

Radiation Doses in Interventional Radiology Procedures: The RAD-IR Study

Part III: Dosimetric Performance of the Interventional Fluoroscopy Units

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PURPOSE: To present the physics data supporting the validity of the clinical dose data from the RAD-IR study and to document the performance of dosimetry-components of these systems over time.

MATERIALS AND METHODS: Sites at seven academic medical centers in the United States prospectively contributed data for each of 12 fluoroscopic units. All units were compatible with International Electrotechnical Commission (IEC) standard 60601-2-43. Comprehensive evaluations and periodic consistency checks were performed to verify the performance of each unit's dosimeter. Comprehensive evaluations compared system performance against calibrated ionization chambers under nine combinations of operating conditions. Consistency checks provided more frequent dosimetry data, with use of each unit's built-in dosimetry equipment and a standard water phantom.

RESULTS: During the 3-year study, data were collected for 48 comprehensive evaluations and 581 consistency checks. For the comprehensive evaluations, the mean (95% confidence interval range) ratio of system to external measurements was 1.03 (1.00–1.05) for fluoroscopy and 0.93 (0.90–0.96) for acquisition. The expected ratio was 0.93 for both. For consistency checks, the values were 1.00 (0.98–1.02) for fluoroscopy and 1.00 (0.98–1.02) for acquisition. Each system was compared across time to its own mean value. Overall uncertainty was estimated by adding the standard deviations of the comprehensive and consistency measurements in quadrature. The authors estimate that the overall error in clinical cumulative dose measurements reported in RAD-IR is 24%.

CONCLUSION: Dosimetric accuracy was well within the tolerances established by IEC standard 60601-2-43. The clinical dose data reported in the RAD-IR study are valid.

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Abbreviations: DAP = Dose-area-product, IEC = International Electrotechnical Commission, IRP = Interventional Reference Point, PMMA = polymethylmethacrylate, the RAD-IR study = Radiation Dose in Interventional Radiology Study

SOME fluoroscopy-guided procedures are associated with a risk of radiation injury to the skin. For most interventional radiology procedures, there is little or no published information on skin dose, either for average dose or for the frequency with which skin dose exceeds a given threshold (1). A multicenter protocol was developed to create a radiation dose database for each of 21 different interventional radiology procedures. During a 3-year period, seven academic medical centers in the United States participated in the SIR Radiation

Dose in Interventional Radiology Study (RAD-IR), collecting data from 2,142 cases. The purpose of the RAD-IR study was to document the expected dose ranges resulting from interventional radiology procedures.

The results of the RAD-IR study are reported in several parts. Part I provided overall dose data for a number of interventional radiology procedures, identified procedures associated with higher radiation doses, analyzed the effect of operator training level on dose and provided recom-

mendations for recording overall dose (2). Part II provided skin dose data for the subset of cases where these data were collected (3).

This report presents the physics data that validate the reliability of the previously reported dosimetry data. It was necessary to validate the accuracy of the dosimetry for the duration of the RAD-IR project. As a result, we can report on the stability of these systems over time.

All RAD-IR systems were compliant with the dosimetric portions of the

International Electrotechnical Committee's (IEC) standard on safety for interventional fluoroscopes (IEC 60601-2-43) (4). (Basic information regarding the IEC is found in the Appendix.)

MATERIALS AND METHODS

Radiation Dose Quantities

The unmodified word "dose" is used with only one of its many meanings in this report and others of the RAD-IR series (a glossary of radiobiological terms is included in Parts I and II of the RAD-IR study) (2,3). In this report, dose means air-kerma without scatter. This meaning is consistent with the usage found in relevant Federal Drug Administration (FDA) and IEC documentation (4,5,6).

Skin dose can be calculated from air-kerma at the skin with use of well-known techniques and measurements of x-ray beam quality and field size at the skin. In the usual interventional radiology environment, the skin dose is approximately 40% greater than the air-kerma.

