Guidelines for
Patient Radiation Dose Management

Society of Interventional Radiology
Safety and Health Committee
Donald L. Miller, MD, Chair¹

Committee Members (authors): Michael S. Stecker, MD¹, Stephen Balter, PhD¹, Richard Towbin, MD¹, Donald L. Miller, MD¹, Eliseo Vano, MD², Gabriel Bartal, MD², J. Fritz Angle, MD¹, Christine P. Chao, MD¹, Alan M. Cohen, MD¹, Robert G. Dixon, MD¹, Kathleen Gross, MSN,RN, BC,CRN¹, George G. Hartnell, MD¹, Beth Schueler, Ph.D¹., John D. Statler, MD¹, Thierry de Baère, MD and John F. Cardella, MD¹ for the SIR¹ Safety & Health Committee and CIRSE² Standards of Practice Committee.

The opinions expressed herein are those of the authors and do not necessarily reflect those of the United States Navy, the Department of Defense, or the Department of Health and Human Services.
CORRESPONDING ADDRESS:

Michael S. Stecker, MD

c/o Debbie Katsarelis

3975 FAIR RIDGE DR, STE 400, NORTH FAIRFAX, VA 22033

(703) 691-1805 OR (404) 616-6753

[FAX] (703) 691-1855

Michael S. Stecker, MD¹
Assistant Professor of Radiology
Brigham & Women’s Hospital
75 Francis Street
Angiography & Interventional Radiology
Boston, MA 02115

Work: 617-732-7256
Fax: 617-277-8331
mstecker@partners.org

Stephen Balter, PhD¹
Medicine and Radiology
Columbia University Medical Center
627 W 165th Street
New York, NY 10032

Work: 917-856-5971
Fax: 212-472-2249
sbalter@aol.com

Richard Towbin, MD¹
Phoenix Hospital for Children
6311 N 47th Pl
Paradise Valley, AZ 85253

602-546-1207
rtowbin@gmail.com

Donald L. Miller, MD¹
Uniformed Services University of the Health Sciences
Dept. of Radiology and Radiologic Sciences
4301 Jones Bridge Rd.
Bethesda, MD 20814

National Naval Medical Center
Department of Radiology
8901 Wisconsin Ave
Bethesda, MD  20889-5600
Work: 301-295-4334
Fax: 301-295-0769
Donald.Miller@med.navy.mil

Professor Eliseo Vano, ²
Complutense University
Radiology Department, Medicine School
Madrid, SPAIN  28040
34913941551
eliseov@med.ucm.es

Gabriel Bartal, MD²
Director Dept Diagnostic and Interventional Radiology
Meir Medical Center
Dept of Radiology
Kfar Saba,  44281
ISREAL
011 972-9-7472532
gbartal@gmail.com

J. Fritz Angle, MD¹
University of Virginia Health System
Dept of Radiology
PO Box 800170
Charlottesville, VA  22908
Work: 434-924-9401
Fax: 434-982-0887
jfa3h@virginia.edu

Christine P. Chao, MD¹
Dept of Radiology
Kaiser Medical Center
99 Montecillo Rd
San Rafael, CA  94903
904-536-1825 (cell)
c.chao.md@gmail.com

Alan M. Cohen, MD¹
Professor and Chief Vascular/Interventional Radiology
University of Texas
6431 Fannin Street, Suite 2.100
Robert G. Dixon, MD¹
UNC
Dept of Radiology
2016 Old Clinic Bldg, CB#7510
Chapel Hill, NC 27599-7510
916-966-6646
Bob_dixon@med.unc.edu

Kathleen Gross, MSN,RN,BC,CRN¹
Greater Baltimore Medical Center
1243 Berans Road,
Owings Mills, Md. 21117
410-560-1172
443-849-2860
rgross@comcast.net

George G. Hartnell, FRCP, FRCR¹
Director, Vascular and Interventional Radiology
Department of Radiology
Cooley Dickinson Hospital
30 Locust Street
Northampton
Massachusetts
MA 01061-5001
Telephone: 413-575-7675
Fax: 413-737-7077
E-mail: george_hartnell@cooley-dickinson.org or gandjhartnell@comcast.net

Beth Schueler, PhD¹
Medical Physics Division
Department of Radiology
Mayo Clinic
Rochester, MN 55905
507-284-6617
Schueler.Beth@mayo.edu
Guidelines for
Patient Radiation Dose Management

Preamble

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 Drive, Suite 400 North, Fairfax, VA 22033.

