7 Radiation Safety During Cardiovascular Procedures

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KEY POINTS

- Interventional cardiologists who use fluoroscopy should be familiar with radiation risks and should know how to manage radiation appropriately.
- Incidents of patient skin injury following fluoroscopy-guided interventional procedures have been reported. Many reported skin effects resulting from fluoroscopic procedures were inadvertent, because the physician was unaware of the radiation dose and consequences.
- Interventional cardiologists must receive training in selection of appropriate fluoroscopic equipment configuration and utilization of dose-management tools. This training should include both general radiation dose-management practices and specific practices for the model of fluoroscopic equipment and personnel radiation protection tools they will use.
- Strategies for minimizing patient radiation dose include using a low dose rate and a low frame rate for fluoroscopy, keeping the image receptor close to the patient, using collimation and moderate x-ray beam angles, and minimizing fluoroscopy time and image acquisition.
- The cumulative radiation dose display provided by the fluoroscopic equipment should be utilized to keep track of patient dose.
- If reference point air *kerma* (kinetic energy released in material) exceeds 5 Gy for a procedure, the interventional cardiologist should inform the patient that a radiation skin effect may occur and provide appropriate follow-up.
- Personnel present during fluoroscopy procedures should use x-ray shielding and should move back from the patient during fluoroscopy to reduce their radiation exposure.

INTRODUCTION

Fluoroscopy-guided interventional cardiovascular procedures provide substantial benefit to patients by relieving symptoms, improving quality of life, and replacing the need for open surgical procedures. These procedures include vascular, electrophysiology, and percutaneous structural heart interventions. Procedure risks may also be substantial and include stroke, myocardial infarction (MI), renal failure, and death. The ionizing radiation required for fluoroscopic guidance in each of these types of procedures also carries risk, particularly for prolonged procedures and obese patients. These radiation risks include radiogenic cancer and skin injury, although many other procedural risks are significantly greater than the radiation risks. Nevertheless, it is important to apply the basic principles of radiation protection for medical exposure to patients. These principles are *justification*—that is, use of radiation should provide more benefit than harm to the patient, and the procedure should be medically indicated—and *optimization*, meaning the patient dose should be managed to be commensurate with the medical purpose, and unnecessary radiation exposure should be avoided.[1] To follow these principles, practitioners who use fluoroscopy should be familiar with radiation risk and should know how to manage radiation appropriately.

RADIATION RISK

Two types of health effects result from radiation exposure, stochastic and deterministic. *Stochastic effects* include cancer and genetic mutations. These effects are caused by damage to cell DNA. Because an effect may result from misrepair of a single cell, stochastic effects are independent of the amount of radiation exposure and are thought to have no lower threshold limit. *Deterministic effects* are tissue reactions from radiation exposure. The severity of tissue reactions increases with dose, and a minimum dose exists below which no observable effect occurs. Tissue reactions of concern related to fluoroscopy use include skin burns, hair loss, and cataracts.

Radiation-induced cancer risk has been studied extensively in many different exposed populations, including survivors of the atomic bomb detonations over Hiroshima and Nagasaki in World War II, patients receiving medical treatments, and workers exposed to radiation. Although the relationship between cancer induction and radiation exposure has been well established for high doses, cancer risk at low dose levels, such as those encountered in diagnostic imaging or from natural sources, is uncertain. Because the latent period for most cancers is long, and the natural incidence of cancer is high, it is difficult to determine cancer risk levels for whole-body doses less than approximately 100 mSv (which is equivalent to the radiation delivered during several complex percutaneous cardiac interventions [PCIs]). As a result, a model is used to estimate cancer risk at low doses from observed high-dose cancer rates. The commonly accepted linear nonthreshold model predicts a fatal cancer risk of 5% per Sv whole-body exposure for a working-age adult.[2] Typical effective dose values (estimation of whole-body dose from a partial body exposure) are 15 mSv for PCI, 7 mSv for diagnostic coronary angiography, 7 mSv for chest computed tomography (CT), and 0.1 mSv for a chest radiography exam.[3] For comparison, natural background radiation levels in the United States average about 3 mSv/year.[4]

Genetic mutations from radiation exposure have been found in animal studies, but no human study has demonstrated any effect. Although radiation-induced heritable effects were initially thought to be a significant radiation risk, it is now accepted that the genetic risk is minimal.

