Radiology

Clinical Radiation Management for Fluoroscopically Guided Interventional Procedures[1]

Donald L. Miller, MD
Stephen Balter, PhD
Beth A. Schueler, PhD
Louis K. Wagner, PhD
Keith J. Strauss, PhD
Eliseo Vañó, PhD

The primary goal of radiation management in interventional radiology is to minimize the unnecessary use of radiation. Clinical radiation management minimizes radiation risk to the patient without increasing other risks, such as procedural risks. A number of factors are considered when estimating the likelihood and severity of patient radiation effects. These include demographic factors, medical history factors, and procedure factors. Important aspects of the patient's medical history include coexisting diseases and genetic factors, medication use, radiation history, and pregnancy. As appropriate, these are evaluated as part of the preprocedure patient evaluation; radiation risk to the patient is considered along with other procedural risks. Dose optimization is possible through appropriate use of the basic features of interventional fluoroscopic equipment and intelligent use of dose-reducing technology. For all fluoroscopically guided interventional procedures, it is good practice to monitor radiation dose throughout the procedure and record it in the patient's medical record. Patients who have received a clinically significant radiation dose should be followed up after the procedure for possible deterministic effects. The authors recommend including radiation management as part of the departmental quality assurance program.

Supplemental material: *http://radiology.rsna.org/lookup /suppl/doi:10.1148/radiol.10091269/-/DC1*

Fluoroscopically guided interventional (FGI) procedures are performed in large numbers in the United States and in Europe. The number of procedures performed annually has increased over the past 20 years (1–3). While the benefits of interventional radiology to patients are well recognized, there are also procedure-related risks. One of these risks, for many FGI procedures, is the potential for patient radiation doses high enough to cause radiation effects. Management of radiation exposure is therefore essential for these procedures.

Radiation Effects

Biologic effects resulting from radiation exposure are traditionally divided into stochastic effects and deterministic effects (4). The classification of some injuries (such as cataract) as deterministic or stochastic is uncertain (5).

Stochastic injuries (cancer induction) are due to misrepair of damage to the DNA of a single cell. The result is a genetic transformation. The likelihood of stochastic effects increases with the total radiation energy absorbed by the different organs and tissues of the patient, but their severity is independent of total dose. The probability of a radiation-induced malignancy due to an invasive procedure is small compared with the baseline probability of developing a malignancy. The likelihood of stochastic effects is greater in pediatric patients, because of their increased susceptibility to radiation and longer potential life span (4,6–8).

Deterministic injuries are largely caused by the radiation-induced reproductive sterilization of cells. This is not expressed clinically until these cells unsuccessfully attempt division or differentiation. The severity of the effect varies with radiation dose. A dose threshold usually exists. The threshold dose is subject to biologic variation (9).

These effects can be severe and clinically devastating. Although commonly referred to as skin injuries, severe deterministic injuries can extend into the subcutaneous fat and muscle (10). Patients may experience years of pain, multiple surgical procedures, and permanent disfigurement (1,11,12). The frequency of major radiation injury is estimated to be between 1:10000 and 1:100000 procedures, but the true risk is unknown because these injuries are often not recognized or reported (9,13,14).

Principles of Radiation Protection

The International Commission on Radiological Protection (ICRP) has formulated three fundamental principles for radiation protection: justification, optimization of protection, and application of dose limits (15,16). The first two apply to all individuals and to all radiation exposures. The third does not apply to medical exposures of patients.

The principle of *justification* is that, in general, "any decision that alters the radiation exposure situation should do more good than harm. This means that by introducing a new radiation source, by reducing existing exposure, or by reducing the risk of potential exposure, one should achieve sufficient individual or societal benefit to offset the detriment it causes" (15,16).

A medical procedure should be performed only when it is appropriate for a particular patient. The RAND Corporation has developed a definition of "appropriate" that is widely used: the expected health benefit (ie, increased life expectancy, relief of pain, reduction in anxiety, improved functional capacity) exceeds the expected negative consequences (ie, mortality, morbidity, anxiety of anticipating the procedure, pain produced by the procedure, misleading or false diagnoses, time lost from work) by a sufficiently wide margin that the procedure is worth doing (17,18). In other words, the anticipated clinical benefits should exceed all anticipated procedural risks, including radiation risk.

The principle of *optimization of protection* is that "the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses should all be kept as low as reasonably achievable, taking into account economic and societal factors. This means that the level of protection should be the best under the prevailing circumstances, maximizing the margin of benefit over harm" (15,16,19).

For FGI procedures, this principle is applied in the design, appropriate selection, and use of equipment, and in day-to-day working procedures. Optimization is best described as a radiation dose to the patient that is commensurate

Essentials

- Radiation dose is optimized when imaging is performed with the least amount of radiation required to provide adequate image quality and imaging guidance.
- If radiation risk factors are present, or a substantial radiation dose is anticipated, a discussion of radiation risk is an appropriate part of the informed consent process.
- Radiation dose should be monitored throughout the procedure and recorded after the procedure.
- Patients who have received a clinically significant radiation dose should be advised of the radiation dose and its implications, and followed up after the procedure for possible deterministic effects.

with the medical purpose and avoidance of radiation that is clinically unnecessary or unproductive.

The principle of *application of dose limits* does not apply to medical exposure (15,16). As the ICRP states: "Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good" (16). For interventional procedures, the medical condition being treated and the nonradiation risks of the procedure typically present substantially greater morbidity and mortality than do the radiation risks (20).

Radiation Dose Estimation

Four special metrics have been developed for radiation dose estimation in fluoroscopic procedures: peak skin dose, reference point air kerma (reference dose), kerma-area product (also known as dose-area product), and fluoroscopy time. Kerma, an acronym for "kinetic energy released in matter," is 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). Air kerma is the energy extracted from an x-ray beam per unit mass of air in a small volume of irradiated air.

Peak skin dose, measured in grays, is the highest radiation dose (entrance surface air kerma) at any portion of a patient's skin during a procedure. It includes contributions from both the primary x-ray beam and from scatter. As of 2010, to our knowledge, no commercially available fluoroscopic unit is capable of calculating or displaying peak skin dose. It is possible to determine peak skin dose by using other methods, but they do not provide real-time measurements (21).

Reference dose, measured in grays, is the air kerma accumulated at a specific point in space relative to the fluoroscopic gantry. It does not include backscatter. The concept of a reference point

first appeared in 2000 (then called the *interventional reference point*) in the International Electrotechnical Commission (IEC) standard for interventional fluoroscopy equipment (22). It was adopted by the U.S. Food and Drug Administration in 2005 (23). The current (second) edition of the IEC standard, published in 2010, refers to this point as the *patient entrance reference point* (24). All interventional fluoroscopes conforming to the IEC standard, and all fluoroscopes sold in the United States after June 2006, are required to display reference dose to the operator at the operator's working position.

