National Electrical Manufacturers Association

Representing Electrical and Medical
Imaging Equipment Manufacturers
www.nema.org

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The Honorable Patrick Gallagher
Director
National Institute of Standards and Technology
U.S. Department of Commerce

RE: Standardization feedback for Sub-Committee on Standards

Dear Dr. Gallagher:

The National Electrical Manufacturers Association (NEMA) is pleased to have this opportunity to provide comments in response to the Request for Information (RFI) initiated by the National Standards of Institute and Technology (NIST), on behalf of the National Science and Technology Council's Sub-Committee on Standards, on the "Effectiveness of Federal Agency Participation in Standardization in Select Technology Sectors" (Docket No. 0909100442-0563-02).

NEMA is the association of electrical and medical imaging equipment manufacturers. Founded in 1926 and headquartered near Washington, D.C., its approximately 450 member companies manufacture products used in the generation, transmission and distribution, control, and end use of electricity. These products are used in utility, industrial, commercial, institutional, and residential applications. The association's Medical Imaging & Technology Alliance (MITA) Division represents manufacturers of cutting-edge medical diagnostic imaging equipment including MRI, CT, x-ray, and ultrasound products. Worldwide sales of NEMA-scope products exceed $120 billion annually.

In order to assist the Sub-Committee on Standards to "develop case studies that Federal agencies can consider in their future engagement in standards development and conformity assessment," NEMA will provide some general comments on federal agency participation in standardization activities as well as specific examples demonstrating the federal role in smart grid, health information technology, nanotechnology, Digital Imaging and Communications in Security (DICOS), and Intelligent Transportation Systems (ITS) standards.

Executive Summary

NEMA is offering general comments on the issue of federal agency participation in standardization activities, followed by responses to specific questions posed in the RFI as reflected in several technology areas. In summary, NEMA expresses the following views:

- In general, the effectiveness of federal agency participation depends on the level of involvement and commitment of resources and manpower to the process.

- Federal agency participation in standardization activities ensures that the needs and requirements of the various agencies, particularly as needed for the development of regulations or for government procurement, is taken into consideration and incorporated into the standards.

- There appears to be general consensus that federal agency participation in standardization activities can have one of two effects. Federal agencies can contribute positively to the standardization activities, resulting in an overall improvement in product reliability and cost containment, or federal involvement can limit or hinder the advancement of technology, resulting in mandates that detract from legitimate research and development efforts in response to realistic market-driven forces.

- Federal agencies participate implicitly in standardization by incorporating references to consensus standards in rules, regulations, and guidance documents. However, keeping these up-to-date is a significant challenge for some federal agencies.

- Participation in standards-writing generally is a voluntary activity, with the expense borne by the individual participants. The costs associated with standards development can impede the timeliness with which work on standards is conducted. The federal government should find ways to creatively incentivize participation in standards development activities. Federal investment in standards development leverages increased participation by other stakeholders.

General

NEMA reviewed several technology areas in which federal agencies participate in standardization activities. In general, the effectiveness of federal agency participation depends on the level of involvement and commitment of resources and manpower to the process. The case studies provided in response to the questions posed in the RFI will provide specific examples of varying levels of agency participation and effectiveness.

Federal agency participation is the exception rather than the rule for many of the International Electrotechnical Commission (IEC) committees with which NEMA is most familiar. This does not seem to negatively impact IEC standards development activity since public policy issues rarely arise in this context. As a result, the federal government generally is content to allow private industry to take the lead on standards development. On occasion, federal agencies have communicated specific needs that have been addressed by the standards development activities of IEC.

Federal participation in the regulatory and public policy aspects of standardization efforts, largely within the International Organization for Standardization (ISO), is more robust, particularly as the ISO addresses broader issues like environmental and worker safety. NEMA also works closely with the Institute of Electrical and Electronics Engineers (IEEE). In the area of human exposure limits to electromagnetic fields, there are a number of federal employees working alongside industry representatives with the IEEE, including individuals from the Federal Communications Commission (FCC), Food and Drug Administration (FDA), Department of Defense (DOD), and the Occupational

Safety and Health Administration (OSHA). These employees contribute actively and readily accept assignments to enable development of standards that will be suitable for the protection of the public.

There is a general consensus among NEMA members that federal agency participation in standardization activities can have one of two effects. Federal agencies can contribute positively to the standardization activities, resulting in an overall improvement in product reliability and cost containment, or federal involvement can limit or hinder the advancement of technology, resulting in mandates that detract from legitimate research and development efforts drive in response to realistic market-driven forces. NEMA's experience has varied among federal agencies and even within the agencies themselves. Several general examples of NEMA's experiences are provided below for the Sub-Committee's review.

- **National Institute of Standards and Technology (NIST):** NEMA has collaborated with NIST numerous times developing and conducting standards capacity building workshops as part of its Standards-in-Trade Program with U.S. trading partners, including many countries from the Americas and Asia. For example, NEMA collaborated on workshops in China and Brazil on Intelligent Transportation Systems, resulting in standing room-only attendance that has since led to the adoption of U.S. private sector transportation standards in Brazil. This program is a prime example of the important supporting role NIST plays in the U.S. voluntary consensus standards system. NEMA also has worked closely with and advised NIST as it developed the Smart Grid Interoperability Panel (SGIP), which will be explored in subsequent sections of these comments as a specific case study.

  In addition, NEMA managed the development of the Requirements for Smart Meter Upgradeability standard (NEMA SG-AMI1). This standard was developed and approved in record time—less than 90 days from start to final approval. The team that developed the standard was comprised of all five major U.S. meter manufacturers, five US electric utilities, a representative from NIST, a contractor to NIST, and a NEMA project manager/facilitator. NEMA, which is an American National Standards Institute (ANSI) accredited standards development organization (SDO), managed this project at the request of NIST.

