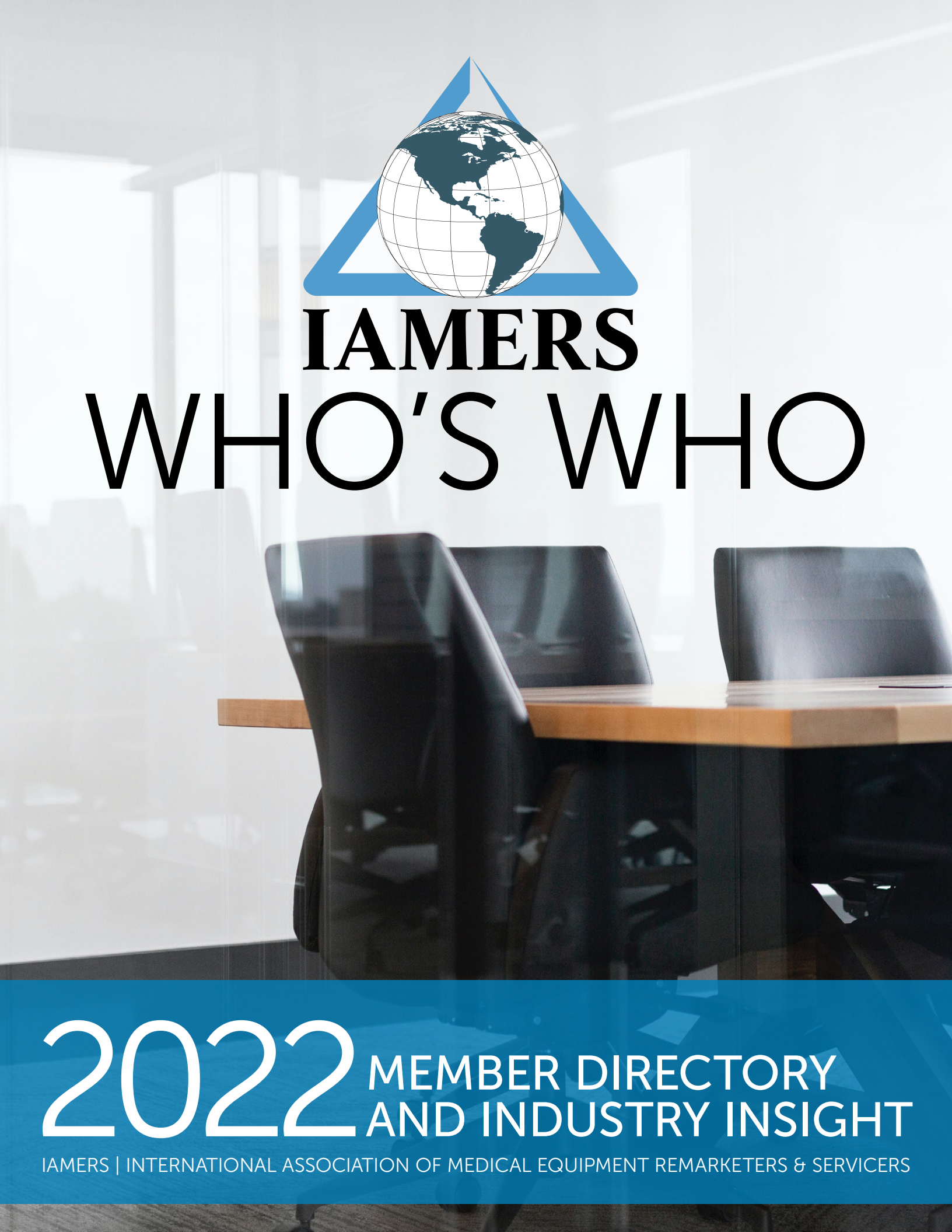

IAMERS

WHO'S WHO

2022 MEMBER DIRECTORY AND INDUSTRY INSIGHT

IAMERS | INTERNATIONAL ASSOCIATION OF MEDICAL EQUIPMENT REMARKETERS & SERVICERS

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AN MXR IMAGING COMPANY

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MXR Imaging Corporate Headquarters:
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888-878-3107

