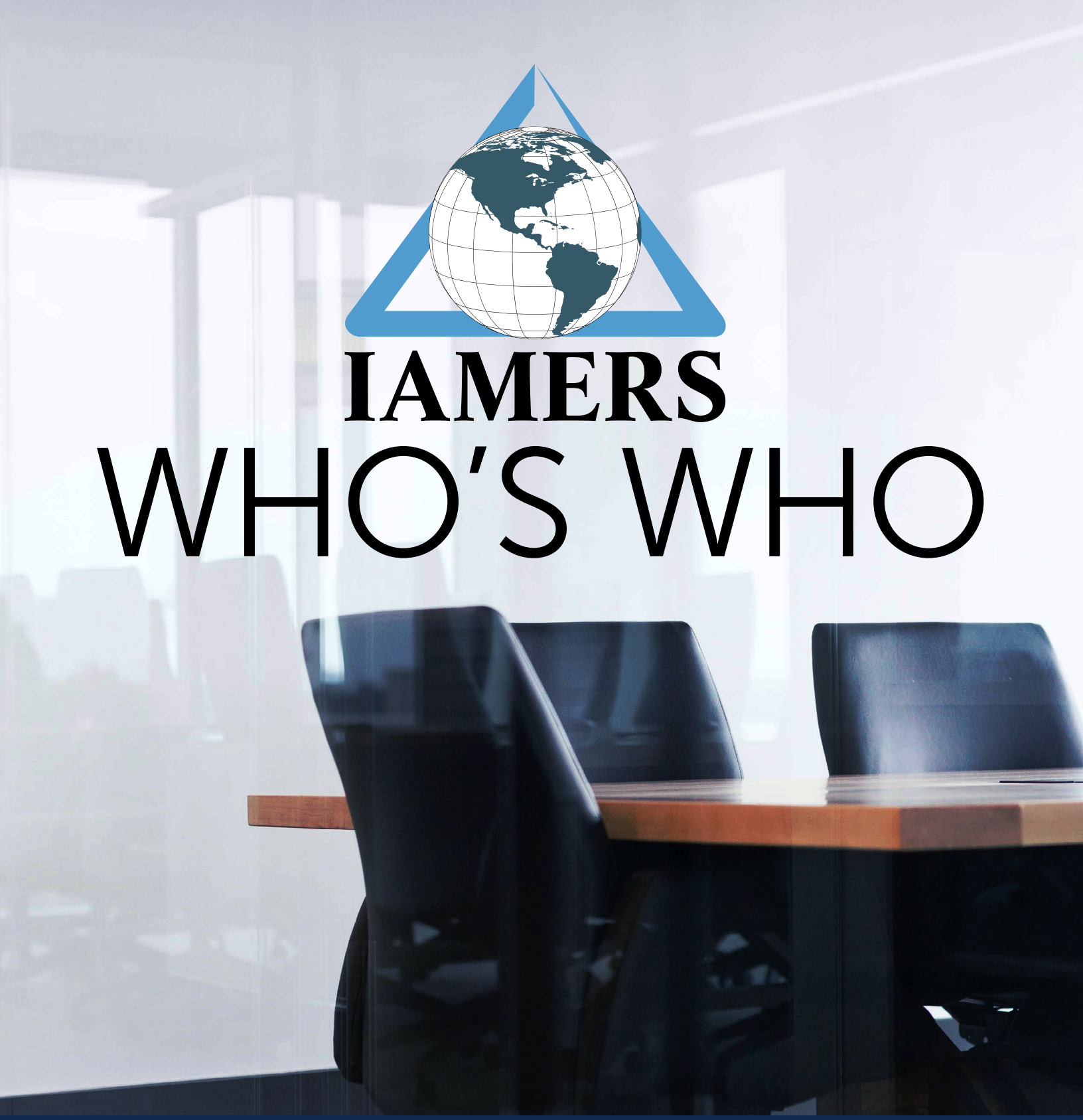

IAMERS

WHO'S WHO

2024 MEMBER DIRECTORY AND INDUSTRY INSIGHT

IAMERS | INTERNATIONAL ASSOCIATION OF MEDICAL EQUIPMENT REMARKETERS & SERVICERS

IMPORTANT DATES AND EVENTS

April 2024 – February 2025

AIUM ANNUAL MEETING
AUSTIN, TX
6 – 10 April

IAMERS 31ST ANNUAL MEETING
CHARLESTON, SC
29 Apr – 1 May

SNMMI | TORONTO, CANADA
8 – 10 June

AAMI | PHOENIX, AZ
14 – 17 June

IAMERS 18TH EUROPEAN MEETING
AMSTERDAM, NETHERLANDS
18 – 19 September

EANM | HAMBURG, GERMANY
19 – 23 October

RSNA
1 – 5 November
Member Reception @ 6:30pm on 2 Dec
The Ivy Room @ 12 East Ohio Street

