Cybersecurity & Medical Imaging Devices

OUR GOAL

Our goal is to protect patient safety and privacy through a regulatory and standards environment that enables the **confidentiality, integrity, and availability** of medical imaging devices and all associated information and infrastructure.

NECESSARY FEATURES OF NEW POLICY:

- Recognition that cybersecurity is a **shared responsibility**. Stakeholders include manufacturers, health delivery organizations (HDOs), patients, regulators, researchers, and others. Maintaining device **safety and effectiveness** is the primary concern of device manufactures.

- Understanding that manufacturers strive to ensure that their devices are developed and supported in a way that enables the **secure operation** of devices. Manufacturers cannot control security within the operational environment.

- Recognition that a secure healthcare environment needs to **rely on standards** for healthcare risk management as opposed to new regulations on medical devices. Securing medical imaging devices is one small part of the ecosystem.

- Avoid mandates for specific cybersecurity risk-mitigation tactics for all stakeholder groups. Cyber threats are constantly evolving. Risk-mitigations must have the **flexibility to respond** to the evolving threat landscape.

- Understanding that information sharing policies should have clear legal guardrails, value for participants, and be inclusive of any potential stakeholder in the healthcare delivery chain. Mature cybersecurity programs like those seen in the financial sector must be implemented by **every stakeholder** to ensure meaningful and appropriate responses to the evolving threat landscape.

- Recognition that the security support life of a medical device will often be less than its useful clinical life, based on the dependency for hardware and software support from third-party software suppliers. Medical Device Manufacturers must work **collaboratively** with Health Delivery Organizations to promote investments in operational risk mitigations and plan for future product upgrades to address emergent security risks during the security support life of the product.

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PURPOSE

This document provides a broad overview of the cybersecurity activities, policies, frameworks, and efforts that the medical imaging device community is actively engaged in.

LIST OF ACTIVITY:

1) Updating the Manufacturer Disclosure Statement for Medical Device Security (MDS2) with input from stakeholders from across the industry, including healthcare delivery organizations, regulators, and manufacturers

2) Participation in the Healthcare Sector Coordinating Council, including the creation and adoption of the Joint Strategic Plan, which outlines a path forward for all committed stakeholders to improve the overall cybersecurity of the sector

3) MITA's Software Bill of Materials efforts, including the MDS2 and combined activities with HDOs, FDA, NTIA, and others

4) Pursuit and achievement of Improved vulnerability disclosure programs through official channels

5) Acceptance and adherence to FDA pre-market and post-market cybersecurity guidance, and engagement in the post-market guidance update, which has provided clear guidelines and improved processes

6) National and international Cybersecurity Frameworks give practical guidance to manufacturers and HDOs, and manufacturers are adopting those frameworks:

    1) Secure Development Lifecycles: NIST SP800-30, ETSI TS 102 165 TVRA, IEC 62443-3-2, ISO 20004 TRA, SAFECODE, OWASP, ISO 27000 Series
    2) Device Security Controls: NIST FIPS 199, ISO 15408 CC, NIST SP800-53, NIST FIPS, ISO 18004/033/367/370, ISO 19592/772, 27040
    3) Secure Use: ISO 15026-1/2, ISO 15443-1/2, IEC 80001-2-2, -2-8, -2-9
    4) Providing Updates: ISO/IEC 29147, ISO/IEC 30111, ISO 27000 series

7) Engagement with the Federal Acquisition Supply Chain Security Act (FASCSA)

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