Skin injury from radiation exposure has been thoroughly characterized for radiation therapy patients. Although fluoroscopy x-ray energies are lower than high-energy radiation therapy x-ray beams, skin effects and threshold dose levels are similar to that of orthovoltage radiation therapy (50 to 250 kilovolt peak [kVp]; Table 7.1). Transient erythema may occur within 24 hours after a radiation dose of 2 Gy or more. Between 2 and 8 weeks from an exposure, epilation may occur with main erythema present for doses greater than 5 Gy, and desquamation may occur for doses greater than 10 Gy.

TABLE 7.1 Tissue Reactions From Single-delivery Radiation Dose to Skin of the Neck, Torso, Pelvis, Buttocks, or Arms

Band	Single-Site Acute Skin-Dose Range (Gy)[a,c,d]	NCI Skin Reaction Grade	Approximate Time of Onset of Effects[a,b]			
			Prompt <2 Weeks	Early 2–8 Weeks	Midterm 6–52 Weeks	Long-term >40 Weeks
A1	0–2	Not applicable	No observable effects expected at any time			
A2	2–5	1	Transient erythema	Epilation	Recovery from hair loss	None expected
B	5–10	1–2	Transient erythema	Erythema, epilation	Recovery; at higher doses, prolonged erythema, permanent partial epilation	Recovery; at higher doses, dermal atrophy or induration
C	10–15	2–3	Transient erythema	Erythema, epilation; possible dry or moist desquamation, recovery from desquamation	Prolonged erythema, permanent epilation	Telangiectasia,[e] dermal atrophy or induration, skin likely to be weak
D	>15	3–4	Transient erythema; after very high doses: edema and acute ulceration, long-term surgical intervention likely to be required	Erythema, epilation; moist desquamation	Dermal atrophy; secondary ulceration due to failure of moist desquamation to heal, surgical intervention likely to be required; at higher doses, dermal necrosis, surgical intervention likely to be required	Telangiectasia,[e] dermal atrophy, induration; possible late skin breakdown; wound can be persistent and may progress into a deeper lesion; surgical intervention likely to be required

[a]The dose range and approximate time period are not rigid boundaries. Also, signs and symptoms can be expected to appear earlier as the skin dose increases.
[b]Abrasion or infection of the irradiated area is likely to exacerbate radiation effects.
[c]*Skin dose* refers to actual skin dose (including backscatter). This quantity is *not* air kerma at the reference point ($K_{a,r}$).
[d]Skin dosimetry based on $K_{a,r}$ or air kerma area product (P_{KA}) is unlikely to be more accurate than ±50%.
[e]Refers to radiation-induced telangiectasia. Telangiectasia associated with an area of initial moist desquamation or the healing of ulceration may be present earlier.
This table is applicable to the normal range of patient radiosensitivities in the absence of mitigating or aggravating physical or clinical factors; this table does not apply to the skin of the scalp.
NCI, National Cancer Institute.
National Council on Radiation Protection and Measurements (NCRP). *Report 168: Radiation Dose Management for Fluoroscopically Guided Interventional Procedures*. Bethesda, MD: NCRP; 2010.

Longer term, for doses greater than 15 Gy, dermal atrophy and secondary ulceration may occur that may require surgical treatment.[5] Examples of fluoroscopic skin injuries are shown in Figs. 7.1 and 7.2. It should be noted that time intervals and dose thresholds given in Table 7.1 are approximate and will vary depending on the patient's health, location of the exposed area, and condition of the lesion. Other factors may also be associated with increased skin response to irradiation, including diseases such as diabetes mellitus and hyperthyroidism and also ataxia, telangiectasia, connective tissue diseases, and exposure to various chemotherapy agents.[6]

