Guidelines for Patient Radiation Dose Management

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Abbreviations: ACR = American College of Radiology, FDA = Food and Drug Administration

THE membership of the Society of Interventional Radiology (SIR) Safety and Health Committee represent experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, these Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr, Ste 400 North, Fairfax, VA 22033.

METHODOLOGY

The SIR produces its safety-related documents using the following process. Documents of relevance and timeliness are conceptualized by the Safety and Health Committee members. A recognized expert is identified to serve as the principal author for the document. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles and regulatory documents is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is evaluated and used to write the document such that it contains evidence-based data, when available.

When the literature evidence is weak, conflicting, or contradictory, consensus is reached by a minimum of 12 Safety and Health Committee members. A Modified Delphi Consensus Method (Appendix A [1]) is used when necessary to reach consensus. For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Safety and Health Committee members, either by means of telephone, conference calling, or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input and criticism during a 30-day comment period. These comments are discussed by the Safety and Health Committee, and appropriate revisions are made to create the finished document. Before its publication, the

document is endorsed by the SIR Executive Council.

INTRODUCTION

In the early 1990s, the U.S. Food and Drug Administration (FDA) received reports of significant radiation-induced skin injuries associated with interventional fluoroscopy (2), prompting the release in 1994 and 1995 of three guidance publications on documenting radiation use (3–5). A number of professional radiological societies, including the SIR, have been working since then to reduce the frequency of these events. In 2007, the American College of Radiology (ACR) published its recommendations on issues related to patient radiation exposure in medicine. This document focuses mostly on diagnostic imaging procedures, such as computed tomography (CT) and nuclear medicine, and not interventional procedures (6). The ACR's 2008 revision of the Technical Standard pertaining to the management of the use of radiation in fluoroscopically guided procedures (7) takes a different, but complementary, approach to the topic than that used in this SIR guideline. Fluoroscopically guided invasive procedures may require the use of significant quantities of radiation for their completion. This can put patients at risk for deterministic radiation injuries. In addition, all irradiated patients are at risk for an increased incidence of stochastic injuries.

These guidelines are written to be used for radiation dose management related to interventional radiologic procedures. The most important processes of care are (*a*) patient selection, (*b*) procedure performance, (*c*) patient monitoring, and (*d*) appropriate documentation and follow-up. The outcome measures or indicators for these processes are individualized patient radiation risk assessment, appropriate informed consent relating to radiation risk, and compliance with recording administered dose.

Concerns over patient radiation doses are valid. Nonetheless, it must be clearly understood that the goal of all interventional radiology procedures is to treat patients and thereby improve their well-being. This will almost always require administration of some radiation and may sometimes require the administration of clinically significant amounts of radiation. In general, the risk of radiation is low compared to other procedural risks, and the benefits of imaging guidance are great (8). Image-guided procedures typically cause less morbidity and mortality than the equivalent surgical procedure. An informed patient will virtually always agree that the potential harm due to radiation is less than the potential harm due to a procedure that is cancelled, incomplete, or clinically inadequate because of concerns over radiation.

DEFINITIONS

Absorbed Dose

The energy imparted per unit mass by ionizing radiation to matter at a specified point. The International System of Units (SI) unit of absorbed dose is the joule per kilogram. The special name for this unit is the gray (Gy). For purposes of radiation protection and assessing dose or risk to humans in general terms, the quantity normally calculated is the mean absorbed dose in an organ or tissue.

Air Kerma

The energy extracted from an x-ray beam per unit mass of air in a small irradiated air volume. Air kerma is measured in grays. For diagnostic radiographs, air kerma is the dose delivered to that volume of air.

Biologic Variation

With respect to radiation, the differences among individuals in the threshold dose required to produce a deterministic effect or the differences in degree of effect produced by a given dose. Biologic variation may be idiopathic, due to underlying disease, or due to patient age. The skin on different parts of the body and different skin types vary in radiosensitivity (9).

C-arm Fluoroscopic System

A fluoroscopic system consisting of a mechanically coupled x-ray tube and image receptor. Such systems typically have two rotational degrees of freedom (left-right and cranial-caudal). Most of these systems have an identifiable center of rotation called an isocenter. An object placed at the isocenter remains centered in the beam as the C-arm is rotated. C-arm fluoroscopes may have either fixed or variable source-to-image receptor distance. Radiation protection strategies differ for these different classes of systems.

Cumulative Dose (CD)

See Reference point air kerma.