ARAB HEALTH | DUBAI, ARAB EMIRATES
27 – 30 January 2025

INDIAN RADIOLOGY CONGRESS
CHENNAI, INDIA
January 2025

IAMERS
INTERNATIONAL ASSOCIATION OF MEDICAL EQUIPMENT REMARKETERS & SERVICERS

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February 2024

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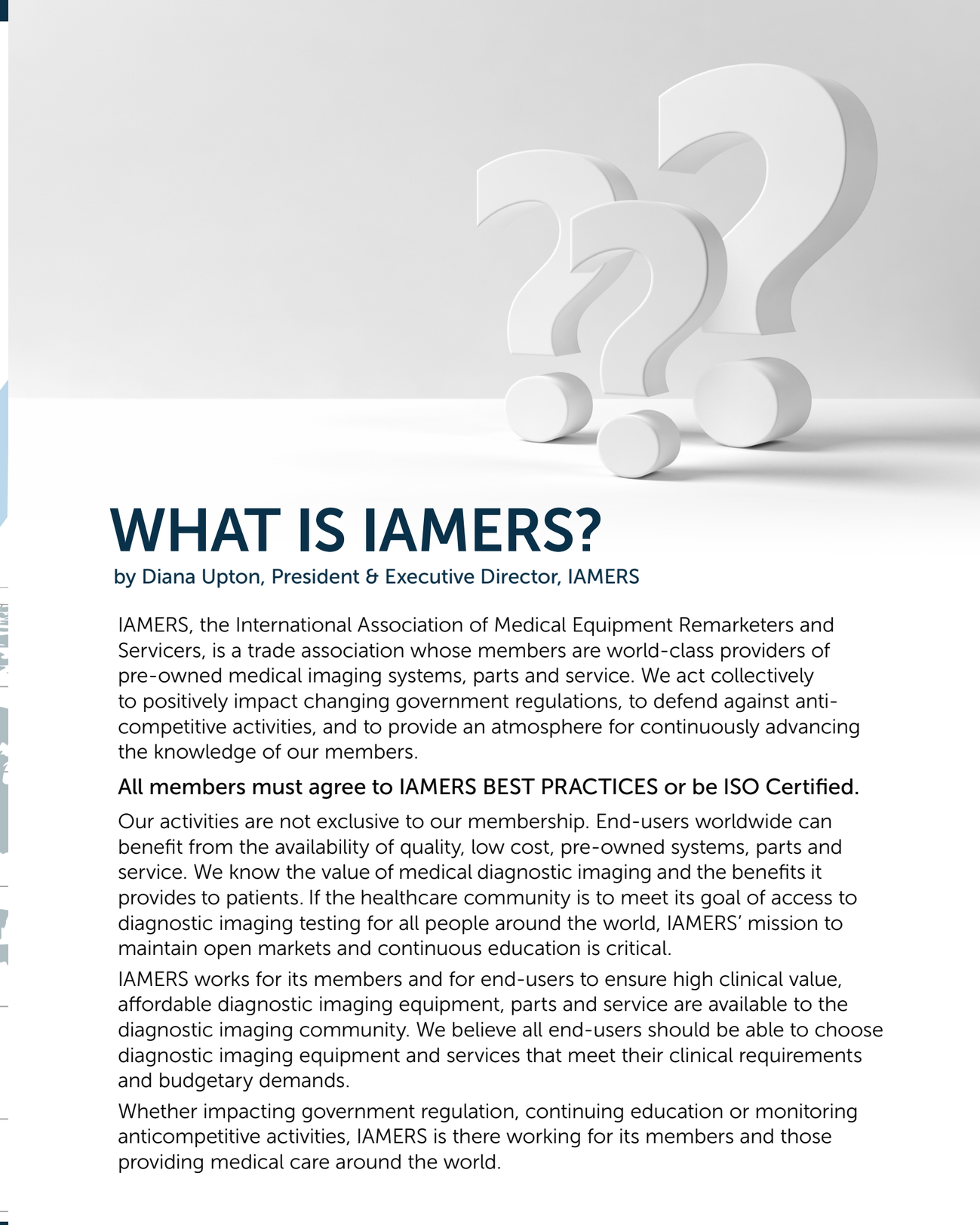


WHAT IS IAMERS?

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.

DON'T FORGET LOGISTICS AND OTHER RISK CONSIDERATIONS ON YOUR NEXT DEAL

By Robert J. Kerwin, IAMERS General Counsel

You've closed the deal and fingers crossed, if all goes well, you will net a tidy sum. You know this because you have done this deal before and with the same party across the pond. You have accurate and recent information on shipping, customs and installation costs. You are dealing with someone you trust and who has never let you down. You got this…or do you; what about when the unexpected risk finally happens?