Although rare, skin injury following fluoroscopy-guided interventional procedures has been reported.[5,7] Many of these injuries involve complex cardiology procedures such as PCI for the recanalization of chronic total vascular occlusions and radiofrequency ablations. A rise in the number of reports to the U.S. Food and Drug Administration (FDA) in the early 1990s led to the release of a public health advisory in 1994.[8] Injury may also result from multiple procedures, even if individual sessions are below the threshold for skin effects. When exposure of the same skin location occurs over several episodes, injury threshold doses will depend on the dose level and the time interval between procedures.[5] It should be noted that many reported skin effects resulting from fluoroscopic procedures were inadvertent, and the physician was unaware of the radiation dose delivered.[9] As a result, patients were not made aware of the potential for skin injury, which caused a delay in the diagnosis of their wound.[7] Skin biopsy should not be performed in areas of suspected radiation skin injury because this leads to a delay in healing and/or to secondary infections.[6] Recording of patient dose, communication with the patient, and follow-up for significant dose levels are important radiation management methods that will be discussed later in this chapter.

RADIATION MANAGEMENT

Procedure optimization includes limiting radiation dose to a level that is as low as possible to accomplish the clinical task. This process requires attention to imaging equipment configuration and to radiation dose management practices. Interventional fluoroscopy systems contain many components that work together to form an image. For the most part, adjusting components to increase radiation dose will result in improved image quality. Although at first glance achieving excellent image quality may appear to be the aim of procedure optimization, this objective will generally result in an unnecessary dose. Instead, the appropriate image quality level that is clinically acceptable should be the goal so that an appropriate radiation dose can be used. Some tasks within an interventional procedure can be accomplished using an image with reduced radiation dose and image quality. Whenever possible, equipment configurations with a lower dose rate should be selected. This is best accomplished by adjusting initial settings to a low dose rate before a procedure begins, then selecting higher dose-rate settings as needed in a limited fashion for a specific imaging task, such as placing a guidewire or deploying a stent, where high spatial resolution and low image noise are needed. Further details about fluoroscopic equipment components will be covered in the next section of this chapter.

Staff training is an important component of procedure optimization. Operators of fluoroscopic systems are in charge of the

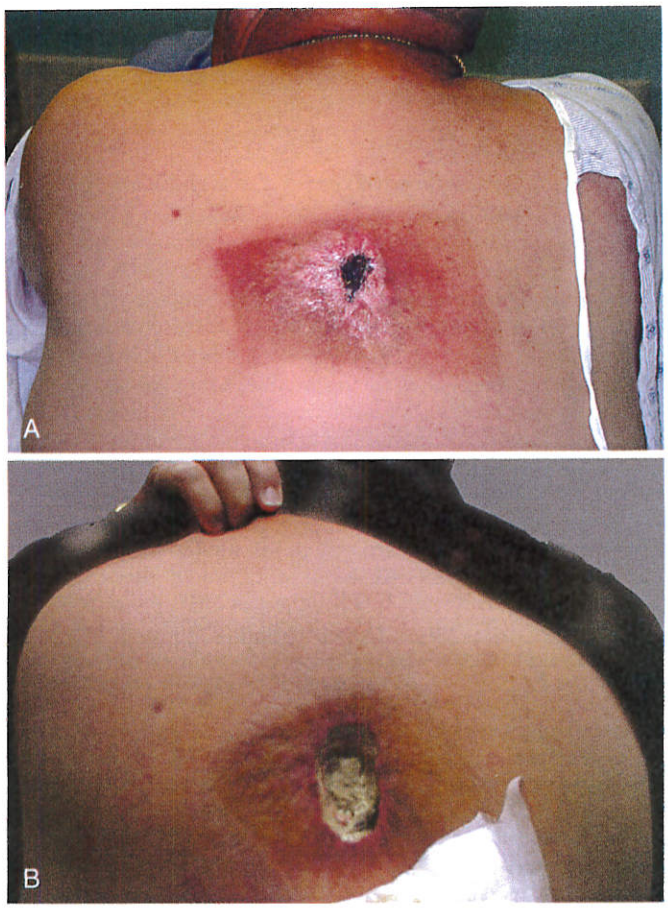

Fig. 7.1 Radiation injury in a 60-year-old man resulting from coronary angioplasty. Images show a time sequence of the injury. (A) At 30 weeks after exposure, a central area of deep necrosis surrounded by indurated and depigmented skin within an area of prolonged erythema is shown. (B) At 38 weeks after exposure, area of deep necrosis has increased in size. (From Balter S, Hopewell JW, Miller DL, et al. Fluoroscopically guided interventional procedures: a review of radiation effects on patients' skin and hair. *Radiology*. 2010;254[2]:326–341, Fig. 8A.)

