Where should we measure the entrance air kerma rate during acceptance testing of the automatic dose control of a fluoroscopic system?

Title page

Where should we measure the entrance air kerma rate during acceptance testing of the automatic dose control of a fluoroscopic system?

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Abstract

In Japan, the entrance air kerma rate (EAKR) to a patient cannot exceed 50 mGy/min in conventional fluoroscopy. However, it's unclear where the EAKR should be measured. We obtained the tube potential and tube current as a function of polymethylmethacrylate (PMMA) thickness, and the EAKR at the interventional reference point (IRP) was measured from the trajectory. The EAKR at the point established by the U.S. Food and Drug Administration (FDA) was calculated from EAKR at the IRP. The EAKR at the IRP exceeded the limit at a PMMA thickness of 22–28 cm. However, the EAKR did not exceed the limit at the FDA point. If the EAKR to a patient is being verified to meet the recent Japanese ruling, the EAKR should be measured at the FDA point, and if the EAKR is being evaluated for determination of the skin dose, it should be monitored at the IRP.

Keywords

Entrance air kerma to patient, Medical law enforcement, Acceptance testing, IRP, FDA point, Interventional radiology

1. Introduction

A ruling enacted by the Japanese Ministry of Health, Labour, and Welfare in 2001 [1] states that the entrance air kerma rate (EAKR) to a patient must not exceed 50 mGy/min in conventional fluoroscopy, and 125 mGy/min in special fluoroscopy in a high-dose-rate mode. Compliance with medical regulations is mandatory for clinical physicists and those in related fields, but it is still unclear where the EAKR to the patient should be measured.

International Electrotechnical Commission (IEC) standard 60601-2-43 defines an interventional reference point (IRP) as a location that is representative of the patient's skin [2]. For typical isocentric interventional equipment, the default IRP is located on the central axis of the X-ray beam at 15 cm on the X-ray tube side of the isocenter.

The U.S. Food and Drug Administration (FDA) defines the C-arm measurement point as 30 cm in front of the image receptor (FDA point) for any source-to-image receptor distance (SID). Fluoroscopic equipment with an SID tracking system must maintain the 88 mGy/min limit at the FDA point at any SID [3].

We introduced new surgical fluoroscopic equipment in December 2011, and its automatic exposure control (AEC) system was verified on acceptance testing. Subsequently, we found that the EAKR at the IRP exceeded 50 mGy/min. To our

knowledge, this is the first report to focus on the location where the EAKR to a patient should be measured to meet Japanese regulations.

2. Methods and materials

As part of the acceptance testing of an Opescope Pleno WHA-200 surgical fluoroscopy system (Shimadzu Corporation, Kyoto, Japan), verification of its AEC system was performed under a fixed geometric arrangement. The system provided two modes: “normal,” a conventional fluoroscopy mode, and “high quality,” a high-dose-rate fluoroscopy mode. Three types of aluminum filters were installed in the system. The experimental setup of this fixed geometry is depicted in Fig. 1, and the technical specifications of this system are listed in Table 1. A lateral X-ray tube position was applied in all measurements.

First, we plotted the tube potential (kVp) and tube current (mA) as a function of the nominal polymethylmethacrylate (PMMA) thickness when an additional copper filter (0, 0.1, and 0.2 mm) was changed, as shown in Fig. 1(A) (trajectory acquisitions). A 0.3 mm copper filter was not applied in the acceptance testing because we do not use the

filter in a clinical setting. We employed PMMA plastic phantom to simulate patient thicknesses varying from 0 to 28 cm.

