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Dockets Management Branch
HFA-305
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket Number 01N-0275
Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components (FR, Dec. 10, 2002, pp. 76056-76094)

To Whom It May Concern:

On behalf of the Diagnostic Imaging and Therapy Systems Division of the National Electrical Manufacturers Association, I am pleased to submit comments relative to the Proposed Rule: **Electronic Products; Performance Standard for Diagnostic X-Ray Systems and Their Major Components.**

NEMA, the National Electrical Manufacturers Association, is the nation's largest trade association representing the electro-industry. NEMA's Diagnostic Imaging and Therapy Systems Division represents the majority of the nation's manufacturers of X-ray imaging, computed tomography, diagnostic ultrasound, radiation therapy, magnetic resonance imaging, and nuclear imaging equipment. In addition, the division represents manufacturers of picture archiving and communications systems.

General Comments:

A. Change in the Quantity Used to Describe X-Radiation from Exposure to Air Kerma

Comment: this change is fully supported: now compliance with the other major documents as ICRU report 60 (1998) will be achieved.

B. Clarification of Applicability of Requirements to Account for Technological Developments in Fluoroscopic X-Ray Systems as Digital Imaging, Digital Recording, and New Types of Solid-State X-Ray Imaging Devices

Comment 1: We appreciate the inclusion of new technologies by replacing the former term e.g. "x-ray image intensifier" by more general terms as "fluoroscopic image receptor" since the new technologies should be included and since the basic safety and most performance requirements stay applicable.

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Comment 2: Imaging performance characteristics
For the new digital detectors there are some specific new characteristics such as detector artifacts and detector dose indicators, which need consideration. We recommend that these characteristics be handled within IEC standards such as IEC 62220-1 on DQE, IEC 60601-1-3 on Radiation Protection, and IEC 61223-3-X on Acceptance Testing.

Specific Comments:

1020.30 Diagnostic x-ray systems and their mayor components

1020.30(h)(2)(i) Statement of leakage: the minimum filtration permanently in the useful beam expressed as millimeters of aluminum equivalent, and the peak tube potential at which the aluminum equivalent was obtained.

Comment: In addition to the peak tube potential, the kV waveform needs to be specified as this has impact on mm Al equivalence Proposal: ≤10% ripple to be in line with today's generator technology and to correspond with the waveform characteristics in other sections of this document

1020.30(h)(6)(Proposed) Display of values AKR and cumulative air Kerma
Comment: For low pulse rate fluoroscopy, the display of air Kerma rate would fluctuate due to sampling periods shorter than the pulse intervals, presenting a non-meaningful, gyrating display. IEC 60601-2-43 requires air Kerma rate displayed only for ≥ 6 P/s.

1020.30(m)(1) Beam Quality-Half-value layer
Comment: The values given in Table 1-3, Minimum HVL for X-ray systems, should state the kV waveform in addition to the peak tube potential. . Proposal: ≤10% ripple to be in line with today's generator technology. For example, 100 kV 3.6mm Al HVL measured with a generator ≤10% ripple is equivalent to 2.7mm Al HVL measured with a self-rectifying or 4-pulse generator.

1020.30(n) Aluminum equivalent of material between patient and image receptor
Comment: The values given in Table 2 for allowable tabletop attenuation, e.g. Tabletop, cantilevered: 2mm Al equivalent are still related to a beam quality as given in Table 1-2 (self rectifying or 4 pulse generator). There is no indication that DHHS is asking for less absorbing tabletops, which the new regulation would have the effect of requiring, and which would be counter productive to the demand of clinicians for tabletops specified for higher patient load. Under the assumption that today's table design is acceptable, the Al equivalent values have to be adapted to the harder beam quality measurements. For the example of cantilevered Tabletop, the value has to be corrected from 2mm Al HVL to 2.3mm Al HVL. All other Tabletop values have to be corrected accordingly.

Following this approach would harmonize the Rule with the IEC 60601-1-3 standard.

mm Al equivalent according to Table 1 (100kV self rectifying/4pulse generator)		mm Al equivalent according to IEC 60601-1-3 (100kV ≤10% ripple)
Front panels of cassette holders	1.0	1.2
Front panels of film changers	1.0	1.2
Cradle	2.0	2.3
Tabletop stationary without articulated joints	1.0	1.2
Tabletop movable	1.5	1.7
...etc.		etc.: See IEC 60601-1-3 table 206

1020.32 Fluoroscopic equipment

General comment:

Entrance Air Kerma Rate at the Fluoroscopic Image Receptor:

Requirement for limitation of Entrance Air Kerma Rate at the Fluoroscopic image detector as an alternative to limits on patient Entrance Air Kerma Rate as used today.

