

ACCE News

Newsletter of the American College of Clinical Engineering

May — June 2020

Volume 30 Issue 3



Focus on COVID-19

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President's Message



As the American College of Clinical Engineering approaches its 30th Birthday, it has been a great honor, joy, and (recently) challenge to serve as its president for almost a year. We started the year with some priorities and goals that were turned upside down over the last couple of months. We have had to cancel many of our planned events (HIMSS, AAMI, and various local gatherings) and in turn we lost a lot of exposure and some of the funds we had allocated to these events. While this could have been very damaging for any organization, due to the great effort and leadership from committee chairs, board members, and our Secretariat, we have been able to weather it and emerge even stronger. Before proceeding with the rest of the newsletter, I want to take a few moments to thank everyone who helped us through these difficult times:

- Education Committee and Symposium Planning members – Thank you for your efforts! You didn't get discouraged when the events were canceled, but were able to put together many virtual events to help bridge the gap left by the cancellations!
- Suly Chi (our Secretariat) – Thank you for your tireless efforts, hundreds of hours calling/emailing committee members and sponsors, and for keeping everything on track and running!
- Board members – Thank you for helping all of us keep it together and steady the ship during these strange times!
- Our sponsors – Thank you for sticking around and for your flexibility and willingness to work with us on different solutions!

During the last couple of months ACCE has been very active in helping our members and Clinical Engineering/HTM professionals throughout the country and the world with resources on COVID-19 as well as being an advocate for our profession and professional rights. The International Committee has been active in signing cooperation agreements, as well as helping put together ACCE's COVID-19 web page with best practices from Italy, Argentina, Spain, Germany, Brazil, UK, and other countries. In addition, they have helped put together webinars with people around the world regarding equipment maintenance during COVID-19 (e.g., with Peru).

A few weeks ago, the Board of ACCE, decided to become more vocal around a major issue in our industry, The Right to Repair. We have partnered with US PIRG (Public Interest Research Group) to advocate for increased cooperation between original equipment manufacturers (OEMs), hospital-based Clinical Engineering/HTM professionals, and independent service organizations (ISOs). We are actively engaging local CE/HTM organizations to speak up on the issue, while being engaged with US

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President's Message

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PIRG to help spread the word through its massive network and help affect change at the state levels.

The Right to Repair has been affecting many hospitals during the pandemic. Many manufacturers haven't been able to send their technicians to hospitals to repair/PM equipment and our hospitals' technicians weren't always qualified to service these devices because manufacturers wouldn't provide training. This in turn led to many devices either not being repaired, or not being PM-ed in time. We believe that every organization that purchases or services medical equipment should have the right to get trained and be able to procure parts to repair the equipment they own. This will make healthcare delivery better, faster, and safer – especially during a pandemic or other national emergency!

As I am writing this message HTM Week is about to start. I want to take a moment to thank all of our members and HTM professionals around the country and the world for the dedication shown during this time! We all know how dedicated clinical engineers and technicians always are, however, the pandemic has brought our dedication to patient care front and center. I always hear from my hospital leadership about how grateful they are about our team, and I know that is true everywhere. And that has been amplified ten times over in the last couple of months. Thank you all for all you do and for showing up for work every day!

At the top of this message I mentioned that ACCE is about to turn 30! What a great accomplishment for an organization that relies on its members to keep it going. I am honored to be here for its 30th birthday! We had many events planned for ACCE's birthday at the AAMI Exchange, however we will have to postpone some of those celebrations (yes, we are postponing them – not canceling them!).

Nevertheless, we are putting together some virtual events in the next few weeks to celebrate ACCE's big 3-0, celebrate some of the members that helped give inception to it, and celebrate some of the members who were supposed to be presented with some of our annual awards at the CE Membership events at the AAMI Exchange. Please stay tuned for information on those events.

In closing, I want everyone to take a moment to reflect on the last couple of months. I don't think any of us could have imagined we'd be where we are now. But here we are, and the fact that we are still here shows how resilient we are and can become, how fast we can adapt to change, and how quickly we can think out of the box. I am doing things I never thought I'd be doing, and I am sure that is true for everyone! While this will pass, let's make sure we all take notes and not forget about these times. There is a lot we can learn and lessons we must pass on to others who weren't "lucky" enough to go through a worldwide emergency like this one.

Again, thank you for your continued support, stay safe, and HAPPY 30th BIRTHDAY TO ACCE!

Ilir Kullolli
President, American College of Clinical Engineering
President@accenet.org

ACCE Membership Renewal

Thank you for being an ACCE member!

If you have not yet renewed for 2020, renewal is past due!

To renew your 2020 membership online with PayPal, please [click here](#) or go to <https://accenet.org/Members/Pages/default.aspx?from=login>.

To renew by postal mail, please remit your renewal check to:

ACCE
5200 Butler Pike,
Plymouth Meeting, PA 19462

If you need an e-invoice, please contact ACCE Secretariat at secretariat@accenet.org

ACCE News

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In Memoriam: George Panagiotopoulos

It is with heavy heart that we announce the loss of one of the great clinical engineers of our time, George Panagiotopoulos. George passed away Sunday, May 24 2020 – just a few weeks after celebrating his 60th birthday. He is survived by his adoring wife, Dimetra, children Alexandra and Antonio, mother Magdalini, sister Alexandra, sister-in-law Angela, brother-in-law Michele, Kosta, and Kip, aunts, cousins, nieces and nephews in the San Francisco Area and Greece, and countless close friends and colleagues. What a gaping hole we feel for losing such a humble, valuable, and gifted son, brother, husband, father, uncle, cousin, friend and colleague.

We will always remember George for his calm demeanor, positive attitude, his passion for the clinical engineering profession, his great analytical mind, and his wealth of wisdom.

George started his career in banking working for Charles Schwab, but soon after he jumped into Clinical Engineer-

ing and found his calling. He worked for Kaiser Permanente in different positions regionally in Northern California, and the last few years nationally. George was an active member of American College of Clinical Engineering, he was a past Board member, helped with different Advanced Clinical Engineering Workshops, and presented at symposiums/conferences on behalf of ACCE.

George had two favorite quotes; “Make the right thing easy to do” and “Live simply, give a lot, expect little”. And he lived his life by those two quotes!

Due to the San Mateo County Shelter in Place Order, we cannot gather together physically. However, a celebration of life will be held in the future.

In lieu of flowers, donations can be



George Panagiotopoulos, April 17, 1960—May 24, 2020

made to Holy Assumption Orthodox Monastery in Calistoga, CA, ([Click here to donate](#)) or the Annunciation Greek Orthodox Cathedral ([Click here to donate](#)).



Ilir and George in March 2020 just before the COVID-19 “Shelter in Place” order.