Dose-Area-Product (DAP) is defined as the integral of dose in the

entire x-ray beam. DAP includes field nonuniformity effects, such as anode-heel-effect, and the use of semitransparent beam-equalizing shutters (eg, lung shutters). DAP is a constant when measured at any distance beyond the final system collimators. DAP can be measured by placing a transmission full-field ionization chamber in the beam between the final collimators and the patient.

Cumulative dose is measured at an arbitrary reference point. The IEC defines the interventional reference point as 15 cm from isocenter toward the x-ray tube (4). Dose and dose rate delivered at a reference point can be obtained either by physical measurement or by calculation.

Dosimetry Components of Imaging Systems in the RAD-IR Study

All interventional fluoroscopy systems used for this study were required to be compliant with the patient dosimetry portions of the IEC standard for safety of interventional fluoroscopic systems (IEC 60601-2-43) (4). At the time that the RAD-IR project was initiated, only a few models of one manufacturer's equipment provided

integrated dosimetry. Compliant accessory instrumentation was available for all major equipment models, but to simplify data acquisition and analysis the authors only recruited sites with integrated instrumentation.

Dose data were displayed digitally in fixed format in units of milligray (mGy). Because of the discrete display of the least-significant-digit, there is a display uncertainty of ± 0.5 mGy in all reported data.

Twelve interventional fluoroscopy units were enrolled in the project. These included four biplane neurological systems (Neurostar, Siemens Medical System, Malvern, PA) and eight single plane body systems (Multistar, Siemens Medical System). Thus, data were available from 16 individual imaging planes. These systems incorporate most modern dose-management technologies.

Each laboratory independently purchased its interventional systems, including the integrated dosimetry instrumentation used for the RAD-IR study, prior to its enrollment in the project. All systems were delivered, installed, and maintained following normal service procedures. They were routinely configured to meet the clinical requirements of each site, with the factory standard settings as a starting point. Configuration settings usually vary for different anatomical regions and clinical tasks. Thus, the data collected from each site represents normal clinical practice at that site.

Skin-dose mapping components were added to several of the systems over the course of the study. This equipment gave us the ability to determine peak skin dose. No additional dosimetry checks were performed on these components.

The primary radiation sensor in each unit is a DAP transmission ionization chamber. At any moment in time, the imaging system's electronics know the position of the beam-defining collimators. The system calculates the average dose rate at the chamber by dividing the measured DAP rate by the known field size. An inverse-square calculation then determines the dose rate at the interventional reference point (IRP). Integrating measured dose rates during the procedure yields total DAP and cumulative dose at the IRP. Dose readings are displayed at

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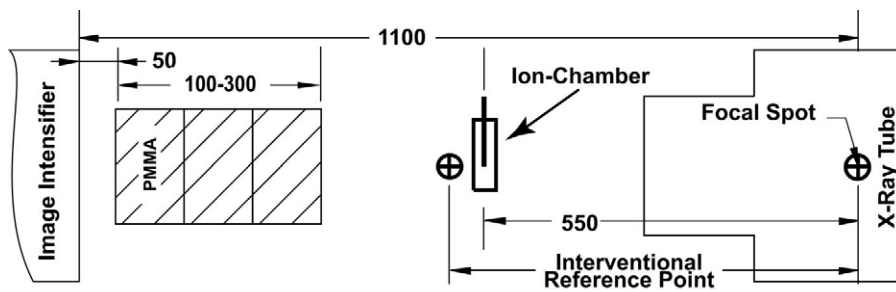
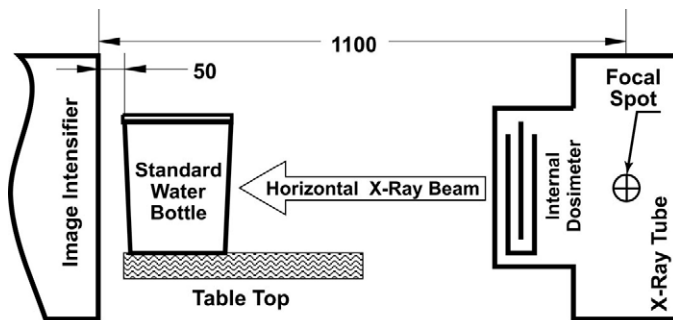
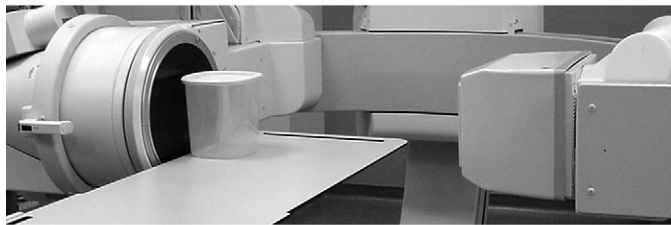


