicated that there would be a follow up group of bylaws amendments in order to do some much needed updating of the bylaws.

In the near future you will receive a ballot containing 5 amendments to various Articles of the current [ACCE Bylaws](#). Note that many Articles have multiple changes proposed, but the Bylaws Task Force has bundled them together by Article to make it easier for you to see the context of the changes and the get the overall picture.

When the ballot arrives, you will have thirty (30) days to vote. The amendments shall be adopted if at least 1/3 of members (quorum) respond, and 2/3 of members responding to the ballot by the deadline vote to approve the amendment. So, please look for the ballot in your inbox and respond promptly!

If possible, please review the proposed changes now from this hyperlink (link to "[ACCE Bylaws - Proposed Amendments Ver5](#)"). This will enable you to breeze through the ballot itself when it arrives.

Alan Lipschultz, Bylaws Task Force Chair  
[BylawsTaskForceChair@accenet.org](mailto:BylawsTaskForceChair@accenet.org)

## Register for the 2016/2017 ACCE Educational Webinar Series

This program will include ten monthly sessions running from September 8, 2016 through June 15, 2017.

Sessions will include Medical Device Patching & Sustainment, Alarm Management, Clinical Workflow Management, Collaborative Support Models: IT, Informatics and Biomedical Engineering, Clinical Engineering: Growing Competencies for Growing Responsibilities, The Joint Commission Update, Health Tech Equity, Patient Safety: Case Studies and Mitigating Strategies from the Trenches, and more.

More Information on the 2016-2017 series and registration forms can be found [here](#).

Please check the [ACCE website](#) for updated information and registration. The [ACCE calendar](#) has also been updated with the dates for the webinar series.

### ACCE Job Website Job Postings

For posting job opportunities, please contact Dave Smith at [advertising@accenet.org](mailto:advertising@accenet.org)



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# Welcome New Members

**Join us in welcoming our newest members, approved by the Membership Committee and supported by the Board of Directors:**

*Stanley Siu Hiu Fai*—Electronics Engineer (Biomedical), Hong Kong Special Administrative Region Government, Hong Kong—Individual Member

*Kevin Nathaniel Cho*—Clinical Support Engineer, BK Ultrasound/Analogic Corporation, MA/USA—Individual Member

*John Stalker*—Director, Clinical Engineering Systems, ISS Solutions, PA/USA—Corporate-Associate Member

*Timothy Langan*—Director of Business Development, ISS Solutions, PA/USA—Corporate-Associate Member

*Tom Bukowski*—CMMS Manager, ISS Solutions, PA/USA—Corporate-Associate Member

*Szu-Ping Tu*—Director, Clinical Engineering, ISS Solutions, PA/USA—Corporate-Individual Member

*Russell Furst*—Director of Clinical Technology Planning, ISS Solutions, PA/USA—Corporate-Individual Member

*Yogesh Rajak*—Clinical Engineer, ISS Solutions, PA/USA—Corporate-Candidate Member

*Joseph Kaminski* - Ass. Vice President Clinical Engineering, ISS Solutions, PA/US—Corporate-Individual Member

*Andrew L. Moser*—Clinical Engineer, Dept. of Veterans Affairs, CA/USA—Institutional-Associate Member

*Anita Veizaj*—Supervisor Biomedical Engineer, Dept. of Veterans Affairs, MI/USA—Institutional-Associate Member

*Cathy M. Hranek*—Chief, Biomedical Engineering, Dept. of Veterans Affairs, PA/USA—Institutional-Associate Member

*Kamecia Bruce*—TCF Biomedical Engineer, Dept. of Veterans Affairs, PA/USA—Institutional-Associate Member

*Luke Bowers*—Biomedical Engineer, Dept. of Veterans Affairs, MO/USA—Institutional-Associate Member

*Mark Bollinger*—RTL Program Manager, Dept. of Veterans Affairs, MO/USA—Institutional-Associate Member

*Zachary Arose*—TCF Biomedical Engineer, Dept. of Veterans Affairs, OH/USA—Institutional-Associate Member