Deterministic Effect

Detrimental health effect for which the severity varies with the dose of radiation, and for which a threshold usually exists (ie, causally determined by preceding events). The effect is not observed unless the threshold is exceeded, although the threshold dose is subject to biologic variation. Once the threshold dose is exceeded in an individual, the severity of injury increases with increasing dose. Examples of deterministic effects include skin injury, hair loss, and cataracts.

Dose

General term used to denote mean absorbed dose or effective dose. The particular meaning of the term should be clear from the context in which it is used. In this document "dose" means the absorbed dose to tissue unless otherwise specified.

Dose-Area-Product (DAP)

See Kerma-area-product.

Effective Dose (E)

The sum, over specified tissues, of the products of the dose in an organ and the tissue weighting factor for that tissue. Current techniques for estimating effective dose use computer simulation based on a "model" body and statistical simulations of radiation exposure. This yields only a gross approximation of effective dose. The stochastic risk to an average member of an irradiated population is expressed in terms of sieverts (Sv). Effective dose is often used in the literature to roughly estimate the radiogenic risk to an individual. Age and sex modifiers, appropriate to the irradiated individual, should be applied to such calculations.

Fluorographic Image

A single recorded image obtained by using an image intensifier or digital flat panel as the image receptor. A digital angiographic "run" consists of a series of fluorographic images.

Fluoroscopy Time (FT)

The total time that fluoroscopy is used during an imaging or interventional procedure.

Interventional Reference Point (IRP)

For isocentric fluoroscopic systems, the interventional reference point is located along the central x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot (10,11). The interventional reference point is close to the patient's entrance skin surface. The FDA prescribes the location of the interventional reference point for several non-isocentric geometries (11).

Isocentric Fluoroscopic System

An imaging system in which there is a point in space through which the central ray of the x-ray beam passes regardless of beam orientation. This point is called the isocenter. An object placed at the isocenter will not move across the field of view as the imaging system is rotated.

Kerma

Kinetic energy released in matter; the energy extracted from an x-ray beam per unit mass of a specified material in a small irradiated volume of that material (eg, air, soft tissue, bone). Kerma is measured in grays. For the x-ray energies covered in this report, the kerma produced in a small volume of material delivers its dose to the same volume (which is not true in high-energy radiation therapy).

Kerma-Area-Product (P_{KA})

The integral of air kerma across the entire x-ray beam emitted from the x-ray tube. Kerma-area-product is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. Kerma-area-product

Table 1 Kerma-area-product Unit Conversion	
Unit Used	To Convert to Gy · cm²
dGy · cm²	divide by 10
cGy · cm²	divide by 100
mGy · cm²	divide by 1,000
μGy · m²	divide by 100

is measured in Gy · cm². Conversion from units reported by commonly used equipment are given in **Table 1**. Kerma-area-product is usually measured without scatter. This quantity was previously called dose-area-product. Earlier publications used the abbreviations 'KAP' and 'DAP' for this quantity.

Peak Skin Dose (PSD)

The highest dose at any portion of a patient's skin during a procedure. Peak skin dose includes contributions from both the primary x-ray beam and from scatter. Peak skin dose is measured in grays (to soft tissue).

Qualified Medical Physicist

An individual who is competent to practice independently one or more of the subfields of medical physics. The ACR recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics (7). The medical physicist must also be familiar with the relevant clinical procedures.

Reference Point Air Kerma ($K_{a,r}$)

The air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (see interventional reference point above) during a procedure. Reference point air kerma does not include backscatter and is measured in grays. Reference point air kerma is sometimes referred to as reference dose, cumulative dose, or cumulative air kerma. Earlier publications used the abbreviations 'CD' and 'RPDose' for this quantity.

Significant Radiation Dose

A selected threshold value that is used to trigger additional dose manage-

ment actions. There is no implication that a dose below the significant dose level is safe or that a dose above the significant dose level will always cause an injury.

Stochastic Effect

A radiation effect whose probability of occurrence increases with increasing dose but whose severity is independent of total dose. Radiation-induced cancer is an example.

Threshold Dose

The minimum radiation dose at which a specified deterministic effect can occur. Threshold doses differ among individuals as a result of biologic variation. The threshold dose for skin injury also differs in different anatomic sites on the same individual.

BACKGROUND

Interventional radiology differs from diagnostic imaging in that interventional radiology procedures are generally therapeutic, thus shifting the risk-benefit ratio for radiation exposure. However, the radiation dose for some interventional procedures may be several orders of magnitude greater than that for simple radiographic studies. A major intervention, such as transcatheter embolization, can deliver an effective dose to the patient of 100 mSv, whereas a typical chest radiograph delivers 0.1 mSv. This can often be reduced if the operator adheres to the principle of ALARA (as low as reasonably achievable) (12).