Donald Dunn, Stanford Childrens CE, George and Ilir at an MRI scanner installation

IFMBE CED Update

The global crisis surrounding COVID-19 has precipitated a huge response by the World Health Organization (WHO) Medical Device Unit - https://www.who.int/medical_devices/en/, led by Adriana Velazquez. WHO requested the volunteer efforts of IFMBE CED who has engaged the worldwide CE community to help.

In response, the Clinical Engineering Division (CED) has rapidly implemented several initiatives as follows:

- Created a COVID-19 Resources website page: <https://ced.ifmbc.org/blog/covid19-resources.html>.
- Ramped up a CED WhatsApp group that now numbers over 200 members from nearly 100 countries. This group exchanges ideas, questions, and COVID-19 best practices.
- Developed “Hacking COVID-19” daily updates now sent to over 5000 global colleagues. Register to join at the CED COVID-19 Resource page above.

CED also facilitated a Global COVID-19 CE Day on April 9 with 500 registrants from 60 countries with preliminary Lessons Learned input from 10 countries (see <https://www.youtube.com/playlist?list=PLhffEvoohI1DsUZRwvvtHTnDjzXjllkHX>).

In addition, CED created and delivered in partnership with WHO five COVID-19

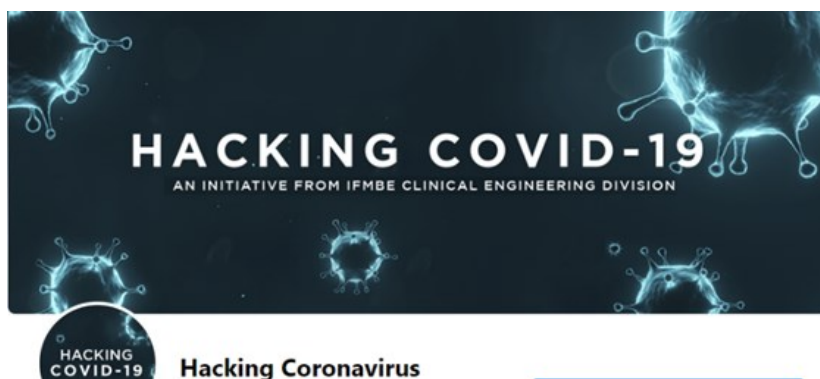
WHO Critical Topics Townhalls, from May 5-19, typically with 250 registrants from 60 countries.

See <https://ced.ifmbc.org/blog/who-ced-covid19-townhalls.html> for more information on oxygen delivery systems, PPE, CPAP/ BiPAP, pulse oximetry, and ventilators.

Other key issues presented included: Supply of necessary equipment and accessories, operation and support, availability of support/maintenance materials (e.g., Operator and Service Manuals in the correct language), and donation issues. Training for operation and support, coordination of various critical activities at care delivery and national levels, and a systems approach and safety management for all of the above were also discussed.

After the concluding Townhall on May 22, CED is planning to provide five Topic Summary whitepapers.

WHO has further engaged CED in weekly meetings to assist the work of other key global providers, notably the Every Breath Counts (EBC) Coalition, see <http://accesschallenge.org/every-breath-counts>, with World Bank, the Bill



Hacking Coronavirus

and Melinda Gates Foundation and others.

After an initial wave of providing information, best practices, and ongoing communication to the global CE Community, WHO has asked CED to assist in the coming months. Assistance will be provided via coalitions such as EBC with LMIC countries* who are facing COVID-19 challenges and emerging needs for country and device-specific CE-HTM virtual training.

Future recommendation include having CED partner with ACCE, AAMI, and the medical device industry via WHO to provide the needed training.

*LMIC <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>

Tom Judd
CED chair
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Welcome New ACCE Members

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

Name	Class	Job Title	Organization	State/Country
Zachary Rudd	Institutional/Associate	Director of Clinical Engineering	Renovo Solutions	WA/USA
Sean Barnard	Institutional/Associate	Clinical Engineer	The Children’s Hospital of Philadelphia	PA/USA
Kevin Hera	Associate	Site Manager	TRIMEDX	NY/USA

CE Responses to COVID-19: Surge Planning for Kaiser Permanente: Re-opening a hospital and more

When St. Vincent's Medical Center announced it would close its doors in January 6, 2020, there was no such thing as COVID-19 in the US. On April 7, 2020, California Governor Gavin Newsom announced the establishment of the Los Angeles Surge Hospital (LASH), a temporary facility that expands access to additional beds and increases ICU capacity for patients who contract COVID-19. Dignity Health and Kaiser Permanente are partnering with the State of California and the County of Los Angeles to open the facility, which will be located on the campus of the former St. Vincent Medical Center in central Los Angeles.

Supporting the new LASH is but one small example of the work that Clinical Engineers have had to do to help healthcare delivery systems throughout the world during this time of disaster. As Kaiser Permanente began planning for COVID19, all facets of the organization came together as one including but not limited to front line staff. Clinical Technology (Kaiser's name for Clinical Engineering), and all its other support services set into motion the framework to ensure that all members needs, from Hawaii to Washington to Georgia, were met. KP CT helped lead the way for COVID19 surge planning. Marlene.Davis@kp.org



The previously closed and former St Vincent Medical Center in Los Angeles is being re-purposed as Los Angeles Surge Hospital by Kaiser And Dignity Health.



Additional Los Angeles surge capacity being added with hospital tents.



Old and new patient monitors tested and provisioned for COVID-19 surge.

More CE Responses to COVID-19: Hospital Albert Einstein, Sao Paulo, Brazil

In Brazil, it all started very fast. In the CE Department we participated daily in the planning meetings and as soon as the first case was confirmed the hospital began working on case growth projections.

We quickly organized ourselves to plan our work on the various COVID-19 projects that all took place at the same time: expansion of ICU beds, creation of a field hospital, expansion of beds in the M'boi Mirim hospital, expansion of beds in Campo Limpo hospital and others.

We surveyed the medical equipment needed to meet the projected demand. We rearranged our planned activities, completed some preventive maintenance prior to its due date, and postponed others. We initially focused on planning activities with the purchasing department and soon the first new equipment began to arrive. That's when the large volume of work really began. We divided ourselves into work groups; one focused on Morumbi and the other focused on external units and other partnerships.

In Morumbi we subdivided into two work groups. One team was responsible for receiving and fulfilling other activities such as unpacking, registering, testing and calibrating equipment. The other team focused on the installation of equipment, delivery of equipment and configuring connected equipment to the IT network.

The challenge was gigantic in all fronts. But the biggest concern was CE staff performance inside the patient rooms where the performance of the team needed to be fast, and very precise, and the support team needed to minimize the time inside the patient room while following all the protection protocols for the corona virus.