For isocentric fluoroscopes (C-arm), the reference point lies on the central axis of the x-ray beam, 15 cm on the x-ray tube side of isocenter (22,23). Since this point is defined relative to the x-ray equipment, not the patient, it moves relative to the patient during most fluoroscopically guided procedures. Reference dose is an approximation of the total radiation dose to the skin. While the position of the reference point is usually close to the patient's skin, it is rarely on the skin surface. Also, during the course of an FGI procedure, 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, estimates of the likelihood of deterministic effects in the skin that are based on reference dose tend to overstate this risk (25).

Kerma-area product, measured in gray–square centimeters ($Gy \cdot cm^2$), is a measure of the total x-ray energy leaving the x-ray tube. It is typically measured with an ionization chamber located near the collimator. Kerma-area product is independent of source-to-skin distance. When the radiation field is confined to the patient, kerma-area product is a good measure of the total x-ray energy absorbed by the patient. Kerma-area product permits a reasonable estimate of the stochastic risk of the procedure. It is widely used in Europe to monitor patient dose during interventional procedures. Kerma-area product is less useful for estimating the likelihood of skin effects, because a large radiation dose delivered to a small skin area may

yield the same kerma-area product as a small radiation dose delivered to a large skin area (26).

Fluoroscopy time is a measure of time, not dose. It does not incorporate the effects of fluoroscopic dose rates or dose due to fluorographic images (eg, digital subtraction angiography runs). It correlates poorly with other dose metrics (21,27). The Society of Interventional Radiology–Cardiovascular and Interventional Radiology Society of Europe (SIR–CIRSE) international guideline on patient radiation management states that fluoroscopy time should not be used to monitor patient irradiation during interventional procedures (28,29).

All statements of patient dose contain some degree of uncertainty (21). Even the most sophisticated dose-measurement instrumentation has unavoidable uncertainties. Converting these measurements into skin dose introduces further uncertainties related to the patient's size and position relative to the beam. Both reference dose and kerma-area product ignore the effect of backscatter from the patient, which can increase skin dose 10%–40%. Estimated skin doses may differ from actual skin dose by a factor of two or more (21).

Radiation Management in Interventional Procedures

The goal of clinical radiation management is to minimize radiation risk to the patient without increasing other risks, such as procedural risks. This is accomplished by managing patient exposure to optimize patient radiation dose and minimize patient skin dose. Radiation dose is optimized when imaging is performed with the least amount of radiation required to provide adequate image quality and imaging guidance (2).

Radiation management requires that factors be considered and that steps be taken before, during, and after an FGI procedure (30). It includes management of the patient, the fluoroscopic equipment, and the process. It also includes quality improvement and quality assurance. Each of these elements is considered in this review. Other aspects of procedure management that are not

specific to radiation management are not described here. The recommendations provided are, in general, from the SIR–CIRSE guideline (29).

Before the Procedure

Estimating the likelihood and severity of patient radiation effects requires consideration of demographic factors, medical history factors, and procedure factors. This process is particularly important when a relatively high radiation dose is expected. For most patients, the skin at the beam entrance site typically receives the highest dose of any tissue in the body and is the tissue at greatest risk for radiation injury. For some procedures, eye dose is of concern. Pregnant patients require special consideration.

Demographic factors.—These include patient age and weight. Young patients have a greater risk of radiation-induced cancer for a given radiation dose than do adults, because of their longer life expectancy and greater susceptibility to radiation effects. Overall, the risk factor is approximately three times higher for newborns than for the general population, and declines to that of the general population by the middle of the third decade of life (4,7,8). The risk of cancer induction is lower in older adults than in younger adults. In individuals in the seventh decade of life, the risk factor is about one-fifth that of the general population (7).

In the conceptus, radiation poses additional risks (31,32). A radiation dose of approximately 50–100 mGy may lead to clinically silent changes in developmental status, and a radiation dose greater than approximately 100 mGy may result in subtle to obvious changes in development, depending on dose (32).

For pediatric patients, we recommend that stochastic risk be considered of greater concern than deterministic effects. Interventional procedures completed on small children seldom use enough radiation to produce deterministic reactions such as hair loss or skin injury. Nonetheless, radiation management in pediatric interventional procedures is essential (33). Adolescents with adult-size bodies and childhood

risk factors deserve special consideration. For adult patients, we consider the risk of deterministic injuries (eg, skin effects, hair loss) of greater concern (1).

Obese patients are at a higher risk of radiation-induced skin injury because of poor radiation penetration and the accompanying closer proximity of the x-ray source to the patient (34). Absorbed dose at the entrance skin site in obese patients can be as much as 10 times higher than in some nonobese patients (35). Many of the documented injuries associated with fluoroscopic procedures are seen in larger patients (11). Obesity also results in high effective doses, especially from procedures in and radiographic examinations of the abdomen. In the extremely obese, radiographic examinations of the abdomen can result in effective doses 50 times greater than those expected for a nonobese individual (36).

Ethnic differences in skin coloration are also associated with differences in radiation sensitivity; individuals with light-colored hair and skin are most sensitive (37).

Medical history factors.—Important aspects of the patient's medical history include genetic factors, coexisting diseases, medication use, radiation history, and pregnancy.

Defects in DNA repair genes may predispose individuals to radiogenic cancer or lower the threshold for the development of deterministic effects (38,39). Many patients with serious and unanticipated radiation injuries may be among the 1% of the population heterozygous for the *ATM* gene, an autosomal recessive gene responsible for ataxia telangiectasia, or may harbor some other *ATM* abnormality (38,39). Other disorders with a genetic component affecting DNA breakage or repair also increase radiation sensitivity, including Fanconi anemia, Bloom syndrome, and xeroderma pigmentosum (38,39). Familial polyposis, Gardner syndrome, hereditary malignant melanoma, and dysplastic nevus syndrome also increase radiation sensitivity (38). Certain familial cancer syndromes may increase susceptibility to radiogenic

cancer, including neurofibromatosis, Li-Fraumeni syndrome, and hereditary retinoblastoma (39).

Autoimmune and connective tissue disorders predispose patients to the development of severe cutaneous radiation effects in an unpredictable fashion. The cause is not known. These disorders include scleroderma, systemic lupus erythematosus, and possibly rheumatoid arthritis (38). Hyperthyroidism and diabetes mellitus are also associated with increased radiation sensitivity (13). Diabetes is believed to predispose to radiation injury secondary to small vessel vascular disease and consequent decreased healing capacity (34,40).

A number of drugs increase radiation sensitivity, including actinomycin D, doxorubicin, bleomycin, 5-fluorouracil, and methotrexate (13). When given in conjunction with radiation therapy, paclitaxel, docetaxel, and possibly tamoxifen can result in cutaneous toxicity (38).

Previous radiation to an area of skin that will be re-irradiated for the planned interventional procedure can increase the risk of deterministic skin effects, depending on the radiation dose from previous procedures and the time interval between previous procedures and the planned procedure (9). Similarly, if the planned interventional procedure uses the same radiation field as the skin entrance portal to be used for future radiation therapy, there may be an increased risk of deterministic skin effects from the radiation therapy.

Other patient-related factors that increase susceptibility to radiation injury include poor nutritional status and compromised skin integrity (38).