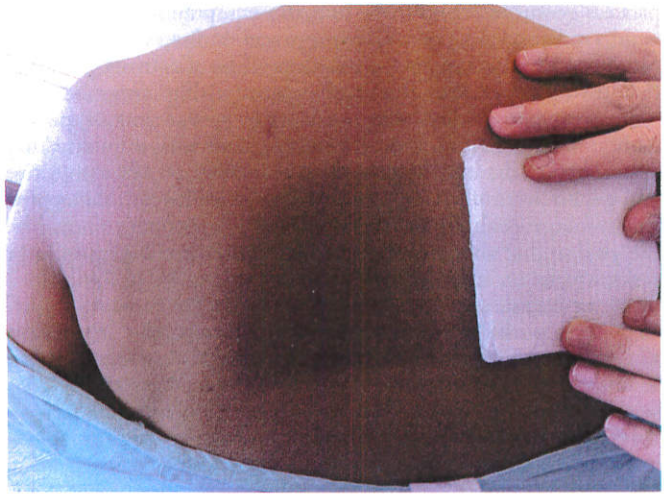

Fig. 7.2 Radiation injury in a 60-year-old woman resulting from a coronary angioplasty. At 18 months after exposure, erythema with dusky coloration is shown.

amount of radiation used during a procedure, which affects the dose to the patient, to themselves, and to other staff in the procedure room. It is important that operators receive training on how to select appropriate equipment configurations and how to utilize dose-management tools. Additional information regarding the components of this training are provided in this chapter.

FLUOROSCOPIC IMAGING EQUIPMENT

Because fluoroscopy-guided interventional procedures have the potential to deliver patient radiation dose levels that can cause skin injury, it is important that the fluoroscopic equipment used be suitable for the task. Several key equipment features are desirable to ensure proper management of patient and staff radiation dose. Some of these features include digital image acquisition, variable-rate pulsed fluoroscopy, added x-ray beam filtration, and patient radiation dose display.[10] Safe and effective patient care in complex interventional procedures is best realized when appropriate equipment is used. Fluoroscopy systems that comply with International Electrotechnical Commission (IEC)[11] standard IEC-60601-2-43 for interventional equipment include these and other elements appropriate for interventional procedures.

Image Chain Components

The basic components of a fluoroscopic imaging chain are an x-ray generator, tube, and beam filter; a collimator; the patient; a grid; and the image receptor, processor, and displays (Fig. 7.3). The operator controls the fluoroscopy system through the exposure foot switch, table-side controls, and configuration selection; the operator monitors the output of the system on the image display and on the radiation use display.

The x-ray generator provides electrical power to the x-ray tube that allows for adjustment of x-ray beam kilovolt peak and tube current (in milliamperes [mA]). The x-ray beam produced is generally pulsed at a rate of 1 to 30 pulses per second with pulse widths between 3 and 20 ms. Another important feature of an x-ray generator is automatic exposure rate control (AERC), which acts to keep the x-ray flux at the image receptor at a constant level as it is panned over body parts of differing thickness and attenuation. This is achieved by automatically adjusting the kilovolt peak, tube current, pulse width, and beam filtration settings through a feedback signal from the image receptor to maintain the x-ray exposure level at the entrance to the image receptor.