  The Smart Meter Upgradeability standard was critical for the expansion of Advanced Meter Infrastructure (AMI) and Smart Meters in the US. At the time the standard was developed (fall 2009) many state commissions were considering adopting AMI systems. However, the commissions were concerned whether the technologies would be forward interoperable and whether they would comply with soon to be established national smart grid standards. The Smart Meter Upgradeability standard closed those gaps by providing technical and security requirements for smart meters so that the firmware used in the meters could be upgraded to support future requirements and future smart meter standards. This standard helped to educate and support state commissions in approving the installation of roughly 50 million smart meters over five years.

- **U.S. Department of Commerce (DOC)/International Trade Administration – Market Development Cooperator Program (MDCP):** Standards have been at the heart of several MDCP awards to NEMA during the past decade. This program has been exceptionally supportive of standards development efforts in the Americas and in China for our industry sector.

- **Office of the U.S. Trade Representative (USTR):** NEMA has worked closely with USTR staff over the past 15 years on many standards and conformity assessment policy issues within the context of the World Trade Organization (WTO), with many of the nations having free trade agreements with the U.S., with the APEC economies, particularly the Sub-Committee on Standards & Conformity, and many of the individual countries in Asia, including China, Japan, Korea, and Thailand, among others.

- **U.S. Trade and Development Agency (USTDA):** NEMA has worked closely with USTDA developing and operating the U.S.-China Standards & Conformity Assessment Cooperation Program, a robust program of capacity building and information exchange covering numerous industry sectors, addressing safety, energy efficiency and environment. Experts of NEMA members' Smart Grid products have steadily increased over the past six years, to hundreds of millions of dollars, as an example of the benefits to such trade development activities centered around standards.

- **U.S. Consumer Product Safety Commission (CPSC):**

  CPSC has played a key role in the development of standards for ground fault circuit interrupter (GFCI) technology. In the 1990s, CPSC focused the manufacturers' and installers' attention on issues relating to occasional reverse wiring during installation, leading manufacturers to incorporate additional installation instructions to the existing markings to eliminate reverse wiring. CPSC staff participated in NEMA-sponsored meetings to discuss these issues, and their influence assisted the industry in aligning patented technologies and safety standards to achieve desired safety goals.

- **U.S. Occupational Safety and Health Administration (OSHA):**

  NEMA has experienced both success and frustration with respect to OSHA's involvement in standardization activities. For example, the participation of OSHA representatives on National Fire Protection Association (NFPA) 70E, *Standard for Electrical Safety in the Workplace*, has been quite beneficial to the NFPA 70E Committee. While OSHA representatives do not vote on proposals or comments, they still provide valuable input on the technical aspects of such proposals. OSHA is represented on the Committee by experts in electrical safety, and when they speak, the Committee listens.

  One way in which federal agencies implicitly engage in standardization activities is through the incorporation of references to national consensus standards into agency rules and regulations. While federal adoption of these standards streamlines the rulemaking process and represents a

cost-effective regulatory mechanism, too often federal agencies cannot keep pace with modifications to the consensus standards, failing to update any regulatory references in a timely manner.

For example, OSHA is required to rely on national consensus standards whenever possible, and has cited references to roughly 200 separate standards in approximately 500 places in OSHA rules and guidance. However, many of these standards are woefully outdated. OSHA's existing regulations for workplace and facility safety signs, for example, cite a 1968 American Standards Association (ASA) standard, which has been replaced by a successor series of American National Standards Institute (ANSI) standards, the most recent of which will be published in 2011. Employers wishing to use state-of-the-art signs conforming to the new ANSI standards face the possibility of being issued a "*de minimus*" non-compliance citation by OSHA because of the agency's legal reliance on 1968-compliant signs. The process for OSHA to update references to standards is burdensome, and there is only one individual within the agency's Directorate of Standards and Guidance assigned to review and update all of OSHA's references to consensus standards. Any benefit OSHA derives from incorporating state-of-the-art consensus standards is virtually negated by the impossible task of keeping them properly updated.

NEMA also has worked with OSHA's Nationally Recognized Testing Laboratory (NRTL) Office, particularly with respect to urging adoption of the IEC Certification for Standards for Electrical Equipment in Explosive Atmospheres (IECEx Scheme) and NRTL acceptance of manufacturers' test data for hazardous location products. OSHA has delayed its review and acceptance of the IECEx Scheme, which facilitates international trade in equipment and services for use in explosive atmospheres while ensuring the required level of safety. Although the U.S. participates with 29 other nations in the IECEx Scheme, OSHA appears reluctant to recognize the IEC 60079, 61241, and 61779 series of standards recognized by the IECEx Scheme as American National Standards (ANS) designated by ANSI.

Similarly, NEMA has attempted to work with the OSHA NRTL office to address the need for NRTL acceptance of manufacturers' test data for hazardous location products. Manufacturers of such products, who had been qualified for and engage in a Client Test Data Program (CTDP), previously were able to perform their own testing. However, toward the end of 2003 one NRTL offering CTDP that included hazardous location products testing was forced to exclude manufacturers' tests from its program. Not allowing NRTLs to accept manufacturers' test data results in an increase in the time-to-market for new products from American manufacturers. To date, OSHA has not provided any substantiation relating to problems encountered with hazardous location CTDP products that have been installed in the market prior to the agency's 1995 interpretation. NEMA has proposed that Procedure 5 of the Notice of Interpretation published in the *Federal Register* (March 9, 1995) be expanded to include test data for products intended for use in hazardous (classified) locations.

The OSHA NRTL office is small, with an inadequate number of personnel assigned to review such matters. Although OSHA NRTL staff have participated in NEMA discussions on both

adoption of the IECEx Scheme and the acceptance of manufacturers' test data, little progress has been made in addressing the needs and concerns. OSHA's lack of action impedes U.S. competitiveness, and without committed staff and monetary resources to participate in, review, and ultimately adopt the recommended policies, the NRTL office will continue to encounter challenges to keeping pace with the evolving world of standards.