Procedure factors.—Some types of interventional radiology procedures are known to be "high dose," that is, associated with skin doses that can be sufficient to produce deterministic effects in an average patient. Examples are shown in the Figure (25). Some interventional cardiology procedures are also known to be "high dose" (20,41). Technical difficulty during other procedures often leads to prolonged procedures and radiation doses that are higher than expected.

Sensitivity to radiation effects also depends on the location of the irradiated skin (38). The scalp is relatively resistant to the development of skin damage, but scalp hair is relatively more sensitive to epilation than hair elsewhere on the body (37).

Interventional procedures in the head and neck often result in irradiation of the eyes, and may result in relatively high doses to the lens of the eye if the orbits are included in the field for much of the procedure. New data suggest that lens opacities (cataracts) occur at radiation doses far lower than those previously assumed to be cataractogenic, in a manner statistically consistent with the absence of a dose threshold (5,42–47). If there is a threshold dose, it is possible that it is less than 0.1 Gy (44,48). The latency period for radiation cataract formation is inversely related to radiation dose (5).

Preprocedure Planning

Evaluation of radiation risk to the patient includes consideration of the relevant demographic, medical, and procedural risk factors discussed above, and the patient's previous radiation exposure, including radiation therapy. Review of dose data from previous radiation-guided interventions, if available, is helpful. If there is a history of previous radiation (especially in the past 60 days) to the same area of skin that will be irradiated for the planned FGI procedure, examination of this skin area for possible radiation changes is appropriate. If changes are present, modification of the procedure may be desirable, if this can be done without undue risk to the patient. Current understanding of radiation effects on the skin suggests, as a practical guideline, that procedures performed with the entrance beam directed at the same area of skin are ideally separated by at least 60 days (9).

Informed consent.—If the preprocedure evaluation suggests that the procedure will require a substantial radiation dose, or that the patient is likely to have a lower threshold for deterministic effects, a discussion of radiation risks as part of the informed consent process

Interventional Radiology Procedures with the Potential for High Skin Doses

Intracranial, facial, or spinal embolization

Embolization elsewhere in the body

Transjugular intrahepatic portosystemic shunt (TIPS) creation or revision

Vascular stent or stent-graft placement in the abdomen or pelvis

Complex biliary interventions

Nephrostomy procedures for stone access and manipulation

Vertebroplasty

List of interventional radiology procedures with the potential for high skin doses.

is appropriate (1,2,29). The SIR–CIRSE guideline on patient radiation management provides sample language (Appendix E1) (online) (29).

Pregnancy.—Except for time-critical emergency procedures, pregnancy status should be determined prior to an interventional procedure (16,32). We recommend that elective FGI procedures not be performed in pregnant patients. If possible, use other modalities (ultrasonography, magnetic resonance imaging) to guide interventions in pregnant patients.

ICRP Publication 84 states that, in general, termination of pregnancy at fetal doses of less than 100 mGy is not justified based on radiation risk (49). For expected conceptus doses above 100 mGy, the pregnant patient should receive sufficient information to be able to make informed decisions based on individual circumstances, including the magnitude of the estimated embryonic/fetal dose and the consequent risks of serious harm to the developing embryo/fetus and risks of cancer in later life (15,16).

When FGI procedures must be performed on pregnant patients, and except for time-critical emergency procedures, we recommend that procedure planning include feasible modifications to minimize conceptus dose, estimation of expected radiation dose to the conceptus, evaluation of the radiogenic risk to the conceptus, and inclusion in

Table 1

Significant Radiation Dose Thresholds

Dose Metric	Threshold
Peak skin dose	3000 mGy
Reference dose	5000 mGy
Kerma-area product	500 Gy·cm^2
Fluoroscopy time	40– 60 min*

Note.—Reprinted, with permission, from reference 29.

*See text for a discussion of fluoroscopy time as an indicator of significant radiation dose.

the informed consent process of the expected benefits and potential risks of the procedure to both the patient and the conceptus. The preprocedure planning process may benefit from involvement of a qualified physicist, if time permits (32).

Equipment.—Procedures that may result in a clinically significant radiation dose, as defined in the SIR–CIRSE guidelines (Table 1), should be performed by using fluoroscopic equipment that is compliant with International Electrotechnical Commission Standard 60601–2-43 (22,24,29). A qualified physicist should verify the measured exposure rates for typical clinical scenarios, and confirm that they are appropriate (50–52). This performance testing should be conducted prior to the first clinical use of the equipment and repeated at least annually to ensure that patient radiation dose rates are consistent with those necessary to provide appropriate image quality (50–53).

During the Procedure

It is the operator's responsibility to optimize radiation dose—to use the least amount of radiation required to provide adequate image quality and imaging guidance. This has the added benefit of reducing operator and staff dose as well as patient dose—a "win-win" situation (54). The recommendations in this section are derived from national and international guidelines (1,2,55,56).

Conceptually, the clinical management of radiation is similar to the clinical management of iodinated contrast media (57). Patient radiation dose should be limited to that required for the

procedure being performed (15,16). This implies that the operator controls the use and monitors the dose of radiation during the procedure. As the procedure continues and more radiation is used, further irradiation of the patient is minimized consistent with clinical requirements. Some patients are more susceptible to harmful effects at a given dose, as a result of the various sensitizing factors noted above. They require special care to control radiation dose, in the same way that contrast material dose is controlled in patients with renal compromise.

Equipment management.—Operator knowledge and experience are important factors in optimizing dose (58). Dose optimization requires attention to several basic principles. These are discussed in detail in several excellent reviews (11,59,60) and are summarized here.

Dose optimization is possible through appropriate use of the basic features of interventional fluoroscopic equipment and intelligent use of dose-reducing technology (61). Many technical parameters can be adjusted during the procedure to reduce radiation use or to improve image quality, depending on the demands of the situation (59). These controls and features affect radiation production, image generation and manipulation, and radiation dose.

The operator must control some operational parameters directly. Collimate appropriately to the imaging task to limit the size of the irradiated area. Position the image receptor as close as reasonably possible to the patient and maximize the distance between the patient and the x-ray tube. Position the patient's arms outside the radiation field unless the arm is intentionally imaged as part of the procedure (59). Use electronic magnification modes and high-dose-rate modes only when necessary. Use the lowest fluoroscopic dose rate that is clinically acceptable. When electronic magnification is necessary, use the lowest acceptable magnification factor. Incremental changes in these operational parameters are multiplicative and markedly affect total dose delivered to a patient's skin. For long procedures,

differences in doses of 8 Gy or more are possible for some combinations of operational techniques (35).

All modern fluoroscopes automatically adjust radiation output during both fluoroscopy and fluorography to accommodate the thickness of the body part being imaged. Patient body part thickness is affected by the choice of gantry angulation during the procedure. Steep oblique or craniocaudal beam orientations increase the length of the radiation path through the body as compared with a posteroanterior (frontal) projection. As a result, these beam orientations require an increase in radiation output, sometimes by a factor of 10 or more, as compared with a posteroanterior projection. The proximity of the x-ray source to the entrance skin surface that is necessitated by these steep angles also results in an increase in skin dose.