Second, we measured the EAKR (mGy/min) at the IRP as shown in Fig. 1(B). We used an Unfors Xi semiconductor detector (Unfors RaySafe, Billdal, Sweden) was used to measure the EAKR without backscatter. The dosimeter has 1 mm of lead behind the detector as protection from backscattered photons. Because using a dosimeter in tandem with AEC leads to unpredictable and undesirable levels of EAKR, AEC was not applied, and the tube potential and tube current were set manually by use of the initially obtained trajectory as a function of PMMA thickness. The EAKR at the FDA point was calculated with these geometrical factors: SID, 90 cm; source-isocenter distance, 55 cm; source-dosimeter (IRP) distance, 40 cm; and source-FDA point distance, 60 cm.

Upon completion of all data acquisition, the tube potential, tube current, average power (W), and EAKR at both the IRP and the FDA point were plotted against the PMMA thickness.

3. Results

Figure 2 shows the fluoroscopic tube potential, tube current, average power (W), and EAKR at the IRP / FDA point and as a function of the PMMA thickness in normal

mode without a spectral filter (0 mm Cu). Chart A of Figure. 2 shows the fluoroscopic tube potential and tube current, chart B shows average power loading, and chart C shows the EAKR at the IRP / FDA point. The tube potential and tube current show a monotonic increase as the phantom thickness is increased up to the thickness that produces the maximum average power load for the system. The maximum tube potential and tube current were 110 kVp and 3.0 mA for the normal mode. The EAKR was also increased with the maximum average power load. The limit for the EAKR at the IRP exceeded 50 mGy/min in the normal mode when a PMMA thickness of 22–28 cm was applied without spectral filter (0 mm copper). However, the limit for the EAKR did not exceed 50 mGy/min at the FDA point.

4. Discussion

The Japan Association on Radiological Protection in Medicine and many others have reported that the EAKR with backscatter must be measured at the IRP by use of PMMA [4]. On the other hand, the IEC, FDA, and Japanese medical regulatory authorities agree that the kerma rates are intended to mean EAKR without backscatter (free in air). Therefore, we applied the EAKR without backscatter to verify the 50 mGy/min limit.

The EAKR at the IRP exceeded the limit of 50 mGy/min when a PMMA thickness of 22–28 cm was applied without a spectral filter (0 mm copper). If the EAKR to a patient is verified at the IRP during acceptance testing, the dose might be overestimated. However, the regulation does not define the measurement point. Then, where should "EAKR to patient" be measured during acceptance testing? The manufacturer must be able to comply with the Japanese regulations to be permitted to sell a system.

Although the Japan Association on Radiological Protection in Medicine and others have proposed that the EAKR be measured at the IRP, the manufacturer applies the FDA point when evaluating the EAKR to a patient (in free air) [5]. Our data show that, on our system, the EAKR at the FDA point was within the limit (50 mGy/min).

Acceptance testing of the AEC with other spectral filters (1-mm Cu, 2-mm Cu) in normal mode and AEC in the high-dose-rate mode also was performed at initial installation. The limits of 50 mGy/min or 125 mGy/min at IRP / FDA point were not exceeded in all circumstances.

The Unfors Xi semiconductor detector is designed for application in conventional radiography and fluoroscopy dosimetry measurement. As such, the lead support was embedded in the detector to shield any backscatter from being detected. It might be important to consider the backscatter from the lead when the EAKR is measured.

However, the detector was duly calibrated with an error of 1.5% in the manufacture's factory.

We have found that (1) when the EAKR to a patient is verified to meet the regulation, the dose must be measured and evaluated at the FDA point, (2) if the EAKR is being evaluated for determining the skin dose in a clinical setting, the dose must be monitored at the IRP, because many investigations and useful conversion factors have been based on its use [6].

5. Conclusions

If the EAKR to a patient is being verified to meet the recent Japanese ruling, the dose should be measured and evaluated at the FDA point, and if the EAKR is being evaluated for determination of the skin dose in a clinical setting, the dose should be monitored at the IRP.

Conflict of interest statement

The authors declare that we have no conflict of interest in this study.