Within the x-ray tube, x-rays are produced by accelerating electrons emitted from a filament (cathode) toward a rotating tungsten disk (anode). The housing that surrounds the x-ray tube contains lead shielding that absorbs x-rays not directed out the exit port. The x-ray production process is relatively inefficient, with less than 1% of the energy input into the x-ray tube converted into x-rays; most of the energy is converted into heat, and x-ray tube heat can build up quickly during clinical procedures that require the capture of multiple images. To achieve a large heat capacity, angiography x-ray tubes are equipped with high-speed anode rotation (over 10,000 rotations/min) and a circulating water or oil heat exchanger with cooling fans. The instantaneous heat capacity of the x-ray tube may become a limiting factor for the selection of technique factors when imaging thick body parts and large patients, particularly when using mobile C-arm fluoroscopy systems. Many systems include an indicator of the thermal condition of the anode, which notifies the operator when the heat level is approaching threshold values.

X-ray tubes for fluoroscopy systems typically contain two focal spots: the *small focal spot* (SF) is selected for all fluoroscopy and image acquisition of thin body parts; the *large focal spot* (LF) is required for imaging thicker body parts, for which higher kilovolt peak and tube current are needed. The smaller the focal spot, the less geometric blur occurs for better spatial resolution (Fig. 7.4).

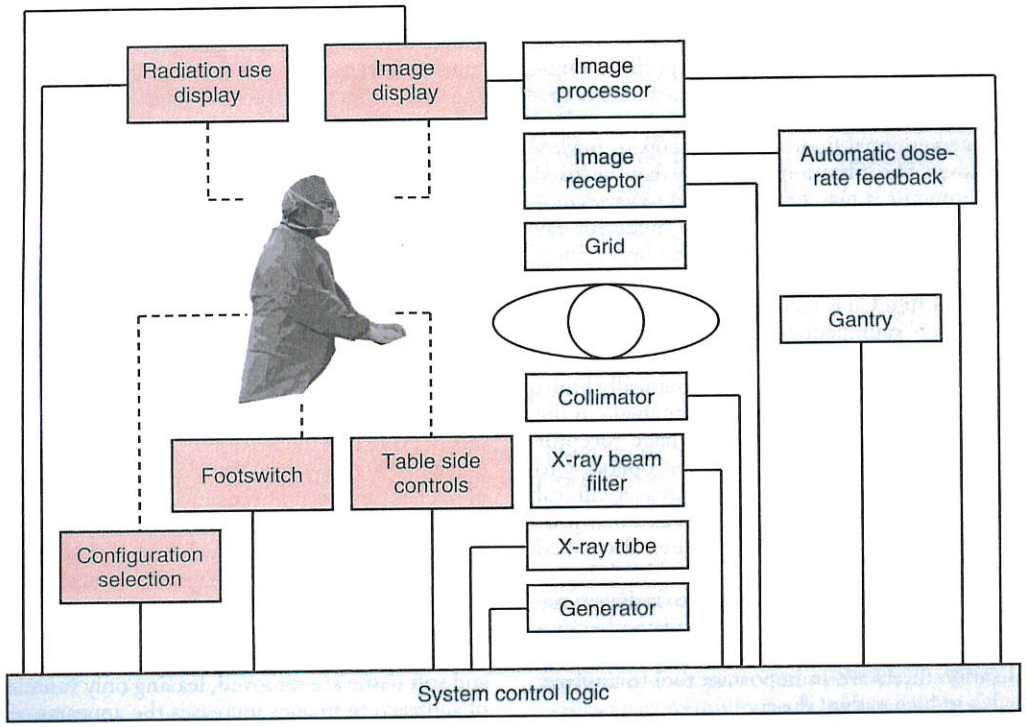

Fig. 7.3 Block diagram of a fluoroscopic imaging system. The imaging chain components (generator, x-ray tube, x-ray beam filter, collimator, image receptor, and gantry) are controlled by the operator through the configuration selection, footswitch, and table-side controls through system control logic via automatic dose-rate feedback. The radiation use display and image display are available for use by the operator.