Comment: We support the change to the existing regulation which promotes the use of additional filtration, which is very effective in reducing patient entrance dose maintaining good image quality when used with X-ray tubes of high loading capability.

1020.32 (h)(2)(i) Proposed –
"Fluoroscopic irradiation time display and signal ...A display of the and units of irradiation time from the beginning of a patients examination or procedure"

Comment: To indicate the accumulated fluoroscopic irradiation time in the control room is a meaningful tool for educational and documentation purposes. luoroscopic time does not represent well the applied dose to the patient. As a result, the new Fluoro Amendment already requires indication of Air Kerma Rate and accumulated Air Kerma at the fluoroscopist working position. A third dose related indication is seen as an overload of information especially for a biplane system where six dose-related indications are now displayed. This could be even counterproductive instead of supporting better dose awareness.

1020.32 (h)(2)(ii) Proposed
"A signal audible to the fluoroscopist shall indicate the passage of irradiation time during an examination or procedure" (1 second every 5 minutes)

Comment: This proposal is appreciated as an improvement compared to the existing solution where the 5min audible signal had to be reset. However, the community of fluoroscopists and especially those performing interventional procedures should comment on whether or not the audible signal reoccurring every 5 min for one second is really useful information to which they will pay attention. For demanding and long interventional procedures, the ones with potentially high dose values applied to the patient, this additional audible warning signal competing for the awareness of the fluoroscopist could be disturbing. Since cumulative air Kerma information will be available and is much more useful information in managing patient exposure, we support the proposal that the requirement for an audible signal every 5 minutes be completely eliminated.

Proposed - The AKR and the Cumulative air Kerma should not deviate from their respective displayed values by more than ±25%

Comment:
Some errors, due to rapidly changing AKR (i.e. pulsed fluoroscopy) can be corrected by calculations, but in reality the worst-case calculation by multiplication of all the single errors does not represent the expected outcome. Using the quadratic sum calculation is a well-proven method to indicate the average expected error. The result in this case would be ±20% ±LSD, assuming perfect steady-state calibration. However, this does not represent the maximum error value a manufacturer has to guarantee, since he must provide additional

margin for initial calibration accuracy and changing environmental conditions. Having these concerns in mind IEC 60601-2-43 has specified an accuracy for dose and dose rate of ±50%.

1020.32(a)(2) Primary protective barrier- Measuring compliance
Page 76091 "……For all measurements, the attenuation block shall be positioned in the useful beam 10 centimeters from the point of measurement of entrance AKR and between this point and the input surface of the fluoroscopic imaging assembly."

Comment:
This setup for measurements clearly deviates from the setup necessary when following the regulations of IEC 60601-1-3, § 29.207.2: "… use a phantom, having an ATTENUATION EQUIVALENT of 40 mm Al, positioned in the X-RAY BEAM as close as possible to the FOCAL SPOT. …"

This difference in methods requires performing two different sets of measurements from each manufacturer. The setup requested by the Proposed Rule with the attenuation block close to the image receptor does not reflect the situation of a patient under fluoroscopic examination: In reality, the patient intersects the whole useful beam, and radiation not attenuated by the patient's tissue will not reach the entrance surface of the image receptor. Under measuring conditions for image receptors with diameters of more than 30 cm (i.e. many modern image intensifiers and flat image plates), the size of the attenuation block (20 cm x 20 cm) is too small to prevent primary radiation not attenuated by the block from passing by and entering into the image receptor plane. This results in 1) higher amounts of shielding materials 2) higher weights of image receptors 3) additional reinforcement to support and counterweight structures. For this reason we propose to use the complete wording of IEC 60601-1-3,
§ 29.207.2 for the FDA's § 1020.32 (a) (2) Measuring compliance. Furthermore, the table format for presentation of measuring requirements (as in IEC) will increase readability and clarity of this paragraph.

NEMA is pleased to submit these comments and looks forward to working with the agency.

Sincerely,

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