



Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record for Fluoroscopically Guided Procedures

Donald L. Miller, MD, Stephen Balter, PhD, Robert G. Dixon, MD, Boris Nikolic, MD, MBA, Gabriel Bartal, MD, John F. Cardella, MD, Lawrence T. Dauer, PhD, and Michael S. Stecker, MD, for the Society of Interventional Radiology Standards of Practice Committee

ABBREVIATIONS

ACR = American College of Radiology, CRCPD = Conference of Radiation Control Program Directors, FDA = Food and Drug Administration, ICRU = International Commission on Radiation Units and Measurements, IEC = International Electrotechnical Commission, IRP = interventional reference point, $K_{a,r}$ = total air kerma at the interventional reference point, NCRP = National Council on Radiation Protection and Measurements, PKA = kerma–area product, PSD = peak skin dose, RDSR = Radiation Dose Structured Report

PREAMBLE

The membership of the Society of Interventional Radiology (SIR) Standards of Practice Committee represents experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally Standards of Practice 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 for standards production.

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., Suite 400 N., Fairfax, VA 22033.

This is the second edition of this document. It is a revision of the original document, which was published in 2004 (1) and reprinted in 2009 (2).

METHODOLOGY

SIR produces its Standards of Practice documents using the following process. Standards documents of relevance and timeliness are conceptu-

alized by the Standards of Practice Committee members. A recognized expert is identified to serve as the principal author for the standard. Additional authors may be assigned depending 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 is performed regarding the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is used to write the document such that it contains evidence-based data with respect to content, rates, and thresholds.

When the evidence of literature is weak, conflicting, or contradictory, consensus for the parameter is reached by a minimum of 12 Standards of Practice Committee members using a Modified Delphi Consensus Method (Appendix) (3,4). 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 Revisions Subcommittee members of the Standards of Practice Committee, either by telephone conference calling or face-to-face meetings. The finalized draft from the Committee is sent to the SIR membership for further input/criticism during a 30-day comment period. These comments are discussed by the Subcommittee, and appropriate revisions are made to create the finished standards document. Before its publication, the document is endorsed by the SIR Executive Council.

From the Center for Devices and Radiological Health (D.L.M.), Food and Drug Administration, Silver Spring; Department of Radiology and Radiological Sciences (D.L.M.), F. Edward Hébert School of Medicine, Uniformed Services University, Bethesda, Maryland; Departments of Radiology and Medicine (S.B.), Columbia University; Department of Medical Physics (L.T.D.), Memorial Sloan–Kettering Cancer Center, New York, New York; Department of Radiology (R.G.D.), University of North Carolina, Chapel Hill, North Carolina; Department of Radiology (B.N.), Albert Einstein Medical Center, Philadelphia; Department of Radiology (J.F.C.), Geisinger Health System, Danville, Pennsylvania; Department of Diagnostic and Interventional Radiology (G.B.), Meir Medical Center, Kfar Saba, Israel; and Division of Angiography and Interventional Radiology (M.S.S.), Brigham and Women's Hospital, Boston, Massachusetts. Final revision received September 7, 2011; accepted September 8, 2011. Address correspondence to D.L.M., 3975 Fair Ridge Drive, Suite 400, North, Fairfax, VA 22033; E-mail: donald.miller@fda.hhs.gov

R.G.D. is an educational consultant for Bard (Covington, Georgia). None of the other authors have identified a conflict of interest.

The views expressed in this article are those of the authors and do not necessarily reflect the official policy or position of the Food and Drug Administration, the Department of Health and Human Services, or the United States Government.