References

1. Japanese medical law enforcement http://law.e-gov.go.jp/htmldata/S23/S23F03601000050.html (accessed May 22, 2011) (Japanese)

2. International Electrotechnical Commission (2000) IEC report 60601. Medical electrical equipment – Part 2-43: particular requirements for the safety of X-ray equipment for interventional procedures. International Electrotechnical Commission, Geneva.

3. 21CFR1020.32, Code of Federal Regulations, Title 21, Volume 8, Revised as of April 2006, DHHS, FDA.

4. Safety guideline to prevent radiation-induced skin injury in interventional radiology. http://www.fujita-hu.ac.jp/~ssuzuki/bougo/book/ivr.pdf (accessed May 22, 2011) (Japanese)

5. Maximum dose rate measurements in fluoroscopy equipment in service manual. M516-2029B. Shimadzu Corporation, Kyoto, Japan. (Japanese)

6. Kwon D, Little MP, Miller DL: Reference air kerma and kerma-area product as estimators of peak skin dose for fluoroscopically guided interventions. Med Phys. 38(7):4196-4204, 2011

Fig. 1

Experimental setup. The trajectory of the tube potential and tube current was obtained in setting (A) as a function of PMMA thickness. Entrance air kerma rates measured in setting (B) are in accordance with the trajectory obtained.

Fig. 2

Fluoroscopic tube potential, tube current, entrance air kerma at the IRP / FDA point, and average power as a function of the PMMA thickness in “normal” mode without spectral filter (0 mm). When 22-cm-thick PMMA was applied to simulate a patient, the EAKR at the IRP exceeded the limit of the Japanese regulation. The EAKR at the FDA point was not exceeded in all circumstances.

Fig 1

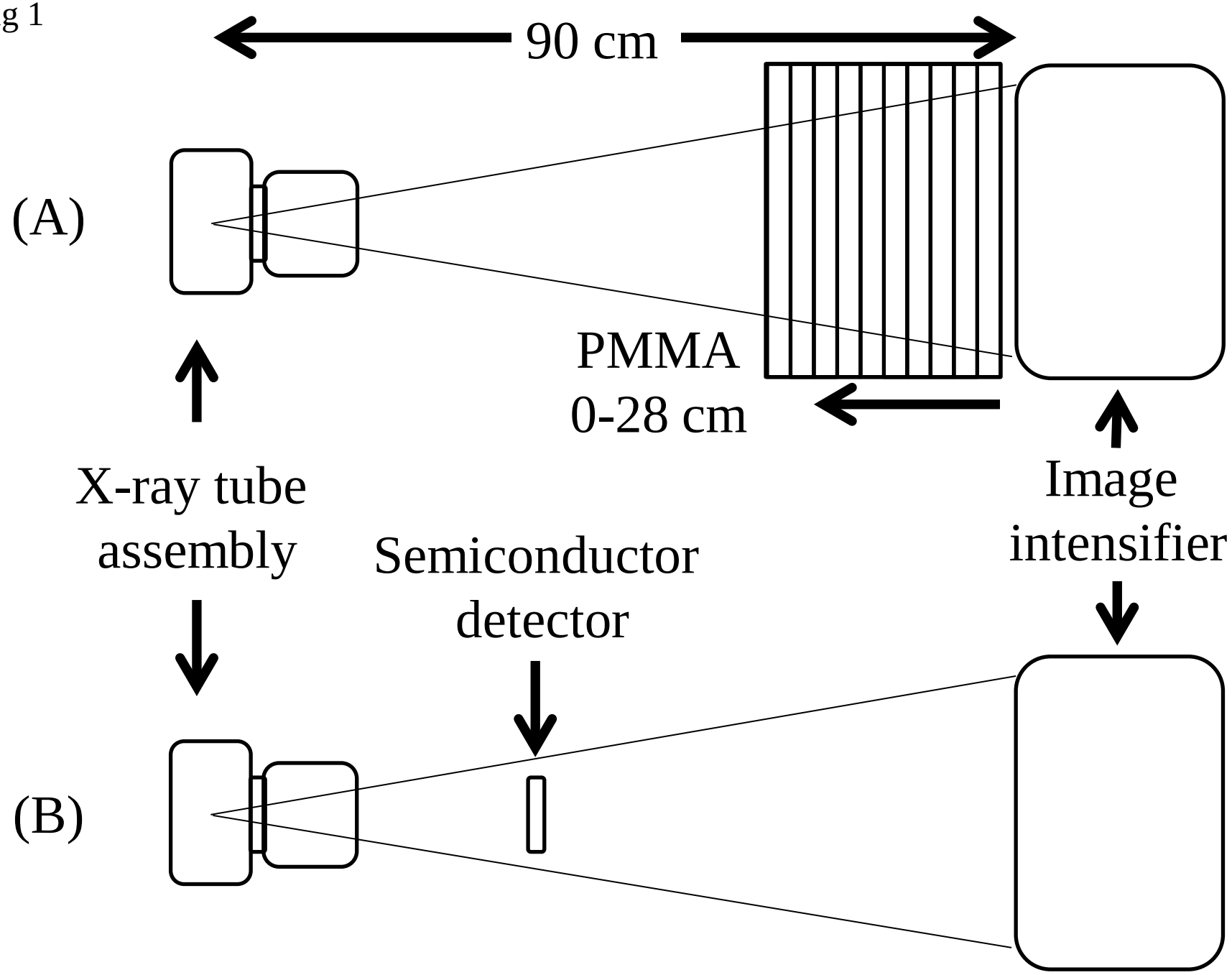
90 cm
(A)
PMMA
0-28 cm
X-ray tube
assembly
Semiconductor
detector
Image
intensifier
(B)