*David Sledge*—Chief Biomedical Engineer, Dept. of Veterans Affairs, NC/USA—Institutional-Associate Member

*Clarice M. Holden*—Supervisory Biomedical Engineer, VA Greater Los Angeles Healthcare System, CA/USA—Institutional-Associate Member

*Lucas Marsh*—Chief Biomedical Engineer, Ralph H. Johnson VAMC, SC/USA—Institutional-Individual Member

*Andrew Yunker*—Biomedical Engineer, Milo C. Huempfer VA Community Based Outpatient Clinic, WI/USA—Institutional-Associate Member

*Kathryn J. Slade*—Biomedical Engineer, Bay Pines VA Healthcare System, FL/USA—Institutional-Individual

*Felipe dos Santos Rosa*—Clinical Engineer, IEB-UFSC, Brazil—Institutional-Associate Member

*Manoel Decio Pinheiro Neto*—Business Manager, PROEL Comercio e Servicos Ltda, Brazil—Associate Member

*Niel Feldmeier*—Director Biomedical Engineering, Norton Healthcare, KY/USA—Individual Member

*Haniff Murray*—Clinical Engineer, Memorial Healthcare System, FL/USA—Associate Member

*Karen Kan*—Senior Clinical Engineer, Massachusetts General Hospital, MA/USA—Individual Member

*Mohammed Y. Farooqui*—Senior Consultant, Shen Milson & Wilks, LLC, Dubai/UAE—Associate Member

*Michaela Schulman*—Clinical Engineer, Universal Consultant Services, MD/USA—Candidate Member

*Dema Assaf*—Clinical Engineer, Universal Consultant Services, MD/USA—Candidate Member

**Welcome to our newest Corporate Member:** ISS Solutions

**Congratulations to the following members who upgraded to individual Member status:**

*David E. Pillittere, CCE*—Manager/Supervisor of Clinical Engineering, Yale New Haven Hospital, CT/USA

*Arleen Thukral, MS*—Chief Biomedical Engineer, Fresno VAMC, CA/USA

**Congratulations to Hussain Ali who was inducted to ACCE Fellow status:**

*Hussain Ali, PE, PMP, CCE, FACCE*—Clinical Engineering Assets/Contracts Manager at ABM Healthcare Support Services



Hussain Ali

# ACCE Congratulates the 2016 Class of Certified Clinical Engineers

Name	Location	Organization
Christopher Falkner	San Francisco, CA	Kaiser Permanente
Michael Heusser	Middletown, CT	Middlesex Hospital
Giuseppe Vartuli	Victoria, Australia	Siemens Managed Equip Services (MES), Fiona Stanley Hospital Project
Manjit Sahota	Bakersfield, CA	Adventist Health, San Joaquin Community Hospital
Qusai Shikari	San Francisco, CA	Kaiser Permanente
Charles Armato	Little Rock, AR	VA
Kevin Kreitzman	Boston, MA	Brigham and Women's Hospital
Elena Simoncini	Boston, MA	VA Boston Healthcare
David Pillittere	New Haven, CT	Yale New Haven Health
Reyman Syed	New York, NY	New York-Presbyterian

## ACCE Calendar

### August 10—October 12 (Wednesdays)

CCE Review Course—Webinar Series

### September 8, 2016

ACCE Webinar: Medical Device Patching & Sustainment

[More info](#)

### September 28, 2016

CE-IT Town Hall: Healthcare IT Risk Management

[Register](#)

### October 13, 2016

ACCE Webinar: Alarm Management—Balancing Clinical Appropriateness and Fatigue

[More info](#)

### November 5-19, 2016

2016 CCE Written Exam

### November 10, 2016

ACCE Webinar: Clinical Workflow Management—Implementing and Sustaining Health Information Systems Integration

[More info](#)

### November 16, 2016

CE-IT Town Hall: Acquisition and Lifecycle Management of Integrated Systems

[Register](#)

Contributions to the ACCE Newsletter are always welcome. For ACCE Newsletter Guidelines, please go to: <http://accenet.org/publications/pages/newsletterinfo.aspx>

# ACCE

AMERICAN COLLEGE OF CLINICAL ENGINEERING

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