Figure 1. Measurement setup for the comprehensive physics protocol. The internal dosimeter is compared to a calibrated external ionization chamber placed in a low-scatter environment.



a.



b.

Figure 2. Schematic (a) and photograph (b) of measurement setup for consistency checks. The container is filled with tap water for use.

the operator's console and the table-side display on each fluoroscopic unit.

The DAP measurement includes the effect of density equalization by the semitransparent blades. However, the calculation of dose and dose rate assumes a uniform radiation distribution across the whole field of view. The calculation simply divides DAP by the field size defined by the beam-limiting collimator. The maximum dose rate in the field is underestimated when the semitransparent blades are used. As an example, if the semitransparent blades cover 25% of the field, the actual dose and dose-rate in the open portion of the field are underestimated by 10%.

When each system is manufactured, the dosimetry components are

calibrated to within the 25% tolerance specified by the IEC standard (4,7,8). The DAP ionization chambers are supplied by the manufacturer (Physikalisch-Technische Werkstätten, Freiburg, Germany) with a calibration certificate over the range from 50 kV, 2.5 mm Al HVL to 140 kV, 3.8 mm Al HVL. These data are used to determine a mean chamber factor. The fluoroscopic equipment manufacturer applies a further empirical correction. This correction is a weighted average of the under-the-table (tabletop and mattress in the beam) and lateral/over-the-table position. This empirically established correction yields a 6% overestimation if the tube is under the table and a 7% underestimation if the tube is in a lateral or over-the-table position. A further uncertainty in skin dose occurs

when nonstandard mattresses are used clinically (9). The mattress effect was not investigated in the RAD-IR study.

Dosimetry Tracking

The behavior of each of the 16 individual imaging planes (eight imaging planes from the eight single-plane fluoroscopic units and eight imaging planes from the four biplane fluoroscopic units) included in the RAD-IR study was tracked over time using two separate protocols. An imaging plane consists of an x-ray tube and an image intensifier linked by a C-arm.

A 'comprehensive physics protocol' was performed when each system was initially enrolled in study, after major repairs, and at the conclusion of the study. Measurements were made with use of each site's clinical 'cerebral' (for Neurostar [Siemens Medical Systems] units) or 'renal' (for Multistar [Siemens Medical Systems] units) system setting. These measurements differ from conventional physics testing in that each measurement set records the behavior of the integrated dosimeter for a range of simulated patient thickness.

The consistency protocol determined the consistency of the dosimetry with use of a standardized phantom. Consistency data sets were obtained on each plane at intervals, mostly in a 1- to 2-week time interval. The consistency data were tracked over time; substantial changes triggered service investigation of the affected unit.

Comprehensive Physics Protocol

Each institution's physicist and staff members performed these evaluations at their own site. The manufacturer's field service engineers assisted on some occasions. Each site was responsible for the selection and calibration its own reference chamber dose. A calibration or compliance certificate was required for each reference chamber.

