AAMI
Advancing Safety in Health Technology

19 July 2019

Dear NIST,

The Association for the Advancement of Medical Instrumentation (AAMI)—a diverse community of more than 8,000 professionals dedicated to the development, management, and use of safe and effective health technology—appreciates the opportunity to comment on the draft "Plan for Federal Engagement in Developing AI Technical Standards and Related Tools." AAMI strongly supports the development of such a strategy.

AAMI is the primary source of consensus standards, both nationally (through ANSI) and internationally (through ISO and IEC), for the medical device industry, healthcare technology managers, and sterilization professionals.

While there are efforts to develop general cross-industry standards, the medical device sector has special needs and considerations due to its regulated nature, and due to the critical need to ensure the safety and efficacy of its products and services. Because of the international nature of the medical technology market, the development of international standards for medical technology is preferable to the development of divergent national standards for this sector.

AAMI is involved in a joint initiative with the British Standards Institution (BSI) to assess standards needs for AI and Machine Learning Algorithms (MLA) incorporated into medical technology, with a particular focus on standards and approaches that can support regulation around the safety and effectiveness of these technologies. The effort involves both the U.K. Medicines and Healthcare products Regulatory Agency (MHRA—the U.K. equivalent to the U.S. FDA in this area) and the U.S. FDA.

While AAMI and BSI are the organizers of this activity, we are including many others who have ongoing medical device-related AI initiatives, including the Consumer Technology Association, the Medical Imaging Technology Association, AdvaMed, the American Medical Association, and NIST. We are including representatives of key ISO and IEC committees in the work and participants are also involved in ongoing related work in HL7 and IEEE.

The initial output of this effort was the publication of a position paper titled, *The emergence of artificial intelligence and machine learning algorithms in healthcare: Recommendations to support governance and regulation*. A copy of that paper is attached.

In that paper, five recommendations with respect to future work on AI were offered:

1. Create an international task force to provide oversight for the direction of standardization activities related to AI in healthcare.
2. Undertake a mapping exercise to review the current standards landscape and identify opportunities for new or modified publications.
3. Develop a scope and proposal for a standard covering terminologies and categorization for AI in healthcare.
4. Develop a scope and proposal for guidance to cover validation processes for AI in healthcare.
5. Create a communications and engagement plan that will continue to build our understanding of the market challenges and educate communities on the benefits of standardization.

AAMI and BSI have begun addressing the above goals and expect to publish a new white paper this fall that will lay out provisional terminology for AI utilized in medical technology, discuss validation options for healthcare AI processes, and discuss options for regulating AI in medical devices.

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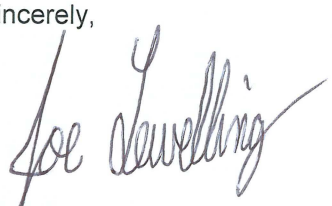
We are also completing a mapping of existing standards or standards in development to the Essential Principles of Safety and Performance of Medical Devices and IVDs, published last October by the International Medical Device Regulators Forum. (This list of essential principles is intended to facilitate global harmonization of regulations for medical devices). This mapping is, of course, intended to also form a gap analysis to determine where new standards may be needed.

While it is not yet clear exactly what standards will be needed, our intent is to take this content to ISO and IEC for inclusion in international standards (through IEC/TC 62, ISO/TC 210 and ISO/TC 215).

Sincerely,



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