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Table 1. Recommendations for Recording Patient Dose from Fluoroscopically Guided Interventional Procedures (1,5,8–10,12,13)

Publication, Year	Publication Type	Fluoroscopic Procedures for which Dose Data Should Be Recorded
Present document	SIR quality improvement guideline	All
CRCPD Technical White Paper: Monitoring and Tracking of Fluoroscopic Dose, 2010 (10)	CRCPD guidance (United States)	All
NCRP Report 168, 2010 (9)	NCRP recommendation (United States)	All
ACR/SIR Practice Guideline for Reporting and Archiving of Interventional Radiology Procedures, 2009 (13)	ACR/SIR practice guideline (United States)	All
ICRP Publication 105, 2007 (12)	International guideline	Determined by dose (presumed measured for all cases)
SIR Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, 2004 (1)	SIR quality improvement guideline	All cases of potentially high-dose procedures and all medium dose procedures that are likely to be repeated; desirable to record radiation dose for all other procedures
ICRP, Publication 85, 2001 (8)	International guideline	Determined by dose (presumed measured for all cases)
US FDA Advisory, 1995 (5)	FDA advisory guideline (United States)	To be decided by each facility; should include TIPS and “percutaneous endovascular reconstruction”

Note.—ACR = American College of Radiology, CRCPD = Conference of Radiation Control Program Directors, FDA = Food and Drug Administration, ICRP = International Commission on Radiological Protection, K_a,r = total air kerma at the interventional reference point, NCRP = National Council on Radiation Protection and Measurements, PSD = peak skin dose, TIPS = transjugular intrahepatic portosystemic shunt.

PATIENT RADIATION DOSE RECORDING

As of 2011, there are no federal regulatory requirements in the United States concerning recording or reporting of radiation dose data for interventional procedures. There are recommendations on this topic from the United States Food and Drug Administration (FDA), the Conference of Radiation Control Program Directors (CRCPD), and national and international advisory bodies (5–10). Regulations or guidance at the state level are not uniform (11). Only a small number of states have addressed this issue. State regulations are typically updated periodically based on CRCPD guidance. If state regulations exceed the requirements contained in this document, practitioners should follow the more stringent state regulatory guidelines. Existing guidelines and recommendations are summarized in **Table 1** (1,5,8–10,12,13). The International Atomic Energy Agency issued its International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources in 1996 (14). This document, currently under revision, provides important safety guidance, but no specific recommendations on dose recording.

Fluoroscopically guided procedures are an essential part of the contemporary practice of medicine. Some fluoroscopically guided procedures are associated with a risk of radiation injury to the skin (9,15). These injuries may be painful, disfiguring, and long-lasting (16). Koenig and colleagues (15), in a comprehensive review published in 2001, reported data on radiation-induced skin injuries in 73 patients. Of these, 47 (64%) were the result of coronary angiography and intervention, 12 (16%) were the result of cardiac radiofrequency catheter ablation, seven (10%) were the result of transjugular intrahepatic portosystemic shunt creation, three (4%) were the result of neuroradiologic interventions, and the type of procedure was not specified for four patients. Deterministic skin effects have been associated with renal angioplasty, multiple hepatic/biliary pro-

cedures, and embolization (8,17–20). In general, the risk of patient injury as a result of radiation exposure during these procedures is low. The frequency of deterministic skin effects is unknown (17,18), but for cardiac interventions has been estimated at less than 0.03% (21), although it is higher for some complex cardiac interventions, such as treatment of chronic total occlusions of the coronary arteries (22).

In a Public Health Advisory of September 30, 1994, the FDA recommended that “information permitting estimation of the absorbed dose to the skin be recorded in the patient’s medical record” (5). The International Commission on Radiological Protection has also recommended recording patient radiation dose in the medical record for certain procedures (8). Monitoring and recording patient dose data for all procedures can be valuable for quality-assurance purposes as well as for patient safety (9,23–25). Feedback to the operator may help to optimize radiation doses overall (20).

The present document revises and updates recommendations made in the first edition of this guideline (1,2). The new recommendations are based on recent national guidelines and recommendations from the CRCPD (10), the National Council on Radiation Protection and Measurements (NCRP) (9), and the American College of Radiology (ACR) (13). The guidelines presented in this document are written for inclusion in quality-improvement programs used to manage radiation dose from fluoroscopically guided invasive and interventional procedures, excluding computed tomographic (CT) fluoroscopy. A measurable part of the radiation management process is the recording of patient dose. The outcome measure or indicator for this process is the compliance rate for data recording. Outcome measures are assigned threshold levels.

