DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
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Gail M. Rodriguez, Ph.D.
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Dear Dr. Rodriguez:

On March 30-31, 2010, FDA held a public meeting on "Device Improvements to Reduce Unnecessary Radiation Exposure from Medical Imaging." FDA sought input on steps that manufacturers of computed tomography (CT) 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. Many of the recommendations focused on incorporating certain features and safeguards set forth in the standards of the International Electrotechnical Commission (IEC), particularly IEC 60601-2-54 (1st ed., 2009), *Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy*, and IEC 60601-2-43 (2nd ed., 2010), *Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures,* which are not covered by the federal performance standard for fluoroscopic equipment.

Your organization has brought to our attention some differences between these IEC standards and the federal performance standards for fluoroscopic equipment found at 21 CFR 1020.32, as well as some aspects of the federal performance standards for fluoroscopic equipment found at 21 CFR 1020.32 that could be further clarified. The purpose of this letter is to convey our current thinking on these topics.

21 CFR 1020.32(c) states that, "X-ray production in the fluoroscopic mode shall be controlled by a device which requires continuous pressure by the operator for the entire time of any exposure.", and 21 CFR 1020.32(j) requires that, "Fluoroscopic equipment manufactured on or after June 10, 2006, shall be equipped with means to display [a last-image-hold] image following termination of the fluoroscopic exposure." You have expressed concern that, if the fluoroscopic exposure is very brief, the last-image-hold will not be usable. Our current thinking is that fluoroscopy should terminate after the release of continuous pressure by the operator, regardless of the quality of the last-image-hold image. Fluoroscopic exposures should not be prolonged by equipment design or configuration in order to produce a last-image-hold image of any particular image quality.

We recognize that it is not physically possible to terminate a fluoroscopic exposure instantaneously at the exact moment that the "continuous pressure" required by 21 CFR 1020.32(c) is released. The performance standard is silent regarding an acceptable tolerance for terminating a fluoroscopic exposure after the operator has released the fluoroscopy switch. IEC 60601-2-54 (1st ed., 2009) is also silent in this regard. From a radiation safety standpoint, the shortest possible time is desirable. Our current thinking is that 50 milliseconds is the maximum acceptable time between the operator's release of the fluoroscopy control and the actual termination of the fluoroscopic exposure. In our previous discussions, you have indicated that this tolerance is feasible technically.

IEC 60601-2-43 (2nd ed., 2010) introduced a new mode of operation for interventional fluoroscopy systems, emergency fluoroscopy. This mode of operation conflicts with the display requirements of 21 CFR 1020.32. That portion of the federal performance standard 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 order to permit the most rapid possible restoration of fluoroscopy capability 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.

Our current thinking is that the emergency fluoroscopy mode, as defined in IEC 60601-2-43 (2nd ed., 2010), is an important safety tool. In the event of an equipment failure from which recovery is possible, it enables a return to limited fluoroscopy capability in minimum time. If, at the time of the failure, the operator is performing a task for which fluoroscopic guidance is critical (e.g., angioplasty, intravascular stent placement, embolization) rapid restoration of limited fluoroscopy capability may prevent a catastrophic complication.

Our current thinking is that the limited functionality provided by the emergency fluoroscopy mode is acceptable, provided that certain measures are in place to provide for an expeditious return to a normal mode of operation. Specifically, we think that manufacturers who enable an emergency fluoroscopy mode as specified 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, should ensure that:

- 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 restored to normal mode (all functions are available, including the display requirements of 21 CFR 1020.32), and
- 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 restored to normal mode (all functions are available, including the display requirements of 21 CFR 1020.32).

We also think that for interventional x-ray equipment that has both recovery modes, the automatic mode should be preferred if it is available. (We understand that for certain recoverable failures, both recovery modes may not be available.) Our current thinking is that a desirable value for the time to recover a minimum set of functions for performing emergency fluoroscopy is less than 1 min, and a desirable value for the time to recover all functions is less than 3 min.

I hope that this letter has adequately explained our current thinking on these topics. Please feel free to contact me if you have any questions.

Sincerely,

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