An overview of the measurement geometry is shown in **Figure 1**. Measurements were made with low scatter conditions at a standard distance from the focal spot of the x-ray tube. Nine data points were taken at each session. The outputs from two fluoroscopic and one acquisition mode were mea-

Table 1
Summary Statistics: Comprehensive Dosimetry Measurements

	Ratio of System to Probe Measurements*					Non-normalized Meant†
	Sample Size	Mean	95% CI	Median	Standard Deviation	
All 30 cm PMMA	144	0.93	0.91–0.95	0.90	0.13	Acquisition mGy/Frame 11.8
All 20 cm PMMA	144	0.99	0.97–1.01	0.97	0.14	5.3
All 10 cm PMMA	143	1.06	1.02–1.11	1.06	0.27	0.5
All Continuous Fluoroscopy	144	1.03	0.99–1.07	1.02	0.24	20 cm PMMA mGy/min 28.3
All Pulsed Fluoroscopy	143	1.02	1.00–1.05	1.01	0.16	14.0
All Fluoroscopy	287	1.03	1.00–1.05	1.02	0.20	—‡
All Acquisition	144	0.93	0.90–0.96	0.90	0.17	mGy/Frame 5.3
All Data	431	0.99	0.98–1.01	0.98	0.20	—‡

* Expected value = 0.93.

† Pooled over all biplane (neuro) and monoplan (body) systems.

‡ Further pooling is not appropriate.

sured with use of three thicknesses of polymethylmethacrylate (PMMA) attenuators (various manufacturers, depending on the site). The distance between the attenuator and the image intensifier was held constant.

Reference measurements were obtained at 55 cm from the focal spot and compared to the cumulative dose readings from the integrated dosimeter in the fluoroscopic unit. The 55-cm distance corresponded to the location of the IRP in the draft version of IEC standard 60601-2-43. The location of the IRP was changed in the final version of the IEC standard (4). The equipment manufacturer then changed the software calculations for cumulative dose in corresponding fashion. The date of installation of the software change was recorded for each system. All prior integrated dosimeter measurements were corrected to correspond to the final IEC IRP.

Data were submitted to the central data collection site immediately. The study design required agreement of $\pm 25\%$ between the reference measurements and the readings of the integrated dosimeter.

Periodic Consistency Checks

A simplified protocol was used to assure consistent behavior of the dosimeters in the intervals between comprehensive checks. The project's de-

sign allowed intervals ranging from 1 week to 1 month between these consistency checks.

This study used a 4.95 L water-bottle phantom (Rubbermaid model 3922; Rubbermaid, Inc., Wooster, OH). It is 21.5 cm in height and 18.5 cm \times 18.5 cm at the top and 17.0 cm \times 17.0 cm at the base. The water bottle was filled with tap water prior to use.

The geometry used for the consistency checks is shown in **Figure 2**. The study required consistent imaging gantry setup and water bottle placement to minimize setup variations as a source of experimental error.

The dose rates for the single most commonly used fluoroscopic mode were determined by integrating 60 seconds of fluoroscopy, and for one acquisition mode by integrating 10 acquisition frames. System settings and operating parameters were also recorded.

Individual sites were required to maintain trend information. This alerted the facility to system instabilities. Data were also immediately submitted to and reviewed at the central data collection site. The project's dosimetry consistency requirement was $\pm 25\%$. This value was selected prospectively based on expected IEC tolerances on dosimeter accuracy. (The final published IEC tolerance for dosimeters built into interventional fluoroscopes is $\pm 50\%$ for readings above

100 mGy (4).) Sites with greater inconsistency were instructed not to contribute any further data to the project until the system was restored to proper operation.

RESULTS

Comprehensive Physics

Forty-eight sets of comprehensive physics measurements were collected during the course of the study, with two to five data sets collected on each individual imaging plane. All sites completed initial and final evaluations for each plane. As anticipated, some imaging planes required additional measurements after x-ray tube replacement.

