The Society for Cardiac Angiography & Interventions

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April 7, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852
http://www.fda.gov/dockets/ecomments

REFERENCE: Comments on Proposed Rule, *"Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components"*

Dear Sir/Madam:

Through this letter, The Society for Cardiac Angiography and Interventions (SCAI) is pleased to provide comments on the referenced Proposed Rule, as published in the December 10, 2002 *Federal Register.*

SCAI is the principal professional society for invasive and interventional cardiologists, with nearly 2,500 members. SCAI's mission is to promote excellence in invasive and interventional cardiovascular medicine through physician education and representation, and the advancement of quality standards to enhance patient care. Focus areas include establishing standards and guidelines for cardiac catheterization and angiography, training, safety and quality assurance, and advocacy.

As the proposed FDA rule regulating X-ray equipment has significant direct impact upon the ability of the physician members of the group to deliver the highest quality medical care, we would like to thank you for opportunity to comment.

SCAI strongly supports the primary objective of the proposed rule, i.e., to improve public health by reducing exposure to unnecessary radiation while maintaining the diagnostic quality of the images. The estimation of benefits and cost of implementation sections reflect considerable thought and are supportive of the recommendations as outlined.

The proposal is well written and clearly reflects the process leading up to this document. The nine significant amendments to the current standard (divided into three distinctive categories) are clearly stated. As physicians, we do not have the technical expertise to comment on the technical specifics of this document. We assume other individuals and organizations will comment in this area. Therefore, we will confine our comments to areas that more directly impact patient care.

SCAI supports the requirements for displaying (directly to the fluoroscopist) information related to duration, rate and amount of x-ray emissions to the patient on all fluoroscopes. The immediate availability of dose information has potential to improve ability of the physician to make risk benefit decisions on patients which is obviously essential to our practice. Similarly, the "last-image hold" feature provides the fluoroscopist the ability to utilize acquired information with no further irradiation to the patient.

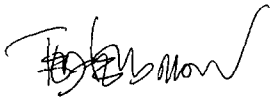
SCAI's major concerns regarding the Proposed Rule are in two areas.

First, with respect to upgrading of old equipment, SCAI clearly believes this is necessary. However, equipment owners may not have the technical expertise needed to certify the work. Thus, the service entity that performs the upgrade should be required to certify compliance. This is similar to the requirement that the installer certify either new equipment, or major equipment repairs.

Second, under the section for information for users (paragraph 1020.30 (g) (5)), "Imaging System Information", SCAI strongly objects to the requirement for labeling modes of operation on x-ray equipment for specific clinical purposes. The manner of use of X-ray equipment has always been based upon the physician's judgment. X-ray equipment is not a static device such as a stent, it is a dynamic instrument that is operated by a skilled physician with clinical judgment that should not be restricted or confined to a label. However, requiring the manufacturer to supply standard dose information for different modes enhances the physician's ability to select the correct mode.

The Society would like to again thank the FDA for the opportunity to comment on this document. We would hope that our concerns will be addressed in the final version of this document. If further correspondence is required, please feel free to contact us at any time. Our administrative offices can be reached at 1 (800) 992-7224.

Sincerely,



Ted E. Feldman, M.D., FSCAI
President

cc: Michael Cowley, M.D., FSCAI
Charles Chambers, M.D., FSCAI