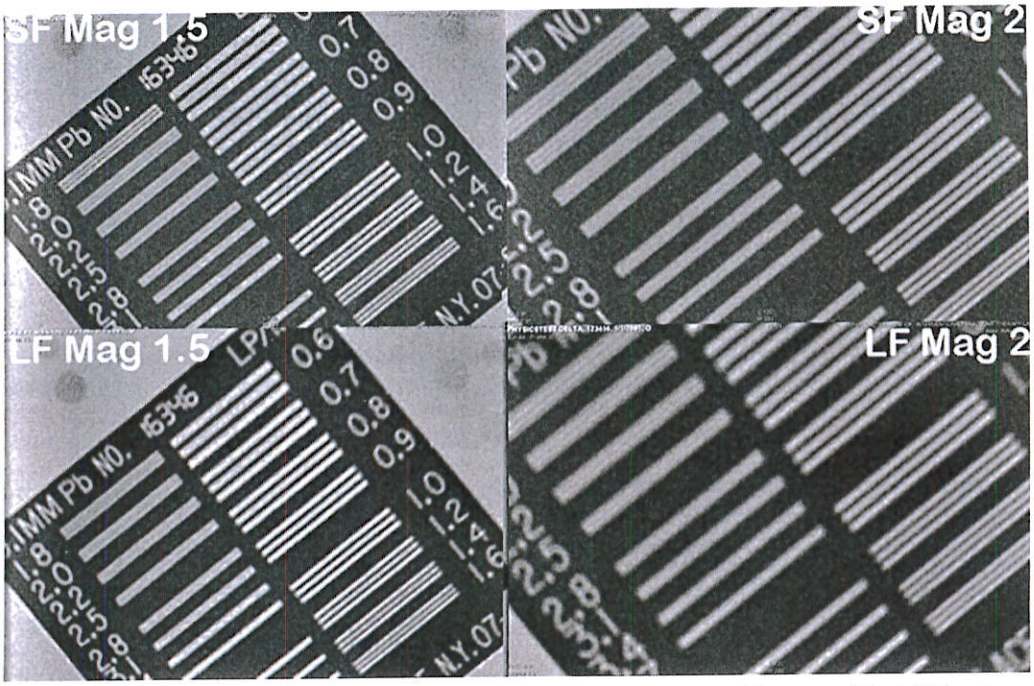

Fig. 7.4 Focal spot size and geometric magnification effect on spatial resolution. Using a small focal *(SF)* spot and low geometric magnification *(Mag 1.5)* maximizes the visibility of the bars in this high-subject-contrast test pattern. The effects of using a large focal *(LF)* spot are seen in the lower left image, increasing geometric magnification *(Mag 2)* is seen in the upper right image, and the incorporation of both are shown in the lower right image.

However, concentrating the focal spot into a smaller area results in increased heat concentration that could reach temperatures hot enough to melt the anode material. Therefore the larger focal spot size is often needed for cine acquisition imaging.

The x-ray beam travels through a sheet of aluminum several millimeters thick before it exits the collimator assembly. This aluminum filtration material is present to attenuate low-energy x-rays from the beam, which are generally absorbed in the first

few centimeters of patient tissue without being transmitted to the image receptor; this contributes to patient skin dose with little impact on image formation. Federal regulations specify a minimum thickness of filtration material be used for all fluoroscopy systems.[12] Additional filtration material, typically copper, is included in angiography and interventional fluoroscopy systems to further reduce patient skin dose. The filtration thickness may be fixed for a given program setting or it may be configured to vary automatically with changes in patient attenuation. Most modern x-ray angiography systems allow for use of additional x-ray beam filters for both fluoroscopic and angiographic imaging, and a minimum thickness equivalent to 0.1 mm Cu is recommended.

The collimator contains radiopaque shutter blades with two levels of control, primary and secondary, that define the shape of the x-ray beam. The *primary collimator control* automatically limits the x-ray beam field of view as operator changes are made in the magnification (zoom) mode selection or source-image receptor distance. The *secondary collimator control* allows the operator to further reduce the size of the x-ray beam to the area of clinical interest. Most fluoroscopy systems used for interventional procedures also contain equalization filters. These filters, also called *contour filters* or *wedge filters*, are partially radiolucent blades used to provide modest beam attenuation, which serves to reduce x-ray intensity in areas with low patient attenuation that may otherwise lead to areas of white glare in the images. Use of secondary collimation and equalization filters are an important tool to improve image quality and also reduce patient dose.

