May 31, 2019

Dr. Walter Copan
Under Secretary of Commerce for Standards and Technology
U.S. Department of Commerce
National Institute of Standards and Technology
100 Bureau Drive
Gaithersburg, Maryland 20899

Re: NIST Request for Information on Artificial Intelligence Technical Standards and Tools

Dear Dr. Copan,

As the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA), is invested in the development and proliferation of cutting-edge technology. Artificial intelligence (AI) is an important technology, particularly in the healthcare sector, and our organization supports the NIST effort to drive development of appropriate AI technical standards in order to enable the creation of new AI-related industries and the adoption of AI by today's industries.

Medical imaging equipment manufacturers are currently engaged in several cross-stakeholder initiatives to improve the AI landscape, both within the healthcare industry and across multiple industries. In this letter we will highlight the current status of several of these key efforts, describe the needs and challenges of achieving technical AI standards, and discuss the ideal role for Federal agencies in the use of AI standards.

Both national and international standardization efforts are well underway for both healthcare-specific issues and broad cross-industry issues. MITA is currently working within the medical imaging equipment manufacturer space to create frameworks for AI development concerns unique to the medical imaging space. A list of key efforts can be found in Appendix A.

Through our engagement in many of these standard development efforts, MITA has consistently encountered the following needs and challenges:

Flexible frameworks are necessary for AI. It is clear that AI will require a significant amount of flexibility to achieve its potential. Any frameworks, guidelines, regulation, or other requirements will need to be mindful of the vast number of different AI systems and structures,

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and avoid creating situations where progress in one area of AI is hindered by restrictions in another.

Inaccurate perceptions that AI is new and different. The perception that the use of AI is new and radically different than traditional software is inaccurate and requires a plan for education. It will be important for the on-going development and adoption of AI to keep AI in the proper perspective relative to existing medical device guidances and regulations. Much regulatory oversight already exists for AI-enabled medical devices, as well as a long history of responsible development and marketing in the US – and by MITA members.

Intellectual Property protection is paramount. There are challenges around the protection of intellectual property. Transparency in AI algorithms and data sets can bring benefits to trustworthiness, but must also be weighed against the importance of proprietary code to competition and innovation. The strategy must strike a balance to encourage the development of AI.

This means that the involvement of Federal agencies should have distinct focus – providing oversight that encourages innovation and allows safe, effective AI a path to market. AI, like all information technology, benefits from rapid development cycles and restricting access to technologies by imposing unnecessary burdens would negatively impact the creation of new AI-related industries in the US, and the adoption of AI by today's industries. In addition, agencies should avoid "choosing winners" by defining some small number of approved processes for developing AI. Software development lifecycles are unique, and while there are consistent indicators of quality, it would be counter-productive to the NIST AI effort to encourage any single way as correct. The most effective approach to develop standards enabling market access is through private-public partnerships, with global industry expert input. Such global approach has been utilized by ISO and IEC, and has been proven to be effective. We encourage NIST to utilize the global approach to accomplish the goal of the Executive Order.

MITA is eager to share the depth of our knowledge and experience in medical imaging devices, our expertise and innovation in AI software development, and broad stakeholder engagement with NIST and other stakeholders in this effort. If you have any questions, please contact Zack Hornberger, Director of Cybersecurity & Informatics, at zhornberger@medicalimaging.org or (703) 841-3285.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.

APPENDIX A
List of Key AI Standards Projects

Organization	Application	Activity
ISO JTC1 SC42/WG1 "Foundational Standards"	All industries	Developing AWI 22989 AI Concepts and Terminology Developing AWI 23053 Framework for AI using ML Developing DIS 20546 IT - Big Data - Overview and Vocabulary
ISO JTC1 SC42/WG2 "Big Data"	All industries	TR 20547 Framework and application process TR 20547 Reference architecture Business process management for data analytics Characteristics and capabilities Best practices
ISO JTC1 SC42/WG3 "Trustworthiness"	All industries	Bias in AI systems and AI aided decision making Overview of Trustworthiness in AI Assessment of the robustness of neural networks - Part 1 Overview Guidance for AI Risk Management
ISO JTC1 SC42/WG4 "Use cases"	All industries	Use cases and application
ISO JTC1 SC42/ JWG SC40	All industries	Joint work to develop papers regarding governance of AI
ISO JTC1 SC42/SG1 "Computational approaches and characteristics"	All industries	SG1 Computations approaches and characteristics
Xavier AI Working Group	Quality Operations	Paper on using AI to improve quality ops (est. publish Summer 2019)
CTA R13 AI Committee	Consumer Technology	Developing common terminology for AI in multiple industries Plan to develop standards for Explainability and Trust
IEEE	Multiple Industries	Standard for fail-safe design of autonomous and semi-autonomous systems Metrics for ethical artificial intelligence and autonomous systems Ethically driven nudging for robotic, intelligent, and autonomous systems Quality Management of Datasets for Medical Artificial

		Intelligence
UL	Multiple Industries	Developing STP 4600 for the Evaluation of Autonomous Products
MITA	Medical Devices	Guidelines for AI Imaging Algorithms
FDA	Medical Devices	Develop regulatory model for US
AAMI/BSI	Medical Devices	Position paper - gaps in current medical device standards Medical Device AI Standard (planning stage)
DICOM	Medical Devices	Standard for consistent display of AI results on medical displays
Xavier	Medical Devices	Published Good Machine Learning & CLS Paper Explainability & Trust Paper (est. publish Summer 2019)
AMA	Healthcare	Position paper supporting augmented intelligence
World Health Organization & ITU-T	Healthcare	Developing a standardized assessment of AI-based solutions in healthcare. Goal is to accelerate adoption of AI in healthcare by helping HDOs evaluate potential applications.