In order to better assist the NSTC Sub-Committee in its review of the specific program areas highlighted in the RFI, NEMA has broken down its responses to many of the questions posed by providing specific examples for "Smart Grid"and "Other technologies involving significant Federal agency participation in standards setting," including--

- **Digital Imaging and Communications in Security (DICOS)**: DICOS v01, published in August 2010, provides a data interchange protocol and interoperable, extensible file format to facilitate data information interchange (demographic information, digital x-rays, computed tomography (CT) images, and threat detection reports) for airport security screening purposes. Specifically, DICOS is a file and data interchange format that permits exchange of meta-data and images irrespective of the brand of screening device that is used to capture a security image, and associated meta-data related to checked baggage, carry-on luggage, parcels, and personnel in an airport environment.

- **Intelligent Transportation Systems (ITS)**: Technology Area 6 as identified in the RFI should also be expanded to include Transportation. The U.S. Department of Transportation has expended resources for 15 years in support of Intelligent Transportation Systems (ITS) standards development. A summary of the DOT's program can be found at *http://www.standards.its.dot.gov.* Of particular interest to NEMA and its member companies are the National Transportation Communications for ITS Protocol (NTCIP) family of data communications protocol standards, and the Advanced Transportation Controller (ATC) family of hardware and software standard specifications.

- **Nanotechnology:** Nanotechnology standards setting is carried out through ISO TC 229, *Nanotechnologies*, and IEC TC 113, *Nanotechnology standardization for electrical and electronic products and systems*. In a broad sense, ISO TC 229 establishes fundamental standards for terminology and nomenclature, measurement and characterization, and for environmental health and safety (EHS) aspects. IEC TC 113, formed in 2006, establishes standards for performance assessments of nanoscale subassemblies used in electrical and electronic applications.

  The Draft 2010 Strategic Plan of the National Nanotechnology Initiative, the coordinating document that sets forth the role of each government agency in nanotechnology advancements, pointed to the need for continual support in the area of research into novel applications and environmental health and safety aspects of nanotechnology; however, it lacked emphasis on the importance of international standards-setting to facilitate the

commercialization of nano-enabled products, and the need for active U.S. participation in standards-setting.

NEMA submitted a number of comments in this regard during the public comment period, because the NNI Strategic Plan is the vehicle by which NIST can drive interagency communication through the NNCO on further participation in standards-setting. NIST participation in nanotechnology standards as an agency has been very positive, with experts appointed to projects involving terminology, measurement and characterization, performance assessments, and EHS. Other agencies, however, such as DOD, DOE, DHS, and others also need to participate in the work of nanomanufacturing standardization for end product applications of interest to them.

The Medical Imaging Technology Alliance (MITA), a division of NEMA, is submitting separate comments in response to the RFI with respect to "Health Information Technology." A copy of those comments is attached. These comments represent NEMA's perspective on federal agency participation in Health IT standardization activities.

Responses are not provided for every question by each technology area; however, NEMA hopes that the following answers and comments will benefit the NSTC Sub-Committee's understanding of federal agency participation in the standardization process.

Standards-Setting Processes

Smart Grid:

The best example of government participation in standards-setting for Smart Grid is the National Institute of Standards and Technology's (NIST) Tom Nelson, who currently chairs the ANSI C12 committee. As the chair, Mr. Nelson is an open, unbiased facilitator who has integrated seamlessly with industry in every aspect of the committee's business and doesn't attempt to sway or influence the activities of the committee. Because of the role C12 plays in Advanced Metering Infrastructure (AMI), the intersection of the customer and the utility in Smart Grid, it is extremely important that the government, and particularly NIST, have a detailed understanding of the functionality of standards such as C12.

Currently, C12 is used widely in the United States as a metering standard and in select other areas within the Americas. Europe, Asia, and the African continent use a patchwork of other standards, which is largely dominated by the metering standard propagated by the IEC. Going forward, the impact on competitiveness will be the ability of C12 to out-maneuver the IEC and update and improve their standard at a faster rate. With the release of C12.22 in April 2009, the standard now has the ability to support an underlying communications network in the operational development. Future improvements to the standard will include the development of a testing methodology to verify accuracy and interoperability and a standardized methodology for upgrading deployed meters. This ability to "future-

proof" a meter will be a major competitive advantage because it provides a measure of security for investing money in the grid today.

In a broader sense, it is important for the federal government to continue to communicate a vision for the grid. The Energy Independence and Security Act of 2007 (EISA) provided a starting point, but unfortunately, the legislation only represents a snapshot in time. In the years since its passage, the private and public sectors have learned a lot about the ways we can improve the methods for electricity delivery, and the landscape of technology will continue to change at a rate that will vastly outpace the legislative and regulatory environment's ability to adapt. By communicating five- and ten-year objectives, the industry can continue to strive to develop technologies and the standards to support that vision.

Other Technologies:

Who participates in standards- settings activities?

- **DICOS:** DICOS v01 was developed under the auspices of the National Electrical Manufacturers Association (NEMA), an ANSI-accredited standards developer. Participants in the DICOS standards-setting effort include a total of 17 companies with a software or hardware interest in the airport security scanning arena, including large and small companies. In addition, representatives (either employees or consultants) of the U.S. Department of Homeland Security (DHS), its Transportation Security Administration (TSA), and NIST provided guidance in development of the DICOS v01 standard.

- **ITS:** The U.S. DOT's ITS Standards Program was started to *expedite* the development of information technology standards for ITS, and to *balance* the participation between public and private sectors. For the ATC and NTCIP, NEMA has executed two memorandums of understanding (MOUs) with the American Association of State Highway Transportation Officials (AASHTO), which are the 50 state DOTs; and the Institute of Transportation Engineers (ITE), a professional society of international practitioners from private and public sectors, and from public sector agencies from the federal to local level. With this partnership, NEMA, AASHTO and ITE assure wide participation.