Methodology

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 using electronic medical literature databases. Then a critical review of peer-reviewed articles and regulatory documents is performed with regards 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, reference 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 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 made to create the finished document. Prior to its publication the document is endorsed by the SIR Executive Council.

Introduction
In the early 1990s the United States Food and Drug Administration (FDA) received reports of significant radiation-induced skin injuries associated with interventional fluoroscopy (1), prompting the release in 1994 and 1995 of three guidance publications on documenting radiation use (2-4). 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 and nuclear medicine, and not interventional procedures (5). The ACR’s 2008 revision of the Technical Standard pertaining to the management of the use of radiation in fluoroscopically-guided procedures (6) 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. Additionally, 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 1) patient selection, 2) procedure performance, 3) patient monitoring, and 4) 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 wellbeing. This will almost always require administration of some radiation and may sometimes require the administration of clinically significant amounts of radiation. Generally, the risk of radiation is low compared to other procedural risks, and the benefits of imaging guidance are great (7). 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 which 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 Gy. For diagnostic x-rays, 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 (8).

**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 (SID). 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 (i.e., 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 E use computer simulation based on a “model” body and statistical simulations of radiation exposure. This yields only a gross approximation of E. The stochastic risk to an average member of an irradiated population is expressed in terms of sieverts (Sv). E 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 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 IRP is located along the central x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot (9,10). The IRP is close to the patient’s entrance skin surface. The FDA prescribes the location of the IRP for several non-isocentric geometries (10).

**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 (e.g. air, soft tissue, bone).
Kerma is measured in Gy. 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
radiotherapy).

Kerma-area-product ($P_{KA}$): The integral of air kerma across the entire x-ray beam emitted from
the x-ray tube. $P_{KA}$ is a surrogate measurement for the entire amount of energy delivered to the
patient by the beam. $P_{KA}$ is measured in Gy·cm². Conversion from units reported by commonly used
equipment are given in Table 1. $P_{KA}$ is usually measured without scatter. This quantity was
previously called dose-area-product. Earlier publications used the abbreviations KAP and DAP for
this quantity.

Table 1. Kerma-Area-Product Unit Conversion

<table>
<thead>
<tr>
<th>Unit used</th>
<th>To Convert to Gy·cm²</th>
</tr>
</thead>
<tbody>
<tr>
<td>dGy·cm²</td>
<td>divide by 10</td>
</tr>
<tr>
<td>cGy·cm²</td>
<td>divide by 100</td>
</tr>
<tr>
<td>mGy·cm²</td>
<td>divide by 1000</td>
</tr>
<tr>
<td>µGy·m²</td>
<td>divide by 100</td>
</tr>
</tbody>
</table>

Peak skin dose (PSD): The highest dose at any portion of a patient’s skin during a procedure.
PSD includes contributions from both the primary x-ray beam and from scatter. PSD is measured in
Gy (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 (ABR) in Diagnostic Radiological
Physics or Radiological Physics (6). 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 IRP above) during a procedure. $K_{a,r}$ does not include
backscatter and is measured in Gy. $K_{a,r}$ is sometimes referred to as 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
management 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 for simple radiographic studies. A major intervention, such as transcatheter embolization, can deliver an effective dose (E) to the patient of 100 mSv, while 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) (11).

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. In some circumstances, other organs (lens of the eye, thyroid, breast) may be also at risk. Children are uniquely sensitive to radiation injury.

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.
Table 2. Deterministic effects of single-delivery radiation dose to the skin of the neck, torso, pelvis, buttocks and arms.

<table>
<thead>
<tr>
<th>Band</th>
<th>Single-site Acute Skin-Dose Range (Gy)(^1)</th>
<th>NCI Skin Reaction Grade</th>
<th>Approximate time of onset of effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Prompt &lt; 2 weeks</td>
</tr>
<tr>
<td>A1</td>
<td>0-2</td>
<td>N/A</td>
<td>- No observable effects expected</td>
</tr>
<tr>
<td>A2</td>
<td>2-5</td>
<td>1</td>
<td>- Transient erythema</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Erythema, epilation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Recovery</td>
</tr>
<tr>
<td>B</td>
<td>5-10</td>
<td>1</td>
<td>- Transient erythema</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Erythema, epilation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Possible dry or moist desquamation</td>
</tr>
<tr>
<td>C</td>
<td>10-15</td>
<td>1-2</td>
<td>- Transient erythema</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- After very high doses, edema and acute ulceration; long-term surgical intervention likely to be required</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- Moist desquamation</td>
</tr>
<tr>
<td>D</td>
<td>&gt; 15</td>
<td>3-4</td>
<td>- Transient erythema</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>- After very high doses, edema and acute ulceration; long-term surgical intervention likely to be required</td>
</tr>
</tbody>
</table>