We also had to establish some new protocols such as changing of soda lime and sterilization of the ventilatory subsystem of anesthesia equipment.

What about today? We hold daily meetings to monitor the evolution of cases and daily we plan the use and maintenance

of equipment. Currently we are working to reestablish the "new normal" for the department.

Berthone Venancio Soares
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The field hospital at Pacaembu Stadium, Sao Paulo, Brazil



Inside the field hospital at Pacaembu Stadium, Sao Paulo, Brazil

Here at ECRI, we're pulling together socially distant teams to help our members and posting the results on our free COVID-19 response center at <https://www.ecri.org/coronavirus-covid-19-outbreak-preparedness-center>.

Our Health Devices group is looking into the seemingly endless variety of ways to build DIY ventilators that automatically squeeze an Ambu bag or DIY UV disinfection systems to expose used PPE to UVC light to reduce its pathogen load (more on that later). Our Aging Services Group is launching a new initiative with LeadingAge PA, an association of nonprofit senior care facilities in Pennsylvania. We just received an extension of our Healthcare Horizon Scanning contract with Patient Centered Outcomes Research Institute (PCORI) to look for, think through, and provide provisional guidance on prospective COVID-19 treatments. And our weekly lab tour webinars have covered everything from PPE conservation and decontamination, ventilator splitting, infusion pump shortages, hallway positioning, and dialysis challenges. Every day we learn more, and here are two stories from the journey.

Are you a manufacturer?

Missing the chance to pull out your hand tools and smell some solder? We've trialed a DIY UVC-based decontamination system for n95 respirators made out of a length of HVAC conduit and UV light bulbs, asking questions like:

Does it work? Does it put out enough of the right wavelength of UV light? Does the light reach both sides of the respirator with a sufficient dose to achieve an expected pathogen reduction of at least 3 log?

Does it work safely? Does the device pose risks to operators like a risk of exposure to UVC radiation or sharp edges?

Do we think that the design is easily replicable? Will an "average" clinical or biomedical engineer be able to find the right parts and complete assembly it in a reasonable amount of time?

The answers to questions 1 and 2 will largely depend on question 3, as construction and build quality could vary widely depending on the time, resources, and skill level of the assemblers. Keep an eye out for our final report in a few weeks.

Are you being asked to support or implement infrared (IR) temperature monitoring in your institution?

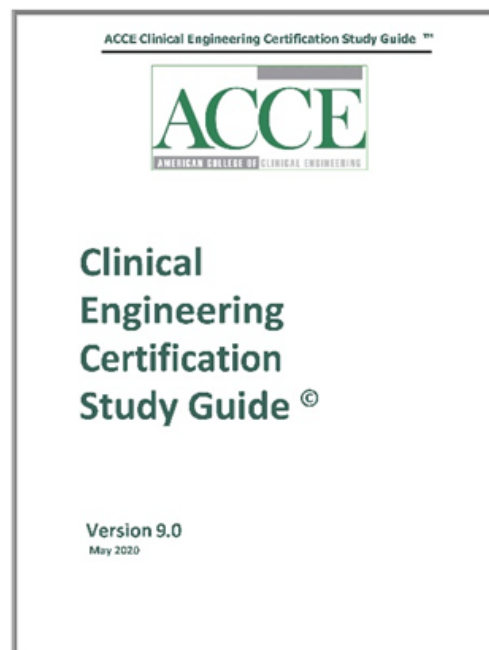
We're getting more and more requests for quotes and product recommendations, and our Clinical Evidence team has been hard at work figuring out whether these systems provide a real safety benefit. Unfortunately, temperature screening programs using IR alone or with a questionnaire for mass screening are ineffective for detecting infected persons, based on our review of evidence from 2 large systematic reviews, 3 simulation studies, and 6 diagnostic cohort studies. Under best-case scenarios, simulation studies suggest such screening will miss more than half of infected individuals. They are ineffective for mass screening because of the low number of infected individuals

who have fever at the time of screening and inconsistent technique by operators. Several authors concluded that IR thermometry even when used with a questionnaire was not reliable for screening due to environmental temperatures, false answers to questionnaires, and use of fever-reducing drugs. Using such an approach to reduce infection risk from visitors and staff entering healthcare facilities could provide a false sense of safety. FDA guidance states, "Temperature-based screening, such as thermal imaging, is not effective at determining if someone definitively has COVID-19... A diagnostic test must be performed to determine if someone has COVID-19." For more coverage on this issue, please see the ECRI position statement at <https://assets.ecri.org/PDF/COVID-19-Resource-Center/COVID-19-Clinical-Care/COVID-ECRI-HTA-Temperature-Screening-3.pdf>

As always, send us your questions, your concerns, and your cool pandemic response ideas- we're here to help!

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

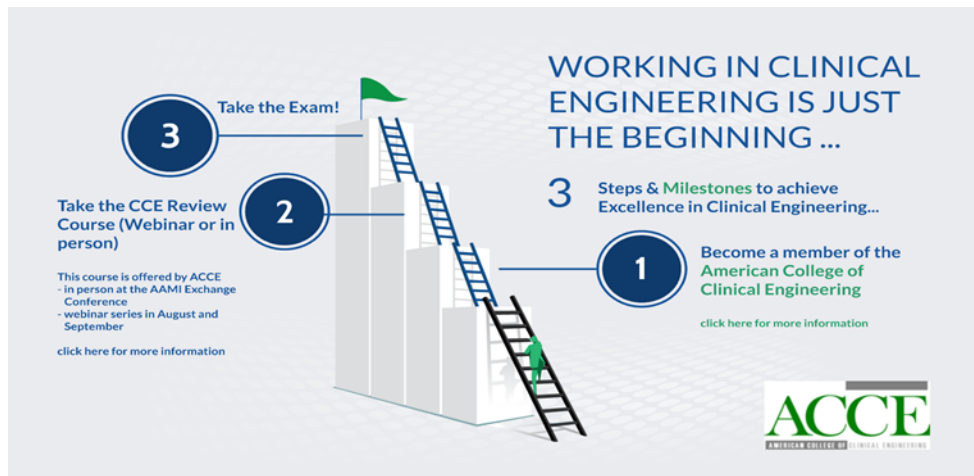
New CCE Study Guide Released



ACCE has just published the new 2020 CCE Study Guide, version 9.0. Many thanks to the group that updated this latest version: Kim Greenwood, Bhaskar Iduri, Steph Liddle, Alan Lipschultz, and Chris Riha.

ACCE also thanks the contribution of all the volunteers who have contributed to past updates of the CCE Study Guide.

Order your copy [here](#).