  Section 5206 of the Transportation Equity Act for the 21st Century (TEA-21) mandated that the U.S. DOT "develop, implement, and maintain a National Architecture and supporting standards and protocols to promote the widespread use of ITS technology, ensuring interoperability and efficiency to the maximum extent practicable."

- **Nanotechnology:** The National Institute of Standards and Technology (NIST) and National Institute of Occupational Safety and Health (NIOSH) offer a federal agency perspective in nanotechnology standards. Other participants include nano-material suppliers and end product customers.

What are the most important reasons for participation?

- **DICOS:** The important reasons for commercial company participation are the same as the reasons for participation in any standards development organization—an opportunity for a company's voice to be heard and its opinion reflected in a standard that may subsequently be adopted as the basis for regulation or procurement. Government agency participation via DHS- and TSA-designates ensured that the needs and requirements of DHS and the TSA were considered in a timely fashion during the development of DICOS v01, and that DICOS v01, as published, appropriately reflected agency interests.

  In addition, because homeland security needs are "immediate," to expedite the development and completion of DICOS v01 DHS and TSA participated financially in the funding of the standard. With this funding incentive provided by DHS and TSA, additional company and NEMA personnel resources were devoted to DICOS v01 development to ensure project completion within the (approximately) one-year timeframe dictated by DHS and TSA needs.

  For some sectors, standards serve as one element of agency procurement specifications, and DICOS v01 is now available for consideration as one such element. This was one driver encouraging DHS and TSA financial support.

- **ITS:** The private sector wants input on standards with which their products hope to conform; the public sector desires input on standards for the products and systems their agencies procure, install, operate, and maintain. Both sides hope that standardization produces open market opportunities and reduces life cycle costs.

- **Nanotechnology:** For national metrology institutes, the key reason for participating in nanotechnology standardization activities is to ensure uniformity in testing and measurement methods. For the private sector, the value of participation is derived from setting appropriate reliability and durability assessment methods.

What are the benefits of developing standards for this sector?

- **DICOS:** In the airport security sector, there are a number of known participants, many of which have provided hardware, software, integration, and/or maintenance services to DHS and TSA. However, a number of these solutions are proprietary, and it is understood that one manufacturer's security scans are not, generally, "readable" on another manufacturer's devices. By developing DICOS v01 as a single standard for data and meta-data representation and data transmission, interoperability is encouraged—permitting, for example, images captured on one manufacturer's device to be read on the device of another manufacturer. For government agencies, this interoperability is vital in that scans produced by one manufacturer's equipment can be viewed on another manufacturer's equipment, enabling viewing and evaluation at locations in addition to the original screening location, both within and outside of the original airport.

The benefit of a standards-based approach is inter-manufacturer data exchange, e.g., interoperability, data integration and data fusion are enabled. A standards-based approach also encourages enhanced data mining, pattern recognition, comparative analysis, predictive analysis, and automatic inspection (algorithm-based inspection) techniques. System architectures evolve into system-of-systems architectures. Point decisions become increasingly targeted against actual threats.

- **ITS:** The benefits include the potential for interoperability of remotely-controlled traffic management devices (traffic signals, message signs, sensing stations), the potential for interchangeability of replacement equipment and major subsystems, and the potential for reduced life cycle costs. In the United States, there are over 300,000 intersections with traffic signals, many of which are operated from Traffic Management Centers. Section 1201 of the SAFETEA-LU requires the Secretary of Transportation to establish a Real-time System Management Information Program to provide, in all states, the capability to monitor in real-time the traffic and travel conditions of the major U.S. highways and to share that information to (1) improve the security of the surface transportation system, (2) address congestion problems, (3) support improved response to weather events and surface transportation incidents, and (4) facilitate national and regional highway traveler information.

- **Nanotechnology:** Nanotechnology standards will facilitate mass manufacture of reliable nano-enabled products and systems.

How do the standards impact organizations and their competitiveness?

- **DICOS:** Prior to DICOS v01, a number of manufacturers provided proprietary solutions to TSA for airport security scanning. Should future acquisitions be based on DICOS v01 (or a successor standard), interoperability is likely to increase, and reliance on proprietary solutions likely will decrease. Since DHS and TSA represent a significant portion of the "market" for such solutions, it is likely that the relative placement of various companies within the marketplace might change, as individual companies are more or less successful in implementing DICOS v01 as part of the solutions offered to TSA.

  DICOS functions as an enabler of change from a proprietary focus to a focus on interoperability, and the value added through interoperability. In this environment, companies evolve to solution and system providers, as opposed to single-point solution providers.

  Initially, participating companies expressed concern regarding a perceived negative impact on individual companies' competitiveness. Some concern was also expressed regarding prospects for additional use of non-commercial entities' products, such as the use of university-developed search algorithms.

- **ITS:** The ATC and NTCIP standards have the potential to increase buyer/seller understanding of products and their options, increase competitiveness among sellers, and spur innovation for economic production.

- **Nanotechnology:** The standards will serve to improve communication between suppliers and customers and offer a level playing field on how performance is measured.

How has the standardization spurred innovation in the technology sector(s) that is the subject of your comment?

- **ITS:** For the U.S. traffic management device market, there are several to many suppliers of the different types of equipment. The structure of the ATC and NTCIP standards allow most remote control functions and hardware features to be standardized, but vendor- and agency-unique functions and features can be added with "extensions." Sellers differentiate their mostly standards-based products with innovative features—such as improved user interfaces, improved packaging, and cross-applications in new deployment areas.

- **Nanotechnology:** Although the standards-setting process is in its infancy, nanotechnology standards intend to remove barriers to innovation through common measurement methods.

What is the current phase of the standards development process for this technology?