\(^1\) Skin dosimetry is unlikely to be more accurate than ± 50%.

\(^2\) Refers to radiation-induced telangiectasia. Telangiectasia associated with an area of initial moist desquamation, or the healing of ulceration, may be present earlier.

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. NCI = National Cancer Institute.
Adapted from Reference 12
The incidence of deterministic injuries increases with increasing body mass, the nature and complexity of the procedure, the radiation history of the patient, the presence of other disease processes (e.g. 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 (13).

It should also be noted that prolonged fluoroscopy/fluorography with a PSD greater than 1500 rads (15 Gy) to a single field over a period of six months to one year is a reviewable sentinel event as mandated by the Joint Commission (14,15). The American Association of Physicists in Medicine (AAPM) is working to have the definition of this sentinel event modified, because the Joint Commission defines a sentinel event as an “unexpected” (14) outcome, and implies that a reviewable radiation overdose is “preventable” (15). 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 (16).

Although much of radiation dose management is based upon sequelae that can be seen, albeit delayed weeks to months, stochastic effects must also be considered. 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 breast or gonadal tissue (2,17).

The likelihood of stochastic effects increases with the total radiation energy applied to the patient. In small children, it is possible to impart a high dose to the whole body if poor collimation technique is used. 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 21% (18). Using 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 ten years is about 16.5% for a 60-year-old male (18). The possible radiogenic increase is too small to be documented statistically in the entire worldwide interventional patient population. The situation may be different in pediatric patients, because of their increased susceptibility to radiation and longer potential life span (20). However, other than embolization of congenital arteriovenous malformations, the risk to children is lessened since many of the procedures performed on them are generally lower in complexity. In addition, children’s smaller body mass results in lower doses. Additional consideration does need to be given to adolescent patients who have an adult-sized body, but a child’s elevated risk coefficients.

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 technological 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 PSD, although aftermarket methods for estimating PSD are available (21,22). However, all equipment used in the United States provides total FT, and many systems manufactured within the past fifteen years have $P_{KA}$ measurement capability. All equipment manufactured after June 10, 2006 and sold in the United States must also provide air kerma rate at the IRP and cumulative air kerma ($K_{a,r}$) (23). For several reasons, FT correlates poorly with PSD (24), but if it is the only measurement available, it is better than not monitoring at all. $K_{a,r}$ correlates with PSD better than does $P_{KA}$, although both $K_{a,r}$ and $P_{KA}$ have wide variability for different instances of the same procedure (24,25). In the RAD-IR study (25), the linear regression between PSD and $K_{a,r}$ (CD), and the linear regression between PSD and $P_{KA}$ (DAP) were:

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

\[
\text{PSD (mGy)} = 249 + 5.2 \times P_{KA} \text{ (Gy·cm}^2\text{)}
\]

(Note: the coefficient has been changed to allow use of the more standardized units for $P_{KA}$)

It should be kept in mind that these “conversion formulas” are approximations, and not precise replacements for actually measuring the PSD. Particularly, they are invalid below $K_{a,r}$ of about 500 mGy and/or $P_{KA}$ of about 50 Gy·cm\(^2\), as the y-intercept was not forced to zero in the original calculations. However, they may be used to estimate the PSD 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 $P_{KA}$ measurements ignore the effect of backscatter from the patient. Backscatter can increase skin dose 10% to 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 E as it is distributed over a large area. Scans performed during guidance of the needle, catheter or probe are the main contributor to the PSD since they are repeatedly performed in approximately the same location (26,27). The cross-sectional images for guidance are performed with reduced dose settings and each delivers a factor of 5 to 15 times less PSD relative to typical diagnostic scans.

