RADIOLOGICAL SOCIETY OF NORTH AMERICA
820 JORIE BLVD., SUITE 200, OAK BROOK, IL 60523-2251
TEL 1-630-571-2670 FAX 1-630-571-7837
RSNA.ORG

RSNA® Radiological Society of North America

April 7, 2025

Re: Docket No. FDA-2024-D-4488 for "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations"

The Radiological Society of North America (RSNA) is a non-profit organization representing over 52,000 medical imaging professionals in more than 150 countries around the world. Our mission is to promote excellence in patient care and healthcare delivery through education, research, and technological innovation.

Radiology and medical imaging are among the most data-intensive fields in medicine, and AI-driven technologies are already transforming clinical practice. With over 76% of the more than 1,000 FDA-cleared AI algorithms designed for radiological applications, radiology remains at the forefront of AI tool development and deployment. As the largest professional society representing radiologists, RSNA offers a unique and vital perspective on the development, regulation, and integration of AI-enabled medical devices. As such, RSNA appreciates this opportunity to provide comments in response to FDA's Draft Guidance, Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations (Docket No. FDA-2024-D-4488).

Radiologists have unique insights into the clinically relevant applications, benefits, and risks of these tools, whose development and deployment will be significantly impacted by the FDA's regulatory approach. As front-line users of AI-enabled medical devices and physicians ultimately responsible for patient safety, radiologists understand the imperative that AI tool outputs be both transparent and explainable. Radiologists rely on AI tools as decision-support systems that complement—but do not replace—clinical judgment. While AI tools serve this supportive role, radiologists must be able to interpret and contextualize their outputs. The draft guidance does not sufficiently emphasize the need for explainability in AI models or describe how explainability may differ depending on the function of the algorithm and its output. RSNA believes that the purpose of explainability is to support clinical judgment and help users recognize when an AI tool's output may not be accurate. We urge the FDA to require tool developers to clearly document AI decision-making processes in marketing submissions and to incorporate standards for explainability that are calibrated to the type and intended use of the algorithm. Additionally, user interfaces for AI-enabled devices should provide clinically meaningful and interpretable insights. We recommend the FDA include user interface design and intended user information as essential components of marketing submissions.

The lack of standardization across AI tools can impact their ability to make meaningful conclusions. For example, different algorithms designed to perform similar tasks may produce results using different formats, labels, or thresholds. This inconsistency complicates clinical interpretation and makes it difficult to compare tool performance or substitute one model for another. To address this, we recommend the FDA encourage the development and adoption of standardized output formats and reporting frameworks. We encourage FDA to work with clinical and industry partners to define standard formats and terminology for AI tool outputs used in radiology and other medical specialties. Greater standardization would enhance clinical usability, facilitate benchmarking, and support more reliable integration of AI-generated information into radiologic practice.

Many radiology practices report performance variability of AI tools when applied to their specific patient populations. This variability underscores the need for robust local validation and continuous monitoring. AI models must be evaluated not only during development but also post-deployment to detect "diagnostic drift," where even minor change to the algorithm or its data inputs may lead to clinically significant discrepancies in outputs. Therefore, we recommend that the FDA strengthen requirements for transparency in AI model updates and ensure that significant modifications are clearly communicated and accessible for revalidation by end users. Moreover, developers should be expected to adopt standards that guide algorithmic output, monitor for performance variation, and identify and mitigate potential biases as part of their testing and update protocols.

The effectiveness of AI models depends heavily on the quality and make-up of the data used in training and validation. AI-enabled medical devices often struggle with generalizability, particularly when trained on datasets that are not representative of relevant clinical populations (e.g. an AI tool trained on adult datasets will struggle when applied to pediatric data). Ensuring equity and safety requires rigorous validation criteria that assess model performance across demographic and clinical settings. We encourage the FDA to mandate developers to disclose their data sources, dataset composition, and methodologies for identifying and addressing algorithm bias. Transparent reporting of data sources, data make-up, and algorithm bias mitigation strategies is necessary to prevent disparities in AI tool performance and to promote high-quality care for all patients.

We also request additional clarity in the guidance regarding lifecycle management and regulatory expectations for AI model updates. Given that AI-enabled tools evolve over time, RSNA believes it is essential for the FDA to outline the circumstances under which retraining or model modification would necessitate a new marketing submission. Furthermore, the FDA should consider establishing a requirement that developers notify users when substantial changes are made to a model’s behavior or clinical outputs. These notifications are crucial for maintaining clinician trust and ensuring continued patient safety.

RSNA has previously provided comments on the FDA’s Predetermined Change Control Plan (PCCP) framework and continues to support its implementation. In prior comments, RSNA emphasized the need for dual-reporting mechanisms and active clinical involvement in post-market performance evaluation. We reiterate our recommendation that FDA adopt a dual-reporting mechanism, enabling both developers and end users—such as radiologists—to report deviations in AI tool performance. Radiologists may identify nuanced clinical scenarios that were not considered during initial development and testing but that meaningfully affect safety and effectiveness. Radiologists frequently encounter edge cases and workflow nuances not addressed during initial validation, which can inform safe, real-world AI deployment. A dual-reporting pathway would enhance FDA’s post-market surveillance and promote greater accountability among developers while supporting clinicians in maintaining high standards of patient care. Such a mechanism would give FDA a more complete understanding of AI tool performance in the field.

AI-enabled devices must function seamlessly within existing radiology workflows to ensure widespread adoption and clinical utility. Many currently available AI systems are not seamlessly integrated into PACS and other radiology workflow platforms, resulting in inefficiencies and limiting their utility in real-world practice. We urge the FDA to encourage developers to demonstrate workflow compatibility and interoperability during the premarket submission process. Additionally, FDA should consider establishing expectations for when human oversight in AI-assisted workflows is required and when AI could act autonomously. In scenarios requiring oversight, it is critical that radiologists remain the final decision-makers in clinical interpretation.

RSNA appreciates the opportunity to provide comments on this important draft guidance. We value FDA's leadership in developing a regulatory framework that promotes innovation while protecting patients. To that end, we respectfully urge greater emphasis on transparency, explainability, data diversity, post-deployment monitoring, workflow integration, and output standardization. We welcome continued dialogue with the agency to ensure AI-enabled medical devices are developed, validated, and implemented in ways that support clinicians and advance patient care. 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