- **DICOS:** DICOS v01 was published in August 2010, and addresses modules specific to particular technologies (CT and digital radiography), as well as modules that are expected to apply to these and future technologies: Owner, Object of Inspection (OOI), General Scan, General Series, and Threat Detection Report (TDR) modules. Each of these DICOS v01 modules is designed with extensibility to some known and some unknown future technologies in mind.

  Development of a revision of DICOS v01 was initiated in February 2011, with funding from DHS/TSA, as well as member resources. DICOS v02 (a revision of DICOS v01)is expected to address: (1) Advanced Imaging Technology (formerly known as whole body imaging); (2) revision of the TDR IOD, to reflect the decision of the Transportation Security Officer (TSO); (3) proposed revisions to DICOS v01, based on testing conducted against such standard, for DICOS v02; (4) enhancement of the data transmission capabilities of DICOS v01; and (5) NEMA balloting and publication of DICOS v02.

- **ITS:** In 2011, the NTCIP standards development is 18 years old, and has produced over 50 standards publications and guidance documents. Most NTCIP standards publications are in their second or third major version revisions. In 2011, the ATC standards development is 12 years old, and has produced four standards publications.

- **Nanotechnology:** The standards development process for nanotechnology is in its very early stages.

How has the process worked so far?

- **DICOS:** NEMA's standards development process worked well in the development, balloting and publication of DICOS v01. The publication was provided to agency sponsors on schedule, and was accepted as a deliverable under the NEMA/DHS/TSA contract. The 17 NEMA member companies who participated in DICOS v01 development, along with DHS and TSA representatives, collaborated effectively, respecting others' submissions and opinions.

- **ITS:** The U.S. DOT RITA-sponsored development has worked very well to: (1) bring the public and private sector stakeholders to the same standards-drafting table and facilitate the exchange of user needs and requirements; (2) expand the number of devices for which standards could be written; (3) reduce the time for drafting standards by providing private expert consulting resources; (4) allow increased public agency participation through travel reimbursement; (5) improve the scope and content of the standards by imposing System Engineer process steps; and (6) improve the content quality by requiring internal traceability within the standard.

- **Nanotechnology:** To date, the process has worked very well, although more stakeholders need to be consulted as part of the consensus-building process.

When developing standards, how are the standards-setting processes managed and coordinated?

- **DICOS:** NEMA, an ANSI-accredited standards developer, complied with its existing standards procedures for the development of DICOS v01.[1]

- **ITS:** Standards-setting remains under the control of the standards development organizations (SDOs), and is agreed to by the MOU terms and conditions among NEMA, AASHTO, and ITE.

- **Nanotechnology:** The standards-setting processes for nanotechnology are managed and coordinated through the International Electrotechnical Commission (IEC) approval process.

Is there a strategic plan that identifies the standards needs and defines the standards development life cycle?

- **DICOS:** DHS and TSA identified a need for DICOS to serve as a common format for data transmission and representation for airport security screening data, and a critical element on the path to interoperability in this vital national security area. As for future revisions to DICOS, NEMA has worked in conjunction with DHS/TSA, NEMA members, and other stakeholders to identify which revisions are more immediate, which can be addressed later in the future, and the timing, process and resource requirements for these revision projects.

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[1] See NEMA Standards Procedures at: http://www.nema.org/stds/aboutstds/upload/SPP-2008_final_updated.pdf.

- **ITS:** There are several planning documents that identified and guided the ITS standards, and the NTCIP in particular, including (1) the National ITS Architecture, version 6.1[2]; (2) the U.S. DOT ITS Strategic Research Plan 2010-2014 (issued in December 2009), which defines the strategic direction for the U.S. DOT's ITS research program for the next five years; and (3) NTCIP 8001, Joint Standardization Policies and Procedures.

- **Nanotechnology:** The IEC TC 113 Strategic Plan[3] governs the nanotechnology standards development process.

Are there barriers to developing high level strategies for standard-setting activities?

- **DICOS:** As with any strategic plan, and particularly for those involving national security, frequent review and, if necessary, revision is required to reflect current security needs and requirements; the changing levels of resources available to the project; and any other factors, a newly-identified threat, or technology (as examples) that may influence schedule, deliverable or sequence of development. Sustainable funding is sometimes a barrier to the development of high-level strategies for standards-setting activities. Funding from DHS and TSA mitigated this concern, enabling smaller companies (with fewer resources) to participate in expedited standards development.

- **ITS:** The utility of strategic plans correlate to their specificity. However, wider agreement and support often derives from generalized and vague terms, and plans for standards are no different. Perhaps the greatest barrier to ITS standards strategic plans are the requirement for five-year review and maintenance of IT-based standards as technology progresses.

Perspectives on Government's Approach to Standards Activities

Smart Grid:

As cited by Dr. Gallagher and Mr. Chopra at the January 25, 2011 roundtable discussion held at the U.S. Department of Commerce, the government's role as convener is critical in accelerating the standards development process, as is the case of the Smart Grid Interoperability Panel (SGIP). Focusing on the interoperability aspect (the "I" in SGIP), the challenge that SDOs in the electrical industry are facing is the need to consider the functionality of their standards in a broader context. As we strive to achieve greater levels of interoperability in the grid, our standards are likely to come into contact with a greater number of other standards.

TCP/IP and Wireless are two such examples. In the simplest sense, communication protocols are the primary tool through which operational and control information is shared. A majority of the existing electrical standards were not designed to communicate with such a vast variety of dissimilar objects. The

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[2] National ITS Architecture, version 6.1, is available at: *http:www.iteris.com/itsarch/*
[3] Available at: *http://www.iec.ch/cgi-bin/getfile.pl/sbp_113.pdf?dir=sbp&format=pdf&type=&file=113.pdf*

government, as the convener of the SGIP, provides a forum through which the SDOs and their constituents can come together to design communications models that allow for greater interoperability, supporting both legacy and future systems.

