February 7, 2022

Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Re: (FDA-2021-N-1272) FDA Discussion Paper, 3D Printing Medical Devices at the Point of Care; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to provide input to the Food and Drug Administration (FDA) regarding the discussion paper released December 10, 2021, titled "3D Printing Medical Devices at the Point of Care" (FDA-2021-N-1272).

Anatomic Models – "Very Low Risk" Device Characteristics
The ACR generally agrees with FDA's acknowledgement that 3D printed medical devices have varying levels of risk, and that FDA should extend regulatory flexibility to lower risk 3D printed devices produced by Health Care Facilities (HCFs) responsible for the medical use of the devices.

For 3D printing activities related to radiology, "anatomic models" as described by the ACR and the Radiological Society of North America's *3D Printing Registry Data Dictionary* are typically of significantly lower risk than anatomic/surgical guides and implanted devices.[1] Anatomic models, when used by the same HCF that created them, are appropriately characterized as meeting FDA's "very low risk" designation due to the following characteristics:

- Not intended to be used for primary diagnosis or treatment.
- Not intended for use on, or within, patients.
- Does not replace clinical workflow and standard care provided to patients.
- Intended to supplement planning, simulation, templating, and/or collaboration between care team members without the intent that clinician users rely primarily on the 3D printed model.
- The format of the 3D printed model is a secondary visualization of medical device data that is independently reviewed via means other than the physical model, such as via the radiology software device that enabled the 3D printing process.

Enforcement Discretion for "Very Low Risk" Devices
Healthcare providers have extensive professional and regulatory responsibilities to patients, federal and state agencies, accreditors, payers, and others that provide additional assurance of the safety and effectiveness of "very low risk" devices created and medically used by HCFs. Accordingly, the ACR recommends that FDA

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[1] Radiological Society of North America and American College of Radiology, *3D Printing Registry Data Dictionary.* Dec. 4, 2021. https://nrdrsupport.acr.org/support/solutions/articles/11000073770-3d-printing-data-dictionary

exercise enforcement discretion (i.e., does not enforce the requirements under the Federal Food, Drug, and Cosmetic Act) for 3D printed anatomic models and other "very low risk" devices created by the same HCF that is responsible for the medical use of the device.

This targeted approach to exercising enforcement discretion for lower risk devices would be consistent with how FDA has approached low risk subtypes of software device functions in certain areas of digital health oversight, such as clinical decision support,[2] mobile medical applications,[3] and medical device data systems.[4]

Terminology – HCF Versus POC
The ACR recommends that FDA use "HCF" instead of "POC" for describing the 3D printing setting in question. In general, "point of care" in other areas of medical practice (e.g., ultrasound imaging, testing) is often used to describe procedures at the patient's bedside. This is not accurate terminology for describing 3D printing activities currently performed by HCFs, as 3D printers are not located in patient procedure rooms.

Additionally, healthcare experts and components involved in the 3D printing process may not always be physically located in the same buildings or areas. Examples include, but are not limited to, offsite radiology practices/departments, collaborations between specialty departments of the same medical institution, and collaborations between medical centers and engineering schools that share an academic affiliation. Each of these examples should be considered 3D printing by the HCF responsible for medical use of the device.

Moreover, a HCF performing the printing could serve in a traditional manufacturer-type capacity to a disparate HCF where the patient care is provided using the printed device. Therefore, some delineation between HCFs that create the device and HCFs that use the device may be necessary if separate entities, but without using "POC" as the descriptor.

The ACR welcomes continued dialog with FDA staff regarding 3D printing of medical devices by HCFs. Please contact Gloria R. Romanelli, JD, ACR Senior Director of Legislative and Regulatory Relations, at gromanelli@acr.org, or Michael Peters, ACR Government Affairs Director, at mpeters@acr.org or (202) 223-1670 with any questions or concerns.

Sincerely

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Chair, Board of Chancellors
American College of Radiology

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[2] Food and Drug Administration, *Clinical Decision Support Software; Draft Guidance for Industry and FDA Staff*. Sept. 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-decision-support-software
[3] Food and Drug Administration, *Policy for Device Software Functions and Mobile Medical Applications; Guidance for Industry and FDA Staff*. Sept. 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-device-software-functions-and-mobile-medical-applications
[4] Food and Drug Administration, *Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices; Guidance for Industry and FDA Staff*. Sept. 2019. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices