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April 20, 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 Draft

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) and its Members appreciate the National Institute of Standards and Technology's (NIST) continued work to support the development and adoption of artificial intelligence and machine learning technologies. We offer the following comments to improve the usability and clarity provided by the draft framework.

Harmonization and coordination with concurrent artificial intelligence (AI) work should remain a top priority for the NIST framework. In particular, the Standards work underway within ISO/IEC SC42 should be more thoroughly incorporated. If deviations from the ISO/IEC SC42 work are necessary, they should be thoroughly explained, and proposed alternatives clearly defined.

The exploration of risk on page 5, within section 4.1, starting on line 19, is cause for continued confusion. Line 19 introduces risk as "a measure of the extent to which an entity is negatively influenced by a potential circumstance". But line 24 backtracks this description and asserts that "certain risks can be positive". Directly proceeding this, in line 23, the paper refers to "the impact of AI systems", which is a different topic than risk. The intent in these two paragraphs is unclear. We propose removal of the reference to positive risks entirely and clear separation of "risk" and "impact".

In the same section, risk is described as a function of "adverse impacts that could arise if the circumstance of event occurs" and "the likelihood of occurrence". We suggest a revision to simplify and clarify these parameters: risk is a function of 1) the likelihood an event occurs, and 2) the severity of the event impact.

Finally, we suggest that the term “harm” be replaced with a generalized term already used in the paper: “impact”, or “negative impact”. Harm is a term of art in some industries, like healthcare, and its use here could create uncertainty for some organizations.

In addition to our comments in response to the draft framework, we encourage NIST to prioritize dialogue with industry experts in future workshops, roundtables, and comment opportunities. Industry experts can provide real-world perspectives on operational AI technologies, which would support clear and actionable recommendations for AI risk management. Industry experts are also best positioned to relay the difficulties associated with AI development, such as the tensions between data accessibility, data quality, data privacy requirements (such as those applied to private health information), and data evaluation expectations.

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 zhornberger@medicalimaging.org or by phone at 703-841-3285.

Sincerely,

A handwritten signature in black ink, appearing to read "Patrick Hope". The signature is fluid and cursive, with a large initial "P" and a long horizontal stroke at the end.

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.