While many federal agencies may participate in the standards activities for Smart Grid, the three who are most involved are NIST, DOE, and the Federal Energy Regulatory Commission (FERC), with NIST clearly being the most visible and active. However, one of the real challenges, as highlighted in the January 31, 2011 FERC Technical Conference on Smart Grid Standards, is the process of moving standards into regulation. While NIST shoulders the load of shepherding its industry partners through the standard selection and development process, DOE and FERC have the luxury of sitting back and playing the role of critic in the regulatory process. A more balanced approach is clearly needed.

The FERC policy statement on smart grid that was released in June 2009 is extremely vague and doesn't address any of the issues now facing NIST and the SGIP. In fact, the SGIP wasn't formed until November 2009, and didn't start conducting any meetings until early 2010. At this point, it would be beneficial for FERC to update its policy statement and provide greater detail with respect to what the agency is looking for from the standard-setting process, as well as the features and performance objectives the agency will look to implement through regulation. FERC also needs to define what will satisfy its definition of "sufficient consensus" as described in EISA so that NIST and the SGIP have a target.

While the FERC Technical Conference in January 2011 was a good starting point, the format didn't allow the conversation to go far enough to help FERC, NIST, or industry define effective solutions. In particular, the testimony from the panelists indicated that there were concerns over access to the five families of standards (cited as a cost issue) and the fact that there were no hard-and-fast methods for securing their implementation, but at no point did any of the panelists state that standards would not deliver Smart Grid functionality relative to the four application areas FERC mentions in its policy statement. While every panelist responded to FERC Chairman Jon Wellinghoff's question that sufficient consensus did *not* exist around the standards, the question was not asked in a way to determine whether or not there was an appropriate, time, place, and method for implementing the standards that could be agreed to on a broad industry basis. It seems logical that the regulatory process within FERC needs to tease the notions of time, place, and method from the bevy of questions that exist in the electrical services marketplace.

In terms of "pure criticism" of the federal government's approach to Smart Grid standards, there are two. First, neither the aforementioned U.S. Department of Commerce Roundtable nor the FERC Technical Conference included a speaker from a standards development organization. It is unrealistic to have an effective public forum on standards-setting without involving the SDOs. Second, the DOE needs to weigh in on Smart Grid standards. While NIST and FERC have "put a stake in the ground" through the publication of the NIST Framework and FERC Policy Statement, DOE noticeably has failed to declare its intentions.

Other Technologies:

What methods of engagement are used by Federal agencies to participate in private sector-led standards development?

- **DICOS:** The standard methods of engagement are: (1) Actively participating in ongoing standards development efforts (versus "commenting at the end"); (2) providing stable funding; and (2) providing baseline test environments (for example, product compliance independently determined by objective government agency).

- **ITS:** Several methods of engagement are used by federal agencies to participate in private sector-led standards development, including U.S. DOT funding support of SDO project management staff; participant travel; expert consultant engagement; support of standard-family websites; review of proposals for standard work items; government employees' or contractors' participation at committee meetings; and membership in email listserves.

- **Nanotechnology:** Federal agencies participate in nanotechnology standards development through membership on the U.S. Technical Advisory Groups (TAGs) to IEC TC 113 and ISO TC 229.

How transparent is each method?

- **DICOS:** Each method is transparent in that they are easily understood and published to all parties.

- **ITS:** For the ITS standards SDOs, the process is open and transparent.

- **Nanotechnology:** For nanotechnology, the TAGs are well structured and utilize established consensus processes.

How effective is each method?

- **DICOS:** Similar methods have been effective in the past, such as the Joint Photographic Experts Group (JPEG) standard (2000 edition). For each method: (a) as stakeholders, it is common for representatives of federal, state, and local government to participate actively in the development of private sector-led standards. Effectiveness increases as government representatives become more active, providing immediate feedback, for group consideration; (b) government funding permits those companies who might not have resources available for standards development to participate, and effectively focuses participants on speed and deliverables; and (c) as a provider of test environments, or test criteria, again, it is common for government agencies to evaluate equipment as part of an agency procurement process.

- **ITS:** The funding support provided for ITS standards activities buys a high level of input and control of the standards format and content.

- **Nanotechnology:** Participation in the TAGs is very effective.

How could the methods be improved?

- **DICOS:** As with any other standards development efforts, improvements may include compressed development or increased funding; however, development of a standard within approximately one year is admirable, and increased funding is unlikely in the current economic environment.

What other methods should the Federal agencies explore?

- **ITS:** Federal agencies should explore the use of Wiki-based collaborative development.

- **Nanotechnology:** To avoid duplicate efforts in nanotechnology standards development, no other methods should be pursued.

What impact have Federal agencies had on standards activities?

- **ITS:** For the ITS sector, federal agencies have had a significant impact on standards activities. ITS standards represent a very important way that the U.S. DOT leverages the deployment of their programs around the United States, with deploying funding from the Title 26 Federal "gas tax."

  The U.S. DOT RITA funding of the ITS standards program has provided several benefits, such as:
  - Compensated expert technical consultants to perform the drafting and revision of standards, rather than volunteer contributors;
  - Compensated project management staff at the SDOs, rather than SDO member-funded staff;
  - Travel reimbursement for public sector participants, to bring their end-user perspective and comments to the standards-setting table;
  - Shortened development time to achieve approved standards;
  - Expansion of the number of standards publications to provide a modular library, rather than just a selected inventory of volunteer-produced documents; and
  - Assistance with outreach and education to the stakeholder community about ITS standards.