Do you have a plan to manage risk? Have you taken into account the non-contract parties who could impact on your expected return, including those with whom you may have no contractual relationship? These may include consolidators, forwarders, customs brokers and banks. How about the local practices, ordinances or laws which may apply to your deal? What impact, if any, do the numerous treaties and regulations have on your deal?

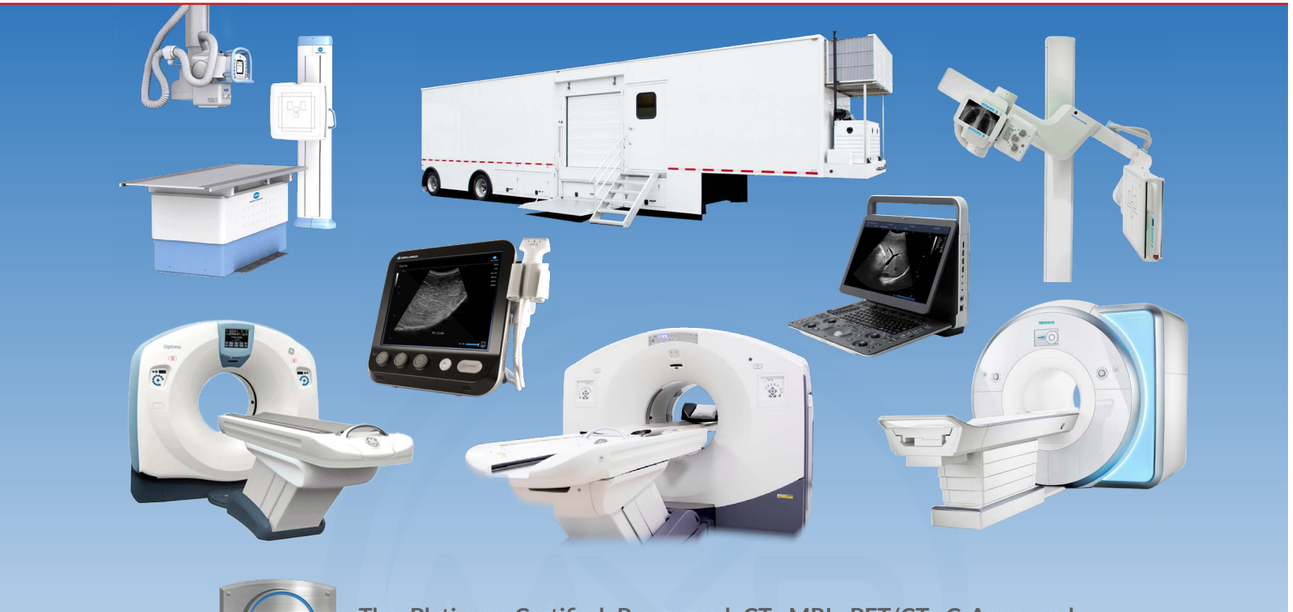
Geographically, if medical equipment moves from Europe to the United States or for that matter to any region in the world, the rights of buyer and seller may vary considerably with respect to liability for the unexpected. Laws concerning carrier liability are often independent and vary depending upon whether the device is being transported by sea, air or over land or some combination of these transportation modes. So, it's important to keep aware of: (i) how transportation risk is being handled in different jurisdictions; (ii) what insurance you may need to cover the risk; and (iii) what is the plan in the event of loss, damage or delay. As the U.S. Seventh Circuit Court of Appeals noted several years ago in a widely discussed U.S. court case, Chicago Prime Packers vs Northam Food Trading, under the United Nations Convention on Contracts for the International Sale of Goods ("CISG") the buyer bears the risk of "[l]oss of or damage to the goods after the risk has passed to the buyer….unless the damage is due to an act or omission of the seller." But the parties could well contractually (and frequently do) agree to treat various risks differently. However, this is not the end of the challenges which frequently happen behind the scenes on an international transaction with regard to risks such as to who bears the burden of costs and insurance. Bottom line: know what your contract (and the contract with the shipper) says when the unexpected happens? While in the United States, the state Uniform Commercial Code may well interpret a contract to provide that the risk of loss passes to the buyer upon his/her receipt of the equipment, other jurisdictions or the contract may well have a different interpretation.

But, while you are examining costs and insurance coverage, you should

PRACTICE TIP

As buyers of imported medical equipment know, there are FDA requirements for importation of radiation emitting medical equipment. FDA Form 2877 requires specific information, much of which you should request the Seller to provide, before closing the sale. If the Seller is the manufacturer, this will presumably be no big deal. However, the FDA and the manufacturer treat this information as proprietary. There is no FDA database to be accessed if your equipment is being held in FDA detention because you have not provided this information. So, negotiate obtaining this information ahead of time as it will speed things along and save you a lot of possible headaches.

—Diana Upton, President, IAMERS



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also be looking at licensing, entry problems, safety regulations, security and, if applicable, environmental problems. Hopefully, your pre-contract negotiations anticipate these issues in your deal. With a tip of the hat to Captain Obvious, it is a lot harder to address these issues once the contract is signed.