IMPORTANT DATES AND EVENTS

March 2022 – February 2023

AIUM
12 – 16 April 2022
San Diego, CA

IAMERS 28TH ANNUAL MEETING CHARLESTON, SC
27 – 29 June 2022
Sponsored by Nationwide Imaging Services and MXR

AAMI | SAN ANTONIO, TX
3 – 6 June 2022

SNMMI | VANCOUVER, BC
11 – 14 June 2022

ECR | VIENNA, AT
13 – 17 July 2022
Member Reception @ 7pm Thursday 14 July
Palais Hansen Kempinski Hotel

IAMERS 16TH EUROPEAN MEETING STRASBOURG, FRANCE
14 – 16 September 2022

EANM
15 – 19 October 2022
Barcelona, ES

RSNA
27 November – 1 December 2022
Member Meeting @ 4:30pm Monday 28 November
Member Reception to follow @ 6:30pm
The Ivy Room @ 12 East Ohio Street

IAMERS
INTERNATIONAL ASSOCIATION OF MEDICAL EQUIPMENT REMARKETERS & SERVICERS

WHO'S WHO CONTENTS

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February 2022

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WHAT IS IAMERS?

by Diana Upton, President & Executive Director, IAMERS

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 anticompetitive activities, IAMERS is there working for its members and those providing medical care around the world.

A VIEW FROM THE HOSPITAL

By Samantha Jacques, PhD, FACHE, AAMIF

So, it's already 2022 and in some ways, it feels like 2020 v2 and Groundhog Day, and in other ways it feels like we made 10 years' worth of progress in just a few short years. Here's my view of the old, the new, and how to keep up.

THE OLD

COVID – I get asked often what life is like right now within the hospitals. I'm sure everyone is sick of talking about it, however we, in the hospitals, are still showing up to work every day to do battle.

The biggest current struggle is the vaccine mandate by the federal government. Recently, the Supreme Court blocked the mandate for employers with more than 100 employees but upheld it for health care entities. What you might not know is that this health care mandate includes you. Not only all healthcare workers are included, but all vendors, contractors, students, and volunteers are covered in the CMS rule. I know there are some states with local state laws that are pushing back on the federal mandate, however most of us in this field are not lawyers and can barely keep up. Many health systems are reaching out individually and having you go through some attestation process and asks that you manage your

staff's vaccination status and/or medical/religious exceptions. Please don't argue with your healthcare partners over this. We don't control it anymore than you do. Hospitals can lose Medicare/Medicaid funding if you don't comply. Please put some type of system in place and have it ready for your healthcare partners. The easier you make this on us, the more grateful we are.

The rest of the COVID déjà vu is similar to previous waves. Access to sites may be limited, more requirements go in place and budgets are stretched to the breaking point. As vendor partners, please do what you can to keep up. Our regulatory requirements and devotion to our patients haven't changed. Please keep communicating, providing the best service you can, and be understanding in our changes in direction or priority with little warning. We're all just trying to make it through the day while doing out best for our patients.

Samantha Jacques is the Vice President of Clinical Engineering at McLaren Health Care, headquartered in Grand Blanc, Michigan. McLaren is an integrated health network including 15 hospitals, ambulatory surgery centers, imaging centers and Michigan's largest network of cancer centers. She is the vice-chair of the AAMI Healthcare Technology Leadership Council and an executive committee member of the Healthcare Sector Coordinating Council. She is active in ACCE, the Medical Device Serving Community and CHIME and has recently co-authored a book entitled "Introduction to Clinical Engineering". Prior to McLaren, she was Director of Clinical Engineering at Penn State Health & Texas Children's Hospital. She has a PhD in Biomedical Engineering and is a fellow of the American College of Healthcare Executives and AAMI.