CT fluoroscopy (CTF) employs continuous low dose CT scanning 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 PSD from CTF-guided procedures may reach those from other interventional procedures (28). To date, reports of skin effects due to CT are extremely rare and have been associated with the combination of repeated multi-detector CT studies and fluoroscopic procedures in the same anatomic area (29).

The PSD from a CT scan performed without table incrementation is proportional to the tube current (mA) and exposure time (s) and approximately proportional to the square of the tube potential (kVp), although this varies considerably between CT systems (30,31). Reducing any of these parameters will reduce PSD, but image quality may be adversely affected due to an increase in image noise. Real-time dose monitoring uses indices developed for CT scans in which the patient is translated through the x-ray beam, and overestimates PSD by approximately a factor of two (30,32). This overestimated PSD and the total procedure time are shown on the in-room monitors of almost all modern interventional CT systems, resulting in an additional margin of safety for avoidance of skin injury.

The E from a CT-guided interventional procedure is a relatively complex calculation based on indices derived from standard dosimetry phantoms and specific to a particular scanner (30,31). 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 (e.g. mAs), the initial diagnostic quality scan performed to localize the anatomy of interest is the primary contributor to the total E. Estimates of E for typical CT exams can be found elsewhere (27,31).

Society of Interventional Radiology Guidelines

Radiation dose management requires a comprehensive approach including pre-procedural planning, intra-procedural management, and post-procedural 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 assure 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 (7). 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 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.
Pre-procedural Planning

*Individual Training:* All operators should meet institutional requirements for privileges to use fluoroscopy. All nurses, technologists, and other personnel shall receive initial and refresher training in patient radiation management; this should occur at least annually.

*Equipment:* Rooms which are only equipped with FT 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 pre-procedure 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 (33):

- embolization (including chemoembolization)
- renal and/or visceral angioplasty or stent placement
- transjugular intrahepatic portosystemic shunt (TIPS) 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 pounds) or greater than 135 kg (300 pounds)
- intervention in pediatric and young adult patients involving substantial absorbed dose to radiosensitive organs (e.g. 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 could, within a reasonable likelihood, result in a skin dose metric that will require follow-up (e.g. 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 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 non-invasive diagnostic imaging methods were inadequate for procedure planning, IR 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. Pre-procedure imaging can assist in the planning of IR 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 non-invasive cross-sectional imaging modalities (e.g. ultrasound, MRI, magnetic resonance angiography (MRA), MR cholangiopancreatography, CT, multidetector CT angiography (MDCTA)) is recommended in the work-up of IR 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 in order to decrease total-patient radiation dose. Decreasing the tube voltage and using automatic tube current modulation can result in substantial dose reductions without compromising diagnostic image quality (34,35). Pre-procedure diagnostic imaging may reduce procedure time and complication rates, and reduce fluoroscopy time and the number of fluorographic images obtained.

Reconstructed images from MRA and MDCTA allow accurate depiction of anatomy and treatment planning. For example, in some cases MRA may be helpful for determining internal iliac arterial anatomy prior to uterine fibroid embolization (36). It is feasible to replace DSA with cross-sectional imaging as the initial modality for the evaluation of peripheral arterial disease (37,38). Although it requires radiation, use of MDCTA instead of DSA may result in a reduced total radiation dose to the patient (39). This must be balanced against the well-known limited ability of MDCTA to evaluate the lumen of extensively calcified arteries (40). For evaluation of acute gastrointestinal bleeding, MDCTA 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 pre-procedural 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 non-diagnostic pre-intervention 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.
Intra-Procedural 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 values given below were chosen both as simple round numbers for ease of use and so that three notifications, regardless of the dose metric used, necessitates patient follow-up. The following rules should be applied in order of availability of radiation monitoring technology (Table 3):

- For fluoroscopy units that can provide estimates of PSD, the operator is notified when this reaches 2000 mGy, then every 500 mGy after that.
- For units with reference point air kerma ($K_{a,r}$) capability, initial notification is given at 3000 mGy, and then every 1000 mGy thereafter. Given the formulas above, this corresponds to an initial PSD of about 1800 mGy and an increment of about 500 mGy.
- For units with $P_{K_A}$ capability, the notification level is based on a procedure-dependent nominal x-ray field size at the patient’s skin. Using a 100 cm$^2$ 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 PSD of about 1800 mGy and an increment of about 500 mGy. Note that different brands of fluoroscopes report $P_{K_A}$ using different units; conversion factors are given above in Table 1 of the Definitions section.
- For units that can only monitor FT, the operator is notified when the total FT 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 (DSA or unsubtracted). All fluoroscopes display FT. However, because of poor correlation with other dose metrics, it should be used with caution to monitor patient irradiation.