The presence of bone in the beam is also important. Bone is more difficult to penetrate than soft tissue. Its presence causes the fluoroscope to increase radiation output to maintain image quality. Overlying bone also makes it more difficult to identify superimposed catheters and other medical devices. This may prolong the procedure. Beam orientations that place bone in the radiation field increase the dose rate and total radiation dose to the area.

Fluoroscopy time can be minimized with judicious use of intermittent fluoroscopy, last image hold and, where available, "virtual" or electronic collimation. Fluoroscopy is only necessary to observe motion or to guide positioning of devices within the body. Last-image-hold images and fluoroscopy loops are usually satisfactory for intraprocedural review purposes, and do not subject the patient to additional radiation.

Reduced-dose pulsed fluoroscopy has the greatest potential for maintaining patient radiation exposure at low levels (35). However, manufacturers implement pulsed fluoroscopy with different methods. Some pulsed fluoroscopy modes yield a higher dose rate than conventional fluoroscopy (62). It may be necessary to consult the manufacturer of the fluoroscopic equipment or

to have a medical physicist measure the dose rate for each pulsed fluoroscopy mode.

Minimizing the number of images obtained during a procedure requires planning. With modern angiographic units, it is easy to set the unit to acquire images at two or more images per second and to perform the entire angiographic run at that rate. This is neither necessary nor desirable. Filming sequences with variable frame rates minimize the number of images obtained while assuring that no important information is lost. Angiographic units can be preprogrammed with the same imaging sequences used previously for film hard copy (62).

When the only purpose of an image is to document what is seen at the last image hold, there is no need to obtain additional fluorographic images if the last image hold demonstrates the finding adequately and can be stored. Many modern systems can store fluoroscopy loops. If a fluoroscopy loop provides adequate information for diagnosis or documentation, storing it in lieu of an additional subtraction angiography run or additional fluorographic images provides substantial dose savings.

The assistance of a qualified physicist or a field service engineer from the manufacturer may be required for adjustment of some technical factors. These include pulse rate, pulse width, and pulsed kilovolt peak during fluoroscopy and fluorography, beam filtration, fluoroscopic and digital imaging dose settings at the image receptor, a variety of image processing parameters, and video frame averaging (to reduce the appearance of noise on the image).

Dose reduction should not impair image quality. The principle of justification is quite clear that *any* decision that alters the radiation exposure situation should do more good than harm (15). This specifically includes reducing exposure. Images that are inadequate for diagnosis or for guiding interventions introduce the risk of catastrophic complications.

Skin dose.—In general, measures that reduce total radiation dose will also reduce peak skin dose. Minimizing

peak skin dose requires adherence to general methods for reducing total dose as well as use of specific methods to reduce peak skin dose (62).

Two simple, basic techniques, used together, will reduce peak skin dose (62). The purpose of these techniques is to reduce the skin dose at any one point on the skin surface by irradiating different portions of the skin at different times during the course of the procedure.

The first technique, dose spreading, changes the position of the radiation field on the patient's skin by using small amounts of gantry angulation, table movement, or both (60,63). Spreading the skin dose in this way reduces peak skin dose and also reduces the size of the skin area subjected to the peak skin dose. This reduces the size of the skin area at highest risk.

The second technique is collimation. This is as important as dose spreading. Even with dose spreading techniques, different irradiated fields can overlap on the skin surface. The overlap area receives a higher dose. Tight collimation may prevent overlap, especially with biplane fluoroscopic units, and markedly improves the effectiveness of dose spreading techniques (62).

Eye dose.—Irradiation of a patient's eyes should be minimized, consistent with clinical requirements. When imaging the head and face in the frontal plane, eye dose is reduced when the radiation beam enters the head in a posterior-anterior direction. Beam collimation that excludes the orbits from the radiation field also reduces eye dose.

Conceptus dose.—When an FGI procedure is performed on a pregnant patient, one goal is a conceptus dose that is the practicable minimum for the procedure. Some procedures can be performed with little or no direct exposure to the conceptus. If radiation exposure to the conceptus is limited to scattered radiation, the result is often very low and usually acceptable risk levels (32). Consider placing extra, previously unused personnel monitors anteriorly and posteriorly on the patient's pelvis for prospective documentation of conceptus radiation dose. This may yield important

information for later decisions about medical care (32).

Monitoring radiation dose.—The SIR–CIRSE guideline states that radiation dose should be monitored throughout the procedure (29). This responsibility may be delegated to a technologist, nurse, or other person depending on the institution's policies and needs, but a specific individual should be tasked with this responsibility.

Dose monitoring ensures that the operator is aware of how much radiation is being administered. It is routine for the operator to concentrate on the clinical requirements of the interventional procedure. The operator may lose awareness of the patient's radiation dose. Designation of another individual to monitor dose and inform the operator prevents this from occurring.

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. However, all personnel participating in the procedure share a responsibility for achieving radiation management and safety goals. All staff should be able to recognize and correct unsafe practices or bring them to the attention of others who can correct the situation (55).

Most institutions in the U.S. will use reference dose for dose monitoring. As of 2010, skin dose estimates and maps of skin dose distribution are not generally available in real time during the procedure. Kerma-area product may also be used. Fluoroscopy time correlates poorly with other dose metrics (21,27). It should be used with caution

to monitor patient irradiation during interventional procedures (28,29). For high-dose or potentially high-dose procedures, fluoroscopic equipment capable of estimating and displaying reference dose or kerma-area product in real time should be used (29).

The operator should be advised of the patient's radiation dose when it exceeds certain specified values and at regular intervals thereafter (Table 2) (29). The values in Table 2 have been chosen so that they are round numbers and so that three notifications, regardless of the dose metric used, indicate that patient follow-up is necessary (29). When using reference dose or skin dose with a biplane system, each plane is considered independently, unless the fields overlap. If there is overlap, doses from the two planes are added. When using kerma-area product to estimate stochastic risk with a biplane system, the doses from each plane are added, regardless of whether overlap is present (29).

Significant radiation dose.—For radiation monitoring during the procedure and patient management after the procedure, it is useful to consider the concept of a *significant radiation dose* (29,57). This is a threshold value used to trigger additional dose management actions, including patient follow-up. There is no implication that a radiation dose below the significant dose level is completely safe or that a radiation dose above the significant dose level will always cause an injury.

The significant radiation dose level will vary depending on both patient and procedure parameters (Table 1) (29).

Table 2

Summary of Radiation Monitoring Dose Notification Thresholds

Dose Metric	First Notification	Subsequent Notifications
Peak skin dose	2000 mGy	500 mGy
Reference dose	3000 mGy	1000 mGy
Kerma-area product	300 Gy·cm^2*	100 Gy·cm^2*
Fluoroscopy time	30 min	15 min

Note.—Reprinted, with permission, from reference 29.

*Assuming a 100 cm^2 field at the patient's skin. The value should be adjusted to the actual procedural field size, but this is rarely practical.

These values are intended to trigger follow-up for a radiation dose that might produce a clinically relevant injury in an average patient. Lower values may be used at the discretion of the facility, especially when previously irradiated skin is involved (2,55). Mahesh (64) has suggested a two-level threshold for tracking radiation dose.