This document does not outline how these patient radiation dose data

When Dose Should Be Recorded	Which Dose Metric Should Be Recorded
Always Always	All available dose data All available dose data
Always Always	All available dose data All available dose data
PSD > 1 Gy if procedure likely to be repeated; PSD > 3 Gy if procedure not likely to be repeated All potentially high dose procedures, regardless of dose; procedures with Ka,r of 1–3 Gy, if likely to be repeated; ideally in all other cases	PSD and location, skin dose map In descending order of desirability: skin dose mapping, PSD, Ka,r, PKA, fluoroscopy time/number of images
PSD > 1 Gy if procedure likely to be repeated; PSD > 3 Gy if procedure not likely to be repeated If skin dose equals or exceeds a threshold dose set by each facility (1–2 Gy suggested as threshold dose)	PSD and location, skin dose map Skin dose; skin dose map or verbal description of site

are to be used in a quality assurance program. Detailed advice on this topic is provided elsewhere (9,24).

DEFINITIONS

Absorbed dose. The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the point of interest. The SI unit is J kg^{-1} with the special name gray (Gy).

Air kerma. The energy released per unit mass of a small volume of air when it is irradiated by an x-ray beam. For diagnostic x-rays, air kerma is the same as the absorbed dose delivered to the volume of air in the absence of scatter. Air kerma is measured in Gy.

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 or a result of underlying disease. Different areas and types of skin also differ in radiation sensitivity.

C-arm fluoroscopic system. A fluoroscopic system in which the image receptor and x-ray tube are mounted at the opposite ends of a C-shaped arm. This design allows the x-ray tube and image receptor to be rotated about the patient through at least 90° relative to the patient with no motion of the x-ray tube relative to the image receptor. Most such systems have an identifiable center of rotation called the isocenter. An object placed at the isocenter remains centered in the beam as the C-arm is rotated.

Cumulative dose (CD). See “reference air kerma.”

Deterministic effect. Effects that occur in individuals who receive greater than a threshold dose; the severity of the effect varies with the dose above the threshold. An example is radiation-induced erythema (skin). These effects are also termed tissue effects.

Dose. As used in this document, dose is the same as the absorbed dose unless specified as “equivalent dose” or “effective dose.”

Dose-area product. See “kerma–area product.”

Effective dose. The sum, over specified tissues, of the products of the equivalent dose in a tissue and the tissue weighting factor for that tissue (26). Effective dose is measured in Sieverts (Sv). Stochastic risk factors are usually stated relative to effective dose.

Equivalent dose. A quantity used for radiation protection purposes that takes into account the different probability of effects that occur with the same absorbed dose delivered by radiations with different radiation weighting factors. Equivalent dose is measured in Sv.

Fluorographic image. A single recorded image obtained with use of an image intensifier or flat digital panel as the image receptor. A digital angiographic “run” consists of a series of fluorographic images, often subtracted from a mask image to create digital subtraction angiography images. Fluorography requires a much higher dose than fluoroscopy (27).

Fluoroscopy. An x-ray technique that provides real-time images using a continuous field of x-rays transmitted through the area of interest to an image receptor (image intensifier or flat-panel detector). Fluoroscopy is used to observe moving objects for relatively long periods of time (seconds

to minutes), generally without the intent of preserving the images. However, on most fluoroscopy equipment, the last image of the real-time image series can be saved (last image hold), and on newer equipment the last several seconds of fluoroscopic images can be saved (fluoroscopy loop). The radiation dose for fluoroscopy is much less than for fluorography.

Fluoroscopy time. The total time that fluoroscopy is used during an imaging or interventional procedure. For each fluoroscopic series, the fluoroscopic time is measured from the start to the end of x-ray production (start of first pulse to the end of the last pulse). Fluoroscopy time does not include the time used for fluorography.

