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MEDICAL IMAGING
& TECHNOLOGY ALLIANCE
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1300 North 17th Street ▪ Suite 900
Arlington, Virginia 22209
Tel: 703.841.3200
Fax: 703.841.3392
www.medicalimaging.org

September 22, 2022

Ms. Reva Schwartz, et al
National Institute of Standards and Technology
ATTN: Information Technology Laboratory
100 Bureau Drive
Gaithersburg, MD 20899

Re: NIST AI Risk Management Framework, Version 2

Dear Ms. Schwartz:

As the leading trade association representing the manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices, the Medical Imaging & Technology Alliance (MITA) applauds the National Institute of Standards and Technology (NIST) in its continued work to enable development and adoption of artificial intelligence and machine learning technologies. We thank NIST for considering many of our prior AI Risk Management Framework comments and urge that same careful consideration for the comments below.

We understand that this framework intends to describe "a process for managing AI risks across a wide spectrum of types, applications, and maturity – regardless of sector". However, the document today does not do enough to accommodate the discrepancies between sectors which would enable successful use. For instance, the healthcare sector uses a very specific definition for the term "harm" as provided in the HHS document "Guidance for Industry: Q9 Quality Risk Management[1]". Harm is defined as "**damage to health**, including the damage that can occur from loss of product quality or availability" (emphasis added). This definition and usage is substantially different than the definitions and usage of "harm" throughout the framework. Unless a new word or term is used, and the discrepancy rectified, the framework will be difficult for MITA members to use.

The framework also makes no mention of industries, such as medical device manufacturing, which already have established risk management procedures to ensure quality (i.e., *ISO 14971:2019 Medical devices — Application of risk management to medical devices*). At a minimum, the framework should make explicit reference to regulated industries like medical device manufacturing and state unequivocally that this framework should be considered a supplement to those existing mechanisms. It should also explain that, since the framework is meant to be broad, it may not be a necessary tool for organizations who have mature risk management processes in place.

[1] https://www.fda.gov/media/71543/download

Thank you for your attention to these comments. We look forward to continued engagement with NIST in pursuit of AI excellence. If you have any questions, please contact Zack Hornberger, Director of Cybersecurity & Informatics, at _____ or by phone at _____.

Sincerely,

Patrick Hope
Executive Director, MITA

MITA is the collective voice of manufacturers of medical imaging equipment, radiopharmaceuticals, contrast media, and focused ultrasound therapeutic devices. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging innovations. These products include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. MITA Member company technologies are an important part of our nation's healthcare infrastructure and are essential for the screening, diagnosis, staging, managing and effectively treating patients with cancer, heart disease, neurological degeneration, and numerous other medical conditions.