IMPORTANT DATES AND EVENTS
March 2021 – April 2022
ECR
3 – 7 March 2021
Virtual only
AIUM
11 – 14 April 2021
Virtual only
IAMERS 27TH ANNUAL MEETING
Cancelled Due to COVID-19 Restrictions
AAMI | CHARLOTTE, NC
4 – 7 June 2021
Currently scheduled to be in-person
SNMMI | WASHINGTON, DC
12 – 15 June 2021
Currently scheduled to be in-person
ARAB HEALTH | DUBAI, UAE
21 – 24 June 2021
Currently scheduled to be in-person
IAMERS 16TH EUROPEAN MEETING
AMSTERDAM, NETHERLANDS
Cancelled Due to COVID-19 Restrictions
EANM
20 – 23 October 2021
Location TBD Spring 2021 | Virtual
RSNA
28 November – 1 December 2021
Member meeting @ 5pm Monday 29 November
Member reception to follow @ 6:30pm, Ivy Room
IAMERS 27TH ANNUAL MEETING
CHARLESTON, SC
27 – 29 April 2022
Belmond Charleston Place Hotel

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January 2021

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IAMERS, the International Association of Medical Equipment Remarketers and Servicers, is a trade association whose members are world-class providers of pre-owned medical imaging systems, parts and service. We act collectively to positively impact changing government regulations, to defend against anti-competitive activities, and to provide an atmosphere for continuously advancing the knowledge of our members.

All members must agree to IAMERS BEST PRACTICES or be ISO Certified. Our activities are not exclusive to our membership. End-users worldwide can benefit from the availability of quality, low cost, pre-owned systems, parts and service. We know the value of medical diagnostic imaging and the benefits it provides to patients. If the healthcare community is to meet its goal of access to diagnostic imaging testing for all people around the world, IAMERS’ mission to maintain open markets and continuous education is critical.

IAMERS works for its members and for end-users to ensure high clinical value, affordable diagnostic imaging equipment, parts and service are available to the diagnostic imaging community. We believe all end-users should be able to choose diagnostic imaging equipment and services that meet their clinical requirements and budgetary demands.

Whether impacting government regulation, continuing education or monitoring anti-competitive activities, IAMERS is there working for its members and those providing medical care around the world.

WHAT IS IAMERS?

BY DIANA UPTON, PRESIDENT & EXECUTIVE DIRECTOR, IAMERS
How Different is Your Work World Since COVID 19?

We asked a variety of people (some IAMERS members and some valued friends) what impact COVID has had on their workday.

by Diana Upton

I spoke with Nancy Godby, Director of Radiology at Cabell Huntington Hospital in Huntington, WV.

West Virginia was the last state to be hit with the coronavirus. Now West Virginia is a red zone and the rules at Cabell Huntington are a lot different than pre-virus times. Huntington, and periphery, has a population of about 350,000. Cabell Huntington is a teaching hospital with 300+ beds.

Here are some of the changes at Cabell Huntington.

There are no visitations. Patients are dropped off at the front door and cannot receive visitors during their stay. There are few exceptions to this rule – maternity being one of the exceptions.
There are no vendors allowed in the hospital. The exception is for service of equipment and only by appointment.

Throughout my many years of calling on hospitals, it was commonplace to bring in food. Whether donuts to the nursing station or brownies to the radiology department, this was a salesman’s show of love. Cabell Huntington currently has a restriction that no food to be brought in for sharing. Communal meals and buffets have been stopped for now out of an abundance of caution for staff members at the hospital. They have also asked staff members not to bring food from home to share with others. Everything in the cafeteria is pre-packaged and employees are cautioned to socially distance when eating, especially in breakrooms. Water fountains have also been turned off as a precaution throughout the hospital.

Like many places, there’s been an increase in COVID since Thanksgiving. Things were looser in the summer.

Nancy has a staff of 130 people. Most, at present, want to wait to see if others have any negative effects before taking the vaccine.

Of course, like all hospitals, masks and proper protective gear is always worn.

Out of curiosity, I asked Nancy what is was like to go into a grocery store. Does everyone wear a mask in the grocery store? Where I live – in New Jersey, everyone in the grocery store has a mask on. Rarely do I see an exception. Nancy told me everyone walks into the store with the mask on, but many pull it down once they’re past the door. Go figure.

I’m happy to say that Nancy plans on taking the vaccination when it’s her turn.

My next interview was with Guy Wiriath and Thomas Poirier of Value Medical located in Saint Malo, France. In the first three months of the pandemic there was no entry into hospitals in France with minimum service being done on equipment. France was one of the hardest hit countries early on.