Procedures performed using biplane fluoroscopic systems are a special situation with regards to determining significant doses. The dose received from each plane should be considered independently when the fields do not overlap. When they do overlap, or it is uncertain if they overlap, the doses are added.

Using radiation dose information during the procedure.—A radiation dose notification prompts the operator to consider the dose already delivered to the patient and the additional radiation necessary to complete the procedure. It is an opportunity to consider the risks and benefits of proceeding. Radiation risk is only one of many risks of medical procedures. A procedure should not be stopped solely because the significant radiation dose level has been exceeded (57). 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 patient detriment due to radiation. Further, if the procedure is stopped before the desired clinical result has been reached, radiation risk is incurred without corresponding clinical benefit.

Even with optimal technique, it is not always possible to keep peak skin dose below the threshold for skin effects. This does not necessarily indicate poor operator technique. It is not necessarily a contraindication to performing or continuing a procedure. Patient factors, radiation doses from previous procedures, anatomic variations, disease and lesion complexity, the type of procedure, and the clinical indication for the procedure may combine so that a prolonged procedure with a high radiation dose is unavoidable. The decision to proceed or to halt is properly based on all the benefits and risks of the FGI procedure as well as the benefits and risks of any alternative therapies.

In some circumstances, a planned and clinically necessary intervention or series of interventions may require a sufficient dose of radiation to reach the Joint Commission's threshold for a sentinel event of 15 Gy over a period of 6 months to 1 year (64,65). The Joint Commission has defined a sentinel event as an "unexpected" outcome, with the implication that any radiation dose over 15 Gy is unexpected and "preventable" (66,67). In this scenario, however, the radiation dose is neither unexpected nor preventable. The scenario is different from, say, a retained surgical sponge (another scenario classified by the Joint Commission as a sentinel event), especially if a portion of the 15 Gy is due to FGI procedures or radiation therapy in the recent past, with radiation delivered to the same area of skin (65). Examples of situations where it may be necessary to exceed a combined skin dose of 15 Gy for multiple procedures include, among others, multiple percutaneous coronary interventions, multiple or staged neuro-embolization procedures, and multiple transjugular intrahepatic portosystemic shunt procedures.

After the Procedure

Recording radiation dose.—It is good practice to record patient radiation dose in the patient's medical record for all FGI procedures (1,2,21,55,56,68). Recorded data should include the following elements, in the priority order listed, if they are available: skin dose maps, peak skin dose, reference dose, kerma-area product, fluoroscopy time, and number of acquisition frames (21). (As of 2010, skin dose mapping and peak skin dose estimation are not generally available.) Fluoroscopy time should not be the only recorded value if other dose metrics are available (1,21,29,55,68). If the patient is pregnant, dose to the conceptus should also be evaluated and recorded. This may require consultation with a qualified physicist (32).

Actions triggered by a significant radiation dose.—The operator is notified when a significant radiation dose has been administered (29). The operator writes an appropriate note in the patient's medical record, stating that a significant radiation dose has been administered and indicating the reason (29,56,57). This information may be included in the postprocedure note. A radiation note in the medical record may also be valuable even if these thresholds are not exceeded (eg, for patients in whom other high-dose interventional procedures involving radiation exposure to the same area are planned or have already been performed within the past 6 months).

Follow-up of patients who have received a significant radiation dose is appropriate at 10–14 days and 1 month after the procedure (Appendix E2) (online) (2,29,56,57). This can be done by telephone, with a clinic visit needed only if the patient reports skin changes at the radiation entrance site (see below). Risks associated with irradiation of the lens may be excluded from follow-up, due to the long latency period for these effects.

Patient follow-up.—If follow-up for possible radiation effects is needed, it is appropriate to make these arrangements before the patient leaves the facility. Follow-up for lesser radiation doses may be desirable in special situations, such as previous recent irradiation of the same anatomic region. If any of the thresholds in Table 1 are met during a procedure, monitoring of doses for additional procedures performed within the subsequent 6 months is appropriate, with these doses generally considered additive to the dose already received (29).

Patients are advised if they have received a substantial radiation dose (2,21,29,56,57,68). As appropriate, patients, caregivers and responsible healthcare professionals should be made aware of the possible radiogenic cause of relevant signs and symptoms (1). A patient who has received a significant radiation dose should be given written instructions for follow-up of possible radiation effects in addition to their other discharge instructions (Appendix E2) (online) (29).

The patient and caregivers are instructed to notify the operator and/or qualified physicist of the results of

self-examination of the irradiated area (positive or negative) (29). They are also instructed to notify the operator (or designee) if any signs or symptoms of a possible radiogenic deterministic effect are observed. Clinical follow-up is arranged if the examination is positive or there are suspicious signs or symptoms. It is wise to regard relevant signs and symptoms as radiogenic unless an alternative diagnosis is unambiguously established (9,57). If a radiogenic cause has not been ruled out, referral to a dermatologist experienced in managing radiation injuries (ie, injuries from radiation oncology treatments) is appropriate, as are provision of available skin dose information to the dermatologist and collaboration with the patient's treatment team (38).

Review of all positive patient reports by a qualified physicist and discussion of the findings with the operator help to evaluate the dosimetric aspects of the procedure. The physicist may also assist in facilitating clinical follow-up. Individual institutions may have other recommendations and/or requirements for patient follow-up.

Quality Assurance and Quality Improvement

Radiation management in interventional radiology is a quality process. Its primary goal is to minimize the unnecessary use of radiation.

Reference levels.—National and international advisory bodies have supported the use of reference levels (RLs) (1,56,69,70). These and other organizations have provided guidelines on measuring radiation dose and setting RLs (15,71–74). Depending on the source, RLs can be based on phantom studies, clinical examinations with "standard patients," or clinical examinations of large numbers of patients. Understanding the relationship of a facility's dose data to the RL requires consideration of both equipment and the patient population. With such insights, feedback generated by RLs has yielded reduction in x-ray use in diagnostic procedures (75).

RLs help avoid radiation dose to the patient that does not contribute to the medical imaging task (71,76). They

are a guide to what is achievable with current good practice, rather than optimum performance, and are neither dose limits nor thresholds that define competent performance of the operator or the equipment (74). A mean dose for a procedure that is less than the RL does not guarantee that the procedure is being performed optimally (77).

The ICRP considers RLs a useful tool to help optimize patient radiation dose in FGI procedures (15). Recent studies have presented RLs for cardiovascular procedures (78–81) and a limited number of interventional radiology procedures (75,82–89). Unfortunately, the observed distributions of patient doses for most types of FGI procedures are very wide, because the dose for each instance of a procedure is strongly dependent on individual clinical circumstances. A potential approach is to include the "complexity" of the procedure in the analysis (16,78,90). Since, at present, complexity cannot be quantified (with the exception of some interventional cardiology procedures), this adjustment is not yet possible for FGI procedures (78,90).