Prepare to get certified in Clinical Engineering! ACCE 2020 CCE written exam review webinar series

Date: Wednesdays – August 12 through October 14, 2020
Time: 12:00PM – 1:00PM (Eastern Time)

Faculty: Elena Buckley, Tobey Clark, Ted Cohen, Frank Painter



Registration Deadline: August 3, 2020

This 10-session series will be presented by ACCE Faculty who are CCEs. The class will be outline and present the material in each of the main subject areas covered on the exam. The course will help you identify areas in which you need further review and help you prepare for the CCE examination. Attendees will receive a copy of the new 2020 CCE Study Guide and a copy of the presentation material.

Email your [registration form](#) to secretariat@accenet.org

Rates are pro-rated according to this World Bank classification [table](#)

	Countries/column 1	Countries/column 2	Countries/column 3	Countries/column 4
ACCE Members	USD 225.00	USD 150.00	USD 100.00	USD 70.00
Non-members	USD 350.00	USD 235.00	USD 150.00	USD 100.00

Disclaimer: This course is prepared and offered by individuals who are not involved in the preparation of the CCE Exam.

CCE Prep: Technology Management— Assessment and Replacement Planning

Welcome to the fourth in a new series of CCE Prep columns. In this column we will be providing sample questions and other information about preparation for the CCE examination. The sample questions are based on topics from the ACCE Body of Knowledge survey and the CCE Study Guide, version 8. Answers and rationale for the answers will also be provided. Note that the authors of this column do NOT have any affiliation with the CCE Board of Examiners and have no access to the actual exam questions. If you have specific topics you would like us to cover in this column, or if you are a CCE and you would like to write sample questions for this column, please contact the ACCE News editors.

1. What factors should be used to assess a new medical equipment item in each of the four key areas for technology assessment - Need, Impact, Cost, and Benefit?

Answers:

Need - Analysis from demographics and utilization of related current technologies, and projections of utilization and application based on disease conditions of the population served.

Impact - Infrastructure requirements, training needed, users and maintainers of the technology, effects on other technologies serving the same disease states.

Cost - Total cost of ownership which would include costs to purchase, install, space, maintain, update software, software licenses, train, personnel, financing, consumables, accessories, utilities, insurance, disposal, etc.

Benefit - evidence-based proof of clinical outcomes - mortality, morbidity, increase in effectiveness, reliability, ease of use, etc.; risks & safety concerns evidenced by recalls, incidents, and potential for harm; and sustainability of the technology.

2. What are two aspects of technology assessment of medical devices and systems that make it different from the

assessment of a drug?

Answer

Aspects which are different for medical devices and systems:

Total cost of ownership over the life cycle may include infrastructure such as utilities, environment controls, network connections, and building space; installation; maintenance; software updates; software licenses; training; personnel; financing; consumables; accessories; insurance; disposal; etc.

Human factors engineering design is important related to the level of user education required and the potential for operator error which may cause patient harm and additional costs.

Outcomes for devices and systems are typically in terms of diagnostic yield and therapeutic advantages, whereas drugs also have a focus on quality of life improvements.

3. What issue would have the highest weight in determining when to replace a medical device?

- a. Unresolved safety issues
- b.. Age
- c.. More advanced technology available
- d. Anecdotal user complaints

Answer

a. Unresolved safety issues would be the highest priority item. If the device has recalls that have not resolved the issues, device alerts and adverse events continue, or if it lacks key currently available safety features, this would be a cause for rapid replacement. Age by itself is not an absolute priority even if it is beyond the AHA estimated replacement guidelines as it may still be supportable in a cost-effective fashion. In general, more advanced technology by itself would not give the device the

highest weight. Anecdotal user complaints are not a strong reason to replace an item. As the saying goes: "The squeaky wheel doesn't always get the oil."

4. Which technology would have the highest disposal cost?

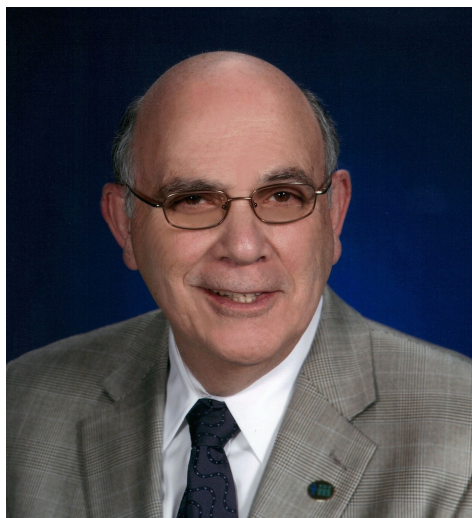
- a. Centrifuge
- b. Cobalt radiotherapy unit
- c. Physiological monitoring system server
- d. Radiographic system

Answer

b, Cobalt Radiotherapy unit – Due to the high cost of disposal of the radioactive source, the cobalt radiotherapy unit would have the highest disposal cost. In 2008 dollars, decommissioning and disposal has a cost ranging from \$250,000 to \$850,000 according to the NRC. De-installation of a radiographic room and disposal of components would probably be next especially if it has PCB containing capacitors. Lower disposal costs are associated with servers as data must be completely deleted or destroyed, and boards placed in proper waste streams. Centrifuges typically would have the lowest disposal costs although if disassembled, careful techniques related to blood borne pathogens must be followed.

Tobey Clark
tobey.clark@its.uvm.edu

Congratulations to 2020 CE Hall of Fame Inductees: Ray Zambuto & Adriana Velazquez



Raymond Peter Zambuto, B.S. (EE), M.S. (BioE)

Ray Zambuto has been inducted into the Clinical Engineering Hall of Fame in recognition of his significant contributions to the advancement of the profession in three key areas: Ray co-founded one of the nation's first shared clinical engineering services which helped to grow and expand the field of clinical engineering. He was also a prime driver of many of the clinical engineering initiatives in clinical systems engineering and the integration of medical and information systems, directly influencing the careers of many. Finally, Ray foresaw the vital importance of establishing strong relationships between CE and IT leaders in their respective professional organizations and became the driving force behind ACCE becoming a co-sponsor of and a key player in IHE's Patient Care Device Domain (PCD).

Ray entered the clinical engineering profession in 1968 and worked with some very prestigious engineers and physicians at some very significant hospitals and organizations. Early in his career he was drawn to cardiology and the technology that supported the science. Like many clinical engineers, Ray had the opportunity to be involved in the development of new technologies, such as the Counter Pulsation Balloon Pump, Thermodilution Cardiac Output, and Holter Monitoring. Intrigued with the field of com-

(Continued on page 11)



Adriana Velazquez Berumen, BSc (BME), MSc

Adriana Velazquez has been inducted into the Clinical Engineering Hall of Fame in recognition of her significant contributions to the advancement of the profession in several key areas. For many years Adriana has been an extremely influential advocate for clinical engineering all around the world and especially in underdeveloped countries. She has done this by relentlessly lobbying healthcare planners and clinical professionals at every opportunity on the benefits of clinical engineering to their patients.