The reference ionization chambers used at each site were required to have a current compliance or calibration certificate, were presumed to be accurate and were used as standards of reference. Given the level of expected uncertainty in the clinical instruments, the protocol did not document the uncertainties of the individual reference ionization chambers. Therefore, dividing the built-in reading by the reference chamber's reading normalized each measurement. For geometry (measurements obtained with a horizontal beam), the expected value is 0.93. This reflects the effect of the manufacturer's application of the average-angulation-attenuation-factor.

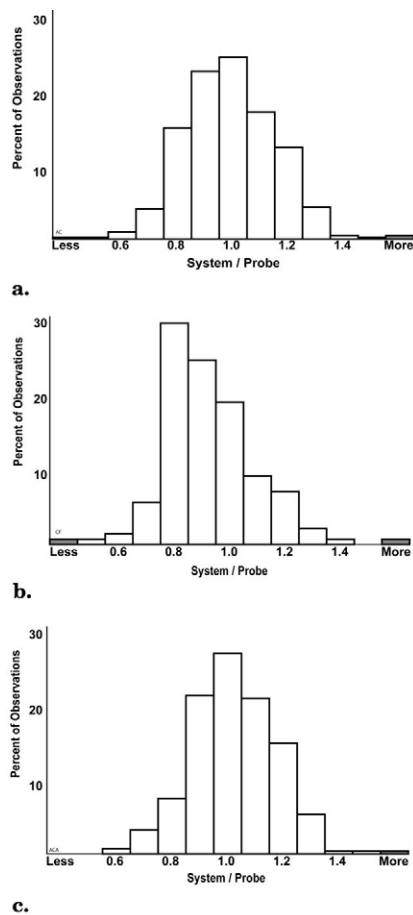


Figure 3. Histograms of comprehensive measurements. The plotted parameter is the ratio of the reading of the integrated dosimeter (part of the imaging system) divided by the reading of the external ionization chamber. **(a)** Histogram of all of the ratios observed during the course of the project. The pooling includes all sites, all measurements, all modes, and all PMMA thicknesses. **(b,c)** Subsets of pooled fluoroscopic and acquisition (fluorographic) measurements. IEC tolerance for the integrated dosimeter is 25%. The IEC tolerance for an interventional system is 50% for readings greater than 100 mGy. Please refer to the discussion for further details. Solid columns represent data less than or greater than the range of 0.5 to 1.5.

Table 1 provides descriptive statistics for various subsets of the comprehensive physics dosimetry data. These data are depicted graphically in **Figure 3**. The effect of PMMA thickness (a surrogate for patient thickness) is shown in **Figure 4**.

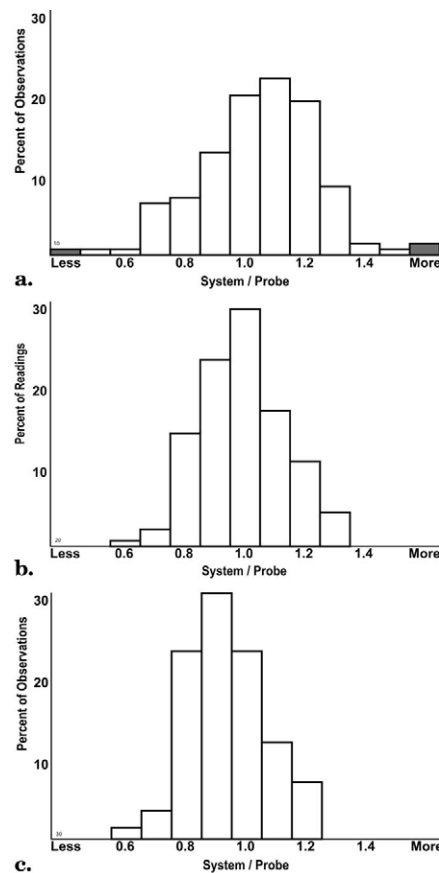


Figure 4. Histograms of effects of **(a)** 10 cm, **(b)** 20 cm, and **(c)** 30 cm PMMA (patient surrogate) thickness. All comprehensive data (fluoroscopy and acquisition) for each thickness has been pooled.