To use RLs, an institution or individual practitioner collects radiation dose data for cases of a procedure performed in their own practice. The recommended number of cases varies from 10 to more than 50, with the latter number suggested because of the high individual variability of cases of FGI procedures (71,85). If local practice results in a mean radiation dose that is greater than the RL, the fluoroscopic equipment should be investigated. If the fluoroscopic equipment is functioning properly and within specification, operator technique and procedure protocols should be examined (77). Investigations are also appropriate where local values are substantially below the RLs, as excessively low doses may be associated with poor image quality (78,90).

Specific processes.—Radiation dose management begins with appropriately selected, properly functioning x-ray equipment. Equipment should be appropriate to the intended clinical use and properly installed and configured prior to clinical use. Both the technical

performance of the equipment and its expected clinical uses will change over time. A qualified medical physicist should test the equipment on at least an annual basis (50,51). The National Council on Radiation Protection and Measurements recommends a semiannual interval (52). There are three possible outcomes to this acceptability review, beyond compliance with local regulatory standards: The equipment is acceptable for all intended uses, acceptable for a limited range of intended uses, or not acceptable until repaired or replaced.

Clinical radiation dose management requires collection of dose data from each FGI procedure. This is combined with patient, operator, and procedural information to provide a picture of dose utilization for each procedure. The data set ideally includes patient demographic data (height, weight, age), available dosimetric data, the procedure performed, the room in which the procedure was performed, and the physicians or other operators performing the procedure, with an indication of their roles.

We suggest the following quality assurance and quality improvement process. We recommend that procedures resulting in a significant radiation dose be identified and reported to the laboratory director and laboratory quality manager on a periodic basis. A monthly report is helpful, to ensure that patients with high doses receive appropriate education and follow-up. A weekly report is appropriate for facilities performing high volumes of procedures or frequent high dose procedures (57).

We recommend discussing reported potential radiation injuries at the next laboratory quality assurance meeting, with any available diagnoses, planned patient follow-up, and outcomes (57). Unless a nonradiogenic diagnosis has been established, we recommend reviewing the procedure for appropriate use of radiation in the clinical context. It may be appropriate to periodically re-report on the status of known radiation injuries. Additionally, periodic reporting of these cases to the institution's radiation safety officer is desirable (29).

If the database storage format permits it, we suggest analyzing the entire database on a periodic basis to determine the mean and interquartile dose values for each procedure type performed commonly in the laboratory, the five highest dose values for each of these procedure types, the variation of mean and third quartile dose from room to room for the same procedure, the variation of mean and third quartile dose from operator to operator for the same procedure, and unexplainable deviation from available guidance levels on a laboratory basis.

In conclusion, FGI procedures provide great benefit to patients, but also entail risks, including the risk of radiation effects. Minimizing the likelihood and severity of radiation effects requires appropriate and properly functioning equipment, a radiation management process that extends from preprocedure planning through postprocedure follow-up, and a robust quality assurance and quality improvement program. Radiation injuries cannot always be avoided, but an informed and motivated physician can reduce their incidence and severity.

References

1. International Commission on Radiological Protection. Avoidance of radiation injuries from medical interventional procedures. ICRP publication 85. Ann ICRP 2000;30(2):7–67.

2. National Cancer Institute. Interventional fluoroscopy: reducing radiation risks for patients and staff. NIH Publication No. 05-5286. Bethesda, Md: National Cancer Institute, 2005. http://www.cancer.gov/cancertopics/interventionalfluoroscopy/allpages. Accessed June 13, 2010.

3. United Nations Scientific Committee on the Effects of Atomic Radiation. Sources and effects of ionizing radiation. New York, NY: United Nations, 2000.

4. Little MP. Risks associated with ionizing radiation. Br Med Bull 2003;68:259–275.

5. Kleiman NJ. Radiation cataract. In: Working Party on Research Implications on Health and Safety Standards of the Article 31 Group of Experts, ed. Radiation Protection 145: EU Scientific Seminar 2006: new insights in radiation risk and basic safety standards. Brussels, Belgium: European Commission, 2007;81-95. http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/145_en.pdf. Accessed June 13, 2010.

6. Thierry-Chef I, Simon SL, Land CE, Miller DL. Radiation dose to the brain and subsequent risk of developing brain tumors in pediatric patients undergoing interventional neuroradiology procedures. Radiat Res 2008;170(5):553–565.

7. Hall EJ. Radiation biology for pediatric radiologists. Pediatr Radiol 2009;39(suppl 1):S57–S64.

8. National Research Council. Health risks from exposure to low levels of ionizing radiation: BEIR-VII Phase 2. Washington, DC: National Academy Press, 2006.

9. Balter S, Hopewell JW, Miller DL, Wagner LK, Zelefsky MJ. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. Radiology 2010;254(2):326–341.

10. Monaco JL, Bowen K, Tadros PN, Witt PD. Iatrogenic deep musculocutaneous radiation injury following percutaneous coronary intervention. J Invasive Cardiol 2003;15(8):451–453.

11. Koenig TR, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part 2, review of 73 cases and recommendations for minimizing dose delivered to patient. AJR Am J Roentgenol 2001;177(1):13–20.

12. Frazier TH, Richardson JB, Fabré VC, Callen JP. Fluoroscopy-induced chronic radiation skin injury: a disease perhaps often overlooked. Arch Dermatol 2007;143(5):637–640.

13. Koenig TR, Wolff D, Mettler FA, Wagner LK. Skin injuries from fluoroscopically guided procedures: part 1, characteristics of radiation injury. AJR Am J Roentgenol 2001;177(1):3–11.

14. Padovani R, Bernardi G, Quai E, et al. Retrospective evaluation of occurrence of skin injuries in interventional cardiac procedures. Radiat Prot Dosimetry 2005;117(1-3):247–250.

15. The 2007 Recommendations of the International Commission on Radiological Protection. ICRP publication 103. Ann ICRP 2007;37(2-4):1–332.

16. Radiation protection in medicine. ICRP Publication 105. Ann ICRP 2007;37(6):1–63.

17. What do we mean by appropriate health care? Report of a working group prepared for the Director of Research and Development of the NHS Management Executive. Qual Health Care 1993;2(2):117–123.

18. Sistrom CL. In support of the ACR Appropriateness Criteria. J Am Coll Radiol 2008;5(5):630–635; discussion 636–637.

19. National Council on Radiation Protection and Measurements. Limitation of exposure to ionizing radiation. NCRP Report No. 116. Bethesda, Md: National Council on Radiation Protection and Measurements, 1993.

20. Miller DL. Overview of contemporary interventional fluoroscopy procedures. Health Phys 2008;95(5):638–644.

21. Miller DL, Balter S, Wagner LK, et al. Quality improvement guidelines for recording patient radiation dose in the medical record. J Vasc Interv Radiol 2004;15(5):423–429.

22. International Electrotechnical Commission. Medical electrical equipment: part 2-43—particular requirements for the safety of x-ray equipment for interventional procedures. Report 60601. Geneva, Switzerland: International Electrotechnical Commission, 2000.

23. Electronic products; performance standard for diagnostic x-ray systems and their major components. Final rule. Fed Regist 2005;70(111):33997–34042.

