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April 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville MD 20852

RE: Docket No. 01N-0275

SUBJECT: Comments on 21 CFR Part 1020 "Electronic Products; Performance Standard For Diagnostic X-Ray Systems And Their Major Components; Proposed Rule", as published in the Federal Register Vol. 67, No. 237, Tuesday December 10, 2002

To whom it may concern:

Thank you for the opportunity to submit comments on FDA's Proposed Rule 21 CFR Part 1020, "Electronic Products; Performance Standard For Diagnostic X-Ray Systems And Their Major Components". The more than 4000 members of the Society of Interventional Radiology (SIR) are board-certified radiologists with special training, expertise and interest in interventional fluoroscopy and in radiation safety. We believe that we are well qualified to comment on the Proposed Rule from the viewpoint of end users of diagnostic x-ray systems.

It is now obvious that there has been a substantial increase in the potential risk of tissue damage (particularly skin injury) secondary to radiation exposure as fluoroscopically guided interventional procedures have become more complex and the physicians performing them more diverse.(1) In addition, the increased use of radiation for diagnosis and intervention contributes to the total population radiation burden. FDA's proposed rule is therefore clearly a step in the right direction—towards optimizing radiation use in interventional fluoroscopy.

Specifically, we have the following comments on the Proposed Rule:

- **§ 1020.30(b)** The term "exposure" is also used in the Proposed Rule with a different meaning to the one defined here. SIR recommends that FDA add an additional definition of "exposure", such as "activating an x-ray tube for the purpose of creating x-rays".

  SIR also recommends that the definition of the term "mode of operation" be changed to be in accordance with the International Electrotechnical Commission (IEC) defined term "MODE OF OPERATION".(2) SIR recommends that this term be redefined by FDA to include all sets of

technical factors which are selectable by the operator with a single control at the operator's normal working position, using either tableside controls or foot pedals.

- **§ 1020.30(h)(5)** SIR strongly supports FDA's goal of providing an easily accessible set of instructions describing the main operational controls and functions of the equipment. SIR strongly supports FDA's proposal that this information be consolidated into a special section of the user's manual or, preferably, a single user's manual. This should include a brief description of the functions of each control accessible to the operator at the operator's normal working position. All of this information is of enormous value to the end user, and most of it is currently scattered throughout the manufacturer's documentation.

- **§ 1020.30(h)(5)(ii)** SIR believes strongly that this section should be deleted. Fluoroscopic equipment is essentially multipurpose. SIR also notes that any mode of operation can and may be used for specific imaging tasks or clinical procedures not specified by the manufacturer, at the discretion of and based on the clinical judgment of the operator. The mode of operation is selected by the operator, based on the dosimetric characteristics of the mode of operation and the clinical requirements of each case. SIR believes strongly that this choice is part of the practice of medicine, and is not subject to regulation by FDA.

  SIR recommends that § 1020.30(h)(5)(ii) be rewritten to require the manufacturer to provide dose data for each mode of operation, as specified by the manufacturer in accordance with § 1020.30(h)(5)(i), with the dose data determined under the conditions defined by the IEC (typical patient and maximum).(2) In addition, FDA should specify that for each fluoroscopic mode of operation listed in § 1020.30(h)(5)(i), the manufacturer must provide the dose rates for each available frame rate.

- **§ 1020.30(m)(2)** SIR supports FDA's proposal that certain fluoroscopic systems provide the option of selecting and adding x-ray filtration to the diagnostic source assembly over and above the amount needed to meet the proposed new minimum HVL values. Patients will benefit from the additional ability to reduce skin exposure during long interventional procedures. FDA's proposal will aid in dose optimization. However, if additional filtration is placed in the beam at any time, either manually or automatically, the amount of filtration should be indicated at the control console or at the operator's working position.

- **§ 1020.30(q)(2)** SIR recommends that this paragraph be modified to include the requirement that the assembler must provide the reports required by subpart B of part 1002 of this Chapter to the owner of the diagnostic x-ray system.

- **§ 1020.32(b)(4)(ii)** SIR believes that the requirements described in this section are acceptable.