Interventional reference point (IRP). For C-arm type fluoroscopic systems with an isocenter, the IRP is located along the central ray of the x-ray beam at a distance of 15 cm from the isocenter in the direction of the focal spot. The IRP is defined by International Electrotechnical Commission (IEC) standard 60601-2-43 (28). The second edition of this standard renamed the IRP as the patient entrance reference point (29), but the term IRP is more commonly used.

Isocenter. For C-arm type fluoroscopic systems, the point in space between the focal spot and the image receptor through which the central ray of the x-ray beam passes, regardless of beam orientation.

Kerma. Abbreviation for kinetic energy released in matter; the amount of energy transferred from the x-ray beam to charged particles per unit mass in the medium of interest. For diagnostic x-ray procedures, this is equivalent to absorbed dose in the specified medium (eg, air, soft tissue, bone). Kerma is measured in Gy.

Kerma-area product (PKA). The integral of air kerma (absorbed dose to air) across the entire x-ray beam emitted from the x-ray tube. The International Commission on Radiation Units and Measurements (ICRU) symbol for kerma-area product is PKA (30). PKA is usually calibrated in the absence of scattered radiation. PKA, formerly known as dose-area product, is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. PKA is measured in Gy·cm². It may be measured with a dosimeter or calculated within the fluoroscope.

Peak skin dose (PSD). The highest dose at any portion of a patient's skin during a procedure.

Reference air kerma (Ka,r). As defined by the IEC (28), it is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry (the interventional reference point) during a procedure. There is no ICRU symbol for reference air kerma. NCRP report no. 168 uses the symbol Ka,r (9). Ka,r does not include scatter from the patient. It is measured in Gy. Ka,r is also called reference point air kerma and was formerly called cumulative dose or cumulative air kerma.

Stochastic effects. A radiation effect whose probability of occurrence is assumed to increase 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 occurs. Threshold doses differ among individuals as a result of biologic variation. The threshold dose for skin injury also differs at different anatomic sites in the same individual.

GENERAL PRINCIPLES

Dose Estimation

Radiation-induced effects are divided conventionally into deterministic and stochastic effects (16,31). The likelihood of these effects in any individual patient cannot be predicted unless that patient's radiation history is known. This is the principal reason for recording patient radiation dose. Monitoring and recording patient dose data can also be valuable for both quality-assurance purposes and for improving patient safety (9,32). Feedback to the operator may help to optimize radiation doses overall (20).

Table 2. Patient Radiation Dose Metrics for Fluoroscopy

Peak skin dose
Reference air kerma
Kerma-area product
Fluoroscopy time

Note.—Each metric is defined in the Definitions section.

Patient radiation dose may be measured and recorded in different ways. Four metrics have been developed for measuring dose during interventional fluoroscopic procedures (Table 2). These methods differ in usefulness and availability. In the United States, one method is universally available, two are relatively common, and one is extremely uncommon. Note that none of these methods are applicable to dose measurements for CT fluoroscopy. Dose measurement and recording for CT fluoroscopy are not discussed in this document.

The simplest and most widely available measurements are fluoroscopy time and number of fluorographic images. These are analogues of dose; that is, they do not measure dose directly. By themselves, they are insufficient to determine patient dose. To estimate patient dose from fluoroscopy time and number of fluorographic images, the fluoroscopic dose rate and the dose per image must also be measured or estimated. Fluoroscopy time and number of fluorographic images are the least useful measures of patient dose.

PKA is a commonly available measure of the total radiation energy entering the patient. It is a good indicator of stochastic risk for the patient, correlates with operator and staff dose, and has been recommended by the ICRU for patient dose monitoring for fluoroscopic procedures (30,33–35). PKA meters may be integrated into the fluoroscopic unit or installed as add-on devices. The principal deterministic risk to the patient is radiation-induced skin injury, including epilation (ie, hair loss). The likelihood and severity of radiation injury at any point on the skin are related to the dose delivered to that portion of skin (16,19,36). PKA is a surrogate measure of skin dose. It does not correlate well with skin dose for individual cases of a procedure (37–44). A large dose delivered to a small skin area yields the same PKA as a small dose delivered to a large skin area. PKA is therefore not an ideal indicator of deterministic risk for fluoroscopically guided procedures.