DOES YOUR PURCHASE/SALE CONTRACT TAKE INTO ACCOUNT YOUR TOP RISK CONCERNS?

What if there are delays or equipment losses which neither you nor the buyer/ seller expected? Isn't this exactly what happened during the pandemic when supply chain issues made availability and delivery questionable? Many might say that global uncertainties are still on the rise. Causes of current delays include reportedly low water levels in the Panama Canal. This reportedly reduced the number of transits and impacted permissible cargo weights. Another more recent cause is the frequency of vessel attacks in the Red Sea off the coast of Yemen. These attacks have reportedly caused shippers to change significantly Suez Canal and other routes to add weeks to their expected arrivals. By all accounts geopolitical events are causing delays of several weeks or more and are responsible for substantial losses. How does your risk plan address geopolitical uncertainties?

WHO IS COVERING THE RISKS/COSTS?

On an international basis, one of the contract challenges, to keep in mind, is that the same contract term might well be interpreted differently depending upon laws of a particular jurisdiction. As a result, the International Chamber of Commerce prepared in 1921 a comprehensive digest of trade terms known as 'Incoterms' which are often used to avoid the confusion which may otherwise exist with various trade terms, the interpretation of which may differ. You will want to know that Incoterms are periodically updated. The latest update was published in 2020. These terms serve to establish in the contract where and how some of the shipping risks and costs are possibly transferred. Accordingly, it is important to know the definition of key trade terms. If Incoterms are being used in the contract, you should know which Incoterms favor

PRACTICE TIP

It's advisable to know the difference on CIP and CIF Incoterms and when they should be used and what they cover.

CIP can be used for all transport forms. It should always be used when shipping in a dedicated container. This covers the Institute Cargo Clause (A) as Maximum Coverage. CIF can only be used for sea transport. It should only be used for part loads-never full loads. It covers the Institute Cargo Clause (C) as minimum coverage.

–Christian Frandsen, Agito Supply Chain Manager

you depending upon whether you are importing or exporting. If your standard contract is not being used, be sure to understand what is being incorporated as some of the trade terms and conditions may well not be obvious. Moreover, they could be incorporated simply by adoption by reference to other terms referenced online.

ARE YOUR TOP RISKS COVERED IN YOUR CONTRACT OR SHIPPER'S CONTRACT?

Don't be so sure that your contracts have all the possible 'delays', 'losses' or unexpected events covered by additional terms such as the 'Force Majeure' or 'Act of Terrorism' events incorporated in some contracts. Pre-pandemic most of us did not really know what 'Force Majeure' 'Act of God' or 'Impossibility of Performance' might mean– other than as a 'boilerplate' contract provision which was never exercised. Now you really need to know what these previously 'boilerplate' terms mean.

If your contract does not view certain losses as 'unforeseen' events, you will want to assess—who bears the loss under the trade terms? If you are the Buyer, you will not necessarily want to agree to the Incoterm "EXW or Ex Works" which means that "upon exiting the factory" the buyers take on all the shipping and customs costs and any risks linked to transporting the equipment to its destination. Note: Even the Seller may decide that EXW may not always make the most sense as he/she will not be in control of export customs formalities. The exporter may find in a tax inspection that the decision to bill without collecting the taxes could leave the exporter open to situations like customs litigation. A similar result could happen if the Incoterm "DAP" or Delivered in Place or DPU (Delivered At A Specific Destination) is used.

IS YOUR RISK CONCERN COVERED IN YOUR INSURANCE?

Not only should the appropriate Incoterms be designated by the contracting parties, but you should also determine whether the insurance coverage should be on the 'high' side or 'low' side. Don't simply designate insurance coverage without further definition. Assuming that you own this risk under the trade terms of the contract, then the analysis turns to whether you are insured for this risk. Perhaps, if an unexpected event does happen, consider, in addition to transit insurance, if you have applicable business interruption insurance. Sometimes business interruption insurance covers only part of the damage—as it may be limited to "direct physical loss or damage to covered property." It's worth checking. Check your insurance policy, to see if it runs for a specified period of time or for the duration of the transport or even if it is limited to a particular shipment.

While these Suggestions may seem cumbersome, implementation of a risk program addressing these concerns will greatly assist in avoiding losses. Several years ago, the cargo vessel Felicity Ace caught fire while crossing the Atlantic near the Azores. The ship sank with nearly 4000 cars in its cargo hold including many luxury vehicles. The loss reportedly exceeded $485,000,000. While thankfully no lives were lost in the Felicity Ace debacle, the sinking of this cargo vessel serves as a stark reminder that your logistics/risk plans need somehow to anticipate the unexpected.