The U.S. DOT RITA funding of the ITS standards program also has created some conflicts:

- The U.S. DOT staff may have the expectation that standards are like any other government-funded deliverable, and should be provided on-schedule and on-budget, regardless of volunteer availability or SOD approval delays;
- Other U.S. DOT-funded support contractors may try to influence the standards-setting process, or the standards publication scope and content;
- Other U.S. DOT-funded support contracts, with experience in the systems engineering process for large aerospace and defense systems, have introduced some confusion and delay when trying to adapt those process methodologies to SDO-based standards-setting; and
- The U.S. DOT-funded support contracts have to exercise caution on their conflicts of interest, between advising RITA on standards publication work items worth of funding and then contributing to or steering the development and direction of those same standards work items. In fact, the U.S. DOT's Office of the Inspector General reviewed RITA, finding that "the JPO needs to address conflicts of interest among its support contractors. These conflicts raise questions about the support contractors' abilities to render impartial advice and services to the ITS program."[4]

- **Nanotechnology:** Involvement from NIST has had a very positive impact in nanotechnology standards-setting, where expertise has been very helpful, particularly at the working group levels.

How well do Federal agencies coordinate their roles in standards activities in the sector of interest?

- **DICOS:** Early in the process, DHS and TSA clarified their respective roles, agreed to coordinate, and made this known to participants.

- **ITS:** There is good coordination for ITS standards among the sponsoring Research and Innovation Technology Administration (RITA) ITS Joint Program Office, the Federal Highway Administration (FHWA), and the Federal Transit Administration.

- **Nanotechnology:** With some exceptions, outside of NIST, activity on and the importance of nanotechnology standards is not widely communicated, even though multiple federal agencies stand to benefit from the objectives of the National Nanotechnology Initiative.

When Federal agencies have been involved in standards setting efforts in a technology sector, how has the progress of standards setting efforts in this technology sector changed after Federal agencies became involved?

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[4] U.S. DOT Office of Inspector General Report No. AV-2009-040, "The Joint Program Office's Management of the Intelligent Transportation Systems Program Needs to Be Improved," March 11, 2009

- **ITS:** Federal agency involvement in ITS standards development resulted both in an acceleration of the process with respect to funding for expert consultants, and a slowing down of the process by content, method, and contracting issues.

- **Nanotechnology:** Federal agencies have been involved from the beginning in the development of nanotechnology standards.

Are Federal agencies generally receptive to input from other participants in standards-setting activities?

- **ITS:** Yes, federal agencies are receptive to input from other participants for ITS standards development activities.

- **Nanotechnology:** Yes, federal agencies have been receptive to input from other participants in nanotechnology standards-setting activities.

Does receptiveness tend to depend on whether the Federal agency is a regulator or a customer?

- **ITS:** No, the RITA and FHWA program managers are experienced transportation professionals who recognize that the relatively small highway transportation industry often requires switching perspectives.

In those sectors where Federal agencies play a significant role in standards activities, how valuable and timely is the work product associated with this effort?

- **ITS:** The ATC and NTCIP standards are very timely and valuable. Agency procurement documents sometimes reference draft standards, or the procurement issuance is held up waiting for the approved standard(s) that are referenced.

- **Nanotechnology:** For nanotechnology, federal agency input is significant since NIST plays a vital role in nanotechnology research and development.

Issues Considered During the Standards Setting Process

The RFI acknowledges that "various factors (e.g., technology, competition, innovation, intellectual property rights, foreign regulations, etc.) arise and are considered and addressed during standards development" (FR at 76398). The Sub-Committee has requested information on how federal agency participation in standards-setting activities has impacted the consideration and resolution of these issues.

Smart Grid:

An issue that needs further clarification is the role that the National Technology Transfer and Advancement Act (NTTAA), as implemented in the Office of Management and Budget Circular A-119,

will play in the federal standards-setting process. While the NTTAA is widely seen as a valuable guide, some context is necessary for determine how it will be interpreted for the Smart Grid. For illustrative purposes, TCP/IP is a perfect example.

The proponent of TCP/IP, the Internet Engineering Task Force (IETF), is not an accredited standards body, does not ballot standards amongst its membership, and for the most part, instead of publishing a "standard" simply releases it to the public in the form of an approved "Request For Comment" (RFC). Using the strictest interpretation of the NTTAA, because of these factors TCP/IP should not be permitted anywhere, at anytime within the federal government. In reality, however, practically every federal agency has an Internet web page, and networks as critical as the Department of Defense Secure IP Routing Network (SIPRnet) use the protocol. It would be beneficial to clarify how this concept squares with the NTTAA so the rule can be applied consistently across various product types.

Foreign Smart Grid regulations are considered and applied in the same manner as any U.S. developed standards. One of the challenges we face is gaining access to the foreign standards in order to conduct a proper review of their applicability. This was one of the points discussed during the FERC Technical Conference related to the International Electrotechnical Commission (IEC) standards. The U.S. federal government can help by encouraging foreign interests to provide access to the standards as the SGIP goes through the review process. The American National Standards Institute (ANSI) is coordinating this effort for U.S. SDOs, and could do the same for IEC standards as the host of the IEC U.S. National Committee.

As a SDO, NEMA is very sensitive to the issue of simply giving standards away, even if it is part of a sanctioned review process. Standard sales are a line of business for many SDOs, and our business case for publishing standards could be seriously damaged if the so-called "review copies" were distributed and re-distributed on a wide-scale basis. One recommended solution would be that for these large national priorities, the U.S. federal government could consider a grant to the involved SDO to make their library available to the Committee.

Perhaps the biggest threat to intellectual property rights is misinformation. One concept that is continually debated in the context of Smart Grid is the notion of "open" or "openness." It is one thing for a device to be built to an open standard (such as an ANSI standard that is available to anyone in a non-discriminatory manner); it is another thing altogether for a manufacturer to disclose the methods they use inside of their devices to conform to that standard. Open architectures in the grid, based on publicly available specifications, are a good thing; asking manufacturers to expose their method of accomplishment in the name of "openness" is not.

NEMA is an ANSI-accredited SDO and consequently follows the ANSI requirements for inclusion of intellectual property rights in standards. Generally, that policy has worked well and very few issues have arisen over the years.