Now it’s business as usual in France but with precautions. Masks are mandated everywhere and; they must be real surgical masks. Cute and outfit-coordinated masks are not de rigueur in France. If you travel on any public transportation and you don’t have a proper surgical mask one is given to you.

Beaches are not open. There’s no golf. There’s an 8pm curfew. In the early stages of the virus there was a 6pm curfew. There’s only take-out. No in-restaurant dining.

But the schools are open and; business is good for Value Medical.

Being French there’s always a couple of kisses when you greet friends and associates. First one cheek and then the other. It makes me conscience of all the RSNA and ECR receptions that IAMERS has had and all the hugs I participated in as people walked through the door of our receptions. I’m really hoping that the kisses and the hugs continue at some point. Guy and Thomas wondered if this virus will make their children abandon the kisses.

And people wear their masks, and correctly at that, in the grocery store. If I might digress, I’ve become obsessed with grocery stores since COVID 19 began. In the absence of a normal life, it’s become my COVID hobby.

Speaking with Mads Vittrup of FlexRay Medical in Aalborg, Denmark he remarked “Business during COVID-19 equals working from home and no travels. First half of the year felt like dead silence - the second half was like the roaring twenties as demand skyrocketed. Throughout the entire time crossing borders has been very difficult - getting equipment in or out of hospitals even more so.

If I were to sum up 2020: All tough work with no chance of having fun on the expense”. Since Mads is the CEO of FlexRay Medical, he gets a pass on that last comment.

I was pleased to hear that masks are properly worn in grocery stores.

Dr. Katelyn Bittleman is a Policy Analyst for the Compliance and Quality Staff in the Center for Devices and Radiological Health’s [CDRH] Office of Product Evaluation and Quality at the U.S. Food and Drug Administration. She is also the liaison between CDRH and the Medical Device Servicing Community which is comprised of industry and healthcare working groups.

Most everyone at CDRH is working from home these days. Before the pandemic Katelyn was working at home two days a week. While she prefers
the mix of the office and working at home, at present, it’s solely working from home. She’s made her home office very high tech with double monitors and a standup desk.

She says the best thing about working at home, besides the commute, is sweatpants. I’m with her on this one. It’s infuriating that one needs a bit of makeup and a proper blouse to be on a Zoom call. Luckily no one ever sees the sweatpants on the Zoom calls.

Speaking of Zoom (and its competitors), Katelyn says she spends 2 – 6 hours per day on teleconferences. I think I like those better than Zoom, where no one can see that you don’t have makeup on. Katelyn and her teammates do get together on video for what she calls “coffee klatches”.

Katelyn is a new mom for the second time and she went through labor with a mask on.

She uses online pickup for her groceries.

Lastly, I spoke with my good friend Himanshu Gupta from EverX in Sydney, Australia. I asked him how his workday has changed. “Yes it has changed. On one hand we face a drastic reduction in workload due to COVID related restrictions in travel to sites and meeting customers as well as interstate travels. Our workday has shrunk as well. On other hand things are ever changing so many projects get scheduled and then get cancelled or postponed at very last moment due to new interstate reduction of travel and quarantine. But the show must go on. New systems have to replace the old units at COVID flexible project times.

With Australia being cut off from the world and EverX being one of the top quality engineering companies in this part of the world, someone has to do the work to get systems out professionally and safely and as such EverX fits the bill perfectly.

There is a complete ban on international arrival. So many companies who had been dabbling in the domestic Australia market simply have found us as an able and reliable partner to work with us as they well understand the unique and challenging work conditions this country poses.”

I asked Himanshu if life was back to normal in Sydney. “Yes and No - This virus has no fixed path – it’s a silent typhoon that unleashes its wrath when one assumes everything is getting back to normal. Life is now at NEW Normal in Sydney. We can go out and meet customers, when essential, but restrictions change every week depending on COVID outbreaks. I must say Sydney and Australia is definitely far better off than most other countries which are facing the brunt of COVID at this time. The struggle is to stay safe and keep others safe at this stage by limiting non-essential travel and interactions of the whole team at EverX.”

I asked Himanshu about working at home or going to the office. “During a very limited period of lock down, everyone stayed at home and when restrictions eased, we played one team at a time in office. Now everyone comes to the office and works from the office. Every team member is fully aware of the risks and responsibility and takes due care to protect their family as well as colleagues which we call our extended family members. All our team members have the flexibility, per their workload, to work out what hours / days are best for them to come to office or work from home.”

Himanshu said that he misses going to their offices in the U.S. and Japan. He misses going to meetings like RSNA and ECR. Yet Zoom and MS Teams have helped. He thinks they use video conferencing about 2 – 3 hours per day.