Deterministic injuries occur only after the radiation dose to the tissue exceeds a given threshold dose. In interventional fluoroscopy procedures, the tissue of concern is the skin—although the lens of the eye is another consideration. The skin at the site where radiation enters the body receives the highest radiation dose of any body tissue. Once the threshold dose is exceeded, the injury becomes progressively more severe with increasing dose, although the true severity of major injuries will only become apparent weeks to months after the procedure (**Table 2**). Very high doses usually produce some symptoms within 24 hours of the procedure.

The incidence of deterministic in-

Table 2
Deterministic Effects of Single-delivery Radiation Dose to the Skin of the Neck, Torso, Pelvis, Buttocks, and Arms

Band	Single-site Acute Skin Dose Range (Gy)*	National Cancer Institute Skin Reaction Grade	Approximate Time of Onset of Effects			
			Prompt (<2 wk)	Early (2–8 wk)	Midterm (6–52 wk)	Long Term (>40 wk)
A1	0–2	NA	No observable effects expected			
A2	2–5	1	Transient erythema	Epilation	Recovery from hair loss	None expected
B	5–10	1	Transient erythema	Erythema, epilation	–Recovery –At higher doses, prolonged erythema, permanent partial epilation	–Recovery –At higher doses, dermal atrophy and/or induration
C	10–15	1–2	Transient erythema	–Erythema, epilation –Possible dry or moist desquamation –Recovery from desquamation	–Prolonged erythema –Permanent epilation	–Telangiectasia† –Dermal atrophy and/or induration –Skin likely to be weak
D	>15	3–4	Transient erythema After very high doses, edema and acute ulceration; long-term surgical intervention likely to be required	–Erythema, epilation –Moist desquamation	–Dermal atrophy –Secondary ulceration due to failure of moist desquamation to heal; surgical intervention likely to be required –At higher doses, dermal necrosis; surgical intervention likely to be required	–Telangiectasia† –Dermal atrophy and/or induration –Possible late skin breakdown –Wound might be persistent and progress into a deeper lesion –Surgical intervention likely to be required

Note.—This table is applicable to the normal range of patient radiosensitivities in the absence of mitigating or aggravating physical or clinical factors. Abrasion or infection of the irradiated area is likely to exacerbate radiation effects. This table does not apply to the skin of the scalp. The dose and time bands are not rigid boundaries. Signs and symptoms are expected to appear earlier as the skin dose increases. NA = not applicable. Adapted from reference 13.
* Skin dosimetry is unlikely to be more accurate than ±50%.
† Refers to radiation-induced telangiectasia. Telangiectasia associated with an area of initial moist desquamation, or the healing of ulceration, may be present earlier.

juries increases with increasing body mass, the nature and complexity of the procedure, the radiation history of the patient, the presence of other disease processes (eg, diabetes mellitus), individual idiosyncrasy, and possibly other factors. The actual risk for major radiation injury is unknown. Based on estimates in the literature and reports to the FDA, the frequency is estimated to be between 1:10,000 and 1:100,000 procedures (14).

It should also be noted that prolonged fluoroscopy/fluorography with a peak skin dose greater than 1,500 rads (15 Gy) to a single field over a period of 6 months to 1 year is a reviewable sentinel event as mandated by the Joint Commission (15,16). The American Association of Physicists in Medicine is working to have the definition of this sentinel event modified because the Joint Commission defines a sentinel event as an "unexpected" (15) outcome and implies that a reviewable radiation overdose is "preventable" (16). In some circumstances, a planned intervention may require a sufficient dose of radiation to reach the Joint Commission's threshold for a sentinel event in order to achieve a life-preserving outcome—especially if the patient has had multiple fluoroscopically guided procedures or radiation therapy in the recent past, with radiation delivered to the same area of skin (17).