The image receptor used for most modern fluoroscopy systems is a flat-panel digital detector. A grid is mounted in front of the image receptor to reduce the scatter contribution to the image. Most detectors for fluoroscopy are of the indirect conversion type, in which a crystalline cesium iodide scintillator absorbs incident x-rays and produces light photons. The light photons are then detected and converted to a stored charge by a matrix array of photodiodes to create a digital image. Flat-panel fluoroscopy detectors are available in square or rectangular formats with sizes that range from 17 to 40 cm^2 typical pixel spacing is between 0.14 and 0.20 mm. Selection of magnification modes is also possible, although spatial resolution may not change. For large fields of view or high–frame-rate imaging, pixel binning (typically 2 by 2) may be used to reduce data transfer rates. However, pixel binning may reduce spatial resolution. Although spatial resolution is decreased, image noise is also decreased because of the large effective pixel size. Spatial resolution may also be limited by the resolution of the display monitor; if this is the case, a digital zoom can be used to better visualize detail.

Image processing is commonly applied to fluoroscopy and acquired images prior to display and archive. Processing is applied to increase image contrast, improve spatial resolution, and decrease the appearance of image noise. Adjustment of image-processing parameter settings allows for fine-tuning of image appearance to the clinical application and user preference. However, it should be noted that image quality improvements from image processing usually require a compromise in some other image quality characteristic. Most fluoroscopy systems acquire cine images with a pixel matrix size of approximately 1024 by 1024. However, when images are archived, the matrix size is typically decreased to 512 by 512. As a result, images viewed on the acquisition display monitor will generally provide the best spatial resolution.

Imaging Modes

Fluoroscopy systems used for interventional cardiovascular procedures typically have three imaging modes: (1) fluoroscopy, (2) acquisition or cine mode, and (3) digital subtraction angiography (DSA). *Fluoroscopy* is used for real-time visualization of moving structures or interventional devices for relatively long periods of time (seconds to minutes); therefore the dose rates with fluoroscopy are the lowest of all the imaging modes. Generally, the operator can select from several different dose rates and frame rates so that the lowest dose rate acceptable for the clinical task can be used. Federal regulations limit the maximum patient entrance air kerma rate to 88 mGy/min under test conditions.[12] Typical patient entrance air kerma rates for fluoroscopy can be highly variable but are generally 20 to 35 mGy/min[13] with a frame rate of 7.5 to 15 frames per second (fps).

Acquisition or *cine mode* is used to acquire quality images for diagnostic and archival purposes. Consequently, cine dose rates are typically 10 to 20 times higher than those used for fluoroscopy, with no maximum regulatory limit. Similar to fluoroscopy, many systems provide several different dose rates for cine acquisition to allow for dose reduction when possible. Cine acquisition frame rates are also selectable, with 15 fps being the typical rate and patient entrance air kerma rates between 150 and 250 mGy/min.[13] Note that the maximum air kerma rate for large patients can exceed 2000 mGy/min. Many systems permit retrospective storage of the last fluoroscopic sequence. Although the noise level is higher than cine, enough information is retained to keep the sequence for review instead of using a much higher dose cine sequence.

DSA is used for imaging noncardiac, stationary vessels. In DSA, a precontrast mask image is logarithmically subtracted from an image obtained at the same location after contrast media has been injected. The result is an image in which overlying bone and soft tissue are removed, leaving only vasculature. The process of subtracting images increases the appearance of noise, so DSA images require the highest air kerma rates, generally between 300 and 500 mGy/min using frame rates of 1 to 4 fps.

PATIENT RADIATION DOSE MANAGEMENT

Comprehensive patient radiation dose management requires consideration of both x-ray system technical parameters and the operator's procedural skills. As a result, formal training of physician and nonphysician staff should be considered essential. All staff should become familiar with concepts and practices that lead to a safe and effective clinical practice.[14–17] Staff education should include a combination of didactic and practical training. Practical, hands-on training in particular provides a controlled environment to teach and learn general concepts and specific practices that lead to safe radiation practices. All new staff should receive organized, formal, and documented training. All staff should receive incremental training when new x-ray equipment or features are introduced into the practice. Such training should broadly cover applicable x-ray imaging physics and image creation, best practices to ensure patient radiation safety, and best practices to ensure staff radiation safety, and it should be specific to the clinical practice and equipment.