So what about New Year’s Eve in Sydney? What fireworks are more famous that those above the Sydney Opera House? Himanshu told me “Just before New Year’s Eve there was a new cluster of cases on northern beaches which escalated restrictions on social gatherings. So we cancelled Christmas parties and New Year’s parties and remained with immediate family. The streets were deserted and there was no mayhem on the streets of Sydney. The fireworks on the bridge which are of global focus every year still went on for a short period and we watched on TV at home with limited friends/family. We didn’t talk about grocery stores.

I want to wish everyone virtual hugs and kisses. I look forward to the time when the IAMERS family can be back together with real hugs and kisses.

Diana Upton,
President, IAMERS
The Accelerating Rate of Change in the HTM Industry

by Sheila O’Donnell

I remember in the eighties that my father had no interest in having a computer on his desk. Back in those days, his administrator would manage his email, print it out and bring it to his office. Slowly, his administrator nudged him to put a computer in his office. He finally agreed to read the email on the computer and push the print button. With paper in hand, my dad would write down his response return it to the administrator to type his response into the email. At home, it was a different story. Mom was quick to buy her first Apple computer and dive in and see all that she could do. Since then she has advanced through several Apple computers, read more books on Kindle than any one I know, and right now at 88 years old she is busy downstairs trying to look something up on her new iPad.

You see, mom embraced the change. She knew these tools could provide her things she couldn’t even imagine yet. She embraced technology and its blinding rate of change.

The Accelerating Rate of Change in the HTM Industry

by Sheila O’Donnell

Today’s leading healthcare technology management providers are also embracing new and rapidly advancing technology tools to perform their work to improve patient safety and to reduce risk. Just about five years ago, I joined Crothall Healthcare Technology Solutions, a leading national Independent Service Organization based out of Mooresville, NC. While I knew leading change was something I loved to do, I could not have fathomed the pace of change our Crothall leadership team would embrace in just a few years. Not only are we open to change and all the benefits it can bring to our clients and operations, we constantly keep our eyes open to the market to see what might be coming next.

So let us take a look at just a few of the innovations in the healthcare technology management market in the last several years. It is impossible to cover every offering and every segment, but I tried to narrow down the segments and suppliers based on experience. My apologies to any supplier that I may have overlooked.

Let’s start with Remote Monitoring and Diagnostics:

Solution One
Remote Monitoring and Diagnostic Capability

In 2017, Glassbeam expanded its market portfolio to include healthcare machine data analytics. What does that mean? Machine data analytics provides both healthcare and service personnel data to drive decision making. For healthcare providers, utilization analytics help them understand the “how’s” and “what’s” of equipment use. For healthcare providers this capability might answer questions like: “Is that new stand-alone ER MRI being fully utilized? What are the most prominent studies on that equipment?” For healthcare technology service personnel, Glassbeam provides predictive and performance criteria, possibly warning of an impending CT tube failure or prompting notification of helium levels falling. And that is just scratching the surface of Glassbeam’s machine data analytics.

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Solution Two

IoT Healthcare Technologies Cyber Security Offerings. Asimily, Medigate, Ordr, and Zingbox

In 2014 Forbes Magazine wrote an article to explain a new acronym being used rapidly adopted “IoT.” IoT stands for the “Internet of Things.” Forbes describes IoT in the following way:

“Simply put this is basically connecting any device with an on and off switch to the Internet and/or to each other....The IoT is a giant network of connected ‘things’ [which also includes people-people, people-things, and thing-things].”*

Even more recently a subset of IoT has been created which directly applies to our industry. IoMT “Internet of Medical Things” for Healthcare Technologies Cyber Security Offerings refers to the connection of medical devices to hospital networks and protecting them from unwanted intrusion. Since 2014, amazing advances have been made that allow providers to identify devices make, manufacturer, IP addresses and correlate them with risk profiles. Based on these profiles, these offerings prioritize risk and vulnerability mitigation strategies for connected medical devices, a top priority of healthcare leaders today. The “Table 2: IoT Healthcare Technology Cyber Security” demonstrates the rapid advancement of crucial technology and investment in healthcare cybersecurity since 2014.

Table 2: IoT Healthcare Technologies Cyber Security

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Solution Three

Enhanced Computerized Maintenance Management Systems

Our last rapidly advancing technology for healthcare technology management is in the area of Computerized Maintenance Management Systems (CMMS) in this profile is for the lifecycle asset management of medical devices.