Although much of radiation dose management is based on sequelae that can be seen, albeit delayed weeks to months, stochastic effects must also be considered. The likelihood of stochastic effects increases with the total radiation energy applied to the patient. The principal injury is the induction of a malignancy. The probability of a radiation-induced malignancy caused by an invasive procedure is small compared to the "natural" frequency of malignancies. Based on published data, the frequency of fatal malignancy in the U.S. population is about 21% (18). With use of the linear no-threshold model, a typical interventional procedure is estimated to increase the risk of developing a fatal cancer by less than 0.5% in adults (estimating a worst-case effective dose of 100 mSv, which is multiplied by a risk of 5% per Sv [19]), assuming a normal life span. The probability of a new (non-radiation-induced) malignancy being diagnosed in the next 10 years is about 16.5% for a 60-year-old man (18). The possible radiogenic increase is too small

to be documented statistically in the entire worldwide interventional patient population.

It is particularly important to include the risk of stochastic effects in risk-benefit considerations when treating pediatric and young adult patients and when procedures involve substantial absorbed dose to radiosensitive organs, such as thyroid, breast, or gonadal tissue (3,20). The risk of cancer induction is elevated in children relative to that of adults because of their increased susceptibility to radiation and longer potential life span (21,22). The risk is approximately three times higher for newborns and declines to that of adults by the middle of the 3rd decade of life (21). Hence, additional consideration must be given to adolescent patients, who have an adult-sized body but a child's elevated risk coefficients. However, other than embolization of congenital arteriovenous malformations, the risk to children is lessened because many of the procedures performed on them are generally lower in complexity. Furthermore, children's smaller body mass generally results in lower doses—although in small children it is possible to impart a high dose to the whole body if poor collimation technique is used.

New technology has allowed reduction of both the fluoroscopic and fluorographic dose rates without reduction in image quality. However, the increasingly complex nature of many of the interventions performed may negate this technologic dose-rate savings, requiring the use of significant amounts of radiation for their completion.

As of 2008, no manufacturer sells fluoroscopic equipment capable of providing real-time monitoring of peak skin dose, although aftermarket methods for estimating peak skin dose are available (23,24). However, all equipment used in the United States provides total fluoroscopy time, and many systems manufactured within the past 15 years have kerma-area-product measurement capability. All equipment manufactured after June 10, 2006, and sold in the United States must also provide air kerma rate at the interventional reference point and cumulative air kerma (11). For several reasons, fluoroscopy time correlates poorly with peak skin dose (25), but if it is the only measurement available, it is better than not monitoring at all. Reference point air kerma correlates with peak skin dose better than does kerma-

area-product, although both reference point air kerma and kerma-area-product have wide variability for different instances of the same procedure (25,26). In the RAD-IR study (26), the linear regression between peak skin dose and reference point air kerma ($K_{a,r}$ is referred to in that document as CD) and the linear regression between peak skin dose and kerma-area-product (P_{KA} is referred to in that document as DAP) were as follows:

$$PSD \ (mGy) = 206 + 0.513 \times K_{a,r} \ (mGy)$$

$$PSD \ (mGy) = 249 + 5.2$$

$$\times P_{KA} \ (Gy \cdot cm^2) \ (\text{Note: the coefficient}$$

has been changed to allow use

of the more standardized units

for kerma-area-product).

It should be kept in mind that these "conversion formulas" are approximations and not precise replacements for actually measuring the peak skin dose. Particularly, they are invalid below reference point air kerma of about 500 mGy and/or kerma-area-product of about $50 \ Gy \cdot cm^2$, as the y-intercept was not forced to zero in the original calculations. However, they may be used to estimate the peak skin dose by using data that are more readily available.

In addition, all statements of patient dose contain some degree of uncertainty. Even the most sophisticated dose-measurement instrumentation has unavoidable uncertainties related to variations in instrument response with changes in beam energy, dose rate, and collimator size. Converting these measurements into skin dose introduces yet further uncertainties related to the patient's size and position relative to the beam. Finally, clinically available dose and kerma-area-product measurements ignore the effect of backscatter from the patient. Backscatter can increase skin dose 10%–40%, depending on the beam area and energy. Estimated skin doses may differ from actual skin dose by a factor of two or more. Users of dose data should be aware of these uncertainties.

Monitoring patient radiation dose must also be performed during CT-guided interventions. In CT-guided procedures, the initial localizing scan contributes the most to effective dose because it is distributed over a large

area. Scans obtained during guidance of the needle, catheter, or probe are the main contributor to the peak skin dose because they are repeatedly performed in approximately the same location (27,28). The cross-sectional images for guidance are obtained with reduced dose settings, and each delivers a factor of 5–15 times less peak skin dose relative to typical diagnostic scans.