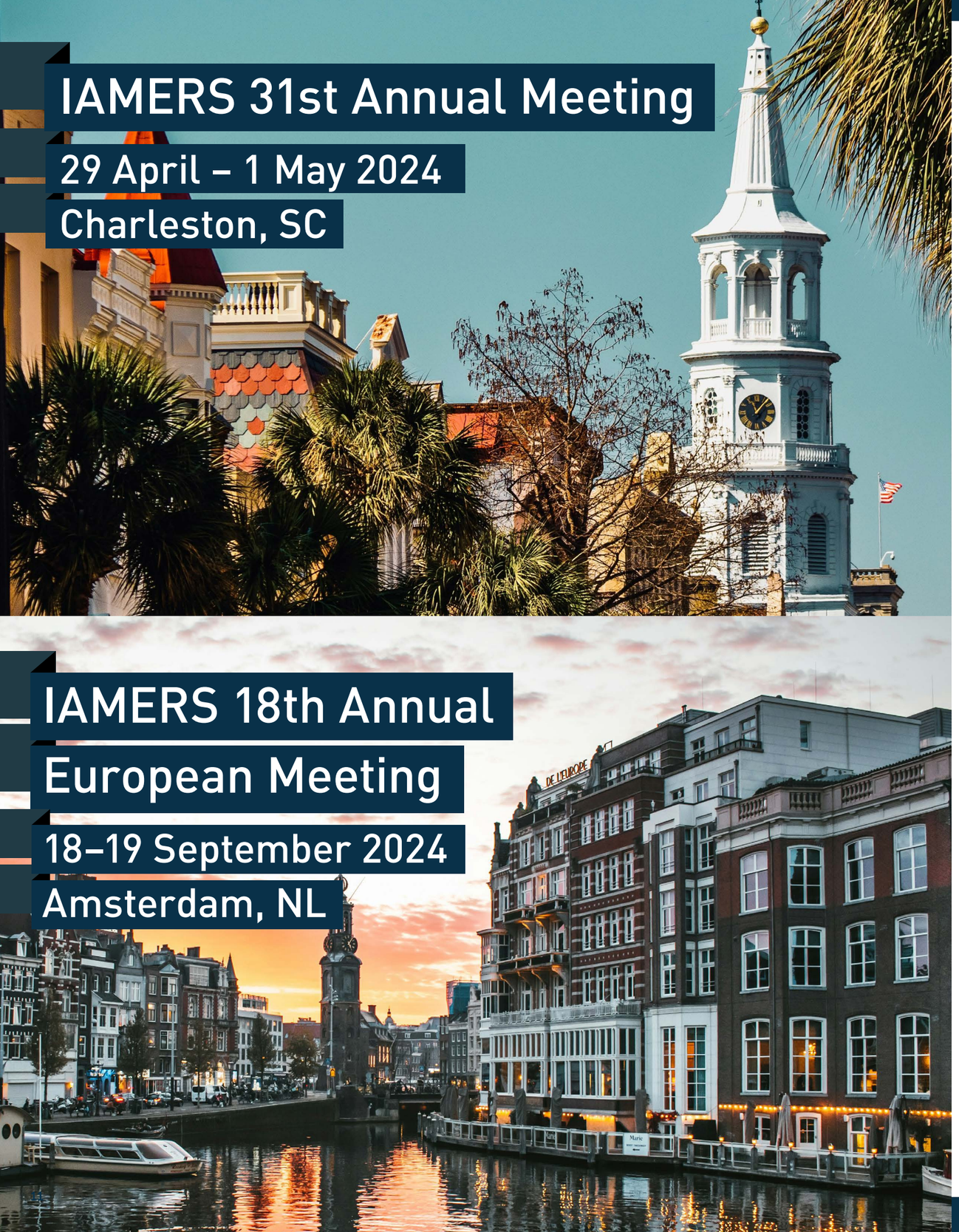
PRACTICE TIP

It's advisable to have one general insurance policy/agent-covering all transport cargo-instead of the shipping line or freight forwarder's choice.

Give a Full Description in Your Insurance Application of the Collateral. If you are shipping pre-owned or used medical equipment, be sure to say so in addition to the serial number, original equipment manufacturer and other equipment specific details. Many insurers do not cover pre-owned/used unless it is specifically requested. Some insurers almost seem to be looking for a reason to limit or deny coverage. Don't let your equipment description be part of that reason.

–Hiren Desai, CEO, Medinnova Systems, Pvt, Ltd, Gujarat, India

Robert J. Kerwin serves on behalf of IAMERS as an approved industry observer to the EU Medical Device Coordination Group. The comments and observations contained in this article are his own.



IAMERS 31ST ANNUAL MEETING
FEATURED SPEAKERS

Dr. Mike Bivins
Urology Centers of Alabama
Birmingham, Alabama

Dr. Bivins will offer candid reflections on 2024 hospital trends, including current imaging trends.