Table 1. Technical information on Shimadzu Opescope Pleno WHA-200 surgical fluoroscopic system

1. X-ray tube	
1.1 Focal spot size	0.6 mm
1.2 Target angle	8 °
2. X-ray tube assembly	
2.1 Total filtration	2.9 mm Al equivalent
2.2 Spectral filters	0.1 mm Cu, 0.2 mm Cu, 0.3 mm Cu
3. C-arm / geometry	
3.1 Source-image receptor distance	90.0 cm
3.2 Source-isocenter distance	55.0 cm
3.3 Source-IRP* distance	40.0 cm
3.4 Source-FDA* point distance	60.0 cm
3.5 Field of view	23.0 cm / 16.0 cm (diamter)
4. Fluoroscopic mode	
4.1 Pulse rate	0.5, 1, 2, 3.75, 7.5, 15, **30** (continuous) *
4.3 Tube potential	40-110 kVp
4.3 Maximum tube current	9.0 mA

Note:* Continuous mode was applied in the acceptance testing. IRP and FDA are interventional reference point and Food and Drug Administration, respectively.

Fig 2 (A)

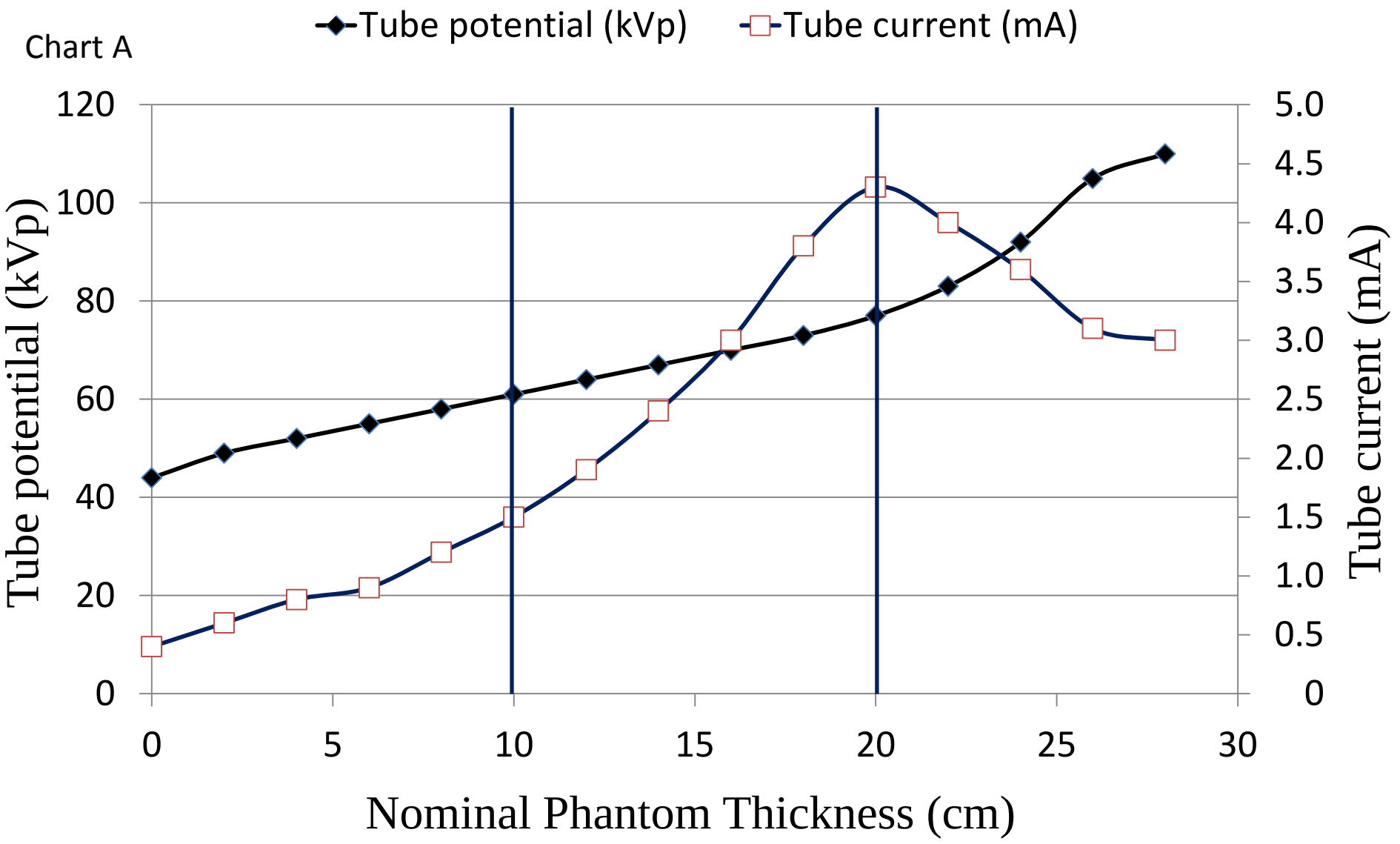
Chart A
Tube potential (kVp)
Tube current (mA)
Tube potentilal (kVp)
Tube current (mA)
Nominal Phantom Thickness (cm)
0
20
40
60
80
100
120
0
0.5
1.0
1.5
2.0
2.5
3.0
3.5
4.0
4.5
5.0
0
5
10
15
20
25
30

Fig 2(B)