24. International Electrotechnical Commission. Medical electrical equipment: part 2-43—particular requirements for the safety of x-ray equipment for interventional procedures. Report 60601. 2nd ed. Geneva, Switzerland: International Electrotechnical Commission, 2010.

25. Miller DL, Balter S, Cole PE, et al. Radiation doses in interventional radiology procedures: the RAD-IR study. Part II. Skin dose. J Vasc Interv Radiol 2003;14(8):977–990.

26. McParland BJ. Entrance skin dose estimates derived from dose-area product measurements in interventional radiological procedures. Br J Radiol 1998;71(852):1288–1295.

27. Fletcher DW, Miller DL, Balter S, Taylor MA. Comparison of four techniques to estimate radiation dose to skin during angiographic and interventional radiology procedures. J Vasc Interv Radiol 2002;13(4):391–397.

28. O'Dea TJ, Geise RA, Ritenour ER. The potential for radiation-induced skin damage in interventional neuroradiological procedures: a review of 522 cases using automated dosimetry. Med Phys 1999;26(9):2027–2033.

29. Stecker MS, Balter S, Towbin RB, et al. Guidelines for patient radiation dose management. J Vasc Interv Radiol 2009;20(7 suppl): S263–S273.

30. International Atomic Energy Agency. Patient dose optimization in fluoroscopically guided interventional procedures. IAEA-TECDOC-1641. Vienna, Austria: International Atomic Energy Agency, 2010. http://www-pub.iaea .org/MTCD/publications/PDF/te_1641_web .pdf. Accessed June 13, 2010.

31. International Commission on Radiological Protection. Biological effects after prenatal irradiation (embryo and fetus). ICRP publication 90. Ann ICRP 2003;33(1-2):5–206.

32. American College of Radiology. ACR practice guideline for imaging pregnant or potentially pregnant adolescents and women with ionizing radiation. Practice Guidelines and Technical Standards 2008. Reston, Va: American College of Radiology, 2008;23-37. http://www.acr.org/SecondaryMainMenu Categories/quality_safety/guidelines/dx /Pregnancy.aspx. Accessed June 13, 2010.

33. Sidhu MK, Goske MJ, Coley BJ, et al. Image gently, step lightly: increasing radiation dose awareness in pediatric interventions through an international social marketing campaign. J Vasc Interv Radiol 2009;20(9): 1115–1119.

34. Bryk SG, Censullo ML, Wagner LK, Rossman LL, Cohen AM. Endovascular and interventional procedures in obese patients: a review of procedural technique modifications and radiation management. J Vasc Interv Radiol 2006;17(1):27–33.

35. Wagner LK, Archer BR, Cohen AM. Management of patient skin dose in fluoroscopically guided interventional procedures. J Vasc Interv Radiol 2000;11(1):25–33.

36. Yanch JC, Behrman RH, Hendricks MJ, McCall JH. Increased radiation dose to overweight and obese patients from radiographic examinations. Radiology 2009;252(1):128–139.

37. Geleijns J, Wondergem J. X-ray imaging and the skin: radiation biology, patient dosimetry and observed effects. Radiat Prot Dosimetry 2005;114(1-3):121–125.

38. Hymes SR, Strom EA, Fife C. Radiation dermatitis: clinical presentation, pathophysiology, and treatment 2006. J Am Acad Dermatol 2006;54(1):28–46.

39. Allan JM. Genetic susceptibility to radiogenic cancer in humans. Health Phys 2008; 95(5):677–686.

40. Herold DM, Hanlon AL, Hanks GE. Diabetes mellitus: a predictor for late radiation morbidity. Int J Radiat Oncol Biol Phys 1999; 43(3):475–479.

41. Padovani R, Quai E. Patient dosimetry approaches in interventional cardiology and literature dose data review. Radiat Prot Dosimetry 2005;117(1-3):217–221.

42. Vano E, Gonzalez L, Fernández JM, Haskal ZJ. Eye lens exposure to radiation in interventional suites: caution is warranted. Radiology 2008;248(3):945–953.

43. Worgul BV, Kundiyev YI, Sergiyenko NM, et al. Cataracts among Chernobyl clean-up workers: implications regarding permissible eye exposures. Radiat Res 2007;167(2): 233–243.

44. Neriishi K, Nakashima E, Minamoto A, et al. Postoperative cataract cases among atomic bomb survivors: radiation dose response and threshold. Radiat Res 2007;168(4):404–408.

45. Klein BE, Klein R, Linton KL, Franke T. Diagnostic x-ray exposure and lens opacities: the Beaver Dam eye study. Am J Public Health 1993;83(4):588–590.

46. Hall P, Granath F, Lundell M, Olsson K, Holm LE. Lenticular opacities in individuals exposed to ionizing radiation in infancy. Radiat Res 1999;152(2):190–195.

47. Minamoto A, Taniguchi H, Yoshitani N, et al. Cataract in atomic bomb survivors. Int J Radiat Biol 2004;80(5):339–345.

48. Nakashima E, Neriishi K, Minamoto A. A reanalysis of atomic-bomb cataract data, 2000-2002: a threshold analysis. Health Phys 2006;90(2):154–160.

49. International Commission on Radiological Protection. Pregnancy and medical radiation. ICRP publication 84. Ann ICRP 2000;30(1):1–43.

50. American College of Radiology. ACR technical standard for diagnostic medical physics performance monitoring of radiographic and fluoroscopic equipment. Practice Guidelines and Technical Standards 2008. Reston, Va: American College of Radiology, 2006;1139-1142. http://www.acr.org/SecondaryMain MenuCategories/quality_safety/guidelines/ med_phys/radio_fluoro_equipment.aspx. Accessed June 13, 2010.

51. American Association of Physicists in Medicine. Quality control in diagnostic imaging. AAPM report no. 74. Madison, Wis: Medical Physics Publishing, 2002.

52. National Council on Radiation Protection and Measurements. Quality assurance for diagnostic imaging. NCRP report no. 99. Bethesda, Md: National Council on Radiation Protection and Measurements, 1988.

53. Strauss KJ. Interventional suite and equipment management: cradle to grave. Pediatr Radiol 2006;36(suppl 2):221–236.

54. Miller DL, Vañó E, Bartal G, et al. Occupational radiation protection in interventional radiology: a joint guideline of the cardiovascular and interventional radiology society of europe and the society of interventional radiology. Cardiovasc Intervent Radiol 2010;33(2):230–239.

55. American College of Radiology. ACR technical standard for management of the use of radiation in fluoroscopic procedures. Practice Guidelines and Technical Standards 2008. Reston, Va: American College of Radiology, 2008;1143-1149. http://www.acr.org /SecondaryMainMenuCategories/quality_ safety/guidelines/med_phys/management_ fluoro_procedures.aspx. Accessed June 13, 2010

56. Hirshfeld JW Jr, Balter S, Brinker JA, et al. ACCF/AHA/HRS/SCAI clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures. A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training. J Am Coll Cardiol 2004;44(11): 2259–2282.

57. Balter S, Moses J. Managing patient dose in interventional cardiology. Catheter Cardiovasc Interv 2007;70(2):244–249.