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By having a keen eye to your clients’ needs and emerging technologies, today’s Healthcare Technology Management companies have leaped past the break-fix models of the past. We are truly partnered with our clients to improve patient safety and to reduce risk while optimizing the life cycle of their medical device investments. We must not blink. Who knows what is next?


Sheila O’Donnell is the Vice President of the Technical Resources for Crothall Healthcare Technology Solutions in Charlotte, North Carolina. Prior to Crothall, she held executive leadership roles with GE Healthcare and Aramark. She has an MBA from James Madison University and is a Six Sigma Master Black Belt.
WHAT ARE THE BENEFITS OF JOINING IAMERS?

You might be wondering why it is in your interest to join IAMERS. After all, you’ve been successfully managing your business for a while now. What can IAMERS bring to the picture? Well let’s take a snapshot just over the past few years:

- We have seen efforts to pass legislation and require new regulations both in the U.S. Congress and in the EU, which could dramatically affect your business.
- 2020 promises more of the same as some manufacturers have spent millions of dollars on lobbyists to push many of these same issues.
- Some manufacturers have spent even more time to suggest sometimes that you are possibly conducting your business operations in a potentially unsafe or unsound manner. We know you act safely and ethically but do your customers feel the same way?
- These same manufacturers are pushing for imposition of costly and unnecessary standards for your business... all the while being sometimes reluctant to cooperate with promptly providing service keys, equipment technical information and software updates and upgrades.

So, how will you keep informed about the developments which affect your business? How will you ensure your voice will be heard – all the while preserving your relationship with those who most impact your business? Ask yourself the following questions about joining IAMERS:

- Could any individual company successfully engage the Federal Government in a dialog to protect the interest of our industry or our customers?
- Could any individual company provide a platform for dealing with the industry challenges posed by the OEM’s?
- Could any one company, hard as it may try, be able to enforce an international industry Code of Ethics?

This is the Mission of IAMERS. It is job #1 for us. These are a few of the reasons why membership in IAMERS has come to mean so much to those involved in the pre-owned diagnostic imaging equipment industry.

IAMERS’ mission remains, after 27 years, to help all of us do business in a more efficient and profitable manner while maintaining the highest possible standard of ethics in the industry. The IAMERS Code of Ethics benefits you and your customers. It provides your customers with an unmatched level of security when doing business with you – an IAMERS member.

IAMERS will continue to serve as a liaison for the industry to the FDA, the EU, and equipment manufacturers alike. But that’s not its only job. IAMERS also monitors federal and state legislative initiatives and supports issues which are helpful to our industry and the healthcare providers it serves.

Join IAMERS and see the difference.

- IAMERS holds industry meetings which serve as both educational and networking opportunities.
- Additionally, IAMERS provides a steady flow of information on issues which affect your day to day business. There is strength in numbers and strength in unity.
- By joining and participating in IAMERS your voice can be heard loud and clear.

Participation in IAMERS ensures the continued growth of your business and of our industry.
Providing imaging equipment sales, service, training, and supplies throughout the nation and beyond. Our product portfolio is diverse in options of new, used, and reconditioned equipment for CT, MRI, PET/CT, Ultrasound, General Radiology Imaging, as well as radiation protective apparel, PPE, ultrasound probes, positioning aids, and much more.

In the last year there has been a lot happening in the world of Cybersecurity especially with how it applies to Medical Equipment. Even just recently there has been the first death attributed to Ransomware in Germany as a patient in dire need could not be treated at a local hospital experiencing a ransomware attack and died after being re-routed to another hospital. One of the largest healthcare providers in the U.S., United Health Services (UHS), fell victim to Ransomware as well. In recognition that medical device cybersecurity is a continuing worldwide threat, the International Medical Device Regulators Forum (IMDRF) released a new guidance document around cybersecurity of medical devices, “Principles and Practices for Medical Device Cybersecurity” and that is just the tip of the iceberg when it comes to documents in this realm. The IMDRF recognized that all stakeholders have a shared responsibility regarding cybersecurity and that devices that cannot be reasonably protected against cybersecurity threats with updates and compensating controls, represent cybersecurity risks for patient care. I am delighted to note that IAMERS is working with the industry and its regulators to establish best practices to help reduce cybersecurity threats.

