Policy Clarification for Certain Fluoroscopic Equipment Requirements

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact the Division of Radiological Health at 301-796-2121 or Donald Miller at 301-796-3299 or by e-mail at Donald.Miller@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health

Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

A. Introduction

This draft guidance document describes FDA's intent to clarify the application of certain aspects of the performance standard requirements in 21 CFR 1020.32 for fluoroscopic equipment, when the manufacturer has otherwise complied with certain International Electrotechnical Commission (IEC) standards. Because conformance to certain IEC standards identified in this draft guidance adequately addresses those concerns intended to be addressed by the requirements of 21 CFR 1020.32, FDA does not intend to consider whether firms that provide a declaration of conformity and indicate compliance with applicable IEC standards also comply with 21 CFR 1020.32.

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.

B. Background

In 2005, the Agency amended the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32[1] to account for changes in the technology and use of radiographic and fluoroscopic x-ray systems. The Agency also took the action to fully utilize the International System of Units to describe radiation-related quantities and their

[1] 70 FR 34039, June 10, 2005.

units when used in the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32.[2]

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 focused on incorporating certain features and safeguards set forth in the standards of the IEC, particularly IEC 60601-2-43 (2nd ed., 2010), which are not addressed by the federal performance standard for fluoroscopic equipment.[5]

There are some differences between the IEC standard 60601-2-43 (2nd ed., 2010) and the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32, as well as some areas of the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32 that could be further clarified. FDA believes that under certain circumstances the relevant IEC standards adequately address the risks to health posed by fluoroscopic equipment. As set forth in greater detail below, if the device conforms to IEC 60601-2-43 (2nd ed., 2010) (which concerns x-ray equipment for interventional procedures), FDA does not intend to consider whether firms comply with certain requirements of 21 CFR 1020.32 if firms provide a declaration of conformity with the relevant IEC standard and the applicable measure(s) identified in this guidance.

C. Scope

The products addressed by this draft guidance are both "devices" (pursuant to 21 CFR 892.1650) and "electronic products" (pursuant to 21 CFR 1020.30 through 1020.32). The scope of this document is limited to fluoroscopic x-ray systems, whether stationary or mobile, classified in 21 CFR 892.1650 (titled "Image-intensified fluoroscopic x-ray systems"), with product codes JAA, OWB, and OXO. They are classified as class II devices in accordance with 21 CFR 892.1650(b). For the purpose of this draft guidance, 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.[6] Systems that accomplish angiography by using an image intensifier or

[2] 70 FR 33998, June 10, 2005.
[3] Agenda and transcripts are available at: http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm201448.htm. Public docket submissions are 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 8376, February 24, 2010.
[5] 21 CFR part 1020.
[6] The terms *air kerma*, *dose*, *kerma*, *fluoroscopy*, *image intensifier*, *image receptor*, *radiography*, *solid state x-ray imaging device*, *x-ray field*, and *x-ray system* are defined in 21 CFR 1020.30(b).

a solid state x-ray imaging device to record serial radiographic images are covered under 21 CFR 892.1650 and are also within the scope of this draft guidance.[7]

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

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.
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> (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.

Three product codes are currently associated with this regulation and addressed by this draft guidance:

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

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

There are some differences between the IEC standard 60601-2-43 (2nd ed., 2010) and the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32, as well as some areas of the federal performance standard for fluoroscopic equipment found at 21 CFR 1020.32 that could be further clarified. These points are described below, with FDA's recommendations.

- 21 CFR 1020.32(c) requires continuous pressure by the operator for the entire time of any exposure. If the exposure is too short, the last-image-hold will not be usable. However, to comply with 21 CFR 1020.32(j), fluoroscopic equipment manufactured on or after June 10, 2006, must be equipped with means to display last-image-hold image following termination of the fluoroscopic exposure.

[7] The terms *air kerma*, *dose*, *kerma*, *fluoroscopy*, *image intensifier*, *image receptor*, *radiography*, *solid state x-ray imaging device*, *x-ray field*, and *x-ray system* are defined in 21 CFR 1020.30(b).

Fluoroscopy should terminate after the release of continuous pressure by the operator, regardless of the quality of the last-image-hold. This requirement is inherent to compliance with the FDA's performance standard, and is consistent with IEC 60601-1-3 (ed. 2.1, 2013) clause 6.2.1. Fluoroscopic exposures should not be prolonged by equipment design or configuration in order to produce a last-image-hold of any particular image quality.

We do not intend to consider whether devices comply with 21 CFR 1020.32(c) when the device implements the following measure and manufacturers inform FDA by providing a declaration of conformity with this measure: Beginning from the time when the operator terminates the fluoroscopic exposure (e.g., by releasing pressure on the foot pedal), the fluoroscopy equipment stops the fluoroscopic exposure no more than 50 milliseconds later, regardless of the image quality of the resultant last-image-hold image.[8] This approach will help reduce unnecessary radiation exposure to patients.

- There is a conflict between the IEC and the federal performance standard or fluoroscopic equipment found in 21 CFR 1020.32. The IEC provision for emergency fluoroscopy mode, with limited functionality, in IEC 60601-2-43 (2nd ed., 2010) clause 201.4.101, conflicts with the display requirements of 21 CFR 1020.32.[9] 21 CFR 1020.32 requires, among other things, 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 exposure. In contrast, in order to permit the most rapid restoration of fluoroscopy capability possible in the event of a malfunction, the IEC emergency fluoroscopy mode permits limited functionality and does not require these displays while in emergency fluoroscopy mode.

  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 and is permissible provided that certain measures (as set forth below) are in place to provide for an expeditious return to a normal mode of operation.[10]

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8 See Letter from FDA to Medical Imaging & Technology Alliance (April 17, 2014) ("From a radiation safety standpoint, the shortest possible time is desirable. ...50 milliseconds is the maximum acceptable time.") (available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM394296.pdf).

9 See 21 CFR 1020.32 (f), (h), (j), and (k).

10 See also Letter from FDA to Medical Imaging & Technology Alliance (April 17, 2014) (further discussing the limited functionality provided by the emergency fluoroscopy mode when accompanied by certain other measures) (available at http://www.fda.gov/downloads/MedicalDevices/ResourcesforYou/Industry/UCM394296.pdf).

- We do not intend to consider whether devices, while operating in the emergency fluoroscopy mode, comply with the display requirements of 21 CFR 1020.32 when these devices implement the following measure, and manufacturers inform FDA by providing a declaration of conformity with this measure. Manufacturers enable an emergency fluoroscopy mode as specified in the IEC standard in IEC 60601-2-43 (2nd ed., 2010) clause 201.4.101, with either an automatic or manual recovery method or both to return to the normal mode of operation and, as applicable,

  (1) for the manual recovery method, for failures from which recovery is possible, the time to return to the normal mode of operation does not exceed 10 minutes from the time the operator has initiated the recovery of the equipment to the time the equipment is in normal mode (all functions are available, including the display requirements of 21 CFR 1020.32), and

  (2) for the automatic recovery method, for failures from which recovery is possible, the time to return to the normal mode of operation does not exceed 10 minutes from the time the equipment fails to the time the equipment is in normal mode (all functions are available, including the display requirements of 21 CFR 1020.32).