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Policy Clarification for Certain Fluoroscopic Equipment Requirements

Guidance for Industry and Food and Drug Administration Staff

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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Preface

Public Comment

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I. Introduction

This guidance document intends to clarify FDA's interpretation of certain aspects of the performance standard requirements in 21 CFR 1020.30 and 1020.32 for fluoroscopic equipment.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[1]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

In 2005, the Agency amended the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32 to account for changes in the technology and use of radiographic and fluoroscopic x-ray systems and to fully utilize the International System of Units to describe radiation-related quantities and their units when used in the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32.[2]

[1] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.
[2] 70 FR 33998, June 10, 2005.

On March 30-31, 2010, the Agency held a public meeting on "Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging."[3] FDA sought input on steps that manufacturers of computed tomography and fluoroscopic devices could take to reduce unnecessary radiation exposure to patients, and asked a number of specific questions related to equipment features, labeling, premarket submission requirements, user training, and quality assurance measures.[4] Many of the recommendations FDA received at the public meeting focused on incorporating certain features and safeguards, to the extent possible, that had been identified in recently amended IEC standards.[5]

Based on this discussion, it became clear that there are some areas of the federal performance standard for fluoroscopic equipment, found at 21 CFR 1020.30 and 21 CFR 1020.32, that could be further clarified.

III. Scope

The products addressed by this guidance are both "devices" as defined in section 201(h) of the Federal Food, Drug and Cosmetic Act (FD&C Act) and "electronic products" as defined in section 531 of the FD&C Act. As such, these products are subject to the laws and regulations in the FD&C Act and its implementing regulations that apply to devices, as well as those applicable to electronic products. In particular, these products are subject to, among other laws and regulations, 21 CFR 892.1650, 1020.30, and 1020.32. This guidance is limited to fluoroscopic x-ray systems, whether stationary or mobile, classified as follows:

21 CFR 892.1650 – Image-intensified fluoroscopic x-ray system.

> (a) *Identification*. An image-intensified fluoroscopic x-ray system is a device intended to visualize anatomical structures by converting a pattern of x-radiation into a visible image through electronic amplification. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.
>
> (b) *Classification*. Class II. When intended as an accessory to the device described in paragraph (a) of this section, the fluoroscopic compression device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to §892.9.

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[3] Final white paper available at: https://www.fda.gov/radiation-emitting-products/initiative-reduce-unnecessary-radiation-exposure-medical-imaging/white-paper-initiative-reduce-unnecessary-radiation-exposure-medical-imaging.
Public docket available at: http://www.regulations.gov/#!docketDetail;dct=FR%252BPR%252BN%252BO%252BSR;rpp=25;po=0;D=FDA-2010-N-0080.

[4] 75 FR 8375, February 24, 2010.

[5] Specifically, IEC, 60601-2-43, *Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures* and IEC, 60601-2-54, *Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.*

The following product codes are currently associated with this regulation and addressed by this guidance:

- JAA – system, x-ray, fluoroscopic, image-intensified
- OWB – interventional fluoroscopic x-ray system
- OXO – image-intensified fluoroscopic x-ray system, mobile

An image-intensified fluoroscopic x-ray system refers to any fluoroscopic x-ray system with an image receptor comprised of either an image intensifier or a solid-state x-ray imaging device.

Angiographic x-ray system devices, classified in 21 CFR 892.1600, are not addressed by this guidance, as they do not have the capability to perform fluoroscopy.

IV. Specific Portions of the Performance Standard that are the Subject of this Guidance

Three aspects of the federal performance standard for fluoroscopic equipment (21 CFR 1020.32) are described below, with FDA's clarifications:

- Fluoroscopic Irradiation Time

  21 CFR 1020.32(h)(2) requires that x-ray controls manufactured on or after June 10, 2006, provide a display of the fluoroscopic irradiation time at the fluoroscopist's working position (fluoroscopic irradiation time is more commonly known as "fluoroscopy time"). Specific requirements are provided at 21 CFR 1020.32(h)(2)(i) and (ii).