In the last year the IMDRF document may be the one that garners the most attention. However, there are other cybersecurity best practice initiatives underway that deserve mention. The public/private industry work group formed following the passage of the 2015 Cybersecurity Act and know as the Section 405(d) Task Group produced a publication titled Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP) and deserves mention. Geared towards two groups of stakeholders, small vs medium/large hospitals the HICP is comprehensive. Also of note is the work that the Department of Commerce is doing via the National Telecommunications and Information Administration around a Software Bill of Materials www.ntia.gov/sbom. Everyone may be perhaps, familiar with a traditional bill of materials, but what if there was one that detailed the software entities pack-
aged in medical products that might need patching and compensating controls incorporated over the life of the system? The National Electrical Manufacturer’s Association – Medical Imaging and Technology Alliance (MITA) released at the end of last year the newly updated Manufacturer Disclosure Statement for Medical Device Security, which provides a format which may be used to provide information on standard security controls incorporated into medical devices. If adopted, it may well provide answers to many of the current best practice questions Hospitals have before installing a device.

The Healthcare Sector Coordinating Council (HSCC) previously published a Joint Security Plan (JSP) https://healthsectorcouncil.org/the-joint-security-plan/ which has aged well, but may be in need of some additional thoughts around how to handle “Legacy Medical Equipment” from a cybersecurity perspective. In that vein they have convened a task group to draft a work product to address what is legacy equipment, how does it become legacy, and what do we do with it when it is? They also are proposing ideas around how to prevent devices from becoming legacy equipment going forward. The HSCC has additional task groups addressing everything from Model Contract Language, to Vulnerability Communications and even Future Gazing and thinking about how to address cyber risks in emerging technology. Of note in this discussion has to be that the FDA – CDRH has issued its list of proposed guidances to be released in 2021. These will include Clinical Decision Support Software, Remanufacturing of Medical Devices, Content of Premarket Submissions for Software Contained in Medical Devices, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, and Premarket Submission Considerations for Artificial Intelligence and Machine Learning software. Looking beyond the industry and regulatory guidances, there are emerging software solutions which will help monitor risk. When looking at the cyber space and considering how to mitigate risk, there are many tools available. There are several documents of best practices like the HICP and JSP. However, there are also new emerging technologies that circumvent endpoint protection. Traditionally cybersecurity was approached from a perspective of secure the device by adding endpoint protection to the it in the form of anti-malware. Network security was focused on partitioning off individual units or segmenting whole groups of devices in their own network to prevent automated attacks from jumping from device to device and crippling an organization. With cloud computing there have been many changes in network architecture and the tools available. One of the biggest questions for the longest time that many organizations struggled with was, "what have I got on my network?" Many did not have a Source of Truth aligning each device, with its network ID and relevant software etc. There are now cloud based software solutions that passively detect every network node and identify it for an organization. That information can be used with tools like the Identity Services Engine (ISE) on a Cisco network, to remotely manage network traffic and isolate particular endpoints without the need for a hardware appliance. At the 2019 RSNA several major manufacturers released a network appliance firewall solution to isolate their devices from a network, and here it is not a year later, and that technology is starting to be replaced with software solutions for savvy network engineers. In addition to cloud passive detection and network administration, there is now even cloud-based antimalware so that updating antimalware on a unique device is becoming a thing of the past. This may have implications for the 3rd party sales market in that devices previously unable to be protected may have extended viability.

Cybersecurity is with us as a topic for good. It is a topic that touches many others and seems ubiquitous with modern life. With any robust discussion of Cybersecurity there is also an easy transition to the topic of AI. AI can be described as Artificial Intelligence or Augmented Intelligence but for those interested, please consider starting an educational journey with a visit to Xavier Health, or the World Health Organization both of whom, seem to be establishing themselves as authorities on the subject. It seems that as the digital age progresses Cybersecurity is one of the fields that supports, enables, and more each day, is critical to - the success of Medical Equipment. Medical Care depends on three things; Patients, Care Providers, and the Technology that stands between those two. Cybersecurity is what will keep that Technology performing appropriately going forward.
IAMERS MEMBERS ARE INTERNATIONAL

For over 25 years, IAMERS has been the only trade association dedicated to extending the useful life of diagnostic imaging equipment—globally. Our members provide state-of-the-art pre-owned medical imaging equipment and services where new equipment is not an option. IAMERS membership includes the most capable and ethical companies in the industry—many of whom are ISO certified. On behalf of its members, IAMERS works with governments worldwide to ensure a competitive atmosphere.

O UR MEMBERS CAN BE FOUND IN

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Japan | Netherlands | New Zealand | Philippines | Poland | Spain | Switzerland | United Kingdom | United States

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Dutch-based AGITO Medical provides healthcare solutions to hospitals, clinics and distributors worldwide. With more than 3,600 square meters of storage space, test bays for MRI, CT and x-ray including cold storage for more than 7 MRI’s, our warehouse is constantly stocked with high quality used imaging equipment. Our services also include Spare Parts from all major manufacturers and Mobile Rental Solutions.

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