Table 3. Summary of Radiation Monitoring Dose Notification Thresholds

<table>
<thead>
<tr>
<th>Parameter</th>
<th>First Notification</th>
<th>Subsequent Notifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSD</td>
<td>2000 mGy</td>
<td>500 mGy</td>
</tr>
<tr>
<td>$K_{a,r}$</td>
<td>3000 mGy</td>
<td>1000 mGy</td>
</tr>
<tr>
<td>$P_{K_A}$</td>
<td>$300$ Gy·cm$^2$ *</td>
<td>$100$ Gy·cm$^2$ *</td>
</tr>
<tr>
<td>FT</td>
<td>30 min</td>
<td>15 min</td>
</tr>
</tbody>
</table>

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

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 SID
should be maximized and the Object-to-Image Receptor Distance (OID) 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.

For CT-guided procedures, dose can be reduced by using low mAs techniques after performing
the localizing scan (26), as well as by reducing the number of slices acquired and increasing the
pitch for spiral scans (27). Also, the “quick-check” method of CT fluoroscopy may offer reduced
radiation dose compared to the “real-time” method (45). Finally, like all other interventional
procedures, there is a learning curve that reduces patient doses over time.

**Post-Procedural Care**

_Dose Documentation:_ Estimated radiation dose is recorded in the medical record for every
procedure. Existing SIR Guidelines for recording patient radiation dose are followed (46). If FT 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.

The operator is promptly notified if any of the following occur: the final PSD exceeds 3000
mGy, the $K_{ar}$ exceeds 5000 mGy, the $P_{KA}$ exceeds 500 Gy·cm$^2$, or the FT 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 (6), 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 average patients.
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. Additionally, arrangements for radiation follow-up are made if any radiation dose metric exceeds the thresholds given above.

### Table 4. Thresholds for Patient Follow-Up

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Threshold</th>
</tr>
</thead>
<tbody>
<tr>
<td>PSD</td>
<td>3000 mGy</td>
</tr>
<tr>
<td>$K_{a,r}$</td>
<td>5000 mGy</td>
</tr>
<tr>
<td>$P_{KA}$</td>
<td>500 Gy·cm²</td>
</tr>
<tr>
<td>FT</td>
<td>60 min</td>
</tr>
</tbody>
</table>

**Patient Follow-Up:** Patients receiving a significant radiation dose are followed 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 PSD greater than 3000 mGy, a $K_{a,r}$ greater than 5000 mGy, or a $P_{KA}$ greater than 500 Gy·cm² (Table 4). An FT greater than 60 min 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.

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. 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 compliance rate of less than 95% prompts additional radiation safety training. There is a review of the medical necessity for radiation utilization for those procedures that are above 95% of the dose-distribution histogram for the institution, for procedures commonly performed at that institution.
Alternatively, comparison may be made to local, regional or national compilations of dose data, when available (33,48). Additionally, there is periodic reporting to the institution’s radiation safety officer regarding those cases in which the radiation follow-up was positive. 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 program.
References


Protection and Measurements, 1990.


41. Liang CJ, Tobias T, Rosenblum DI, Banker WL, Tseng L, Tamarkin SW. Acute gastrointestinal
bleeding: emerging role of multidetector CT angiography and review of current imaging


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 (1,2).

References:
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 Post-Procedure 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.
Acknowledgments

Dr. Michael S. Stecker authored the first draft of this document and served as topic leader during the subsequent revisions of the draft. Dr. Donald L. Miller is chair of the SIR Safety and Health Committee. Dr. John F. Cardella is councilor of the SIR Standards Division. All other authors are listed alphabetically. Other members of the Standards of Practice Committee and SIR who participated in the development of this clinical practice guideline are (listed alphabetically): {LIST COMMITTEE MEMBERS OTHER THAN THOSE WHO PARTICIPATED IN A MAJORITY OF CONFERENCE CALLS, MEETINGS, AND DELPHI ROUNDS}.

SIR Disclaimer

The guidelines of the Society of Interventional Radiology attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to SIR guidelines will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested guidelines in the department policies and procedure manual or in the patient’s medical record.