The IEC introduced the concept of Ka,r, then called cumulative dose, in 2000 (28). It is the air kerma value at a specific point, the IRP. Depending on the patient's size, the table height, and the angulation of the beam, the IRP may be outside the patient, may coincide with the skin surface, or may be inside the patient. Ka,r is a cumulative approximation of the total radiation dose to the skin, summed over the entire procedure. During the course of virtually all interventional radiology procedures, the x-ray beam is moved periodically with respect to the patient, and is directed at different areas of the patient's skin. In general, therefore, estimates of the likelihood of radiation-induced skin injury that are based on Ka,r tend to overstate this risk (44). Ka,r is usually measured with a dosimeter integrated into the fluoroscopic unit. Ka,r estimation capability is present in all IEC 60601-2-43 (28,29)–compliant interventional fluoroscopes, all fluoroscopes sold in the United States since June 2006 (45), and in some other systems. It has been available on some interventional fluoroscopy units in the United States since the mid-1990s.

The likelihood and severity of radiation-induced skin injury to the patient as a whole are functions of the highest radiation dose at any point on that patient's skin—the PSD. Conceivably, the reference point could be exactly on the same point of the patient's skin during an entire procedure. In this special case, PSD is equal to Ka,r multiplied by the patient backscatter factor. (Backscatter factors for fluoroscopic procedures are typically approximately 30%.) In most cases, no point on the patient's skin is within the irradiated field for the entire procedure because of gantry angulation, table movement, or both. For this reason, the PSD is usually numerically less than the Ka,r (44).

It is desirable to measure PSD during interventional radiology pro-

cedures, but this has proved difficult in practice (46). PSD may be measured with real-time point-measurement devices applied to the patient (47–49), with thermoluminescent dosimeters applied to the patient, or with dosimetric film interposed between the x-ray beam and the patient (50–53). PSD data derived from point measurement devices are likely to underestimate true PSD unless the measurement device is placed at the exact site of PSD. Exact placement of a point measurement device is unlikely because the PSD is usually confined to a small area of skin, the precise location of which is not known before the procedure (44,47,54). In the past, PSD could be measured with a computerized analysis tool integrated into the fluoroscopic unit (55,56), but this device is no longer sold.

PSD measurement may be accompanied by a display of a skin dose map. A real-time skin dose map is an extremely valuable tool for assisting the operator in minimizing skin dose (56). Dosimetric film may also be used to obtain a skin dose map, albeit not in real time (52,57). The skin dose map may also be added to the medical record at the conclusion of the procedure, thereby indicating not only the magnitude of the skin dose, but its location. This satisfies the most stringent interpretation of FDA, ACR, and International Commission on Radiological Protection recommendations for recording skin dose (6,8,58). Unfortunately, as of 2011, this technology is not commercially available. Alternative methods of dose mapping, such as dosimetric film and thermoluminescent dosimeter arrays, are rarely used because of their inconvenience and cost.

There are current efforts to standardize the export of detailed dosimetric data from the fluoroscope in an open format as a Radiation Dose Structured Report (RDSR) (59–61). The RDSR provides dose and geometric information for each individual irradiation. Integration profiles are provided by the Integrating the Healthcare Enterprise organization (http://wiki.ihe.net/index.php?title=Main_Page) for the purpose of facilitating communication of information such as the RDSR between fluoroscopes and databases. RDSR data, combined with appropriate mathematical phantoms, should supply sufficient inputs to give modeling algorithms the ability to calculate skin and organ doses (62). It is expected that this technology will become available in the near future (63). RDSR data should also permit calculation and display of a skin dose map (63).

Measurement Uncertainty

All statements of patient dose contain some degree of uncertainty. This results from uncertainties in the physical measurement of dose and further uncertainties when these measurements are used to estimate patient dose. Users of dose data should be aware of these uncertainties.