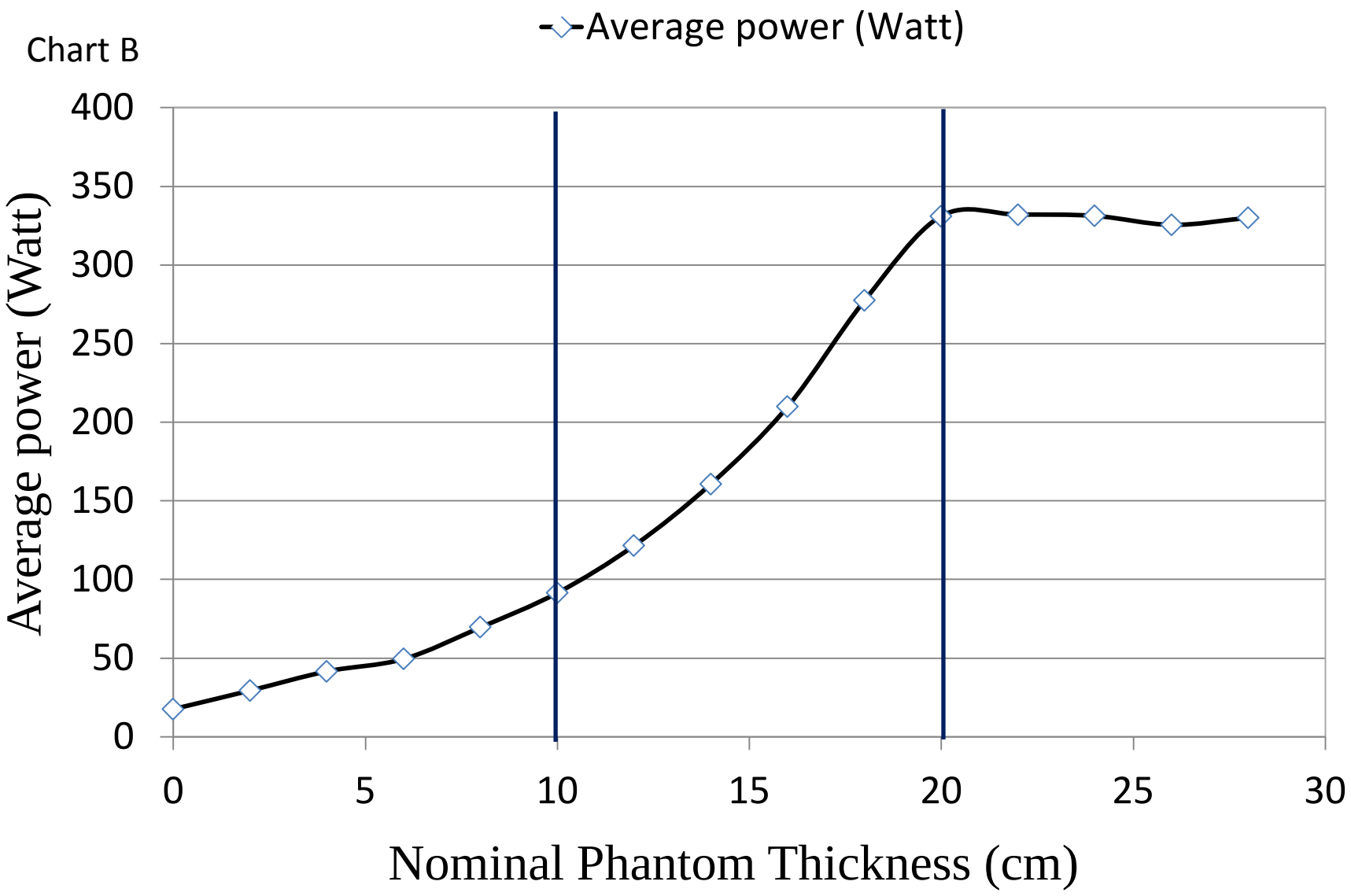
Chart B
Average power (Watt)
400
350
300
250
200
150
100
50
0
Average power (Watt)
0
5
10
15
20
25
30
Nominal Phantom Thickness (cm)

Fig 2(C)