THE NEW

GUIDELINES, WHITEPAPERS, and STANDARDS

I'm not sure if many of you keep up, but many new guidelines, whitepapers and standards have been released in the past year or two. These range in content as well as scope. US based guidelines from the FDA include new and draft guidance and discussion papers on a myriad of topics such as pre-market design for device software functions, remanufacturing, and strengthening cybersecurity practices when servicing medical devices. Other agencies such as AAMI and HSCC have also published or are working on new/updated standards and recommendations on all aspects of medical device servicing and cybersecurity. And all of this is just in the US. Internationally, many groups like the International Medical Device Regulatory Forum (IMDRF) are also working on documents. How do we all keep up? What should we pay attention to?

Here's a few highlights of what I deem important:

FDA

- Discussion Paper: Strengthening Cybersecurity Practices Associated with Servicing of Medical Devices: Challenges and Opportunities. Comments were due this past September, but I'm eagerly anticipating the response of the FDA to the responses of the public. Keep an eye out.
- Remanufacturing and Servicing Medical Devices. Draft guidance was published earlier this year and comments on the draft were also due this past September. Final guidance should be out in 2022 and should be on everyone's must read list.
- Draft Guidance on Premarket Submissions for Device Software Functions. If you're organization creates these types of products, whether software in a medical device (SiMD) or software as a medical device (SaMD) or services, this should be on your review list.

AAMI

- ANSI/AAMI EQ 56:2013 Recommended Practice for A Medical Equipment Management Program is under review. This applies to any entity responsible for the management of medical equipment used as part of the routine care of patients, including health care organizations as a whole; divisions and departments within health care organizations; and outside vendors such as medical equipment manufacturers, shared service providers, and independent service organizations. The major update has been in the works for a while, and comments have already been collected. A standards team is working on reviewing all the submitted comments, and we can hope that the final version will be out in 2022.

HEALTH SECTOR COORDINATING COUNCIL

In 2019, HACC published Health Industry Cybersecurity Practices (HICP) - and the Medical Device and Health IT Joint Security Plan (JSP). If you have never heard of either, they are great resources. This work spawned may other groups that are getting ready to publish a myriad of other recommendations and guidance that are much needed in the industry. There are many task-groups, but the following four are the one's I'm following closely.

- 405(d) – Health Industry Cybersecurity Practices. This task force is working on a reference toolkit for minimum level of healthcare cybersecurity
- Med Tech Legacy Devices – this group is working on business solutions, best practices, and policies for end of support product life management and replacement of legacy medical devices.
- MedTech Model Contracts – this group is working on developing a model cybersecurity contract language for HDO's on medical device procurement and servicing.
- MedTech Vulnerability Communications – this group is developing standardized protocols for medical device cybersecurity vulnerability communications among stakeholders.

How to Keep Up and Engage

With all the chaos of the past few years, some people have recommended waiting out the waves and re-engaging later. I'm here to recommend the exact opposite. Regardless of what it looks like day to day on the front lines, we can't miss being engaged in directing the future movement of the field. Yes, we need to keep operations running and doors open for every patient, but we also need to allocate resources to continually improve the field. This doesn't mean you have to get involved in everything going on across every organization both public and private - but pick something. If you're interest lies in Cybersecurity, join the HSCC and give a few hours a week. If you're more interested in medical equipment management, AAMI is always looking for new members on their standards committees. FDA is always asking for feedback and comments on their guidance and discussion documents.

What I'm most concerned about is there is a small group of very dedicated and engaged community members that get involved in nearly everything. They can't do it alone. They need your input and engagement. Join them.

CYBERSECURITY UPDATE

By Mike Powers, MBA, CHTM, CDP, CMDA

In the last year there has been a lot happening in the world of Cybersecurity with how it applies to Medical Equipment. Even just recently there has been sadly a first death attributed to Ransomware in the US in Alabama, and further cybercrimes emerging. A new zero day seems to crop up every weekend with Log4j emerging as the latest threat. Hence, there is a special focus on the need for guidance in the wake of these sophisticated cyber threats. The International Medical Device Regulators Forum (IMDRF) is working on guidance around Legacy Medical Equipment. The FDA released a new guidance document around cybersecurity of medical devices. All of that is just the tip of the iceberg when it comes to attempts to adopt best practices in this realm.

