



MITA
MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
A DIVISION OF **NEMA**[®]

1300 North 17th Street • Suite 1752
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

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Jamie Ferguson, co-chair
John Halamka, co-chair
Health Information Standards Committee, Clinical Operations Workgroup
Washington, D.C.

Dear Mr. Ferguson and Dr. Halamka:

This letter represents the written testimony of the Medical Imaging & Technology Alliance (MITA) for the HIT Standards Committee, Clinical Operations Workgroup public hearing on March 28, 2011, to address the critical issues of the identification of barriers and enablers for device interoperability.

MITA appreciates the opportunity to share its views with you. We also look forward to providing oral testimony for the *Device Security and Data Security Panel*, at the March 28 hearing. MITA commends the Clinical Operations Workgroup for holding this hearing to address these critical issues.

MITA member companies are uniquely positioned to play a key role in facilitating achievement of systems interoperability based on their extensive expertise and experience. MITA is the medical division of the National Electrical Manufacturers Association (NEMA). MITA member companies manufacture medical products and services which are essential to the sharing of images and imaging reports, including: Imaging modalities, Picture Archiving and Communication Systems (PACS), Radiology Information Systems (RIS) and Hospital Information Systems (HIS).

MITA created the Digital Imaging and Communications in Medicine (DICOM) Standard, which is the standard for the communication of imaging and imaging information. Adoption of the DICOM Standard by the nation's providers will address one of the critical needs of the Nationwide Health Information Network (NW-HIN), namely the need to communicate imaging information between providers. MITA manages, updates, deploys and tests the DICOM Standard on an ongoing basis. In the U.S. market, over 99.5% of imaging systems shipped today include DICOM capability. The DICOM Standard has been accepted nearly universally and is available now for implementation.

In addition, MITA representatives have been actively engaged in the development of the HL7 Standard, Integrating the Healthcare Enterprise (IHE) Profiles, and other standards-based tools. These standards and standards-based tools are designed to address clinical workflow and healthcare practice administration, and enhance systems interoperability through exchange of clinical information.

Provider access to imaging information is key to clinical practice. The ability to access this information depends on achieving interoperability between systems. The effectiveness of the Nationwide Health Information Network (NW-HIN) will depend on the widespread adoption of the capability of exchanging images, imaging information and other patient health data between providers across organizational lines, so that providers can easily access patient information whenever it is needed. Adoption of the DICOM Standard, IHE Profiles, and other standards-based tools, are indispensable to achievement of this goal.

At the March 28 hearing, individual Panels will provide testimony on questions related to health care devices and device interoperability with EHR technology. The Workgroup has set forth general questions posed to all Panels, as well as specific questions which are directed to individually identified Panels. MITA will address below the general questions posed to all Panels, and the questions which are specifically directed to the *Device Security & Data Security Panel*.

General Questions:

Question 1: What is your experience with health care devices and device interoperability? Have you experienced specific problems where standards might contribute to solutions?

MITA Response:

As stated above, MITA manufacturers have extensive experience with the manufacture, testing and deployment of medical imaging and radiation therapy devices, and the manufacture of PACS, RIS and HIS products to facilitate the exchange of information between providers and within the hospital facility. In addition, MITA members have been actively engaged in the development and ongoing management of the DICOM Standard, IHE Profiles and other standards-based tools, all of which are key to establishing systems interoperability. In fact, the DICOM Standard, which is the standard for communication of imaging information, was created by MITA manufacturers and the American College of Radiology (ACR). Also, since the first version of the Standard was approved in 1993, MITA staff has been managing the day-to-day activities of more than 1200 volunteers from around the world who participate in maintaining and extending this Standard. DICOM is a dynamic standard and is continually updated to serve a wide range of clinical needs and to help ensure the smooth flow of clinical information between systems. A formal agreement and three joint meetings per year between DICOM and HL7 help to assure the compatibility of these two critical healthcare standards.

MITA manufacturers have also played a leading role in development of IHE Profiles, and with respect to development of the HL7 standard. IHE Profiles foster systems interoperability by organizing and leveraging the integration capabilities that can be achieved through coordinated implementation of communication standards such as DICOM and HL7. The HL7 Standard is important in establishing common message elements for both clinical and administrative domains to facilitate interoperability of systems. Interoperability issues can be successfully addressed by the use of the DICOM and HL7 Standards, and the IHE Profiles.

Question 2: Are there areas where standards are more mature or less mature?

