MITA®
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF NEMA®

1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

May 31, 2018

The Honorable Greg Walden
Chairman, Energy and Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member, Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, DC 20515

RE: Energy and Commerce Committee Supported Lifetimes Request for Information

Dear Chairman Walden and Ranking Member Pallone:

As the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) commends the Energy and Commerce Committee for its thorough investigation and understanding of the unique, multi-faceted challenges faced by the entire healthcare industry in addressing the issue of legacy medical devices, which MITA defines as any medical imaging device outside of its defined supported lifecycle. MITA also advocates that the key priority in promoting cyber security must be to protect and preserve innovation for every industry stakeholder. The benefits of any regulatory or legislative activity should accelerate such improvements without imposing unnecessary impediments to that innovation.

MITA manufacturers take the security of their products seriously, and consistently improve their security posture to provide improved safety to health delivery organizations (HDOs) and their patients through constant innovation. Some recent examples of our work include a MITA whitepaper titled "Cybersecurity for Medical Imaging"[1], which highlights the shared responsibilities of all stakeholders to maintain a secure environment, and a National Electronic Manufacturers Association (NEMA) whitepaper, "Cyber Hygiene Best Practices"[2], which provides actionable recommendations to manufactures to develop cyber secure products. There has also been consistent collaboration with the US Food and Drug Administration in recent years, which has helped to foster an improved private-public partnership in addressing cyber concerns and encouraging discourse.

Medical imaging devices, such as those produced by MITA members, are necessary components of any health delivery organization. The committee astutely identifies challenges that face both HDOs, such as resource and budget constraints, and manufacturers of medical devices, such as the complex nature of architecting and updating systems already deployed in HDOs, including devices already deployed and in clinical service. MITA suggests that there are further challenges that need to be addressed as the industry moves towards a more secure cyber environment.

It must be stressed again that protecting healthcare systems against cyberattacks is a shared responsibility. Manufacturers, HDOs, and third parties all must work together to guard against

1. "Cybersecurity for Medical Imaging", https://www.nema.org/Standards/Pages/Cybersecurity-for-Medical-Imaging.aspx#download
2. "Cyber Hygiene Best Practices", https://www.nema.org/Standards/Pages/Cyber-Hygiene-Best-Practices.aspx

vulnerabilities across the operating environment. For example, a device connected to the Internet or external networks will require protections that may not be necessary for a local-area network or a standalone device. Practical solutions must reflect the HDO environment, and requires them to work with manufacturers to appropriately utilize the security information provided by manufacturers, government agencies, and other industry bodies to properly assess, architect, and maintain effective cyber security hygiene.

Another unique, significant challenge surrounding medical imaging devices is life cycle disparity. The clinical lifetime for many medical imaging devices, such as MRI machines, can span decades, while the digital lifetime, during which manufacturers are able to provide security updates, may only be a few years. This disparity creates a shared financial burden between HDOs, manufacturers, and public agencies that creates additional tension. Practical solutions to these challenges are a shared responsibility across every healthcare sector stakeholder, and include financial, structural, and organizational aspects.

*** *** ***

Several factors highlight the need for all healthcare stakeholders to work together:

1. Vulnerabilities can be found across the entire supply chain, from software and hardware suppliers, to manufacturers, to hospital infrastructure and staff. Sharing the burden of this responsibility is critical to improving cyber security.
2. Life cycles vary greatly between software and hardware in medical imaging, both during the development life cycle and the useful clinical life.
3. Safety and performance requirements that mandate significant testing before releasing security-related updates hinders the manufacturer's ability to quickly respond to threats.

MITA believes that the following tools and policies can contribute to effective cyber security in medical imaging devices:

- Possession and maintenance of an inventory of devices and components, which puts organizations in a stronger position to effectively mitigate risk.
- Network segmentation and isolation of legacy equipment, which requires knowledgeable IT staff to develop, support, and monitor.
- Utilization of the Manufacturer Disclosure Statement for Medical Device Security
- Proper coordination and utilization of vulnerability disclosure programs

In addition to promoting more collaboration with HDOs, MITA believes the following policies are worth exploring:

- Develop life cycle definitions using existing industry standards, such as NIST 800-64, to ensure consistency and encourage industry collaboration
- Offer incentives to upgrade systems that utilize obsolete operating systems, unsupported third-party commercial software, and outdated hardware.

- Credit customers for remaining warranty coverage on older equipment when they upgrade systems.
- Offer rebates or subsidies as a way to lessen the financial burden of upgrading older technology.
- Discourage continual use of equipment beyond its defined life cycle through loss of accreditation or reduced reimbursements
- Change of the tax code to allow for a shorter deprecation life for capital medical equipment

- Clear manufacturer communication of key dates that include how long a product can expect support based on both software and hardware life cycles.
- Clear recognition that no security support should be expected for any medical device past the end of the support date established for that product.
- Clearer guidelines from international regulatory bodies responsible for medical imaging devices create on qualifying security updates without imposing lengthy and costly verification and validation testing.

MITA stands ready to work with the committee and all stakeholders to address the threats of cyber security. MITA believes the entire healthcare industry can achieve improved cyber security only by embracing the model of shared responsibility. The difficulties and solutions we recommend are only a small part of a more secure medical infrastructure. To the extent Congress has a role to legislate in these areas, we look forward to further engaging your staff to work toward these commonsense solutions.

If you have any questions, please contact Andy Dhokai, Director of Federal Relations, at adhokai@medicalimaging.org or (703) 841-3247.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These

technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.