



QUALITY IS OUR IMAGE

October 31, 2016

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Subject: (81 FR 51201; Docket No. FDA-2016-D-2049) Medical X-Ray Imaging Devices Conformance with International Electrotechnical Commission Standards; Draft Guidance for Industry and Food and Drug Administration Staff; Comments of the American College of Radiology**

The American College of Radiology (ACR)—a professional organization representing more than 35,000 radiologists, radiation oncologists, interventional radiologists, nuclear medicine physicians, and medical physicists—appreciates the opportunity to comment on the draft guidance “Medical X-Ray Imaging Devices Conformance With IEC Standards” published by the U.S. Food and Drug Administration (FDA) in the *Federal Register* on August 3, 2016 (81 FR 51201; Docket No. FDA-2016-D-2049). The following comments were compiled by the ACR Commission on Medical Physics-Government Relations Committee.

#### **General Concerns**

The ACR appreciates the goal of FDA to streamline the premarket submission process and harmonize performance standards with international standards to the extent practicable. However, the College is concerned that unless FDA ensures reasonable availability of IEC’s proprietary standards as directed by the 2016 revision of OMB Circular A-119, the ability of the public to participate in the regulatory process and the public protections and transparency afforded by the Administrative Procedures Act will be severely impaired. The cost of accessing IEC standards is generally prohibitive for nonprofit associations and healthcare providers, particularly when multiple licenses/copies are needed for group/committee review. Additionally, the IEC standards development process is less open to meaningful contributions from public stakeholders than federal rulemaking in the United States. We recommend that FDA continue to refine its internal processes to improve responsiveness to device manufacturers and stay abreast of technological innovation and international standards. However, while doing so, the agency must maintain public participation, transparency, and accountability with respect to all stakeholders as required by U.S. administrative law.

#### **ACR Recommendations**

The ACR recognizes the importance and complexity of streamlining device review. However, the draft guidance is unclear how an interested end-user or consumer (radiologist/medical physicist/technologist/patient) could verify that standards are met. We recommend more discussion in the introduction regarding the estimated access requirements/monetary costs needed for stakeholders to participate in or review the referenced international standards. We also recommend a detailed FDA summarization of each IEC standard incorporated by reference as directed by the clarifications of “reasonable availability” in the 2016 revision of OMB Circular A-119.

Additionally, we urge FDA to include a comprehensive review of the IEC's internal standards development process with a focus on how it compares to the transparency required of FDA as a U.S. federal agency, as well as to the OMB-defined concept of reasonable availability. The ACR's concerns are there may be less opportunity for experts from the provider and patient stakeholder communities to meaningfully influence IEC content development and maintenance, and there may be a lack of accountability of the IEC to indirect, non-industry stakeholders.

The 2016 revision of OMB Circular A-119 suggests that IEC would need to allow open access to all referenced standards during related FDA comment periods and reduce the financial cost of access, among other changes, in order to be reasonably available enough to be incorporated by reference into U.S. federal regulation and/or guidance. The ACR encourages FDA to collaborate with IEC to convincingly accomplish OMB's criteria of reasonable availability, and to refrain from incorporating any voluntary standards as a substitute for FDA performance standards until the criteria are fully met.

The ACR's overarching concern with this draft guidance could be resolved if FDA instead utilizes the federal rulemaking process or the agency's guidance development process to implement the explicit content of relevant international standards for all public stakeholders to openly access, review, and meaningfully comment, rather than incorporating proprietary IEC standards by reference as an alternative to FDA performance standards codified in CFR Title 21. Making all referenced standards fully and reasonably available to the public stakeholders would unquestionably align with the criteria outlined in the 2016 revision of OMB Circular A-119. FDA should also periodically review IEC's internal processes and the reasonable availability of IEC standards to ensure OMB criteria continue to be met in the future.

Thank you in advance for your consideration of these comments. As always, the American College of Radiology welcomes the opportunity for continued dialogue with the FDA. Should you have any questions on the points addressed herein, or if we can otherwise be of assistance, please do not hesitate to contact Gloria Romanelli, ACR Senior Director of Government Relations, at 703-716-7550 / [gromanelli@acr.org](mailto:gromanelli@acr.org), or Michael Peters, ACR Director of Legislative and Regulatory Affairs, at 703-716-7546 / [mpeters@acr.org](mailto:mpeters@acr.org).

Sincerely,

A handwritten signature in black ink that reads "James Brink". The signature is fluid and cursive, with the first name "James" written in a larger, more prominent script than the last name "Brink".

James A. Brink, MD, FACR  
Chair, Board of Chancellors  
American College of Radiology