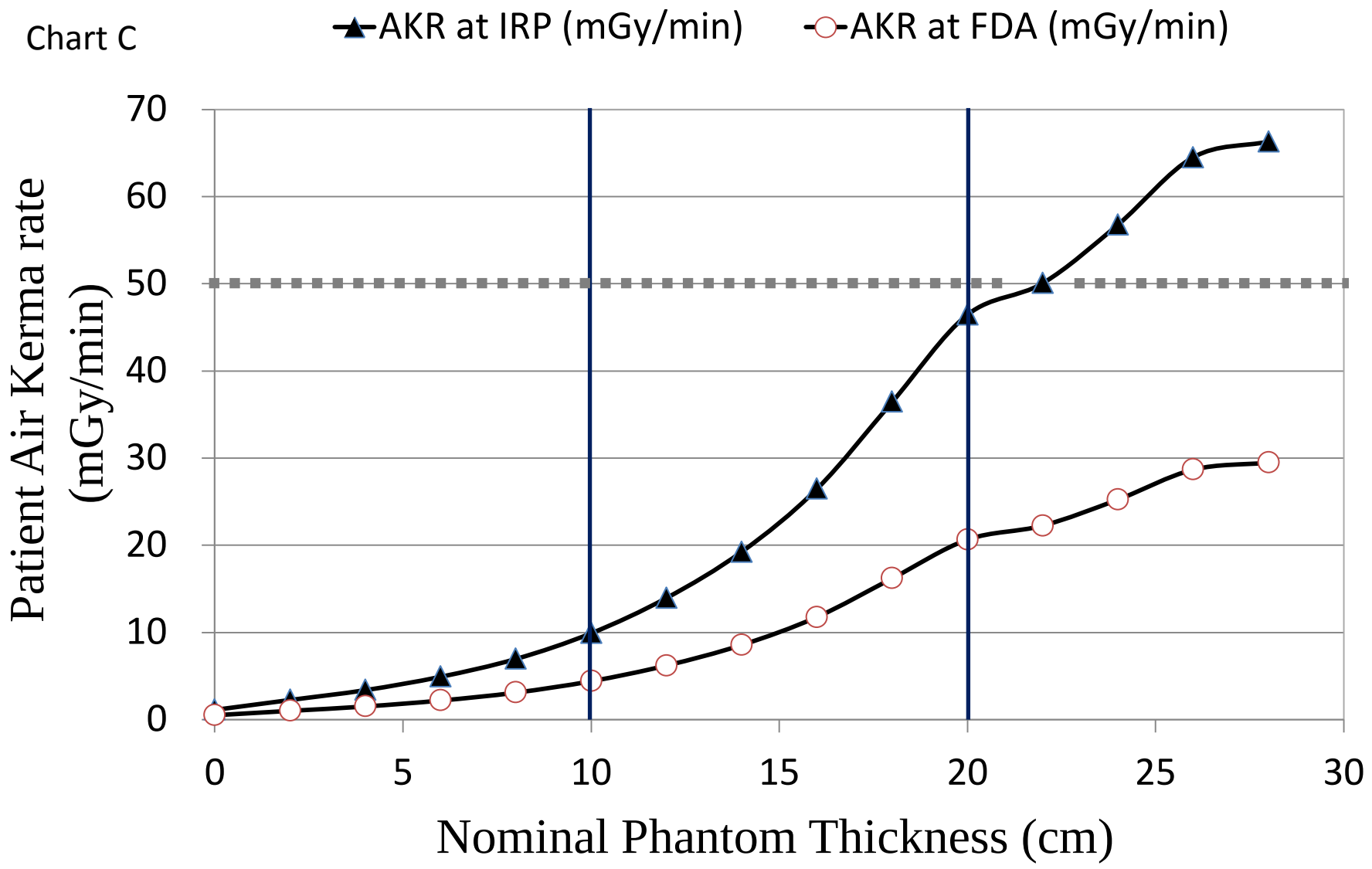
Chart C
AKR at IRP (mGy/min)
AKR at FDA (mGy/min)
Patient Air Kerma rate (mGy/min)
70
60
50
40
30
20
10
0
0
5
10
15
20
25
30
Nominal Phantom Thickness (cm)