In the last year the IMDRF document may be the one that garners the most international attention. However, there are other guidances or industry white papers underway or potentially impactful that deserve consideration. The 405d work by the Health and Human Services Office of Public Health Emergencies, has been released and appropriately titled Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients (HICP). Geared towards two groups of stakeholders, small/medium and large hospitals the HICP is comprehensive and helpful guide.

Also of note is the work that the U.S. Department of Commerce is doing via the National Telecommunications and Information Administration around a Software Build of Materials ("SBOM") www.ntia.gov/sbom . Of note, this work is being rehomed to CISA (the Cybersecurity and Infrastructure Security Agency). As their work with Proof of Concept 3 has concluded and they are looking at Proof of Concept 4 – the call is out for new and more hospitals and vendors to participate and offer insight on how SBOM can be used. Among the challenges to be examined are just exactly what the sticking points may be to adoption. This may raise questions including if SBOM is provided by a used equipment reseller, how will the SBOM be updated and communicated, and how the data published in the SBOM impacts the purchasing hospital's security strategy.

As you may recall from our discussion and article at last year's annual meeting, the Healthcare Sector Coordinating Council (HSCC) previously published a Joint Security Plan (JSP) https://healthsectorcouncil.org/the-joint-security-plan/ which continues to provide solid guidance is now being augmented specifically on the topic of how to best 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 the equipment with challenging issues such as strategies for end of life and end of support? The document being produced by an impressive amount of stakeholders addresses problem areas and proposed ways to think of resolving the issues. Please know, the estimate for publication of that document is later in 2022. Content as of this writing is still being agreed upon with a comment period to follow.

The HSCC has additional impactful task groups addressing everything from Model Contract Language to Vulnerability Communications and even Future Gazing. These task groups are thinking about how to address cyber risks in emerging technology.

It is also noteworthy to point out that the FDA and more specifically the CDRH has released its lists of proposed guidances for release in 2022. These will include Clinical Decision Support Software (the first place most Hospitals encounter AI in Radiology), and its guidance on Remanufacturing of Medical Devices.

When looking at the cyber space and considering how to mitigate risk, there are many tools available. While, as noted, there are several documents containing valuable best practices like the HICP and JSP. There aare also new emerging technologies that assist in providing endpoint protection. Traditionally cybersecurity was approached from a perspective of secure the device by adding endpoint protection 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, as well as risks around data ownership and encryption in transit.

One of the biggest questions for the longest time in managing risk with which many organizations struggled 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. Out today: ORDR, Medigate, CyberMDX, Asimily and the list goes on. That information can be used with tools like the Identity Services Engine (ISE) on a Cisco network, to remotely manage network traffic and isolate endpoints without the need for a hardware appliance. Most of the best of breed options in this vein propose cut and paste network switch code to mitigate risk. Hospitals may have a need based on this and the fact that so many at the smaller hospitals wear several hats. It is often common that the head of IT at a smaller hospital also wears a hat such as, web portal support, IT help desk, and even snow shovel operator on bad weather days.

A lot of hospitals have no comprehensive internal cyber team. That begs the question – would a business product such as "cyber-IT services" be marketable? Yes. The thing is those tools are just tools. Tools with an output that not many know how to interpret or implement can be a challenge – even if it is code that can be copy- pasted into a network switch via a product like Cisco ISE. You could be part of the way to have positive impact in this regard. I can imagine a partnership between an ISO and one of these companies, where the tool operates for the hospital – perhaps as an inclusion on a used product sale. I can further imagine the ISO partner taking that tool's output and interpreting it for the HDO and helping them implement recommendations up to and including mitigating risk for the EOL/EOS product that the ISO just sold. It may be time to re-imagine your traditional role.

