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RSNA® Radiological Society of North America

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Re: Office of Science and Technology Policy - Notice of Request for Information; Regulatory Reform on Artificial Intelligence

The Radiological Society of North America (RSNA) is a leading global organization representing over 52,000 radiologists and medical imaging professionals across 150 countries. Radiology and medical imaging are among the most data-intensive fields in medicine, and AI-driven technologies have already begun transforming clinical practice. Radiology has experienced the highest rate of medical AI tool development and deployment, with more than 76% of the over 1000 FDA-cleared AI algorithms designed for radiological applications.

RSNA plays a pivotal role in advancing artificial intelligence (AI) innovation in medical imaging by serving as a global convener, educator, and research leader. Through initiatives such as the Medical Imaging and Data Resource Center (MIDRC), RSNA has helped build robust, annotated datasets and data standards that support AI development and validation. RSNA's peer-reviewed journals and grant programs foster cutting-edge research, while its AI certification programs and educational offerings equip radiologists with the skills needed to evaluate and integrate AI tools into clinical practice. As host of the world's largest radiology conference, RSNA convenes thousands of professionals annually to showcase emerging AI technologies, facilitate interdisciplinary collaboration, and drive public-private partnerships. RSNA's leadership in image annotation, structured reporting, and standards development—alongside its commitment to fairness, transparency, and safety—positions it at the forefront of transforming radiology through AI.

AI holds extraordinary promise for improving diagnosis, treatment, and access to care. However, that promise can only be fully realized if patients, providers, and the public have confidence that AI systems meet the highest standards of safety, transparency, and accountability. The complexity and opacity of many AI models, particularly those that evolve over time or are trained on sensitive health data, require thoughtful oversight to prevent errors or unintended harm.

Patient safety must remain the central pillar of any discussion surrounding AI governance and regulatory approaches. The goal should not be the least regulation possible, but the *right* regulation—smart, adaptive, and grounded in the shared responsibility to protect patients. Federal AI regulations should be risk-based and proportional, focusing most attention on applications that directly influence clinical decisions or patient outcomes. Streamlined regulatory pathways and clear guidance can and should coexist with robust safety guardrails. In this way, regulation becomes not an obstacle to innovation, but a foundation for trustworthy progress—ensuring that AI enhances, rather than undermines, the integrity of medical practice and patient care.

As highlighted in President Trump's AI Action Plan, the main obstacles to realizing AI's full potential in healthcare are not simply the availability of models, tools, or applications. Instead, the challenge lies in ensuring patient safety and building trust. Because decisions in healthcare directly affect patient outcomes, accelerating the integration and adoption of AI to improve care will require a thoughtful and balanced regulatory approach. Vendors and healthcare organizations face unique and significant hurdles when implementing AI software—barriers that are less prevalent in other industries. Thoughtful regulatory reforms could reduce these burdens without compromising patient safety. These include frameworks that incentivize AI tool developers and end users to collaborate on standardized post-deployment monitoring and reporting mechanisms; ensure that regulation remains adaptable to fast-evolving technologies; support multicenter, prospective validation trials using real-world imaging data; develop explainable and interpretable AI systems for both clinicians and patients; and create benchmark frameworks with public challenge datasets.

RSNA Responses to Key OSTP RFI Themes

(i) ***Barriers to AI innovation***

AI innovation in medical imaging is often slowed by frameworks designed for static technologies rather than adaptive systems. The Food and Drug Administration's (FDA) authority to regulate AI remains constrained by the 1976 Medical Device Amendments to the 1938 Federal Food, Drug, and Cosmetic Act, which were written for human-operated devices. As a result, AI tools are managed under Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD) frameworks that do not fully accommodate continuous learning or recalibration. Once cleared or approved, models must remain "locked," preventing updates that could preserve accuracy and safety over time. Smart regulation should enable safe, monitored adaptation and distinguish between AI models that evolve safely within predefined boundaries and those requiring re-evaluation.

(ii) ***Outdated or misaligned frameworks***

Current device regulations were developed for episodic software updates and fixed performance characteristics. Rigidly applying these older frameworks to AI tools can slow innovation without improving patient safety. Effective oversight must also address how machine behavior changes across different contexts of use, not only how humans operate the system. Clinicians and regulators should have visibility into the parameters and trade-offs influencing AI outputs to ensure transparency and accountability. RSNA supports risk-based and proportional approaches that focus oversight on applications influencing clinical decisions and patient outcomes, while encouraging adaptive regulation that reflects how AI functions in practice.

(iii) ***Underused administrative tools***

Existing mechanisms such as FDA's Predetermined Change Control Plans and pilot programs offer opportunities for safe, adaptive AI deployment but remain voluntary and inconsistently implemented. Expanding the use of these tools and aligning them across agencies could reduce redundancy and support timely access to safe innovations. Congress should consider modernizing FDA's statutory authority to explicitly support continuous performance monitoring, standardized reporting of drift and performance degradation, and post-deployment safety requirements, ensuring that adaptive AI maintains clinical reliability over time.

(iv) ***Structural incompatibility and need for clarity***

Cross-agency coordination among FDA, the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC), and the Centers for Medicare & Medicaid Services (CMS) remains essential. A harmonized approach to definitions, data standards, and post-market surveillance would prevent duplication, close gaps, and promote trust. Complementary reform of data privacy frameworks such as those established under the Health Insurance Portability and Accountability Act (HIPAA) would also enable the responsible use of large, de-identified datasets for training, validation, and monitoring of healthcare AI. Creating secure, compliant pathways for multi-institutional data aggregation would improve model generalizability, reduce performance variability, and ultimately enhance patient outcomes. Modernizing HIPAA's provisions on de-identification, data minimization, and secondary use would support both innovation and privacy protection. Clearer interpretive guidance, developed with clinical experts, can ensure that safety expectations are consistent and transparent.

(v) ***Organizational and cultural barriers***

AI adoption depends not only on policy but on confidence. Regulators, clinicians, and developers need shared frameworks for transparency, explainability, and performance monitoring. Investment in AI literacy and data infrastructure across agencies and the public will help realize the promise of AI while maintaining the highest standards of patient protection.

RSNA values the opportunity to provide input on this Request for Information and looks forward to continued collaboration with the White House Office of Science and Technology Policy and federal agencies. Together, we aim to establish smart and balanced regulatory frameworks for AI in healthcare that uphold patient safety without stifling innovation. For additional information or questions, please contact RSNA's Director of Government Relations, Libby O'Hare (eohare@rsna.org).

Sincerely,

Jeffrey Klein, MD
Chair of the Board
Radiological Society of North America