Josh Block
President, Block Imaging
Holt, Michigan

Creating a Thriving Team Culture
Fostering a place where people love to work

Scott Trevino
Senior VP Cybersecurity, Trimedx
Indianapolis, Indiana

What are the standards that affect your business?
What's evolving with "Right to Repair"?

Mike Powers
System Director, Field Service, Intermountain Health
Salt Lake City, Utah

AI's Roles & Risks

David Hurlock
President, X-Ray America
Charleston, South Carolina

Industry Review – Past, Present and Where We're Headed
BONUS – Take David's walking tour on Monday @ 10am

CYBERSECURITY UPDATE

By Mike Powers, MBA, CHTM, CDP, CMDA

In the last year a lot has happened in the world of Cybersecurity in how it applies to Medical Equipment. In March the US government made cybersecurity a design requirement for Medical Technology, and the FDA consequently issued policy guidance, Federal Register :: Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions; Guidance for Industry and Food and Drug Administration Staff; Availability. In addition in October the White House issued an Executive Order on the the Safe, Secure and Trustworthy Development and Use of Artificial Intelligence Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence | The White House. These two occurrences address the growing sentiment that Cyber safety is a mandatory component of patient safety, as well as going further to impact and address discriminatory algorithms that contain bias impacting patient populations. These are just the tip of the iceberg when it comes to an exciting year.

In the last year cybersecurity as a component of 510k premarket clearance, has really driven home the needs of patient's safety to be represented with little regard for the size and cyber maturity of the organization providing the patient care. If you recall from this discussion 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 has aged well, but had an opportunity 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? The document being produced addresses problem areas and proposed ways to think of resolving the issues. The final document was published in March of 2023 [Health-Industry-Cybersecurity-Managing-Legacy-Technology-Security-HIC-MaLTS.pdf (healthsectorcouncil.org)](). 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. Finally there has been significant discussion from industry parties about creating a subscription based SBOM repository housed at one of the largest trusted industry Cybersecurity stakeholders. Currently in its infancy, this move should see a lot of progress as we head further into 2024.

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, as well as risks around data ownership and encryption in transit. 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. 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 in this. It is often that the head of IT at a smaller hospital also wears a hat such as, web portal support, IT help desk, and snow shovel operator on bad weather days. A lot of hospitals have no comprehensive internal cyber team. That begs the question – would such a business product "cyber IT services" be marketable? Yes. The thing is those tools are tools. Tools with an output that not many know how to interpret or implement, even if it is code that can be copy pasted into a network switch via a product like Cisco ISE. 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 miti-

gating risk for the EOL/EOS product that the ISO just sold. 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 that ongoing, hospitals may change their acquisition practices to require certain cyber deliverables. I expect that in the future some expectations will be around

- 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 spelling out which ports are closed and what passwords can and must be, so that the installer has to be able to create that configuration.

Cybersecurity is with us as a topic for good. It is a topic that touches many others and 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. Industry experts, including HHS (https://hphcyber.hhs.gov/) rightly point out that, "cyber safety is patient safety". 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), and continued recognition that cybersecurity is required for high quality safe and effective patient care, 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.

How Healthcare Systems Can Prepare for Federal Action on Medical Device Cybersecurity

By: Scott Trevino, Senior Vice President of Cybersecurity, TRIMEDX

Federal help is needed to combat breaches, but organizations cannot wait for the government to step in. They should act now to protect their patients.

The U.S. Congress is considering three significant legislative proposals regulating medical device cybersecurity, and the FDA is finalizing its medical device cybersecurity guidance addressing pre-market expectations for device manufacturers. These government actions will aid healthcare systems in shoring up their cybersecurity defenses, but healthcare systems must take additional independent actions to fill security gaps.

Two significant healthcare data breaches occur daily, and more than two-thirds of patient care organizations have been victims. Each breach may have life-or-death consequences. Nearly one in four organizations experienced increased mortality rates after a ransomware breach, and 70% reported longer lengths of stay and poorer patient outcomes due to delays in procedures and testing. On top of patient care impacts, breaches cost healthcare systems more than $10 million on average, higher than any other industry.

An industry report conducted by Ponemon Institute shows healthcare organizations have 26,000 network-connected devices on average. More than half have a known cyber vulnerability, exposing them to cyberattacks. Federal help is needed to combat breaches, but organizations cannot wait for the government to step in. They should act now to protect their patients.

FEDERAL ACTION ON MEDICAL DEVICE CYBERSECURITY

The legislation closest to passing is the Healthcare Cybersecurity Act. Under the bill, the Cybersecurity and Infrastructure Security Agency (CISA) and the Department of Health and Human Services must collaborate on improving cybersecurity measures in medical facilities and provide risk and mitigation training for healthcare personnel. The Senate Committee on Homeland Security and Governmental Affairs amended the House bill and recommended its passage.