CT fluoroscopy employs continuous low-dose CT with real-time image reconstruction and display. It generally increases patient radiation dose compared with conventional CT scans for guidance, where discrete scans are acquired intermittently between manipulations of the needle, catheter, or probe. However, the dose is highly dependent on the operator. The peak skin dose from CT fluoroscopy–guided procedures may reach those from other interventional procedures (29). To date, reports of skin effects due to CT are extremely rare and have been associated with the combination of repeated multidetector CT studies and fluoroscopic procedures in the same anatomic area (30).

The peak skin dose from CT performed without table incrementation is proportional to the tube current (in milliamperes) and exposure time (in seconds) and approximately proportional to the square of the tube potential (kilovolt peak), although this varies considerably between CT systems (31,32). Reducing any of these parameters will reduce peak skin dose, but image quality may be adversely affected due to an increase in image noise. Real-time dose monitoring uses indexes developed for CT scans in which the patient is translated through the x-ray beam and may overestimate the peak skin dose by a factor of up to two (31,33). This overestimated peak skin dose and the total procedure time are shown on the in-room monitors of almost all modern interventional CT systems and may result in an additional margin of safety for avoidance of skin injury.

The effective dose from a CT-guided interventional procedure is a relatively complex calculation based on indexes derived from standard dosimetry phantoms and specific to a particular scanner (31,32). It is not displayed on the system and must be estimated by a qualified medical physicist. Because the CT guidance scans cover a relatively thin section of anatomy and are performed with

greatly reduced dose settings (eg, milliampere seconds), the initial diagnostic quality scan obtained to localize the anatomy of interest is the primary contributor to the total effective dose. Estimates of effective dose for typical CT examinations can be found elsewhere (28,32).

SIR GUIDELINES

Radiation dose management requires a comprehensive approach including preprocedural planning, intraprocedural management, and postprocedural care. It also includes periodic quality assessment.

The informed consent process supplies patients, or their representatives, with sufficient information to make an appropriate decision regarding a proposed procedure. One purpose of this guideline is to ensure that the radiation elements of this informed consent process are appropriately implemented.

Radiation data are available to the operator during the course of a procedure. It is the operator's responsibility to be informed about dose levels and to include radiation dose in the continuous risk-benefit balance used to determine the value of continuing a procedure (8). When using a biplane system, each plane is considered independently unless the fields overlap, in which case doses are additive.

Participation by the radiologist in the follow-up of patients at risk is an integral part of radiation dose management. Close follow-up, with monitoring and management of radiation-induced injury or referral to another specialist, is appropriate for the interventional radiologist.

Preprocedural Planning

Individual training.—All operators should meet institutional requirements for privileges to use fluoroscopy. All nurses, technologists, and other personnel shall receive initial training in patient radiation management when beginning work in the interventional radiology suite. All staff shall also receive refresher training in radiation management that should occur at least annually. Radiation safety training should be in accordance with institutional policy and governmental regulations and generally will include review of the potential adverse effects of radiation on patients, operation of

the institution's fluoroscopic equipment, factors that affect patient dose, and measures that can be taken to reduce dose.

Equipment.—Rooms that are only equipped with fluoroscopy time monitoring should be avoided for procedures that may result in significant radiation dose.

Patient consent.—Radiation risks associated with interventional procedures should be discussed with patients as part of the preprocedure consent process, particularly when the expected dose of radiation may be high. Specifically, but not exclusively, the following procedures have been associated with an increased occurrence of significant radiation dose (34):

- embolization (including chemoembolization)
- renal and/or visceral angioplasty or stent placement
- transjugular intrahepatic portosystemic shunt creation or revision
- complex biliary intervention
- nephrostomy procedure for stone access
- complex, multilevel vertebral augmentation procedures (including vertebroplasty and kyphoplasty)

Radiation risks should also be discussed when the following patient criteria are met, especially when one of the above procedures is planned:

- weight less than 10 kg (22 lbs) or greater than 135 kg (300 lbs)
- intervention in pediatric and young adult patients involving substantial absorbed dose to radiosensitive organs (eg, lens of eye, breasts, gonads, thyroid); examples may include, among others, some embolization procedures, venous recanalizations, cardiac interventions, and some CT-guided interventions
- pregnancy
- procedure anticipated to be technically difficult, unusually prolonged, or that could, within a reasonable likelihood, result in a skin dose metric that will require follow-up (eg, if the operator's experience is such that performance of similar procedures has been associated with an average radiation metric of 50% of the below-noted patient follow-up thresholds)

- radiation therapy has been used or is planned for the same anatomic region
- procedures involving the use of radiation have been performed in the same anatomic region within the previous 60 days; previous irradiation should be reviewed in the context of the additional radiation that the patient is likely to receive

If it is considered desirable to include specific language in the consent form, the example given in Appendix B may be used. It must be remembered that informed consent is more than just a signed document; it is an active process between the physician and patient. A signed form without an adequately detailed dialogue is inadequate. Documentation that the radiation risk discussion was conducted and understood by the patient should be included in the patient's medical record. The patient's previous radiation exposure, including radiation therapy, should also be considered when planning the clinical approach to the current procedure.

