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March 1, 2011

U.S. Department of Commerce
National Institute of Standards and Technology
National Science and Technology's Subcommittee on Technology

RE: Standardization feedback for Subcommittee on Standards

Dear Sir/Madam:

This letter represents the comments of the Medical Imaging & Technology Alliance (MITA), and comes in response to the Request for Information by the National Institute of Standards and Technology (NIST), on behalf of the National Science and Technology Council's Subcommittee on Standards, which was issued on December 8, 2010 in the Federal Register, 75 Federal Register 76397, Docket No. 0909100442-0563-02. The Request for Information is seeking comments on the effectiveness of Federal agencies' participation in the development and implementation of standards, and the adequacy and availability of Federal resources for standards-setting activities.

The purpose of the Request for Information is to help the Subcommittee on Standards develop case studies that Federal agencies can consider in their future engagement in standards development and conformity assessment, in key technology areas. MITA's comments will focus on the key area of health information technology, with regard to implementation of a Nationwide Health Information Network (NHIN).

MITA is the Medical Division of the National Electrical Manufacturers Association (NEMA) and is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. These technologies include:

- Medical X-ray equipment
- Computed tomography (CT) scanners
- Ultrasound
- Nuclear medicine imaging equipment (including radiopharmaceuticals)
- Radiation therapy equipment
- Magnetic resonance imaging (MRI)
- Imaging Informatics Systems

MITA appreciates the opportunity to share its views with you, and commends NIST for its interest in improving Federal agency participation in standards activities. MITA believes that the Office of the National Coordinator (ONC) has not fully recognized that imaging is central to clinical practice, and that the Digital Imaging and Communications in Medicine (DICOM) Standard, which is essential to communication of imaging information, already exists, and is

readily available for implementation. Adoption and use of this standard is key to achievement of the NHIN and work must begin now to ensure its implementation.

Specific Comments

MITA agrees with the findings of the President's Council of Advisors on Science and Technology (PCAST) Report, which found that the Federal government had not optimized its activities for achievement of the NHIN. MITA supports the Report's recommendation that ONC redirect its focus toward achieving a robust health information exchange and an effective functioning infrastructure in which clinical information can be communicated and shared among providers regardless of their location.

One of the key components of the NHIN is the capability to exchange images and imaging reports among providers. This can only be accomplished by adoption and use of universally recognized standards. The DICOM Standard is currently the nearly universally accepted tool which enables communication of images and imaging reports. DICOM is in widespread use by providers worldwide and is available now for implementation.

MITA offered to help ONC implement these capabilities. At meetings with ONC on April 9, 2009 and August 13, 2009, MITA described its experience and expertise on development, deployment and testing of the DICOM Standard, and offered its assistance to facilitate the implementation of NHIN.

In addition, in response to a solicitation for input from the White House Office of Science and Technology Policy, MITA's letter of November 12, 2009 cited those areas where MITA's expertise and experience can provide valuable advice to the Health Information Technology (HIT) Policy Committee. These areas include, for example:

1. Providing actual field examples of clinical facilities which have successfully implemented the DICOM Standard;
2. Conducting a feasibility analysis to demonstrate the benefits of DICOM implementation;
3. Analyzing how providers are likely to receive various proposed solutions based on their individual health information technology capabilities

In our letter of March 15, 2010, in response to the Interim Final Rule issued on January 13, 2010, in 75 Federal Register 2014, MITA recommended that the DICOM Standard be adopted in the initial set of standards as an essential step to achieve the goal of systems' interoperability and Meaningful Use of EHR technology. MITA requested that ONC promptly provide the opportunity for imaging equipment manufacturers to describe and explain the value of the DICOM Standard to achieve this goal. MITA emphasized that it was important that discussions begin promptly to ensure an orderly transition from Stage 1 to Stage 2.

Medical imaging device manufacturers have extensive expertise and experience with respect to the DICOM Standard, and with other standards-based tools, to coordinate radiology report sharing among providers. However, ONC has not yet effectively utilized this expertise, or collaborated with medical imaging device manufacturers to implement these capabilities. As a result, this has created confusion, and in effect has hampered, rather than facilitated, progress toward achievement of the NHIN.

MITA Recommendations

MITA believes that ONC's, and CMS' leadership and participation in the development of the NHIN need to be significantly improved and increased in order to successfully implement this capability. To achieve this goal, we make the following recommendations:

1. ONC and CMS should immediately and publicly acknowledge the criticality of the adoption and use of the DICOM Standard for communication of images and imaging information, and the importance of the use of Integrating the Healthcare Enterprise (IHE) Profiles, such as XDS-I.b, for addressing clinical workflow and interoperability issues.

2. ONC should make the adoption and use of the DICOM Standard and IHE Profiles key goals for the implementation of Meaningful Use of EHR technology in 2013 and 2015, and industry should be a full participant in this process.

3. ONC should revise its strategic planning process to include as full participants not only provider representatives, but also representatives of medical imaging device manufacturers, information technology companies and those organizations with expertise in creation, implementation and testing of health data infrastructure. Based on their participation, and fully utilizing their expertise and experience, the ONC Strategic Plan should be thoroughly evaluated and revised in order to achieve the NHIN.

4. ONC should recognize that by following the DICOM Standard and IHE models, much of the cost of adoption and government overhead can be removed by allowing self-certification of conformance to both DICOM and IHE by manufacturers. This self-certification system has worked well for industry and has been in place for over 20 years.

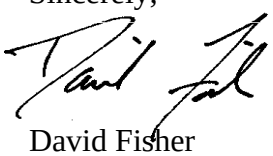
Conclusion

The foundation of the NHIN rests on achievement of systems interoperability, adoption of a robust health information exchange capability, and an effectively functioning infrastructure. The adoption and use of the DICOM Standard, as well as other standards-based tools, must be given top priority to ensure the Meaningful Use of electronic health record technology. This work must begin now to ensure that the necessary steps will be taken in a careful, coordinated fashion.

The active participation and leadership of ONC in the process of development of the NHIN is vital to saving lives, reducing healthcare costs and improving the quality of healthcare delivery for all Americans. MITA stands ready to assist NIST in 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,



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