As we move into 2022 several major manufacturers signed cooperative agreements with cyber companies to be able to add a cybersecurity solution to their portfolio for the hospital client. These service offerings include, network assessment, suggested changes to comply with updates to the HITECH act (fines can be avoided if best practices are in place and PHI is disclosed), how to document compliance, and ongoing monitoring with network traffic rule proposals.

Given all of that ongoing, hospitals may change their acquisition practices to require certain cyber deliverables. I expect that in the future some expectations will be around the following:

- SBOM
- Evergreen device hardware and software proposals.
- Auditing requirements for remote services and remote access staff.
- The ability to encrypt data in transmission.
- Data traceability, storage and ownership requirements.
- Speed at which devices communicate and via what networking medium (hardwire, Wi-Fi, Bluetooth).
- Device support / License support for active directory features to align equipment features with HIPAA requirements.
- HDO network administrator implementation guides which may include identifying which ports are closed and what passwords can and must be, so that the installer has to be able to create that configuration.

Let's face it: Cybersecurity is with us as a topic for good. It is a topic that touches many and now seems ubiquitous with modern life. Cybersecurity is a shared responsibility between the Caregivers, the Environment of that Care, and those that support the Environment and Equipment of care. MITA rightly points out that, "cybersecurity is a shared responsibility between all stakeholders, including manufacturers, healthcare providers, patients, and others." In the world of Cybersecurity, a rising tide does lift all boats. With collaboration and sharing of best practices, participation in organizations like the Health Sector Coordinating Council (HSCC) and Health Information Sharing and Analysis Center (H-ISAC), as well as IAMERS educational programs is worthy of your time. We must all have continued recognition that cybersecurity is required for high quality safe and effective patient care. With a commitment to continued vigilance in this area the future looks bright.

Mike Powers is a Clinical Engineering Director at Intermountain Healthcare, which is headquartered in Salt Lake City, Utah. Intermountain is a health network including 23 hospitals, a medical group, ambulatory surgery centers, insta-care clinics, and imaging centers. He co-leads a task group for the Health Sector Coordinating Council on Legacy Medical Device Cybersecurity. He is a member of the AAMI Healthcare Technology Leadership Committee. Prior to Intermountain, he was the Clinical Engineering Quality Manager at ChristianaCare Health System. He has a MBA in Healthcare Administration from Wilmington University and is a Certified Healthcare Technology Manager, Diversity Professional and Medical Device Auditor.

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.

2021 Q&A RECAP

IAMERS President Diana Upton & General Counsel Rob Kerwin recap 2021 and highlight expected developments in 2022. Diana has served as IAMERS president for 15 years. Rob has served as general counsel for 28 years.

DIANA: As we move into year 2 of the Pandemic, to many people's surprise there's been a lot going on which could impact our industry. In 2021, we saw released the President's Competition Order with reference to 'Right to Repair', the FTC report appropriately titled 'Nixing The Fix' and FDA's sustained work on Remanufacturing and other Guidances. Our readers might be interested in how all thesev things could impact their businesses, so let's take a deeper dive?

ROB: If someone had said 'IAMERS would be as busy as we have been', I would never have believed it. Daily zoom sessions on Standards Committees important to our members, U.S. Copyright hearings, EU MDCG meetings, FDA Guidance developments and weekly meetings stakeholders. More recently, we have had in-person Washington meetings. Indeed, IAMERS is not the only one busy. A quick look at the lobbyist filing disclosures at the U.S. House of Representatives Clerk's office disclosures shows, pandemic or not, there are record levels of advocacy. We see increased expenditures of funds and lobbying resources being expended in an effort by some to further regulate servicers.

DIANA: What do you think are the key 2021 takeaways in Washington? Are further impacts expected in 2022? We still see that many HDOs and manufacturers continue to successfully use IAMERS members when servicing other modalities. This raises the question: if ISOs are really unsafe, why do so many manufacturers use third parties and purchase parts from third parties?