Procedure planning.—In the past, because noninvasive diagnostic imaging methods were inadequate for procedure planning, interventional radiology procedures traditionally comprised diagnostic imaging followed by an intervention, all in the same session. This may no longer be necessary as the quality of diagnostic imaging has greatly improved across all modalities. Preprocedure imaging can assist in the planning of interventional radiology procedures, access routes, and selection of devices. All pertinent prior imaging studies should be reviewed and, when possible, outside images should be examined first-hand instead of simply reviewing reports. When appropriate and feasible, utilization of noninvasive cross-sectional imaging modalities (eg, ultrasonography, magnetic resonance [MR] imaging, MR angiography, MR cholangiopancreatography, CT, multidetector CT angiography) is recommended in the work-up of interventional radiology patients, with preferential use of imaging modalities that do not require the use of ionizing radiation. When CT is employed, there must be careful attention to dose reduction for the diagnostic study to decrease total-patient radiation dose. Decreasing the tube voltage and using automatic tube current modulation can result in substantial dose reduc-

Table 3
Summary of Radiation Monitoring Dose Notification Thresholds

Parameter	First Notification	Subsequent Notifications
Peak skin dose (PSD)	2,000 mGy	500 mGy
Reference point air kerma (K_a,r)	3,000 mGy	1,000 mGy
Kerma-area-product (P_{KA})	300 Gy · cm^2*	100 Gy · cm^2*
Fluoroscopy time (FT)	30 min	15 min

* Assuming a 100-cm^2 field at the patient's skin. The value should be adjusted to the actual procedural field size.

tions without compromising diagnostic image quality (35,36). Preprocedure diagnostic imaging may reduce procedure time and complication rates and reduce fluoroscopy time and the number of fluorographic images obtained.

Reconstructed images from MR angiography and multidetector CT angiography allow accurate depiction of anatomy and treatment planning. It is feasible to replace digital subtraction angiography with cross-sectional imaging as the initial modality for the evaluation of peripheral arterial disease (37,38). Although it requires radiation, use of multidetector CT angiography instead of digital subtraction angiography may result in a reduced total radiation dose to the patient (39). This must be balanced against the well-known limited ability of multidetector CT angiography to evaluate the lumen of extensively calcified arteries (40). For evaluation of acute gastrointestinal bleeding, multidetector CT angiography is a promising first-line examination that provides a time-efficient method for directing and planning patient therapy (41). There is probably also value in preprocedural cross-sectional imaging for procedures such as transjugular intrahepatic portosystemic shunt creation (42), percutaneous access for renal stone disease (43), and complex biliary interventions.

Finally, it must be understood that radiation is only one consideration in procedure planning. Other risks must be considered, such as adverse events due to iodine- and gadolinium-based contrast agents, the potential for misleading, confusing, or nondiagnostic preintervention imaging studies, and increased costs and lost time due to performing multiple tests. These issues must be carefully balanced for each individual patient and each clinical situation.

Intraprocedural Management

Procedural Radiation Monitoring.— Radiation dose is monitored throughout the procedure. This responsibility may be delegated to a technologist, nurse or other personnel depending on the institution's policy and needs and in accordance with relevant laws and regulations. The following rules should be applied in order of availability of radiation monitoring technology (**Table 3**):

- For fluoroscopy units that can provide estimates of peak skin dose, the operator is notified when this reaches 2,000 mGy, then every 500 mGy after that.
- For units with reference point air kerma capability, initial notification is given at 3,000 mGy and then every 1,000 mGy thereafter. Given the formulas above, this corresponds to an initial peak skin dose of about 1,800 mGy and an increment of about 500 mGy.
- For units with kerma-area-product capability, the notification level is based on a procedure-dependent nominal x-ray field size at the patient's skin. With use of a 100-cm2 field, the initial report would be at 300 Gy · cm^2 and subsequently at increments of 100 Gy · cm^2. Given the formulas above, this corresponds to an initial peak skin dose of about 1,800 mGy and an increment of about 500 mGy. Note that different brands of fluoroscopes report kerma-area-product using different units; conversion factors are given above in **Table 1** of the Definitions section.
- For units that can only monitor fluoroscopy time, the operator is notified when the total fluoroscopy time has reached 30 minutes and then in increments of 15 minutes or

less. Notification intervals should be reduced for procedures that involve a relatively large number of fluorographic images (including digital subtraction angiography and cineangiography). All fluoroscopes display fluoroscopy time. However, because of poor correlation with other dose metrics, it should be used with caution to monitor patient irradiation.