As NEMA's General Counsel is a member of the ANSI intellectual property rights policy committee, NEMA has had an opportunity to review that portion of ANFI's response to this RFI relative to intellectual property rights, and directs NIST's attention to the views expressed by ANSI on this subject.

Other Technologies:

- **DICOS:** The development of the DICOS v01 standard followed the NEMA patent policy[5] and encountered no issues in developing a standard that was problematic for the intellectual property rights of the companies who make imaging equipment.

- **ITS:** Issues from the ATC effort mostly have been related to coordination with the largest state DOT (CalTrans) and their own equipment specifications. NTCIP issues have included adherence to the U.S. DOT's "Common Rule" for ownership and use of the standards publication IP, and coordination on the use of "derivative works" from the standards. For the ATC hardware and API standards, and for the NTCIP data directory standards, there have been few issues on the intellectual property of the source material, and few issues on essential patent claims.

- **Nanotechnology:** With respect to nanotechnology standards-setting, federal agency participation has had no impact on the factors listed in the RFI (e.g., technology, competition, innovation, intellectual property rights, foreign regulations, etc.).

Adequacy of Resources

As stated in the RFI, the Sub-Committee "would like to better understand the resources that both private sector organizations and Federal agencies commit to standards-setting activities, constraints on those resources, and how the level of resources affects the success of the effort" (FR at 76398).

Smart Grid:

Standards-writing in the United States is a wholly voluntary activity. While many SDOs such as NEMA have full-time staffs, the technical resources come from industry members of those SDOs who bear all of the labor, travel, and incidental expenses to accomplish the task. In short, every standards effort must fit into an industry business case. If the federal government wants to accelerate this process, as in the case of Smart Grid, it should find creative ways to relieve the financial burden and incentivize the standards-writing activity.

One easy and relatively low-cost solution would be for the government to offer various conference facilities across the country to support SDOs who want to host their technical committees. In the case where the government has a greater interest in accelerating the process, it also could offer a limited

[5] NEMA's patent policy is consistent with the ANSI patent policy, and differs only in that it provides greater details about the procedures to be followed in disclosing essential patent claims in the development of NEMA standards, and it provides a specific definition of what constitutes an "essential patent claim."

number of fixed-price contracts to the participants to partially relieve them from some of the financial burdens.

Other Technologies:

- **ITS:** The ATC and NTCIP efforts remain based on the volunteer, consensus-based standards development process. Even with funded expert consulting resources and paid staff and travel, the availability of the volunteer contributors and reviewers limits the progress.

- **Nanotechnology:** In order to be competitive in global nanotechnology products markets, the United States must be proactive in standards-setting so that other countries and regions are not setting standards for us. Proactive participation requires funding for travel to face-to-face meetings, which cannot completely replace meetings held remotely.

Process Review and Performance Metrics

The RFI states that the Sub-Committee would like to "better understand what methods have facilitated or hindered Federal agencies participation in standardization, recognizing that some standards-setting activities in the case-study technologies may not yet be completed" (FR at 76398). The Sub-Committee poses a series of questions designed to learn from standard-setting processes and determine the appropriate performance methods to assess the effectiveness of such processes. The responses to these questions, where available, are provided below.

Other Technologies:

What lessons about standards development in complex technologies have been learned so far?

- **DICOS:** Achieving consensus in standards development is, by its nature, time-consuming, more so where complex technologies are concerned. While the "best" approach may not be selected, consensus is the only known means to achieve the "buy-in" of stakeholders.

  In general, two lessons were reinforced: (1) get to written, standards-ready text as soon as possible (this avoids long oral discussions, without text for the standard, decreasing development time); and (2) webex-enabled meetings, complemented by individual participant contributions between meetings, are an effective and efficient alternative to face-to-face meetings (again, decreasing development time).

- **ITS:** Oral communication solely is inadequate for effective standard-setting; proposals must be presented in writing. This is particularly important when standards-setting work is conducted via teleconference due to travel funding constraints. Another key lesson is to start with a system block diagram to show the scope of the standardization effort, with expansion to UML diagrams and other graphical methods to unambiguously define the technical specifications being standardized.

- **Nanotechnology:** Standards development for nanotechnology remains in its early stages; there are no lessons to glean from at this point in time.

How have these lessons learned been implemented?

- **ITS:** Progress is driven largely by the agreed budget and schedule necessary to secure funding for the standardization activity.

Have there been any impediments to implementing these lessons?

- **ITS:** As would be generally true with any process based on human interaction and consensus-building, impediments can sometimes include hidden agendas, egos, and unwillingness to compromise.

What kinds of performance metrics are appropriate to measure the effectiveness of the standards-setting process?

- **ITS:** One particular performance metric used is an evaluation of broken threats in traceability testing. The schedule and budget for the standardization activity also serves as a key measure of progress and performance.

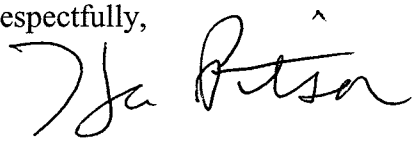
- **Nanotechnology:** Projects are given target completion dates at the outset, and the IEC and ISO ensure that committee meet these target dates or have adequate justification for any resulting delays.

If any such performance metrics have been used, what are the results?

- **ITS:** Standards drafting is mostly a "one-off" activity, and each standard is, for the most part, different. Results vary based on the particular standard.

NEMA appreciates the opportunity to provide these case studies to the NSTC Sub-Committee. If you have any further questions or require additional information regarding the experiences of NEMA and its member companies with federal agencies in standardization activities, please do not hesitate to contact us.

Respectfully,



Kyle Pitsor
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Enclosure

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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.

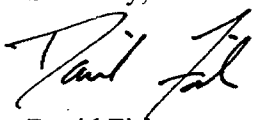
Conclusion

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,



David Fisher
Executive Director
Medical Imaging & Technology Alliance (MITA)