ROB: Excellent points! First off, Right to Repair is clearly gaining more momentum. Bills have been filed in over 15 state legislatures on general rights to repair. As you know, IAMERS supported these state efforts and even testified before the U.S. Copyright Office as it was determining electronic manual exemptions. And good results happened! The Copyright Office after considering the pros and cons decided for the first time in 2021 to permit an exemption from copyright law claims for electronic service manuals. It is an important next step.....though it doesn't fully establish a path for servicers to actually get the electronic manuals if a manufacturer declines to provide them. We will need Congress or the FDA to clarify that this information should be turned over for patient safety.

For now, there has been no new servicer compliance legislation filed like Congressman Costello's bill of a few years ago. You may recall that in 2016 it was my honor to testify before the House Energy & Commerce Committee on the concerns about this legislation. The rest of the Congress could not really see the need for Representative Costello's special legislation and the FDA 2018 Servicer Report actually supports that servicers are safe and integral to the healthcare economy.

Some of the manufacturer organizations still maintain there are adverse events caused by independent servicers going unreported, but even the FDA MAUDE reports, which contain a new box for the reporting of events ostensibly involving a third party, do not reflect increased adverse events by ISOs. We are not expecting further manufacturer supported legislation in 2022. But that hardly means we can stand still. There was not sufficient forward progress on Senator Wyden's right to repair bill to relax IP restrictions being imposed. It was nice to be consulted by his staff on the ins and outs of this area of concern. More recently, I have to say that a highlight of 2021 was our meeting and dialogue with a lead competition lawyer at the White House. We are greatly encouraged that some of the service access issues might well get addressed in the near term.

DIANA: As you know, I attended that Washington meeting and was quite impressed by how smart, informed and sincere the WH lawyer was who listened to our concerns. Why don't you take a moment and summarize how IAMERS members could benefit?

ROB: For me, the WH lawyer did much to dispel the rumor that the President's Competition Order excluded the repair of medical devices or that the WH was somehow exempting medical device right to repair. We discussed that for a lot of complicated reasons related to the assertion by some manufacturers of 'trade secret' claims that the FDA has not enforced the requirement that manufacturers provide A.I.A.T. information--as the 1974 regulation has long required. There is an interesting new component to this puzzle. Some manufacturers are upset about other manufacturers' cooperation. As we discussed, we are hearing from manufacturers about the conduct of other manufacturers as to service access and parts ..... so we know that HDOs and ISOs are not the only stakeholders in the ecosystem frustrated. As you know, even the FTC this past year in their report 'Fixing The Nix' found 'scant evidence' to support the withholding of 'right to repair' information. The FTC Report zeroed in on the fact that some of the reasons

offered by manufacturers for withholding service access information just can't be supported by the evidence. Kudos to IAMERS for the FTC Report's specific reference to testimony and information provided by IAMERS.

DIANA: What's the latest on the Remanufacturing Guidance to be released this year?

ROB: Well as you know, the FDA circulated a draft Remanufacturing Guidance in the Spring of last year. The FDA had held various public meetings and comments prior to its circulation. In many respects except one notable point, it followed the White Paper previously published by FDA. Of particular concern was the section of the FDA Guidance which 'encourages' manufacturers as industry best practices, to provide serving instructions that facilitate routine maintenance and repair of their reusable devices. Moreover, the FDA noted that 'unintentional remanufacturing can occur when entities do not have the instructions necessary to return a device to its original performance and safety specifications. Maybe it's a glitch but you appropriately authorized me, after consultation with the IAMERS Best Practices Committee, to note the unintended consequences in IAMERS' Comment to the FDA: if a manufacturer declines to cooperate in providing service access information, the hospital or the ISO could still be found to have engaged in conduct which is 'remanufacturing'. This reaffirms the need for 'adequate instructions for use' be provided. The FDA received over 80 comments on the Remanufacturing Guidance so we are not expecting a release of the Guidance in the short term. A final guidance is expected later this year and hopefully it will address IAMERS' concerns.