Adriana was a clinical engineering consultant with the Pan American Health Organization (PAHO) from 1991 through 2000, where she worked closely with the health planners in PAHO's member countries educating them on the benefits of having access to clinical engineering services in their healthcare delivery systems and helping to establish the practice of clinical engineering in nine countries.

In her native Mexico, she was instrumental in creating its National Center for Health Technology Excellence (CENETEC) which quickly became a model for other countries. CENETEC's mission was to produce and disseminate information that would assist Mexico's healthcare providers by applying an evi-

dence-based approach to medical device acquisition, use, and support.

From 2008 through today, Adriana has filled senior roles in the Essential Health Technology Department of the World Health Organization (WHO). She has been responsible for the development of 16 WHO books and publications on health technology management for use by governments and providers worldwide. The publications and the complementary educational programs she developed have covered all aspects of the acquisition, use and maintenance of medical technology; including recommendations on regulations, standards, nomenclature, policies, best practices, and implementation guides.

Some of the conferences she has organized have had attendance from over 100 countries. Adriana has created innovative tools (e.g., new websites, the aforementioned publications, regional workshops, collaborating centers, and a group of volunteer subject matter experts) for delivering critical clinical engineering guidance that can be scaled to help improve a region's application of health technology regardless of their location, size, or level of financial resources.

Much of what Adriana has produced at WHO finds its way into regulations and guidance adopted by ministries of health in many individual countries. One great benefit of this is that clinical engineering practitioners can point to credible documents from WHO that help enable them to justify resources and support that those practitioners will need to meet their own government standards.

Adriana has been very effective in

(Continued on page 13)

Ray Zambuto to Hall of Fame continued

(Continued from page 10)

puting, Ray interfaced new technologies with computers as medical engineering liaison to the Harvard Computing Group at Massachusetts General Hospital in Boston. He developed interfaces to allow real-time analysis of cardiac arrhythmias.

In 1973, Ray was named assistant director of the Medical Equipment Program for the Massachusetts Hospital Association. This shared service was one of the building blocks for what would become Technology in Medicine (TiM). Ray was the president and one of the founders of TiM. Over the next forty years, TiM grew from a provider of preventive maintenance to medical equipment to a full service clinical engineering firm. In the late 70s, Ray's responsibilities at TiM changed from providing clinical engineering services to chief executive of the growing company. Ray remained at the helm through two acquisitions. When he retired in 2014, TiM's successor, ABM Health, would employ over 500 individuals and offer a full complement of clinical and healthcare facility engineering, and other related services to healthcare. These services benefited hundreds of healthcare providers nationwide by reducing the costs associated with the technology and improving patient safety.

With all the challenges in healthcare, Ray remained true to his roots and became more active in professional societies and committees. He served as chairman of several committees for AAMI, ASHE, ACCE, HIMMS, IEEE, and SIA. He organized local and national forums where clinical engineers could exchange ideas and best practices. He was a member of the United States Board of Examiners in Clinical Engineering of the ICC and a member of the editorial advisory board for 24x7 magazine.

As an industry expert, Ray has presented papers to numerous national and international audiences. His reach extended beyond clinical engineers to hospital executives, business leaders, and the faculty of various educational institutions. Ray has always been willing to promote the value of clinical engineering. At the same time, Ray continued to develop products and strategies to support the field of clinical engineering. In 1983, Ray worked with Malcolm Ridgway and others to design an insurance approach that reduced equipment maintenance costs for hospitals by employing sound clinical engineering principles. The "product" became an important part of the portfolio offered by MasterPlan, an independent service company that started out as a subsidiary of the Hospital Council of Southern California.

Ray developed computerized maintenance management system (CMMS) applications to drive standardization and service quality at TiM which was one of the first independent service organizations to offer computerized documentation and remote access to medical equipment records.

Ray continued to explore the synergies of medical equipment and IT systems. He published several papers on the topic well before it was more widely accepted within the profession. Working within HIMSS, he helped create paths for clinical engineers and healthcare IT professions to interface and collaborate on healthcare issues.

Below are a few comments from Ray's peers:

"Today many of Ray's pioneering insights are shared by the entire clinical engineering community. Ray was never one to seek the spotlight but was always pleased to see one of his peers get the recognition they deserved. He created the opportunity for hundreds of individuals to

succeed in the profession. Ray's company, TiM was an organization that valued new ideas and doing the "right thing the first time"."

"Ray understood like no other that CEs cannot rest on past accomplishments, nor can CE allow itself to be defined only by medical devices or equipment repair. Ray understood – and actively supported – the expansion of the CE profession into laboratory, radiology, information technology, cybersecurity, health policy, and related fields. He also understood the need to mentor a community of younger, diverse CEs so they could become the future leaders, and gave his time selflessly to that cause."

"During Ray's tenure in ACCE leadership (including two years as president), he recognized the growing importance of medical and information technology convergence and worked to establish strong relationships between CE and IT leaders in their respective professional organizations. Working with HIMSS on behalf of ACCE, Ray ensured that ACCE, clinical engineering professionals and medical device technology would play a significant role in the Integrating the Healthcare Enterprise (IHE) initiative ... an initiative that was originally founded by HIMSS and RSNA to ensure effective integration of IT and imaging processes. As a result of that work ACCE became the co-sponsor for IHE's Patient Care Device Domain (PCD)."

Congratulations Ray from your ACCE family!

AAMI Update: Fellows Honored

2020 AAMI Fellows Honored

Fifteen AAMI members who have provided substantial service and contributions to the health technology field and to AAMI have been selected as the 2020 class of AAMI Fellows. AAMI Fellows are health technology leaders who are recognized for extraordinary achievement in their careers.

The 2020 Class of AAMI Fellows:

John E. Abele, cofounder of Boston Scientific, key founder of AAMI, and a member of the first AAMI Board of Directors.

Steven Baker, PhD, principal consultant at Alpha Bravo Connectivity and clinical assistant research professor at Oregon Health and Science University in Portland, OR.

Damien Berg, regional manager for UCHHealth in Northern Colorado and direct manager for the Medical Center of the Rockies and Poudre Valley Hospitals in Johnstown, CO.

James Caporali, senior director of clinical engineering at Erlanger Health System in Chattanooga, TN.

Mary Ann Drosnock, director of clinical education at Healthmark Industries in Bath, PA.