Consistency Checks

Time interval between measurements.—The RAD-IR study lasted 3 years (2,3). This mandated periodic verification of the performance of the integrated dosimeters. The project protocol specified that a consistency check be performed at weekly to monthly intervals. Most sites had more than one interval of 30 days or more between checks (**Fig 5**). Several of these long intervals occurred during periods in which no clinical data were collected. Thus, 96% of the clinical case data were collected within 30 days of the most recent consistency check. More than half of the clinical cases were collected within 1 week of a consistency check (**Table 2**).

Measurements

The absolute dose values varied from site to site. Fluoroscopic readings were in the range of 2 to 12 mGy for 60 seconds of irradiation. Acquisition readings were in the range of 6 to 59 mGy. As a result, last digit effects proved to be a major factor in the uncertainty of the consistency measurements. Site-to-site variations in dose values were due to variations in the dose mode selection, kVp curve selection and beam filtration at each individual site, in addition to differences between the location of the IRP in Multistar and Neurostar systems (Siemens Medical System).

The basic programming at most of the sites was not changed during the course of the study. However, normal clinical changes were made to the programming in one biplane and one monoplane laboratory. These changes were reflected as step changes in the consistency measurements. Because this was the result of deliberate reprogramming for clinical reasons, the authors did attempt to compensate for these changes. A mean value was calculated for each imaging plane. The data were normalized, using these mean values, on a plane-by-plane basis. The normalized data from the frontal and lateral planes of biplane systems were pooled. (Because each plane is normalized to itself, no further normalization is required to pool the planes of the biplane systems.) Finally, the data from all the systems was pooled. Overall descriptive statistics of the consistency measurements are shown in **Table 3**. Histograms of the overall data pools are shown in **Figure 6**.

DISCUSSION

Sources of error in cumulative dose measurements include DAP sensor output, conversion of DAP to cumulative dose and reference ionization chamber accuracy. Variations in the output of the DAP sensor result from variations in beam energy and filtration, DAP rate, irradiation time, field size, operating voltage, local air pressure, temperature, humidity, and electromagnetic compatibility. The range of phantom material thickness and exposure modes used for comprehensive physics measurements represents the

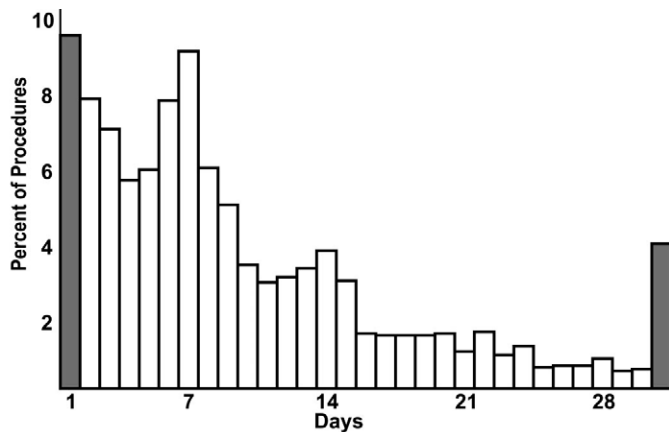


Figure 5. Days between last consistency check and clinical procedure. Minimum (0–1 days) displayed as 1 day and more than 30 days displayed as 31 days.

Sample Size	2142
Minimum	1
Maximum	118
Mean	11
10th Percentile	2
25th Percentile	4
Median	7
75th Percentile	14
90th Percentile	22

typical range encountered in patient imaging—each system was evaluated for a clinical range of kVp, beam filtration selection, and exposure rates. Differences in environmental conditions at the clinical sites (air pressure, temperature, and humidity) over time, and between the test facility and the clinical sites, also contribute to measurement error. With all uncertainty contributions combined, an IEC compliant DAP meter provides an output with a relative uncertainty of no more than 25%. (7,8)

The conversion of the measured DAP to air kerma at the IRP requires estimation of the x-ray beam field size. During system calibration, collimator blade positions are localized to within ± 1 mm at the plane of the image receptor and the source-image distance is localized to within ± 1 mm. For a 20-cm \times 20-cm field-of-view at the image receptor, the upper boundary on the field size error is $\pm 2\%$.

