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Radiological Society
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November 20, 2024

Dockets Management Staff
Food and Drug Administration (FDA)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2024-D-2338

The Radiological Society of North America (RSNA) is a non-profit organization representing over 48,000 medical imaging professionals spanning the full breadth of radiologic subspecialties 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 data-intensive specialties at the forefront of grappling with the numerous ways that artificial intelligence (AI) and machine learning (ML) are transforming the practice of medicine and the delivery of healthcare. No medical specialty has been impacted by this transformation more than radiology, which has seen greater development and application of AI-enabled tools and platforms than any other medical field. Notably, of the 950 algorithms currently cleared for use by the FDA, more than 76 percent are for use in radiology.

Thus, radiologists are the end users of many of the medical devices requiring premarket approval or notification, whose development will be significantly impacted by the FDA's Predetermined Change Control Plans (PCCP) for Medical Devices guidance. As a leading medical society representing radiologists and bringing expertise in the use of AI in medical imaging and practice, RSNA appreciates this opportunity to provide comments on FDA's *Predetermined Change Control Plans for Medical Devices: Draft Guidance for Industry and FDA Staff*. Our comments below focus on how the proposed PCCP guidance might interact with healthcare provider responsibilities and the monitoring process associated with enforcement and deviation from these plans.

RSNA leverages its leadership in medical imaging to coordinate and accelerate the implementation of AI in radiology and is viewed by the broader medical imaging community as a trusted source for data collection and annotation. Since 2017, RSNA has conducted a continuing series of AI Challenge Competitions collecting and annotating ground truth imaging datasets to address high-value clinical applications; fostering research and technological innovation; and focusing the AI research and development community on vital use cases. Informed by the FDA's *Good Machine Learning Practice for Medical Device Development Principles*, and consistent with the Findable, Accessible, Interoperable, and Reusable (FAIR) data framework, RSNA has conducted nine medical imaging AI challenges to date, with our tenth challenge currently in the planning phase. Anywhere from several hundred to over eighteen hundred teams of researchers from around the world have participated in each challenge. For many of these participants, these competitions were their first opportunity to work in medical imaging AI and a number of the winning teams featured cross-disciplinary combinations of researchers, data scientists, physicians, and tool developers.

RSNA's investment in these AI challenges has enabled the generation of annotated datasets in multiple imaging modalities organized specifically to support AI research and tool development. Each challenge addresses a pressing clinical problem, including the determination of pediatric bone age; detection of cervical spine fractures; diagnosis of pneumonia; localization of intracranial hemorrhage; and segmentation of brain tumors. These datasets include tens of thousands of imaging studies (over 2.5 terabytes of data) with annotations provided by subspecialty expert radiologists and supporting clinical data. Importantly, these competitions are also valuable for AI tool developers seeking to ensure their products are trained on datasets complying with FAIR data principles.

Consistent with RSNA's educational mission and role as a convenor, the Society has facilitated the engagement of the broader medical AI community by engaging tool developers, vendors, and users and providing training materials and tutorials. The datasets resulting from each AI Challenge competition have been made persistently available to the research community under open licenses and accompanied by explanatory documentation (with representative data samples reserved for model testing and validation). In addition, numerous research articles and scientific meeting presentations have been published, describing the datasets and methodologies for collection, curation, and annotation, as well as the organization and outcomes of the competitions. Extending beyond AI R&D and education, RSNA's investment in these AI challenges champions transparent AI and helps ensure that downstream users of these AI-enabled tools–both patients and providers–have the best available means of analyzing how these tools make inferences.

Proposed PCCP Guidance and Interactions with Provider Responsibilities When AI-Enabled Tools are Used in Healthcare

The RSNA supports the FDA's proposal of Predetermined Change Control Plans (PCCPs) for mature technologies such as picture archiving and communication systems (PACS). PACS has been widely used and refined over decades, and minor updates to this technology rarely impact diagnostic outcomes. However, the current FDA approval process for these updates slows innovation without offering significant safety benefits.

In contrast, AI tools in radiology are rapidly evolving and bring unique challenges. Many radiology practices report that AI algorithms do not perform as expected on their specific data, necessitating rigorous testing and validation prior to implementation. Radiology practices have also learned that any updates to AI models must be monitored closely to prevent "diagnostic drift," where even minor algorithmic changes can lead to significant diagnostic discrepancies. Given the lack of standardization across AI tools and technologies, different algorithms may yield varied outputs; therefore, any modifications to these tools must be transparent and readily available for revalidation by end users to ensure they meet clinical expectations. Thus, we recommend that FDA consider requiring AI tool vendors to adopt standards that would govern algorithmic outputs and enhance transparency.