  21 CFR 1020.30(b) defines fluoroscopic irradiation time as "the cumulative duration during an examination or procedure of operator-applied continuous pressure to the device, enabling x-ray tube activation in any fluoroscopic mode of operation."

  FDA interprets this definition to mean the cumulation of the entire time that the fluoroscopy control (typically a pedal) is activated by the operator ("operator-applied continuous pressure"). When defined this way, a single minute of continuous pressure on the fluoroscopy control results in a fluoroscopic irradiation time of one minute, regardless of whether fluoroscopy is used in a pulsed or continuous mode, and, if pulsed, regardless of pulse width and pulse rate.

  This interpretation is consistent with statements made by professional organizations. For example, the Society of Interventional Radiology (SIR), in its Standards of Practice, defines fluoroscopy time as "[t]he total time that fluoroscopy is used during an imaging or interventional procedure. For each

fluoroscopic series, the fluoroscopic time is measured from the start to the end of x-ray production (start of first pulse to the end of the last pulse)."[6]

FDA's interpretation of 21 CFR 1020.30(b) is also consistent with the IEC, which defines an "irradiation-event" as the "loading of x-ray equipment caused by a single continuous actuation of the equipment's irradiation switch, from the start of the loading time of the first pulse until the loading time trailing edge of the final pulse."[7]

FDA's interpretation of 21 CFR 1020.30(b) allows for the comparison of fluoroscopic irradiation time among different procedures and different operators. Fluoroscopic irradiation time is an indicator of operator training and performance separate from other radiation dose metrics, such as cumulative air kerma and air kerma-area product.[8]

- Last-Image-Hold

  21 CFR 1020.32(j) requires that fluoroscopic equipment manufactured on or after June 10, 2006, be equipped with means to display a last-image-hold image following termination of the fluoroscopic exposure. A last-image-hold image is intended for review for study, consultation, or education instead of continuing fluoroscopy or obtaining a separate radiograph. If the last-image-hold image is of adequate quality, no additional radiation exposure is necessary, and patient radiation dose is reduced.[9]

  21 CFR 1020.32(c) requires continuous pressure by the operator for the entire time of any fluoroscopic exposure. If the fluoroscopic exposure is too short, the last-image-hold will not be of adequate quality.

  At present, fluoroscopy equipment should be designed so that the fluoroscopy exposure terminates after the release of continuous pressure by the

[6] Miller DL, Balter S, Dixon RG, et al. Quality improvement guidelines for recording patient radiation dose in the medical record for fluoroscopically guided procedures. J Vasc Interv Radiol. 2012;23(1):11-8.
[7] As defined in IEC,61910-1:2014, *Radiation dose documentation – Part 1: Radiation dose structured reports for radiography and radioscopy*.
[8] Stuart S, Mayo JR, Ling A, et al. Retrospective study of the impact of fellowship training on two quality and safety measures in uterine artery embolization. J Am Coll Radiol. 2014;11(5):471-6; Kuon E, Weitmann K, Hoffmann W, et al. Efficacy of a minicourse in radiation-reducing techniques in invasive cardiology: a multicenter field study. JACC Cardiovascular interventions. 2014;7(4):382-90; Xu BJ, Duszak R, Jr., McGinnis RS, Stanfill JG, O'Rear J, An AQ. Increased fluoroscopy time for central venous catheter placement by radiology residents versus staff radiologists. J Am Coll Radiol. 2013;10(7):518-22; Frederick-Dyer KC, Faulkner AR, Chang TT, Heidel RE, Pasciak AS. Online training on the safe use of fluoroscopy can result in a significant decrease in patient dose. Acad Radiol. 2013;20(10):1272-7; Fazel R, Curtis J, Wang Y, et al. Determinants of fluoroscopy time for invasive coronary angiography and percutaneous coronary intervention: insights from the NCDR®. Catheter Cardiovasc Interv. 2013;82(7):1091-105.
[9] IEC, 60601-2-54:2018, *Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*, Annex AA.

fluoroscopist, regardless of the quality of the last-image-hold image. This design is necessary for compliance with the FDA's performance standard (21 CFR 1020.32(c)).[10] 21 CFR 1020.32(c) does not specify a maximum allowable time between release of continuous pressure by the fluoroscopist and termination of the irradiation, nor does it address obtaining a last-image-hold image of adequate quality following very short fluoroscopic exposures.