DIANA: Like you, I have been attending the monthly Medical Device Servicing Group meetings and I have found a motivated group of stakeholders participating. Any thoughts as to the future progress of this group?

ROB: As you know, we worked for many months on the charter and recruited a new member on behalf of the Patients/Public. The MDSG led by Dr. Samantha Jacques is working to amass a lot of good interest in getting everyone around the table. AAMI has done a great job in serving as a neutral facilitator. Very pleased you nominated Trish Payne from Block Imaging to serve on the steering committee and by all reports Trish has contributed in so many important ways to the MDSG. While the Medical Device Manufacturers Association has provided valuable input, I remain concerned that the unexpected departure of ADVAMED and MITA has caused a temporary pause in the FDA's interest in deigning it to be a collaborative community. Given the wonderful members of the working group, I am optimistic we may be able to get ADVAMED and MITA back to the table. It needs to be an important listening post.

DIANA: That speaks nicely to the fact that our advocacy efforts are proceeding collaboratively whenever possible. We continue to have a nice exchange of information with the HDO community and various other stakeholders such as the ACCE. We will be getting further update at our upcoming Annual Meeting in April in Charleston. We are fortunate to have Dr. Samantha Jacques, VP of Clinical Engineering at McLaren Healthcare in Michigan, as our keynote speaker.

ROB: Dr. Jacques has written and spoken extensively on QMS and other issues important to accountability and patient safety. Dr. Jacques and Mike Powers, Director of Clinical Engineering at Intermountain Healthcare in Utah, are important voices on the MDCG and HSCC Cybersecurity for Legacy Medical Devices. I am delighted they will be joining us in Charleston. The Agenda promises to offer a robust educational program per usual.

DIANA: Speaking of Charleston, I am pleased that our host hotel, the Belmond Charleston Place Hotel, is pulling out all stops to welcome us. Perhaps I am overly optimistic, but, as of now, there is no mask mandate in place, and we can do as we always have done.....mingle, network and enjoy each other's company.

ROB: Without a doubt, the Charleston Place Hotel has made us feel welcome. It's not every place that has a movie theater that puts 'IAMERS' on the marquee. Seriously, we expect a terrific agenda, wonderful food and even an insider's tour by our resident IAMERS member reviewing many of the exciting developments discussed here.

DIANA: I know you have been representing IAMERS at the European Commission Working Group on Medical Devices ("MDCG") particularly with respect to Post-Market Surveillance. Anything to report since the EU MDR went live in June of last year.

ROB: The MDCG continues to work on Guidances for the PSUR and other reporting mechanisms. Separately I was really delighted to hear from the EU Directorate on Competition last year relative to our concerns about manufacturer inquiries surrounding the PSUR requirement. The EU Directorate confirmed that our independent non- manufacturing members are not required to disclose their customer lists and equipment locations as part of their cooperation. This information is better received in anonymized fashion. Also, glad to hear from an attorney at the Directorate as he attended an IAMERS meeting 8 years ago and remembers the productive meetings he held. We should consider again inviting the EU Directorate on Competition to our upcoming September Annual meeting in Strasbourg, FR.

DIANA: We will be scheduling an informal member meeting in July, before our cocktail party at the European Congress of Radiology, to discuss MDCG and cybersecurity developments. The meeting will be at the hotel and the reception will follow. As you might recall, this meeting typically takes place in March. ECR made the decision to proceed in July and it promises to be engaging. Our reception will be on Thursday 14th July, as usual, at the Palais Hansen Kempinski.

ROB: Well, the issues continue for many of our EU members, and we hope to update them on some of what we are learning from our Brussels meetings.

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.

OUR MEMBERS CAN BE FOUND IN

Australia | Canada | Denmark | France | Germany | India
Japan | The Netherlands | New Zealand | Philippines | Poland
Spain | Switzerland | United Kingdom | United States

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