Further, we have concerns about how the proposed approach to PCCPs will align with Health and Human Services' (HHS) guidance under Section 1557 of the *Affordable Care Act* (ACA) and the 2023 Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule. The ACA Section 1557 guidance holds healthcare providers accountable for ensuring that AI tools do not inadvertently lead to discrimination based on race, national origin, age, disability, or sex. To meet these obligations, AI tools must undergo robust validation and continuous monitoring to detect and mitigate biases that may affect diverse patient populations. This challenge may become even more complex as algorithms evolve and are updated under PCCPs.

In addition, the HTI-1 final rule established transparency requirements for AI algorithms used in healthcare settings and specified new certification requirements for tool developers. The many ways in which these various rules and requirements will interact with the proposed PCCP guidance is complex and currently unclear. We urge the FDA to incorporate ACA Section 1557 and HTI-1 considerations into its PCCP guidance, requiring developers to identify and address potential biases as part of their testing and modification protocols.

Monitoring Process for PCCP Deviations

The RSNA recognizes the FDA's emphasis on vendor self-monitoring for adherence to PCCPs. However, we have concerns that self-monitoring alone may be insufficient for AI tools in radiology, where practices often rely on multiple AI systems from various vendors. These tools, each with unique functions and outputs, may interact in complex ways that individual vendors are not able to fully anticipate or detect. Given this environment, solely relying on vendors to self-report deviations could leave safety issues unaddressed, potentially impacting patient care.

A dual-reporting mechanism would strengthen this process, allowing both vendors and end users, such as radiologists, to report deviations in AI tool performance directly to the FDA. This mechanism would offer a more comprehensive view of tool behavior, ensuring any potential risks are quickly identified and addressed. Lessons from the Boeing 737 MAX incident, where vendor self-monitoring failed to capture critical flaws, underscore the need for independent monitoring in systems impacting public safety.[1] In that case, vendor-only monitoring did not detect key issues in the Maneuvering Characteristics Augmentation System (MCAS), which led to catastrophic outcomes. Similarly, radiology AI tools could present unanticipated risks if vendors are the sole monitors.

Furthermore, we recommend that the FDA establish a formal process allowing radiologists to request modifications or updates to PCCPs based on real-world experience. Radiologists may encounter unique clinical scenarios or identify data-related nuances that were not considered during initial testing but that could significantly impact tool safety and effectiveness (e.g. use of an AI-enabled tool on a patient population when that same population was not well represented in the algorithmic training data). Creating a pathway for radiologists to provide feedback and request updates would foster collaboration between developers, end users, and regulators, helping to ensure AI tools continue to meet evolving clinical needs while prioritizing patient safety.

Transparency and Validation Around AI Model and Tool Development

Transparency in AI model development and modification is essential for safe and effective clinical implementation. The RSNA strongly recommends that the FDA require vendors to document and disclose all changes to AI tools under PCCPs, with clear version histories and detailed modification notes. This transparency would enable radiology practices to compare versions, validate updates, and troubleshoot issues, especially as AI tools from multiple vendors may need to work in tandem within complex clinical workflows. Long-term access to prior software versions is critical to confirm diagnostic consistency and address any discrepancies that may arise post-update.

Moreover, PCCPs should incorporate rigorous validation criteria that ensure AI models are safe, effective, and equitable. Given the diverse patient populations AI tools serve, validation protocols should explicitly include criteria for detecting and mitigating biases in datasets. We encourage the FDA to mandate developers to disclose their data sources, data composition, and methodologies for bias detection and correction as part of the PCCP. This approach will help to prevent unintended disparities in AI performance across different demographic groups and empower healthcare providers to deliver safe, high-quality, and equitable care to all patients.

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[1] Mongan & Kohli, "Artificial Intelligence and Human Life: Five Lessons for Radiology from the 737 MAX Disasters," *Radiology: Artificial Intelligence*, 2, no. 2 (2020).

RSNA appreciates this opportunity to comment on FDA's *Predetermined Change Control Plans for Medical Devices: Draft Guidance for Industry and FDA Staff* and we look forward to working with FDA as the agency finalizes this guidance. For additional information or questions, please contact RSNA's director of government relations, Libby O'Hare (eohare@rsna.org).

Sincerely,

Umar Mahmood, MD, PhD
Chair of the Board
Radiological Society of North America