For low-dose measurements, the

digital display also introduces error. Cumulative dose is displayed in whole numbers in units of mGy. In IEC 60601-2-43, the tolerance on air kerma values is specified as $\pm 50\%$ for values greater than 100 mGy (4). Cumulative dose is displayed on the fluoroscope in whole numbers in units of mGy. Therefore, mGy resolution of the display is more than sufficient to maintain the stipulated accuracy.

Dose values were determined by subtracting two whole number readings. Assuming an error of ± 0.5 digit in each reading, the upper boundary on the digital display error in each dose value is 1.0. This source of error explains the larger SD seen in 10-cm PMMA system dose-to-probe dose values where system dose averaged 4 mGy. It is estimated that digital display error contributes 3% to the total error in system to probe ratio measurements in the comprehensive physics evaluations.

Fluoroscopic acquisition times of 60 seconds and fluorographic acquisitions of 10 frames were chosen for convenience. Retrospectively, the experimental design should have required fluoroscopic and fluorographic runs sufficient to generate readings of approximately 50 mGy. Digital display error was not a significant contribution to patient cumulative dose measurements in the RAD-IR study because only six of 2,142 cases (0.3%) had cumulative dose measurements less than 20 mGy in an individual plane.

Most of the comprehensive physics measurements in this study were less

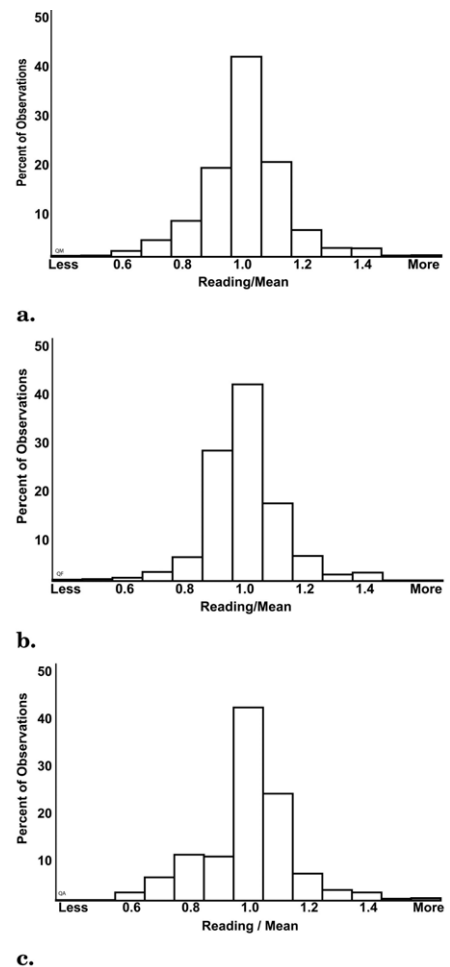


Figure 6. Consistency measurements. The plotted parameter is the ratio of an individual reading to the mean reading for that plane observed during the entire study.

than 100 mGy. Of the 431 comprehensive physics data points collected, two were just outside of the $\pm 50\%$ error range. Both data points were acquired at low dose levels so that digital display error is a significant error contribution. These measurements fall within $\pm 50\%$ with a change of ± 1 digit in the system dose display. The single remaining outlier is so far outside the expected range that it is most likely bad data. Based on the observations reported in Table 1, the authors conclude that the accuracy of the dosimeters integrated into the clinical fluoroscopic systems is within the acceptable range.