MITA Response:

The following standards have been in widespread use for many years and are thus “mature” standards. The DICOM Standard was created in 1993, and is continually being updated to reflect new technologies. It is a mature yet evolving standard and is continually updated to address the needs of providers in clinical practice. The DICOM Committee continues to extend the standard to include newer technologies. In 2010, for example, thirteen major new supplements were added to the 4100 page DICOM Standard. These included a new Part 19 on Hosted Applications and a new capability that will enable electronic display, sharing, storage, and management of the image of an “entire microscope slide” for use in pathology. Work is currently underway to develop “web services” that will provide access to DICOM persistent objects. In addition, the HL7 Standard has been utilized for over 20 years, and is also continuing to evolve to meet changing clinical needs.

Question 3: What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?

MITA Response:

The following standards and standards-related capabilities are essential to the achievement of the meaningful use of EHR technology, including:

1. DICOM Standard – The DICOM Standard enables the communication of images and imaging information between providers.
2. HL7 Standard – The HL7 standard is used for the exchange, management and integration of data. It allows for the flexible and cost-effective exchange of clinical and administrative data to achieve interoperability between healthcare information systems.
3. Integrating the Health Care Enterprise (IHE) Profiles – IHE Profiles are tools which employ the use of standards to address clinical workflow issues, to improve the way computers in healthcare systems share information. IHE Profiles facilitate systems interoperability by organizing and leveraging the integration capabilities that can be achieved by coordinated implementation of established communication standards, such as DICOM and HL7. For example, the IHE Portable Data for Imaging (PDI) Profile enables reliable interchange of image data and diagnostic reports on CDs for importing, printing or displaying this data in a browser. The IHE XDS-I Profile enables sharing of images, diagnostic reports and related information across care sites.

Attention should also be focused on incorporation of a DICOM image viewer into the electronic health record, to ensure that the data which is displayed by the provider’s viewer is identified with the right patient.

Question 4: What do you see as key barriers to effective use of health care devices to advance health and wellness?

MITA Response:

Several key barriers now exist which are impeding the effective use of health care devices to improve health and wellness. These barriers include:

1. Lack of access by providers and hospitals to the patient's medical imaging information;
2. The difficulties providers face in the conversion from an existing paper record system to an electronic health record system; and
3. Reluctance by hospital providers to share patient information when patients move to different health institutions outside of their network for their care.

First, access to the patient's medical imaging information is critical to the ability to render a complete diagnosis of a patient's condition. The lack of access to this information constitutes a significant barrier to the effective use of health care devices. The provider needs to have access to all of the patient's medical information to be available in the electronic health record whenever it is needed to fully take advantage of the benefits of electronic health record technology. For example, immediate access to patient information on previously performed diagnostic imaging procedures will enable the more efficient use of healthcare resources, by helping to reduce the number of duplicate imaging procedures.

Second, it should be recognized that conversion to an electronic health record system from a paper-based system necessarily entails substantial, initial investment costs by the provider, provider training, and changes in provider practice management. Strengthened government incentives are needed to assist providers to help defray the costs associated with conversion to a digital system. Expansion of existing programs to help guide providers through the conversion process is also essential.

Third, hospital providers are reluctant to share patient information when patients travel from one organizational entity to another, due to hospitals' competition for patients. In order to achieve a fully effective use of electronic health records, improved government incentives are needed to encourage sharing of patient data between healthcare systems.

Question 5: If you could wave a magic wand to effect one change to enable more effective and widespread use of health care devices, what would that be?

MITA Response:

MITA believes that the adoption of the DICOM Standard for the communication of imaging information, and its incorporation as a key goal of Stage 2 Meaningful Use is critically important. We recognize the very tight timing issues associated with adding new functionality to Stage 2, and so believe that a roadmap for use of images within certified EHRs that considers both Stage 2 and Stage 3 is critical. We also recognize that there is a well-developed infrastructure for the generation, storage, and display of digital images, and do not believe that EHRs should be pushed to duplicate this functionality. Adoption by providers of an electronic health record system, with the content accessible by standards-based mechanisms, is essential to enable more effective and widespread use of health care devices.

The MU requirements should recognize two different pathways to and from the Imaging workflows. The most basic level of communications is to utilize portable media. This mode is defined in the IHE Portable Media for Imaging (PDI) Profile which is harmonious with the IHE Cross-Enterprise Document Media Interchange (XDM) Profile. Through the use of the PDI and XDM profiles, all imaging studies can be communicated via USB or CD ROM or over e-mail. It should be noted that the PDI/XDM e-mail option is consistent with the Direct Project. The Direct Project specifies a simple, secure, scalable, standards-based way for participants to send authenticated, encrypted health information directly to known, trusted recipients over the internet.

The second pathway is to utilize the mature IHE Cross-Enterprise Document Sharing Profile with the Profile defined for sharing of Imaging – IHE Radiology Cross-Enterprise Document Sharing for Imaging (XDS-I) Profile. With this profile the imaging studies are made available across the XDS environment while utilizing DICOM standard interfaces for the imaging traffic. The XDS-I profile supports all forms of DICOM based objects.