With regard to these notifications, the operator should consider the radiation dose already delivered to the patient and the additional radiation necessary to complete the procedure, along with other factors, in the continuing risk-benefit evaluation. It is understood that it is unlikely that a procedure will be stopped purely because of radiation dose concerns, as the clinical benefit of a successful procedure almost always exceeds any detriment to the patient due to radiation. However, if any of the above thresholds are met in the performance of a procedure, any dose for additional procedures performed within the subsequent 60 days should be closely monitored and generally should be considered additive to the dose already received. As previously stated, biplane systems are a special situation. The dose received from each plane should be considered independently when the fields do not overlap. When they do overlap the doses are additive.

Dose minimization techniques.— Throughout the procedure, the equipment should be operated at the lowest fluoroscopic dose rate that yields adequate images. Pulsed fluoroscopy should be used, at the lowest pulse rate that yields adequate image quality. Care should be taken to use the least amount of fluoroscopic time and acquire the least number of fluorographic images consistent with achieving the clinical goals of the procedure. Appropriate collimation should be used. The source-to-image receptor distance should be maximized and the object-to-image receptor distance should be minimized. Image magnification ("zoom") should be used only when essential clinically. C-arm angles should be varied from time to time if this does not interfere with the conduct of the clinical procedure, in order to minimize skin dose (44). C-arm angulation is of increased importance once the operator receives the first dose notification.

Table 4
Thresholds for Patient Follow-up

Parameter	Threshold
Peak skin dose (PSD)	3,000 mGy
Reference point air kerma ($K_{a,r}$)	5,000 mGy
Kerma-area-product (P_{KA})	500 Gy · cm^2
Fluoroscopy time (FT)	60 min

For CT-guided procedures, dose can be reduced by using low milli-ampere second techniques after obtaining the localizing scan (27) as well as by reducing the number of sections acquired and increasing the pitch for spiral scans (28). Also, the "quick-check" method of CT fluoroscopy may offer reduced radiation dose compared to the "real-time" method (45).

Postprocedural Care

Dose documentation.—Estimated radiation dose is recorded in the medical record, preferably the formal procedure report, for every procedure. Existing SIR guidelines for recording patient radiation dose are followed (46). As detailed in that document, ideally the peak skin dose and kerma-area-product are recorded, as they are the most useful predictors for deterministic and stochastic effects, respectively. If peak skin dose is not available on a fluoroscopic system, reference point air kerma is an acceptable substitute. If none of these other parameters is available and fluoroscopy time is used as the radiation dose metric, recording the total number of fluorographic images acquired during the procedure is also helpful for reconstructing the estimated dose. However, fluoroscopy time should not be used as the only metric of estimated radiation dose if any of the others are available.

The operator is promptly notified if any of the following occur: the final peak skin dose exceeds 3,000 mGy, the reference point air kerma exceeds 5,000 mGy, the kerma-area-product exceeds 500 Gy · cm^2, or the fluoroscopy time exceeds 60 minutes (Table 4). These values are based on the dose conversion equations given above and on the relationships between skin dose and skin effects given in Table 2. They are slightly less conservative than those given in the 2008 ACR Technical Standard (7), and those recommendations may be used instead, according to local preferences. The values used in this SIR guideline are intended to trigger follow-up for a dose that might produce a clinically relevant injury in an average patient. The values used in the ACR document are intended to prompt follow-up for a dose that might result in a minor reaction in an average patient.

The operator writes an appropriate note in the patient's medical record if any of these values are exceeded, signifying that a significant radiation dose has been administered. Notation in the medical record may also be appropriate even if these thresholds are not exceeded, such as for patients on whom other procedures involving radiation exposure are planned or have already been performed within 60 days. In addition, arrangements for radiation follow-up are made if any radiation dose metric exceeds the thresholds given above.

