



QUALITY IS OUR IMAGE

April 8, 2020

Submitted via regulations.gov

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

Re: (Docket No. FDA- 2020-N-0169) Public Workshop - Medical Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing nearly 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to file comments with the Food and Drug Administration (FDA) regarding the March 5, 2020 public workshop, “*Medical Extended Reality: Toward Best Evaluation Practices for Virtual and Augmented Reality in Medicine*” (FDA- 2020-N-0169). The ACR recognizes the myriad possible use cases for extended reality medical devices within diagnostic and interventional radiology. We also recognize the current and future possibilities for leveraging medical imaging data to inform extended reality applications in the surgical subspecialties and other areas of medicine.

Extended Reality Medical Devices in Radiology

Many current extended reality applications for radiology subspecialties are educational/training tools outside the definition of a “medical device” per Section 201(h) of the Food, Drug, and Cosmetic Act. We anticipate that future implementations of extended reality in radiology could include diagnostic tools under FDA oversight, such as:

- Virtual holography and other 3D imaging modalities;
- Virtual displays, menu systems, and interfaces, and other such interactive overlays used with radiology workstations;
- Guided image acquisition overlays for technologist personnel; and,
- Other emerging or unforeseeable uses.

Interventional radiology implementations of extended reality under FDA purview would include:

- Overlays of images and navigational guides during procedures;
- Virtual displays/views, menu systems, and controls during procedures; and,
- Pre-procedure planning and team coordination (although these may or may not meet the medical device definition); and,
- Other emerging or unforeseeable uses.

FDA Considerations for Diagnostic Radiology Implementations

For diagnostic radiology implementations of extended reality-based displays—such as virtual displays used for reviewing imaging studies—it will be key for these technologies to provide appropriately high resolution and calibration functionalities equivalent to FDA’s current requirements for hardware diagnostic radiology displays. In certain scenarios, such as virtual reality, it may even be necessary for the resolution to be higher to increase the visual comfort and psychophysical safety of use. Additionally, FDA should require extended reality display applications to have integrated environmental testing/calibration functionalities akin to features used in mobile medical imaging viewing applications.

FDA Considerations for Interventional Radiology Implementations

Interventional radiology implementations will require similar resolution and calibration functionalities; however, manipulation is perhaps less critical than readability, consistency of visual cues in mixed reality environments, and the anatomical/navigational accuracy of the overlays/guides. Additional risk may be introduced if the physician is required to unnaturally position their bodies or change their fields of view to accommodate or refocus the overlay. Moreover, the FDA will need to consider the different types and methods of radiation shielding, radiation badges, and other physical objects in the interventional radiology suite that may influence the performance, comfortable use, or safety of wearable hardware. For pre-procedure planning or collaborative uses of extended reality, FDA should also consider possible increased risk to patients from cyber sickness or physical/visual fatigue.

Cross-Cutting FDA Considerations

For diagnostic and interventional radiology implementations of extended reality, the FDA should strongly factor in ergonomics (e.g., of the hardware, goggles, etc.) and visual comfort throughout the lengths of time in which physicians can be reasonably expected to utilize these technologies. It should not be expected that physician end-users should alter a procedure or workflow to use the system safely—for example, taking a break to avoid cyber sickness or fatigue when the physician would not otherwise plan to do so. Goggles/hardware must be appropriately adaptable to accommodate end-users’ anatomical and vision system differences, such as eye size and location. Short- and long-term psychophysical consequences (e.g., depth perception complications, degraded oculomotor responses, headaches, etc.) incurred by physician end-users of the hardware and/or software components of these systems must be carefully studied, considered, and avoided in addition to the FDA’s usual considerations for real-world device equivalents of extended reality systems.

The ACR welcomes further dialog with FDA regarding extended reality in radiology. Please contact Michael Peters, ACR Director of Legislative and Regulatory Affairs, at (202) 223-1670 or mpeters@acr.org with questions.

Sincerely,



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