Device Security and Data Security Panel Questions:

Question 17: What are the security requirements for devices in different care settings, e.g. SNIF vs. Hospital vs. Home or other remote monitoring?

MITA Response:

Since 2001, MITA has been a co-sponsor of a Joint Committee on Security and Privacy, along with the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR), and the Japan Industries Association of Radiological Systems (JIRA). The Joint Committee on Security and Privacy has published papers that are very informative on the question of the security of medical devices. Medical devices and electronic health record systems both need to be protected against security risks. The care setting is also not a specific differentiator. In all cases security risks need to be considered and a layered approach to security applied.

Some of the relevant white papers from the Joint Security and Privacy Committee include:

- [Certificate Management for Machine Authentication](#)
- [Defending Medical Information Systems Against Malicious Software](#)
- [Patching Off-the-Shelf Software Used in Medical Information Systems](#)
- [Break-Glass – An Approach to Granting Emergency Access to Healthcare Systems](#)
- [Information Security Risk Management for Healthcare Systems](#)
- [Security and Privacy Auditing In Health Care Information Technology](#)

As with the HIPAA approach to security, it is neither desirable nor productive to specify a fixed set of security controls for all types of medical devices in all healthcare settings. Instead, the most robust approach is to understand the nature of security risk in the care setting and adjust

device-external controls (e.g., isolated, security controlled networks) to the specific installation, and to the specific controls provided directly on the medical device.

The use of a risk assessment is the focus of a recently approved IEC/ISO 80001 Standard – “*Application of risk management for IT-networks incorporating medical devices- Part 1: Roles, responsibilities and activities.*” The description of IEC 80001 is best summarized by Dr. Nick Mankovich, Senior Director of Product Security and Privacy, Philips Healthcare, in an article he wrote for Information Security magazine:

*“This standard lifts security and privacy risk out of the afterthought category into the mainstream of health care delivery. It does this by building around the principle that decisions in any new device integration project in health care need to be built around some simple concepts. In the parlance of IEC-80001-1, medical IT-network risk management proceeds with a careful examination and understanding of **three key properties: (1) safety, (2) effectiveness and (3) data and systems security.** By considering all three, we can first “do no harm” while effectively delivering on the organization’s health care mission. This is done with careful and explicit treatment of the appropriate level of confidentiality, integrity, and availability.”* Mankovich, Nick. “Maintaining health care privacy and security,” Information Security magazine, October 2010.

To foster an understanding of risk and the creation of installation-specific security controls, MITA is the publishing entity for the *Manufacture Disclosure Statement for Medical Device Security (MDS²)*. The MDS² form and instructions for completing it are designed to assist professionals who are responsible for security-risk assessment in the management of medical device security issues. The MDS² form is laid out with a set of high level security capabilities. It is used as a statement by the manufacturer of the security capabilities included with the product, or available for the product. Any missing security capability is disclosed, allowing the healthcare organization to mitigate risk with appropriate external technical, administrative, and physical controls. The MDS² form is currently under revision by MITA and the Health Information and Management Systems Society (HIMSS) to better communicate security and privacy risk in alignment with ISO/IEC 80001.

Question 18: How do existing security standards support network-enabled devices today?

MITA Response:

The standards and mechanisms defined in DICOM and IHE are in widespread use to provide effective protections today. These mechanisms are provided primarily through the use of the IHE Audit Trail and Node Authentication (ATNA) Profile:

- Authentication of systems and encryption of transported information
- Interoperable audit logs
- User authentication and access controls appropriate to the intended use

Breaches in security, when they have occurred, have been primarily due to human error, poor implementation of the required security and privacy mechanisms, accidental loss of printed forms, lack of training in security and privacy awareness of clinical staff, or due to criminal activity such as theft. The standard protection mechanisms have withstood direct attack, and failures, and have most commonly arisen through vulnerabilities in the supporting staff, procedures, or facilities.

Conclusion:

As stated above, MITA has long and extensive expertise and experience in the manufacture of products and services which enable systems interoperability. MITA members' continued, active involvement in the development, deployment and testing of the DICOM Standard, HL7 Standard, IHE Profiles, and other standards-based tools, attest to the central role MITA has played and continues to play in facilitating systems interoperability.

MITA stands ready to lend its knowledge and expertise to the Office of National Coordinator to assist in facilitating the implementation of systems interoperability, and to help achieve the Nationwide Health Information Network (NW-HIN).

We look forward to working with you on this important effort.

If you have any questions, please contact me directly at (703) 841 – 3279 or by e-mail at dfisher@medicalimaging.org.

Sincerely,

/David Fisher/

David Fisher,
Executive Director, Medical Imaging & Technology Alliance (MITA)
Vice President, National Electrical Manufacturers Association (NEMA)