- **§ 1020.32(d)(2)(ii) and § 1020.32(d)(2)(iii)(C)** SIR supports FDA's proposal to establish an upper limit on air kerma rate (AKR) during both normal and high-level control modes of operation. Poorly trained operators may have a tendency to overuse fluoroscopy in general and high-level control modes in particular. This could easily result in increases in the likelihood and severity of radiation-induced skin effects.

- **§ 1020.32(h) and § 1020.32(k)** SIR believes strongly that the proposed display requirements for irradiation parameters should apply to all types of fluoroscopic equipment, and not just to

stationary C-arm fluoroscopes. Any type of fluoroscope may be used to guide a fluoroscopic intervention. For some interventions, particularly orthopedic interventions and aortic stent-graft placement, mobile x-ray equipment is the most commonly used type of fluoroscope. Portable x-ray equipment is less commonly used, but has the potential for use with minimal source-skin distance. Thus, the proposed display requirements should not be limited to stationary C-arm fluoroscopes.

- **§ 1020.32(h)(2)(i)** SIR believes that display of fluoroscopy time and units at the operator's position, as the FDA proposes, is a major advance in radiation dose management and radiation dose optimization. SIR strongly supports this proposal because it provides useful information to the operator in real-time at the operator's working position. We believe that this display will help operators to control radiation dose by providing constant feedback.

  § 1020.32(h)(2)(i) does not specify how irradiation time should be displayed or how this display should be updated. SIR recommends that irradiation time be displayed in units of minutes and tenths of minutes (e.g., 19.4 minutes) and that the display be updated every 6 seconds (0.1 minutes) during fluoroscopic irradiation.

  The underlying principle should be *uniformity of function and action*—fluoroscopic units built by different manufacturers should operate in as similar a manner as possible. Consistency of operation from site to site and from unit to unit reduces the likelihood of operator errors due to unfamiliarity with the idiosyncrasies of individual fluoroscopic units. The goal is to avoid operator confusion when procedures are performed on different occasions with different fluoroscopic equipment in different institutions.

- **§ 1020.32(h)(2)(ii)** SIR strongly supports FDA's proposed change in the nature of the audible signal used to indicate the passage of irradiation time during an examination or procedure. In conjunction with display of irradiation time at the operator's position, as proposed in § 1020.32(h)(2)(i), the proposed audible signal is sufficient. It eliminates the distraction cause by the current audible signal, which must be manually reset every 5 minutes.

  SIR emphatically does *not* support the alternative approach of an audible signal with a user-configurable time period. The audible signal should be standardized, for the same reason that FDA proposes to standardize display requirements for visual indicators of irradiation in § 1020.32(k)(1) through § 1020.32(k)(7), and in accordance with the principal of uniformity in function and action (*vide supra*).

- **§ 1020.32(j)** SIR strongly supports FDA's proposal to require last-image hold (LIH) capability in all new fluoroscopic equipment. This technology is already widely available and is invaluable for reducing radiation dose. LIH capability is necessary for dose optimization, regardless of the nature of the procedure for which fluoroscopy is used. SIR suggests that the term "LIH radiograph" be changed to "LIH image" throughout this section.

- **§ 1020.32(j)(3)** SIR strongly recommends that a means be provided to clearly indicate to the user whether <u>every</u> displayed image is "live" or stored. The requirement expressed in this section should not be limited to LIH radiographs and fluoroscopy, since many systems permit looped replay of serial radiographs or digital cineradiography.

  In addition, SIR strongly recommends that every fluoroscopic unit provide both (a) a momentary audible signal in the procedure room each time that radiation emission is

initiated, and (b) a continuous visual indicator, clearly visible everywhere in the procedure room, at all times when radiation emission is occurring.

- **§ 1020.32(k)(1) through § 1020.32(k)(7)** SIR strongly supports FDA's proposed requirement that new fluoroscopic equipment should display values of cumulative air kerma and AKR at the operator's working position. Visual feedback to the operator on radiation dose and radiation dose rate in real-time is essential if radiation dose is to be optimized. SIR also strongly supports FDA's proposal to standardize these displays, based on the principle of uniformity of function and action.