Patient follow-up.—Patients receiving a significant radiation dose are followed up after the procedure. In this context, a significant radiation dose is a selected threshold value that is used to trigger additional dose management actions (47). For interventional radiology procedures in adults, a significant radiation dose is any of the following: a peak skin dose greater than 3,000 mGy, a reference point air kerma greater than 5,000 mGy, or a kerma-area-product greater than 500 Gy · cm^2 (Table 4). A fluoroscopy time greater than 60 minutes is not itself a dose value, but it is an indirect indicator of a significant radiation dose. There is no implication that a dose below the significant dose level is safe or that a dose above the significant dose level will always cause an injury. In fact, it may be desirable to perform follow-up for lower radiation doses in special situations, such as previous recent irradiation of the same anatomical region.

The threshold values given in Table 3 were chosen both as simple round numbers for ease of use and also so that after three notifications, regardless of the dose metric used, patient follow-up is necessary. In other words, if the fluoroscopic system provides reference point air kerma, but not peak skin dose, the operator would be notified first at 3,000 mGy, next at 4,000 mGy, then again at 5,000 mGy. A reference point air kerma of 5,000 mGy indicates that the patient should have clinical follow-up for deterministic radiation-induced injury. The operator would continue to be notified after each additional 1,000 mGy.

A patient who has received a significant radiation dose is given written radiation follow-up instructions on their discharge instruction sheet. Sample discharge instructions are given in Appendix C. The patient is instructed to notify the operator and/or a qualified medical physicist of the results of self-examination of the irradiated area (either positive or negative). Clinical follow-up is arranged if the examination is positive for findings of deterministic radiation effects. A qualified medical physicist evaluates all positive patient reports regarding the dosimetric aspects of the procedure and discusses these findings with the operator. The physicist may also assist in facilitating clinical follow-up as determined by the operator. There may be other recommendations and/or requirements pertaining to patient follow-up according to a particular institution's policies.

Recommendations for Quality Assessment

A periodic statistical report of dose recording performance and dose utilization is performed. A dose recording compliance rate of less than 95% for any operator prompts additional radiation safety training, as discussed above. There is a review of the medical necessity for radiation utilization for those procedures that are above 95th percentile of the dose-distribution histogram for the institution, for procedures commonly performed at that institution. For example, this review might demonstrate that the specific procedure could have been performed with fewer or shorter fluorographic runs or that better collimation could have been used. Alternatively, comparison may be made to local, regional or national compilations of dose data, when available (34,48). Additionally, there is periodic reporting to the institution's radiation safety officer regarding those cases in which the radiation follow-up was positive for deterministic radiation effects. This includes review of the appropriateness of the radiation dose for those cases.

Appropriate review of image quality in relation to radiation dose should be performed at least annually as part of a comprehensive quality control pro-

gram, as performed by a qualified medical physicist.

APPENDIX: A

Consensus Methodology

Thresholds are derived from critical evaluation of the literature and evaluation of empirical data from Safety and Health Committee members' practices. Agreement was reached on all statements in this document without the need for utilizing modified Delphi consensus techniques (1,491,49).

APPENDIX: B

Example of Documentation of Informed Consent for Radiation Risk

You have been scheduled for an interventional procedure. This involves the use of x-rays for imaging during the procedure and documenting the results. Because of the nature of the planned procedure, it is possible that we will have to use significant amounts of radiation.

Potential radiation risks to you include:

- A slightly elevated risk for cancer several years later in life. This risk is typically less than ½ percent. This risk is low in comparison to the normal incidence of human cancer, which is 33% for women and 50% for men according to the American Cancer Society.
- Skin rashes occur infrequently; on very rare occasions they may result in tissue breakdown and possibly severe ulcers. Hair loss may occur which can be temporary or permanent. The likelihood of either of these occurring depends on the difficulty of the procedure and whether you are sensitive to radiation due to previous procedures, disease, or genetic conditions.

You or your family (proxy) will be advised if we actually used substantial amounts of radiation during the case. If this happens, you will be given written instructions stating that you are expected to have a family member check you for any of the above signs.

APPENDIX: C

Example of Postprocedure Patient Discharge Instructions for High-dose Procedures

X-Ray Usage - one of these two boxes is checked as part of the discharge instruction process:

☐ Your procedure was completed without the use of substantial amounts of x-rays. No special follow-up is needed because radiation side effects are highly unlikely.

☐ Your procedure required the use of substantial amounts of x-rays. Radiation side-effects are unlikely but possible. Please have a family member inspect your _____, for signs of redness or rash two weeks from today. Please call (###) ### - #### and tell us whether or not anything is seen.

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