Periodic consistency checks were used to monitor system performance over time. The overall standard deviation (SD) in relative dose values pro-

Table 3
Summary Statistics: Consistency Dosimetry Measurements

	Ratio of Individual to Pooled Measurements					Non-normalized Mean
	Sample Size	Mean*	95% CI	Median	Standard Deviation	
Biplane Fluoroscopy†	343	1.00	0.97–1.03	0.99	0.16	mGy/min 5.3
Monoplane Fluoroscopy‡	409	1.00	0.98–1.02	1.03	0.10	7.1
All Fluoroscopy	752	1.00	0.98–1.02	1.00	0.13	—§
Biplane Acquisition†	343	1.00	0.96–1.04	1.02	0.19	mGy/frame 1.62
Monoplane Acquisition‡	409	1.00	0.98–1.02	1.02	0.11	2.77
All Acquisition	752	1.00	0.98–1.02	1.02	0.15	—§
All Data	1504	1.00	0.99–1.01	1.02	0.14	—§

* Each plane was separately normalized using the mean value of all measurements obtained on that plane during the study. Thus, all mean values are 1.00 by definition.

† All biplane systems were tested using the site's 'cerebral technique'.

‡ All monoplane systems were tested using the site's 'renal technique'.

§ Further pooling of non-normalized data is inappropriate.

vides an indication of error caused by changes over time. System-related sources of variation in the dose values include variations in DAP sensor output and variations in system automatic exposure control operation.

For the DAP sensor, output variations can result from changes in pressure, temperature, humidity and drift in the sensor electronics. Error in the digital display also contributes to the overall error. Display error was particularly severe for fluoroscopy measurements in biplane systems, where the average dose was 6 mGy. At this dose, a digital display error of ± 1 digit causes an error of 17%.

Variations in automatic exposure control operation can result from changes in the imaging chain, including changes in dose-rate settings made by individual sites during the course of the study. This type of variation is not expected to affect the accuracy of the dose readout. The observed variation was increased by a design error in the experiment. The water bottle has a slight vertical taper and variations in bottle positioning at each site caused small changes in output and integrated dose. For all these reasons, the observed SD in consistency dose readings overestimates the actual error.

The overall error in patient cumulative dose measurements for the RAD-IR study can be estimated as the root mean square combination of com-

prehensive (20%) and consistency (14%) SD. This results in an overall error of 24%. Due to the inclusion of digital display error and variations in automatic exposure control, this is a likely upper boundary on the expected error.

The 48 sets of comprehensive measurements, including dose measurements an order of magnitude less than 100 mGy, document dosimetric accuracy well within the IEC tolerance. The results of the 581 consistency measurements testify to the stability of modern interventional fluoroscopy equipment.

Appendix: The International Electrotechnical Commission (IEC)

The object of the IEC is to promote international cooperation on all questions of standardization and related matters, such as the verification of conformity to standards, in the fields of electricity, electronics and related technologies. This is achieved by issuing publications, including international standards.

A recently approved IEC document, IEC 60601-2-43: Particular requirements for the safety of x-ray equipment for interventional procedures, is of major importance to the interventional radiology community (4). In addition, this document was an important resource in the development of proposed revisions to the FDA

regulations for all fluoroscopes (6). Interventional systems meeting this standard are marked as such. The objectives of this Safety Standard are:

- (i) to establish safety requirements for the design and manufacture of x-ray equipment for prolonged radioscopy (the IEC term for fluoroscopy)-guided interventional procedures;
- (ii) to specify information that is to be provided with such equipment for the assistance of the user and operator in managing the radiation risk arising from these procedures that could affect patients and staff.

The imaging equipment used in all of the laboratories enrolled in the RAD-IR study met the dosimetry requirements of the existing draft of this standard when the project began. A minor change in the definition of the dose reference point in the final document necessitated a correction factor for some of the cumulative dose data at the conclusion of the study (2). All data reported from this project are based on the definitions found in the final published standard.

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