For example, fluoroscopy time can be accurately measured. However, important uncertainties in converting fluoroscopy time to patient dose include the varying effects of patient size, beam orientation, and the configuration of the fluoroscope.

Beam orientation and beam motion during the procedure have a profound influence on the precision of most dose metrics to estimate PSD. If the beam is fixed relative to the patient during the entire procedure, the conversion is relatively straightforward. However, if the beam never strikes the same portion of the patient's skin twice, PSD will be low, even if Ka,r and PKA are high. Virtually all clinical procedures are between these extremes (64).

In addition, 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. FDA tolerance for Ka,r estimation is $\pm 35\%$ (65). 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 PKA measurements are calibrated without scatter. Scatter from the patient can increase skin dose 10%–40%, depending on the beam area and energy (9,30).

Methods for estimating PSD can be ranked from most reliable to least reliable. Estimation of PSD using software is the most reliable, followed by estimation using both Ka,r and PKA, using Ka,r alone, using PKA alone, and, finally, using fluoroscopy time combined with a count of the number of fluorography frames or images (66).

Estimation of PSD is probably within $\pm 50\%$ of the actual skin dose

without backscatter. This means that a reported value of 2 Gy more precisely represents a skin dose value between approximately 1.3 Gy and 3.9 Gy (including the effect of backscatter). Dose estimates reconstructed from fluoroscopy time and number of fluorographic frames are much more uncertain, and, after all corrections are factored in, are probably within approximately +130% and –70% of the best estimated value. For example, a 2 Gy calculated PSD, reconstructed from fluoroscopy time and number of fluorographic frames, is probably more precisely stated as between 0.6 Gy and 4.6 Gy. The uncertainties of estimates of PSD derived from Ka,r or PKA are between these two extremes.

How Skin Dose Should Be Measured

The optimal method includes estimation of PSD. Ideally, this would include real-time skin dose mapping as a means for managing patient radiation dose. As of 2011, other dose metrics are more readily available, and, when available, all of them should always be recorded for interventional fluoroscopy procedures (Table 1). PSD and PKA are the most useful predictors for the risk of deterministic and stochastic effects, respectively. Ka,r and PKA, used together, yield the best estimate of PSD currently available (66). Ka,r is the best single analogue of PSD, even though it does not correlate well with PSD in individual cases (44,66,67). PKA is not as good (44,66,67). Fluoroscopy time alone correlates poorly with PSD (64). Monitoring fluoroscopy time alone also underestimates the risk of radiation-induced skin effects (68). Fluoroscopy time and number of fluorographic images, used together, can provide a better guide to patient dose but are not themselves measures of dose. They do not provide sufficient information for dose calculations and are therefore suboptimal dose metrics. However, if none of the other metrics can be measured, fluoroscopy time and number of fluorographic images, along with the patient's height and weight, can be used for recording patient radiation dose until other means are available.

SIR recognizes that many practitioners have access only to interventional fluoroscopic equipment with minimal or no radiation dose-measurement capabilities. Facilities should be encouraged to purchase interventional fluoroscopic equipment with state-of-the-art dose-measurement and dose-management capabilities and to upgrade existing interventional fluoroscopic equipment with aftermarket devices to improve dose-measurement capability (9).

When Dose Data Should Be Recorded

The ACR–SIR Practice Guideline for the Reporting and Archiving of Interventional Radiology Procedures (13) recommends that radiation dose data be recorded in the final report for all fluoroscopically guided procedures and that, if technically possible, all radiation dose data recorded by the fluoroscopy unit should be transferred and archived with the images from the procedure. This recommendation is consistent with guidance from the NCRP and the CRCPD (9,10), and is adopted in the present quality improvement guideline. Radiation dose data may also be recorded in the immediate postprocedure note and/or the procedure worksheet. Each institution should specify where and how this information is to be recorded in accordance with the needs of its own quality-improvement program and its medical record guidelines.