The FDA is finalizing its medical device security draft guidance. The recommendations provide original equipment manufacturers (OEMs) with a cybersecurity device design approach to address safety through the complete product life cycle, starting with premarket QMS considerations. The document also asks OEMs to consider cybersecurity essential to the FDA's Quality System Regulation (QSR) and establish a Secure Product Development Framework to reduce vulnerabilities.

Other legislation under consideration includes the Strengthening Cybersecurity for Medical Devices Act and the Protecting and Transforming Cyber Health Care (PATCH) Act. The former requires the FDA to create a report identifying medical device cybersecurity challenges, regularly update guidance, and publish information on resources and strategies to improve medical device security. The PATCH Act mandates that OEMs provide pre-market disclosures about a medical device's security.

Congress rejected a Medical Device User Fee Act amendment to give the FDA authority to require OEMs to include certain cybersecurity information before a device goes to market.

PREPARING FOR LEGISLATION

While each proposal supports medical device security, each healthcare system must enact its own cybersecurity policies to experience the maximum benefits. Instead of waiting for Congress, organizations should take proactive steps now.

Cybersecurity teams should start their strategy with the National Institute of Standards and Technology (NIST) Cybersecurity Framework. The process involves:

- Identifying device risk, policies, and legal requirements.
- Protecting networks with safeguards.
- Implementing detection strategies.
- Creating a response and recovery plan.

Accurately quantifying an organization's risk requires a complete inventory of all medical devices. Inventory inaccuracies may be as high as 40%, leaving many vulnerabilities unaddressed. With an accurate record of devices and their known vulnerabilities, use, location, and risk to patient safety, cybersecurity teams can make informed decisions about remediation priorities. Mitigating risks may involve installing an OEM-validated security patch. If none are available, healthcare systems might consider removing a device from the network, putting it on a segmented network, or disposing and replacing.

A comprehensive technology-enabled medical device cybersecurity solution can strengthen a cybersecurity plan by managing inventory, monitoring, and flagging vulnerabilities. In November, FDA published an updated Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook to aid healthcare systems in preparing for a medical device breach.

The federal government acknowledges the risk cyberattacks pose to patient care, but the legislative process is laborious and lengthy. Cybersecurity cannot be delayed. Employing a robust medical device remediation strategy in the interim is critical for healthcare systems to protect patients and their data.

Scott Trevino is the Senior Vice President of Cybersecurity at TRIMEDX

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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.

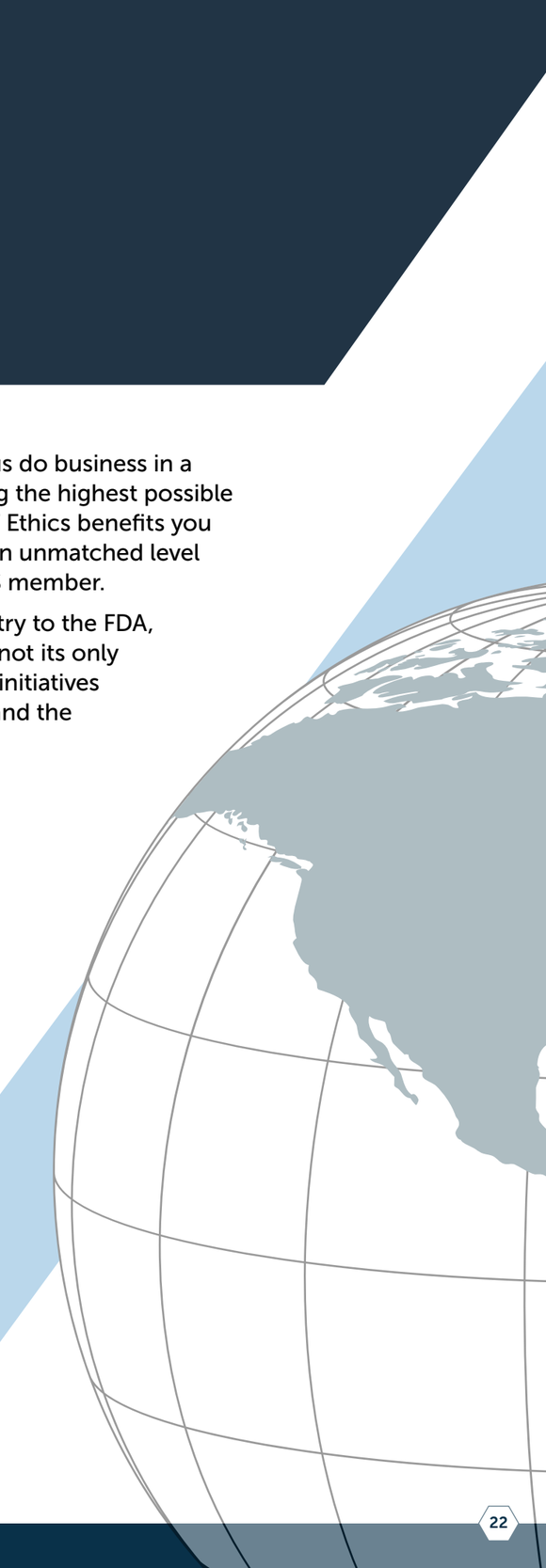
IAMERS' mission remains, after 31 years, to help all of us do business in a more efficient and profitable manner while maintaining the highest possible standard of ethics in the industry. The IAMERS Code of Ethics benefits you and your customers. It provides your customers with an unmatched level of 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