Larry Fennigkoh, PhD, adjunct professor of biomedical engineering at the Milwaukee School of Engineering in Milwaukee, WI.

Greg Gdowski, executive director of the Center for Medical Technology & Innovation and associate professor of biomedical engineering at the University of Rochester in Rochester, NY.

Larry Hertzler, who has worked in the clinical engineering field for 40 years, holding positions in hospitals, hospital systems, equipment insurance, and the largest service organizations in the U.S.

Clark Houghtling, vice president of business development and technical affairs for Cosmed in Hickory, NC.

Jim Keller, business development director for Emergo by UL in Austin, TX.

James Linton, coordinator and professor of biomedical engineering at St. Clair College in Windsor, Ontario, Canada.

Alan Lipschultz, president of HealthCare Technology Consulting in Rockville, MD.

David Osborn, senior manager of global regulations and standards for Philips in Salem, NH.

Arif Subhan, chief biomedical engineer at VA Greater Los Angeles Healthcare System in Los Angeles, CA.

Priyanka Upendra, quality and compliance program director of technology management/ENTECH at Banner Health in Chandler, AZ.

AAMI Virtual Attendance Option

AAMI is transitioning all in-person courses scheduled through June 30, 2020, to a virtual-only format, and offering a virtual option for training courses through the end of 2020.

With AAMI's robust and interactive virtual option, course attendees will receive devices by mail needed for hands-on learning. Participants will also have easy access to course content and will be able to interact live with fellow attendees and instructors.

Existing registrants for AAMI courses have four options: Attend the class virtually, transfer your registration to any upcoming class, choose to transfer your registration to a course yet to be scheduled, or request a refund.

If you have questions about an existing registration, contact education@aami.org. If you are completing a new registration, you will be able to select either live or virtual attendance when you register.

AAMI, BSI and Machine Learning

Healthcare technology management (HTM) professionals are posing important questions about artificial intelligence and machine learning: Are these technologies competent, trusted, and reliable?; what are the data management and quality is-

sues—including potential biases in datasets and in machine learning itself?; and how do risk management, regulatory requirements, and standards for safety and effectiveness apply to machine learning?

AAMI and BSI, the United Kingdom (UK) national standards body, have teamed up to help answer these questions in a new position paper, Machine Learning AI in Medical Devices: Adapting Regulatory Frameworks and Standards to Ensure Safety and Performance. For more information and to download it for free, visit www.aami.org/AIPaper2020

AAMI's eSubscription Mobile App

AAMI will soon be offering eSubscription users the ability to access the platform via a mobile app on their smartphone or tablet. AAMI's eSubscription is a digital service that gives users access to over 400 national, international, and Food and Drug Administration-recognized standards and technical information reports—both active and archived—for one annual fee. With the new app, access will be portable.

Users can go to the eSubscription dashboard online and search for documents by category and keyword. They can also add bookmarks, annotations, comments, or tags to their digital library. The site can be viewed on a desktop, tablet, or smartphone.

Individual and multi-user (enterprise) licenses for eSubscription are available, as well as the option to subscribe to the entire collection of AAMI standards and technical documents or specialized collections, including sterilization, dialysis, human factors, and healthcare technology management.

To learn more about AAMI's eSubscription, go to www.aami.org/esubscription or email esubs@aami.org.

Best of BI&T Awards

A new way of looking at the healthcare

(Continued on page 13)

Adriana Velazquez to Hall of Fame continued

(Continued from page 10)

maintaining relationships with various international clinical engineering professional organizations such as ACCE, AAMI, IFMBE, IFMBE/CED, SOMIB, CORAL, and AIIIC; and she has established WHO Collaborating Centers with universities and organizations that make many valuable programs and resources available to the world clinical engineering community at large.

Adriana's contribution to the advancement of the clinical engineering worldwide has certainly ended up being greater than the sum of her individual accomplishments. Her strategic vision, coupled with her tireless efforts to make clinical engineering programs available in all countries, large and small, advanced and developing, is having a measurable impact on world health.

As some of Adriana's peers have commented:

"What makes her special is that she has established a legacy of planning and acting at the strategic and policy level, beyond the operational boxes, to improve the health of all peoples with the proper health technology support. Her research and documentation of the depth and breadth of the clinical engineering practice worldwide has provided data that empowers the clinical engineers to present their cases to leadership for awareness and support. From the most humble biomedical shops in places such as Africa, to the first world, organizations have benefited from the legacy of CENETEC, WHA60.9 (WHO resolution on Health Technologies), and the rich clinical engineering web resources available at WHO, all from Adriana's efforts."

"She has brought many, many people together in the developing world to learn about health technology best practices and to develop solutions via networking and education. Adriana

has travelled globally, especially to the neediest countries on a regular basis to work with regional and country WHO agencies, ministries of health, and regional and country CE/BME societies. She is also a contributing member of many international societies such as ACCE and IFMBE."

"Adriana always finds ways to connect and collaborate between multiple groups with enthusiasm to bring along the commitment of clinical engineers' roles to improve patient health outcomes based on a safe, accessible, and effective platform. While doing this Ms. Velazquez always promotes the value of engineering education and professional development through training and clinical engineering credentialing programs around the world."

"She has used WHO as a jumping off

platform to reach out to and create global networks for improving healthcare services through policy adoption, educating clinical engineering practitioners, and sharing best practices. She finds ways to innovate program sustainability through WHO collaborating centers and does not give up in the face of limited resources and constraints of manpower/funds/time."

"What I most admire about Adriana is that throughout her career, the patient, not the technology has remained central to her view of our profession. She expressed this most recently at the 2019 AAMI Exchange by stating "Don't think about the equipment, think about who that equipment serves".

Congratulations Adriana from your ACCE family!

AAMI continued

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technology management and clinical engineering professions, a deep dive into medical device recall data, and the value of making small changes that can have a big impact on quality—these are the three articles published in AAMI's peer-reviewed journal, BI&T (Biomedical Instrumentation and Technology), that shaped the health technology world in 2019.

"Selected by the BI&T Editorial Board, this year's winning submissions tackled many of the most pressing issues in health technology—namely, the need to ensure that medical devices are safe and effective, the role that healthcare technology management (HTM) professionals should play in managing those devices, and ways to do so effectively using shrewd planning and management practices," said Editor in Chief Gavin Stern. "Thank you to all of our authors, contributors, editors, and peer reviewers for their role in growing health technology knowledge base."

Best article: "CE/HTM Professional Roles in Healthcare Delivery: Time for a Trajectory Reset?," by Stephen Grimes

Best Research Paper: "User Interface Software Errors in Medical Devices: Study of U.S. Recall Data," by Yi Zhang, Paolo Masci, Paul Jones, and Harold Thimbleby,

Best Column/Commentary: "Applying QMS Principles to a Medical Equipment Management Program," by Rao Bankuru, clinical engineer, and Rachel Yarnevic.