  However, SIR suggests that the requirement for recalculation of the displayed values, as proposed in § 1020.32(k)(2), be modified. Recalculation and re-display of AKR and cumulative air kerma after every 1 sec of fluoroscopy on-time and after every 1 sec of cineradiography, digital cineradiography, digital angiography, digital subtraction angiography, electronic radiography or photospot recording is both feasible and desirable. This method of updating is already standard on at least one manufacturer's equipment. The constantly changing cumulative air kerma and AKR values draw the operator's attention to these indicators and make it more difficult to overlook them through inattention, in the same manner that a flashing light is more difficult to ignore than a light that is constantly lit.

- **§ 1020.32(k)(3)** SIR strongly believes that cumulative air kerma should be displayed at the operator's position at all times, including while fluoroscopy is employed. Otherwise an operator might, for example, use fluoroscopy continuously for 10 min and have no idea what the cumulative air kerma was during that time.

- **§ 1020.32(k)(7)** SIR believes that the requirement for +/- 25% accuracy for display of AKR and cumulative air kerma at the operator's working position may be unnecessarily restrictive. SIR recommends that FDA's Proposed Rule be harmonized with the requirements stated in IEC Report 60601-2-43.(2)

- On the basis of published reports (3,4) and unpublished data previously provided to FDA (5,6) SIR believes that equipment manufacturers should be encouraged to develop methods for estimating or determining peak skin entrance dose in real-time during a fluoroscopically guided procedure. This value should also be displayed at the operator's working position, in the same fashion as air kerma and AKR.

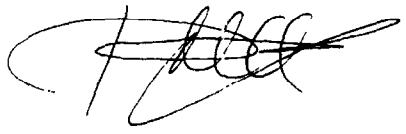
  Ideally, a real-time map of skin entrance dose, also displayed at the operator's working position, would accompany the display of peak skin entrance dose. The skin entrance dose map is an invaluable aid for minimizing skin dose.(3) In addition, the International Commission on Radiation Protection (ICRP) recommends that "a suitable body map with the estimated doses" to the skin should be placed in the patient's record whenever dose data are recorded.(7) A requirement by FDA that this capability be incorporated into new fluoroscopic equipment would facilitate routine implementation of the ICRP recommendation. At least one manufacturer has already developed this capability and offered it for sale in the United States, so it is clearly possible technically. This capability is essential to guide the operator during high-dose procedures. If requirements for a display of peak skin entrance dose and a real-time map of skin entrance dose cannot be incorporated in to the Proposed Rule, they should be considered strongly for incorporation into 21 CFR Part 1020 at the earliest possible date.

- On the basis of published data,(8) SIR strongly encourages FDA to include an additional requirement for both stationary C-arm fluoroscopes and mobile C-arm fluoroscopes. Specifically, SIR recommends that FDA require these systems to include the ability to display collimator and filter position to the operator without emission of radiation. This technology is already commercially available on at least one manufacturer's product line. Both stationary and mobile C-arm fluoroscopes are used for interventional fluoroscopy. Bakker and colleagues have shown that 5% - 8% of total radiation exposure during interventional radiology procedures is due to radiation delivered during *preparation* for imaging, while positioning the table and adjusting the collimators.(8) With the capability described above, and using a last-image hold (LIH) image as a guide for collimator positioning, radiation dose can be reduced without loss of information. This is the essence of dose optimization. If this requirement cannot be incorporated in to the Proposed Rule, it should be considered strongly for incorporation into 21 CFR Part 1020 at the earliest possible date.

- SIR strongly encourages FDA to require that means be provided by the manufacturer to enable qualified personnel to make all measurements necessary to verify equipment compliance with this Proposed Rule.

SIR applauds FDA's efforts on behalf of the American public and appreciates the opportunity to provide these comments on the Proposed Rule. If you have any questions or would like to discuss this in detail, please feel free to contact me at 301/295-4334.

Sincerely,



Donald Miller, MD
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cc: Michael Brunner, MD
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Tricia McClenny

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