58. Bor D, Sancak T, Toklu T, Olgar T, Ener S. Effects of radiologists' skill and experience on patient doses in interventional examinations. Radiat Prot Dosimetry 2008;129(1-3): 32–35.

59. Wagner LK. Radiation injury is a potentially serious complication to fluoroscopically-guided complex interventions. Biomedical Imaging and Intervention Journal [serial online]. 2007;Vol 3, no 2. http://www.biij .org/2007/2/e22/. Accessed June 13, 2010.

60. Mahesh M. Fluoroscopy: patient radiation exposure issues. RadioGraphics 2001;21(4): 1033–1045.

61. Mavrikou I, Kottou S, Tsapaki V, Neofotistou V. High patient doses in interventional cardiology due to physicians' negligence: how can they be prevented? Radiat Prot Dosimetry 2008;129(1-3):67–70.

62. Miller DL, Balter S, Noonan PT, Georgia JD. Minimizing radiation-induced skin injury in interventional radiology procedures. Radiology 2002;225(2):329–336.

63. Norbash AM, Busick D, Marks MP. Techniques for reducing interventional neuroradiologic skin dose: tube position rotation and supplemental beam filtration. AJNR Am J Neuroradiol 1996;17(1):41–49.

64. Mahesh M. How to prepare for the Joint Commission's sentinel event policy pertaining to prolonged fluoroscopy. J Am Coll Radiol 2008;5(4):601–603.

65. Balter S, Miller DL. The new Joint Commission sentinel event pertaining to prolonged fluoroscopy. J Am Coll Radiol 2007;4(7):497–500.

66. Joint Commission. Sentinel Event Policy and Procedures. Updated July, 2007. April 1 2009. http://www.jointcommission.org/Sentinel Events/PolicyandProcedures/. Accessed June 13, 2010.

67. Joint Commission. Sentinel event: radiation overdose FAQs. 2006. http://www.jointcom mission.org/NR/rdonlyres/10A599B4-832D-40C1-8A5B-5929E9E0B09D/0/Radiation_Overdose.pdf. Accessed June 13, 2010.

68. Food and Drug Administration. Public health advisory: avoidance of serious x-ray-induced skin injuries to patients during fluoroscopically-guided procedures. Rockville, Md: Center for Devices and Radiological Health, 1994. http://www.fda.gov/MedicalDevices/Safety /AlertsandNotices/PublicHealthNotifica tions/ucm063084.htm. Accessed June 13, 2010.

69. Amis ES Jr, Butler PF, Applegate KE, et al. American College of Radiology white paper on radiation dose in medicine. J Am Coll Radiol 2007;4(5):272–284.

70. American College of Radiology. ACR practice guideline for diagnostic reference levels in medical x-ray imaging. Practice Guidelines and Technical Standards 2008. Reston, Va: American College of Radiology, 2008; 799-804. http://www.acr.org/SecondaryMainMenu Categories/quality_safety/guidelines/med_ phys/reference_levels.aspx. Accessed June 13, 2010.

71. Wall BF, Shrimpton PC. The historical development of reference doses in diagnostic radiology. Radiat Prot Dosimetry 1998;80(1-3):15–19.

72. International Commission on Radiological Protection. 1990 Recommendations of the International Commission on Radiological Protection. ICRP publication 60. Ann ICRP 1991;21(1-3):1–201.

73. International Commission on Radiological Protection. Radiological protection and safety in medicine. ICRP publication 73. Ann ICRP 1996;26(2):1–47. [Published correction appears in Ann ICRP 1997;27(2):61.]

74. International Atomic Energy Agency. International basic safety standards for protection against ionizing radiation and the safety of radiation sources. Safety Series No. 115. Vienna, Austria: International Atomic Energy Agency, 1996. http://www-pub.iaea.org/MTCD /publications/PDF/Pub996_EN.pdf. Accessed June 13, 2010.

75. Hart D, Hillier MC, Wall BF. National reference doses for common radiographic, fluoroscopic and dental X-ray examinations in the UK. Br J Radiol 2009;82(973):1–12.

76. International Commission on Radiological Protection. Diagnostic reference levels in medical imaging: review and additional advice. ICRP online educational reference. 2003 [November 3, 2008]. http://www.icrp.org /docs/DRL_for_web.pdf. Accessed June 13, 2010.

77. Vañó E, Gonzalez L. Approaches to establishing reference levels in interventional radiology. Radiat Prot Dosimetry 2001;94(1-2):109–112.

78. Balter S, Miller DL, Vano E, et al. A pilot study exploring the possibility of establishing guidance levels in x-ray directed interventional procedures. Med Phys 2008;35(2):673–680.

79. Peterzol A, Quai E, Padovani R, Bernardi G, Kotre CJ, Dowling A. Reference levels in PTCA as a function of procedure complexity. Radiat Prot Dosimetry 2005;117(1-3):54–58.

80. Neofotistou V, Vano E, Padovani R, et al. Preliminary reference levels in interventional cardiology. Eur Radiol 2003;13(10):2259–2263.

81. D'Helft CJ, Brennan PC, McGee AM, et al. Potential Irish dose reference levels for cardiac interventional examinations. Br J Radiol 2009;82(976):296–302.

82. Vano E, Segarra A, Fernandez JM, et al. A pilot experience launching a national dose protocol for vascular and interventional radiology. Radiat Prot Dosimetry 2008;129(1-3):46–49.

83. Verdun FR, Aroua A, Trueb PR, Vock P, Valley JF. Diagnostic and interventional radiology: a strategy to introduce reference dose level taking into account the national practice. Radiat Prot Dosimetry 2005;114(1-3):188–191.

84. Tsalafoutas IA, Goni H, Maniatis PN, Pappas P, Bouzas N, Tzortzis G. Patient doses from noncardiac diagnostic and therapeutic interventional procedures. J Vasc Interv Radiol 2006;17(9):1489–1498.

85. Vano E, Järvinen H, Kosunen A, et al. Patient dose in interventional radiology: a European survey. Radiat Prot Dosimetry 2008;129(1-3):39–45.

86. Aroua A, Rickli H, Stauffer JC, et al. How to set up and apply reference levels in fluoroscopy at a national level. Eur Radiol 2007;17(6):1621–1633.

87. Vano E, Sanchez R, Fernandez JM, et al. Patient dose reference levels for interventional radiology: a national approach. Cardiovasc Intervent Radiol 2009;32(1):19–24.

88. Brambilla M, Marano G, Dominietto M, Cotroneo AR, Carriero A. Patient radiation doses and references levels in interventional radiology. Radiol Med (Torino) 2004;107(4):408–418.

89. Miller DL, Kwon D, Bonavia GH. Reference levels for patient radiation doses in interventional radiology: proposed initial values for U.S. practice. Radiology 2009;253(3):753–764.

90. International Atomic Energy Agency. Establishing guidance levels in x-ray guided medical interventional procedures: a pilot study. Safety Reports Series No. 59. Vienna, Austria: International Atomic Energy Agency, 2009. http://www-pub.iaea.org/MTCD/publica tions/PDF/Pub1346_web.pdf. Accessed June 13, 2010.