FDA interprets the following scenarios as complying with the performance standard in 21 CFR 1020.32(c):

- For a fluoroscopy exposure of more than 0.5 sec, the device terminates the exposure within 0.1 sec from the time the fluoroscopist releases continuous pressure.
- For a fluoroscopy exposure of 0.5 sec or less, the device terminates the exposure within 0.5 sec from the time the fluoroscopist releases continuous pressure.

These termination times address the fact that fluoroscopic irradiation cannot cease instantaneously with release of continuous pressure by the fluoroscopist, due to unavoidable delays imposed by the operation of the necessary electronic circuitry, and provide enough time to create a last-image-hold image that is of adequate quality, as this improves patient safety.

This interpretation should not be unduly burdensome, as it is identical to the measure described in IEC standard 60601-2-54.[11] This approach, which clarifies the maximum time between release of continuous pressure by the fluoroscopist and termination of the irradiation exposure, will help reduce unnecessary radiation exposure of patients and will also allow usable last-image-hold images to be obtained.

- Emergency Fluoroscopy Mode

In the case of an equipment malfunction, it is desirable that a fluoroscope intended for use in interventional procedures enter an emergency fluoroscopy mode, during which time fluoroscopy continues in a limited mode while the fluoroscope attempts to return to normal function. This is an important safety feature for these types of procedures.

FDA's performance standard requires, in 21 CFR 1020.32(f), (h), (j), and (k), that x-ray tube potential and current, fluoroscopic irradiation time, and values of air kerma rate and cumulative air kerma be displayed continuously, and that a last-image-hold be displayed following termination of the fluoroscopic

[10] It is also consistent with IEC, 60601-1-3:2008/AMD1:2013, *General requirements for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment*, subclause 6.2.1.

[11] IEC standard 60601-2-54, subclause 203.6.2.1 (Normal initiation and termination of the irradiation).

exposure, among other things. These displays, however, may not be available in emergency fluoroscopy mode.

Emergency fluoroscopy mode typically involves fluoroscopy in the mode of operation which was used at the time of the recoverable equipment failure, or, if this is not possible, fluoroscopy in the mode of operation as close as possible to the one which was used at the time of the recoverable equipment failure; normal operation of the tabletop; normal operation of the gantry; normal operation of tableside controls for all functions described above; normal operation of irradiation and motion disabling switches; and normal operation of anti-collision functions.

If, at the time of the malfunction, the operator is performing a task for which fluoroscopy is critical (e.g., angioplasty, intravascular stent placement, embolization), the rapid restoration of limited fluoroscopy capability may prevent a catastrophic complication to the patient. The limited functionality provided by the emergency fluoroscopy mode will improve safety, provided that measures are in place for an expeditious return to a normal mode of operation.

As such, we do not intend to enforce the display and other requirements of 21 CFR 1020.32(f), (h), (j), and (k), for devices operating in the emergency fluoroscopy mode, where automatic or manual recovery methods from emergency fluoroscopy mode provide for a return to the normal mode of operation with all functions available (including the display requirements of 21 CFR 1020.32) for failures from which recovery is possible as quickly as reasonably practicable, which generally should not exceed 10 minutes.

This policy is based on considerations found in IEC 60601-2-43 for emergency fluoroscopy mode.[12]

[12] (Ed. 2.1., 2017) subclause 201.4.101.