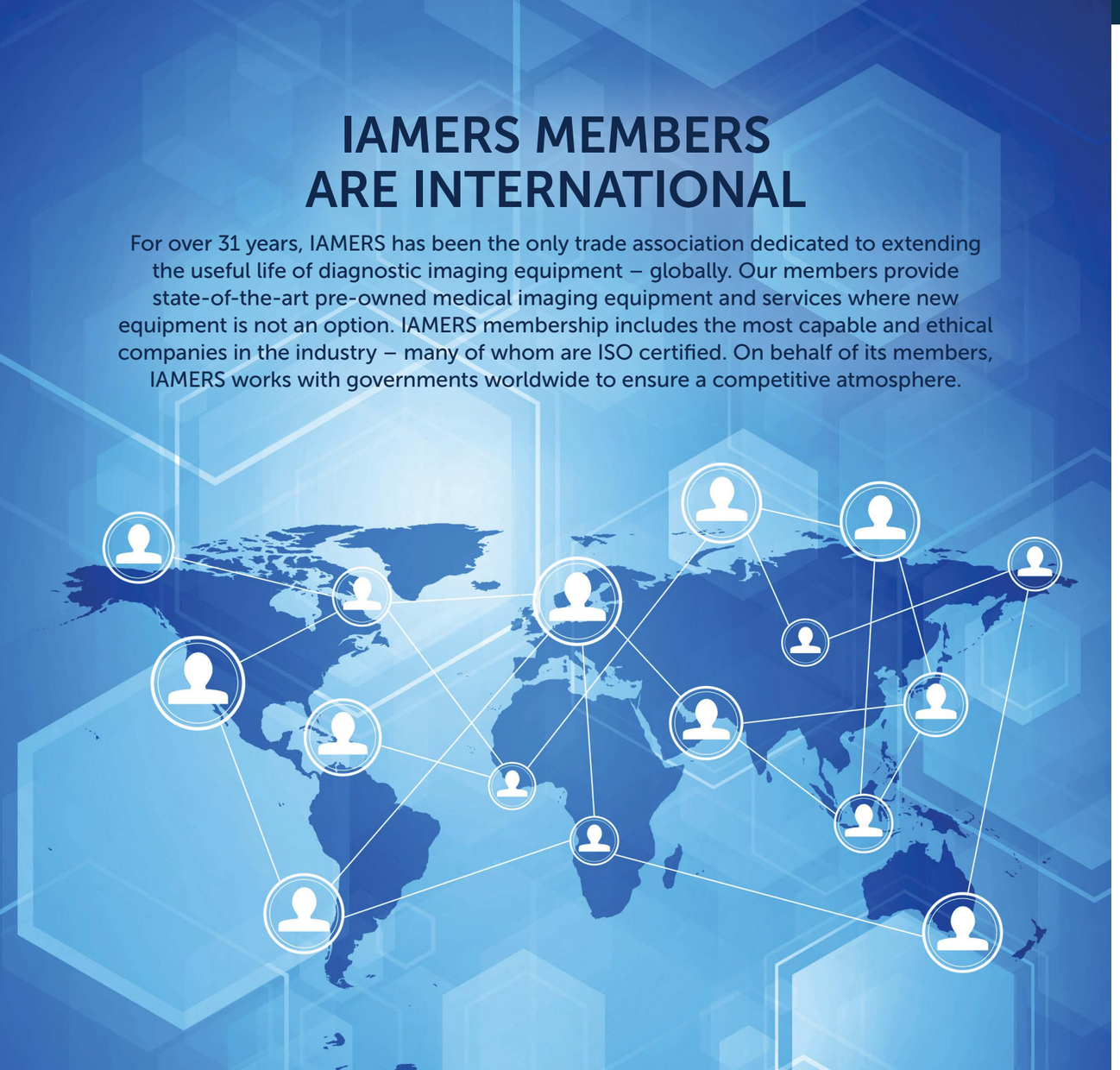
- IAMERS holds industry meetings which serve as both educational and networking opportunities.
- Additionally, IAMERS provides a steady flow of information on issues which affect your day to day business. There is strength in numbers and strength in unity.
- By joining and participating in IAMERS your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

Participation in IAMERS ensures the continued growth of your business and of our industry.



IAMERS MEMBERS ARE INTERNATIONAL

For over 31 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.



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