Bright Ideas Award (awarded by AAMI's Technology Management Council): GE Healthcare's Healthcare Technology Management (HTM) Program, led by Senior Director Donna Marie Dyer in Chicago, IL..

Interested in contributing an article to BI&T? Visit www.aami.org/BIT for more information.

AAMI Staff

International Committee Report

The International Committee (IC) held two virtual meetings since our last report, one on March 20 and the other, May 11. Due to the COVID-19 pandemic and consequent busy schedule for all IC members, these meetings were short and did not involve any guest speakers.

Because of an unfortunate schedule conflict, IC was not able to contribute with speaker(s) to the Argentina's SABI conference in Uruguay, March 4-6, 2020. On the other hand, as the result of the collaboration and mutual assistance agreement with the Asociación Peruana de Ingenieros Clínicos (ASPIC), Binseng Wang delivered a webinar entitled "Evidence-Based Maintenance" supplemented with information on American CE efforts on COVID-19 on May 6.

In addition, IC managed to complete another collaboration and mutual assistance agreement. The new collaborating organization is the Clinical Engineering Association of South Africa (CEASA), which has about 600 members. This is the 12th agreement signed since June 2019.

IC also exchanged information on COVID-19 efforts with the foreign associations listed below and acquired their permission to post their information on ACCE's COVID-19 [webpage](#): Italian association AIIC COVID-19 best practice, Argentinian society SABI COVID-19 resources, Brazilian association ABE-Clin COVID-19 resources, and Spanish association SEEIC COVID-19 resources.

Slides were also presented by AIIC, SEEIC, German and British CE leaders on

their COVID-19 efforts and experience in their joint webinar on April 29, 2020.

Due to the global pandemic and consequent cancellation of several international conferences that IC had originally planned to participate, IC will continue to refocus its efforts in holding webinars and virtual interactions with foreign organizations, as well as established additional collaboration and mutual assistance agreements. Hopefully next year it will be possible to join forces with foreign organizations in hosting in person events.

Binseng Wang, IC Chair
International.chair@accenet.org

Education Committee Report

Due to the overwhelming response to the COVID-19 pandemic needed from Clinical Engineering in the U.S., especially in the Northeast where the upcoming webinar speakers are located, ACCE will be postponing the May and June educational webinars until July and August, respectively. We hope that you can understand the decision to delay these webinar sessions, as

Clinical Engineering is playing a critical role in the COVID-19 preparedness, containment, and response efforts, during this unprecedented time. We hope that your schedules will offer more flexibility at these later dates to attend and more fully engage in these webinar sessions.

The May 14th webinar will be post-

poned to Thursday, July 16th at 12 – 1 PM EDT.

The June 11th webinar will be postponed to Thursday, August 13th at 12 – 1 PM EDT.

ACCE hosted 2 complimentary webinars in April and May to its members:

On April 28: Medical Device Security Vulnerabilities and Disclosures. If you missed the live session, you can view the recording at <https://accenet.org/publications/Pages/Presentations.aspx>.

On May 21: Celebrating the 2020 HTM week: Real-world Management of a Medical Device. If you missed it, you can view the presentation at <https://accenet.org/publications/Pages/Presentations.aspx>.

Thank you to the speakers and moderators!

Eric Aring & Danielle Cowgill
educationchair@accenet.org



ACCE
AMERICAN COLLEGE OF CLINICAL ENGINEERING

May Educational Webinar

"Cybersecurity Tools in CE-IT"

Date/Time:
Thursday, July 16, 2020
12:00pm - 1:00pm (EDT)

Presenter:
David Guffrey, MS, MSM, HCISPP, ITIL
Biomedical Cybersecurity Specialist





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

Following Its Successful Impact on Domestic Clinical Engineering Issues, the HTF is Expanding its Vision

In 2002 the Healthcare Technology Foundation (HTF) was founded on the principle that achieving improvement in the safe use of healthcare technology requires diverse stakeholders to come together in order to utilize their collective knowledge on the design, use, integration and servicing of healthcare technology, systems and devices. In addition to industry, regulators, clinicians and clinical engineers, HTF believes that the public must be included as one of the stakeholders such that they are provided with the means to participate in and gain access to guidance on best practices and the safe use of healthcare technology both in clinical settings and at home.

HTF's mission to "Improve healthcare delivery outcomes by promoting the development, application and support of safe and effective healthcare technologies." is still pertinent. However, it now has the vision of expanding the scope of its projects to become an impact in worldwide healthcare delivery and not just in North America.

Global events, such as the COVID-19 pandemic, demonstrate that international collaboration especially in healthcare is critically needed. Health systems are stressed and are in need for technology, such as protective gear and ventilators, that have not been sufficiently available nor appropriately designed for the challenge. Regulations and work arounds are rapidly changing, adding to the overall confusion of the proper guidance and expertise to follow.

Almost 20 year ago, HTF was founded to address the need for knowledge about improving healthcare technology performance and it achieved that through series of studies about, for example, Alarm Management (<http://www.thehtf.org/clinical.asp>).

HTF also seeks to promote better patient safety and it achieved that through the establishment of the annual Marv Shepherd award, publishing patient safety education brochures (<http://www.thehtf.org/shepherd.asp>), and by providing training on systems risk management (<http://www.thehtf.org/tools.asp>).

HTF promoted the need for demonstration of competency in our field by "saving" the clinical engineering certification program after AAMI decided to discontinue it. Presently, HTF is working on better understanding of the appropriate properties for safe home use of health technology. Indeed, HTF contributed much and now is ready to bring similar focus on the much wider world stage. To do that, its Board of Directors is updating its by-laws and seeking representation from the international clinical engineering community to join the expanded Board. HTF will continue to collaborate with other organizations nationally and internationally to deliver on its vision. If interested in being part of the new HTF, please contact secretary@thehtf.org.

HTF Future Projects

Have a great idea to share? Please let us know if you have any suggestions on projects for HTF that will meet our mission:

Be sure to visit the HTF website, 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!

Jennifer C. Ott, MSBME, CCE, FACCE
Secretary/Treasurer, HTF
secretary@thehtf.org

Advantages of an In-house Clinical Engineer as a Medical Equipment Planner

In my position as senior clinical engineer, I play the following different roles every day.

As healthcare technology consultant, I provide needed information (technology assessment with market analysis) to the clinical team/clinical leadership to help them in making an informed decision in purchasing the right medical equipment as per their needs.