NCRP report No. 168 defines a potentially high radiation dose procedure as one where more than 5% of cases of that procedure result in a Ka,r exceeding 3 Gy or PKA exceeding 300 Gy·cm² (9). Certain procedures are known to be associated with relatively high patient radiation doses and are always classified as potentially high dose (44,69). It is particularly important that patient radiation dose data is recorded for all instances of these procedures. To simplify the categorization of high-dose procedures, SIR has previously recommended that all embolization procedures, transjugular intrahepatic portosystemic shunt procedures, and arterial angioplasty or stent placement procedures anywhere in the abdomen or pelvis should be considered potentially high-dose procedures (1).

Patient radiation dose data should also be recorded for other fluoroscopically guided procedures, even those that are unlikely to result in high patient radiation doses, such as venous access procedures

Table 3. Threshold Rates for Recording of Dose Metrics

Procedure Type	Threshold (%)
Potentially high-dose procedures (all embolization procedures, TIPS creation, arterial angioplasty or stent placement at any site in the abdomen or pelvis)	99
Other fluoroscopically guided interventional procedures (excluding CT fluoroscopy)	95

Note.—TIPS = transjugular intrahepatic portosystemic shunt.

(70). Recording patient dose data for all procedures makes it less likely that the process will be omitted inadvertently for high-dose procedures.

Monitoring and recording patient dose data can be valuable for quality-assurance purposes as well as for patient safety (9,23–25). Feedback to the operator may help to optimize radiation doses overall (20). High doses should prompt further action (9,24,71). Institutions may also wish to participate in the International Atomic Energy Agency's SAFETY in RADiological procedures (SAFRAD) reporting system (<http://rop.iaea.org/saftrad/>), a voluntary, confidential reporting system where the patient's dose report and relevant data are included in an international database for the purposes of education and quality improvement.

DATA RECORDING

Ideally, all available patient radiation dose data should be recorded (13). In the future, this may become an automatic process, as the FDA has expressed an intention to establish requirements for CT and fluoroscopic devices to provide radiation dose information for use in patient medical records or a radiation dose registry (72). For the present, and for the purpose of this guideline, adequate recording of dose metrics is defined as documentation in the patient record of at least one of the following for all interventional procedures requiring fluoroscopy (in descending order of desirability): skin dose mapping, PSD, Ka,r, PKA, and fluoroscopic time/number of fluorographic images (Table 3). Note, however, that this is adequate recording; this document recommends recording all available dose metrics.

In Table 3, all values are supported by the weight of literature recommendations and panel consensus. A higher threshold is set for potentially high-dose procedures because of the higher radiation doses associated with these procedures and the greater risk of stochastic and deterministic effects.

Although practicing physicians should strive to achieve perfect compliance, in practice, all physicians will fall short of this ideal to a variable extent. Indicator thresholds may be used to assess the efficacy of ongoing quality-improvement programs. For the purposes of these guidelines, a threshold is a specific level of an indicator that should prompt a review. When compliance rates fall below a minimum threshold, a review should be performed to determine causes and implement changes if necessary. If recording patient radiation dose data is one measure of the quality of radiation dose management, compliance rates lower than the defined threshold should trigger a review of policies and procedures within the department to determine the causes and implement changes to improve quality. Thresholds may vary from those listed here; for example, patient referral patterns and selection factors may dictate a different threshold value for a particular indicator at a particular institution. Because institutions and interventional fluoroscopic units vary widely in their ability to measure various metrics of patient dose, setting universal thresholds is very difficult and each department is urged to alter the thresholds as needed to higher or lower values to meet its own quality-improvement program needs.

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APPENDIX: METHODOLOGY

Thresholds are derived from critical evaluation of the literature, evaluation of empirical data from Standards of Practice Committee member practices, and, when available, the SIR HI-IQ system national database. Consensus on statements in this document was obtained without the need for a modified Delphi technique (3,4).

SIR DISCLAIMER

The clinical practice 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 practice 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 the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient’s medical record.