I also work as an incident investigator to find the root cause of adverse events associated with medical equipment. I then work with the clinical end-users and manufacturers to find solutions to the root causes, thus eliminating future occurrences. If required, I report the incident to FDA's MedSun (Medical Product Safety Network) program.

I am part of the clinical engineering team which leads our Alternative Equipment Management (AEM) program, and thus help our operations team to maintain equipment safely and use its resources efficiently.

Along with my fellow clinical engineers, I work on service contract analysis making sure that we are getting the services which we are paying the vendor/manufacturer for.

I work with the clinical engineering leadership in developing and reviewing the departmental policies and procedures to maintain the regulatory compliance of medical technology.

For new construction or renovation projects which requires medical equipment planning, I work as a clinical engineering project manager and the medical equipment planner. I use software in planning the medical equipment for the project. But most importantly I apply my knowledge and experience gained through above mentioned different roles in the equipment planning and include the clinical end-users and unit leadership in

making the decisions. Thus, a clinical engineer working as medical equipment planner brings along a vast knowledge of the entire medical equipment lifecycle management and he/she is well versed with the clinical end-users and clinical workflows of his/her institution. Therefore, I believe that in-house equipment planner is more effective than an external medical equipment planner.

However, the major drawback of this is, that the in-house clinical engineer/medical equipment planner can work on a small to medium sized project(s), because he/she is also working on the above-mentioned other roles. Therefore, for large construction projects there is a need to hire an external medical equipment planner. The key to successful completion of external medical equipment planner's work is that the active involvement of the in-house clinical engineer(s) from the beginning. Thus, the clinical engineer will provide a continuous feedback to the external medical equipment planner thus making it a very successful medical equipment planning process.

I am interested to hear from the HTM



Avinash Konkani, Ph.D., AHFP, was, at the time this article was written, a senior clinical engineer at Beth Israel Deaconess Medical Center. He currently works for the FDA, CDRH (see Career Transitions on page 17).

community on their perspectives about my comments and the role of clinical engineering.

Avinash Konkani

avinash.konkani@gmail.com

Volunteers wanted!

If you would you like to volunteer for ACCE, please complete this volunteer [survey](#).

Volunteers are needed to write ACCE News articles (see <https://accenet.org/publications/pages/newsletterinfo.aspx> for important new author guidelines), participate on a variety of committees, and assist in various other roles.

Member Career Transitions

Welcome to our ACCE News feature celebrating job-related transitions for ACCE members. Please contact Suly Chi, ACCE Secretariat (suly@accenet.org), if you would like to be included in an upcoming issue or if you have a suggestion for another member who should be included. Congratulations to Avinash, Inhel, and Ryan on their exciting new roles.



Avinash Konkani, PhD, MS, BE, AHFP

Avinash Konkani

New Title: Biomedical Engineer, Outreach and Partnerships Team 2

New organization: CDRH/Food and Drug Administration, Office of Product Evaluation and Quality - <https://www.fda.gov/medical-devices/medical-device-safety/medsun-medical-product-safety-network>

Avinash is now part of the Medical Product Safety Network (MedSun) program. "The primary goal for MedSun is to work collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices." MedSun's team is responsible for ensuring the continued safety and effectiveness of medical devices after they have reached the marketplace.



Inhel Rekik, MS, CISM

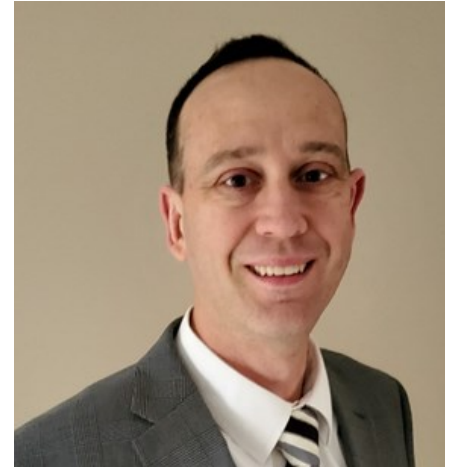
Inhel Rekik

New Title: Sr. Director, Information Security Engineering

New organization: BD (Medical Device) - <http://www.bd.com>

Inhel Rekik was recently appointed senior director of Information Security Engineering for BD (Becton, Dickinson and Company). BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics, and the delivery of care.

As a Healthcare Technology Management professional, Inhel developed an expertise in medical device security as well as Internet of Medical Things (IoMT), IoT, and Operational Technology (OT) security. In her new role at BD, Inhel will serve as the strategic and visionary leader responsible for developing and aligning security engineering initiatives with company-wide programs and business objectives and ensuring that information assets and technologies used in BD medical devices and products, manufacturing, service, enterprise IT, and third-party partners are reasonably secure and resilient.



Ryan B. Knight, CCE

Ryan B. Knight

New title: Senior Clinical Engineer

New organization/department: Blue Water Thinking, LLC - <https://www.bw-thinking.com/>

Blue Water Thinking (BWT) is currently providing support to the Department of Veterans Affairs to modernize VA's medical supply chain program, processes and systems. Ryan supports this program as a Blue Water Thinking clinical engineering subject matter expert. Currently, BWT's support for the Veterans Affairs and Ryan's role include services for the acquisition of essential medical supplies for COVID-19 activities, standing up a program management office in support of a picture archiving and communications system, program management support for the Clinically Driven Strategic Sourcing project, coordinating efforts for the Family of Mobile Inventory Devices, providing assistance with the branding and optimize the National Item File. BWT is a healthcare consulting firm specializing in providing its clients with digital health solutions, strategy and management solutions, and health operations support solutions.

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 \$313). You must [login](#) to the ACCE website to view the code. Then visit LWW.com to enter code.



ACCE CALENDAR

6/14/2020

Last day to renew your 2020 CCE certification

<https://accenet.org/CECertification/Pages/Default.aspx>

6/19/2020

ACCE's 30th Birthday

7/6/2020—7/19/2020

ACCE Board and officer election

7/16/2020

Educational Webinar session#9: Cybersecurity Tools in CE-IT by David Guffrey

[register here](#)

7/24/2020

Deadline to submit CCE Written Exam application

8/12/2020

CCE Prep: Review session #1

[application form](#)

8/13/2020

Educational Webinar session 10: Systems Level Analysis, Moving Beyond the Device, by Prakhar Kapoor

To register, [click here](#)

3/1/2021– 3/5/2021

HIMSS 2021, Las Vegas, NV

5/30/2021—6/4/2021

IUPESM World Congress, Marina Bay Sands, Singapore

6/4/2021—6/7/2021

AAMI Exchange 2021, Charlotte, NC

9/28/2021– 9/29/2021

ICEHTMC-2021

Location: Lake Buena Vista, FL

Celebrating 30 years

1990 - 2020

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