Factors That Contribute to High Skin Dose

The two primary factors that determine skin dose are x-ray system output dose rate (air kerma rate) and duration of exposure. Each of these primary factors has several associated components. Dose rate is determined by a combination of x-ray system configuration, operator selection of operational mode, and patient thickness.[18] Exponential attenuation of the x-ray beam by the patient dictates that the x-ray tube output, and thereby the patient dose rate, increases rapidly as the x-ray beam path length through the patient increases. The instantaneous dose rate for large patients can be 10 or more times greater than that for small patients. Because x-ray intensity decreases as the square of the distance from the source increases, maintaining appropriate radiographic distances can significantly influence patient skin dose. The duration of x-ray exposure directly influences skin dose and varies substantially among patient procedures. X-ray duration varies greatly between procedure types and even among patients undergoing

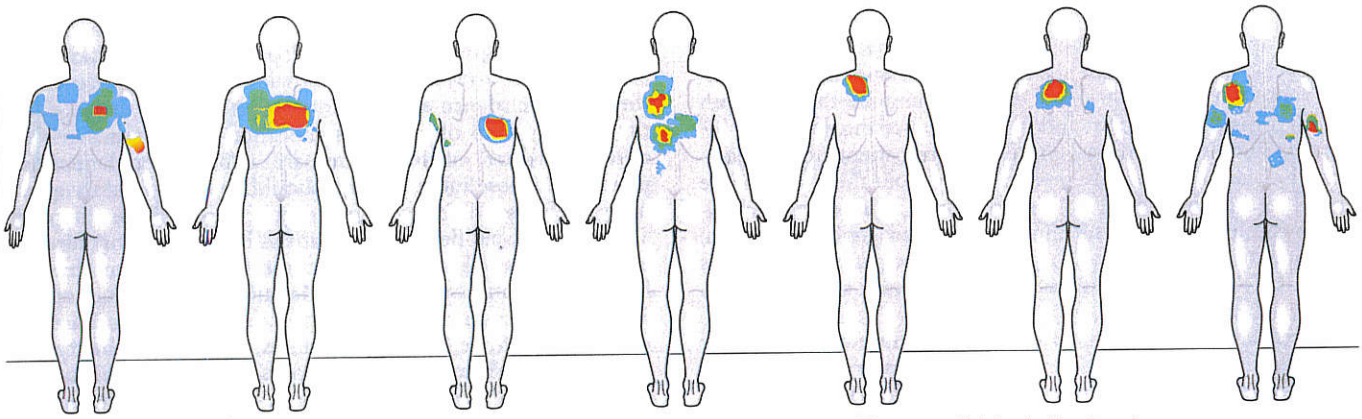

Fig. 7.5 Sample patient skin dose maps for seven different patient exams. The area of highest skin dose is shown in red. Decreasing skin dose is indicated by yellow, green, and light blue. (From Johnson PB, Borrego D, Balter S, et al. Skin dose mapping for fluoroscopically guided interventions, *Med Phys.* 2011;38[10]:5490–5499, Fig. 4.)

similar procedures.[19,20] It is critically important that nontarget anatomy is not in the x-ray beam. In particular, ensure that the patient's arms are never between the x-ray tube and the patient's thorax.

Radiation Dose Measurement

All modern interventional fluoroscopy systems display radiation dose metrics in the procedure room. These metrics include air kerma (K, in mGy) and air kerma area product (P_{KA}, in Gy cm^2, μGy m^2, cGy cm^2, or mGy cm^2). *Air kerma* is a measurement of primary x-ray beam intensity. In the procedure room, the air kerma is reported at a fixed point relative to the gantry that approximates, although not exactly, the location of the patient's skin. When the x-ray beam is on, the instantaneous air kerma rate is reported, and when the x-ray beam is off, the procedure's cumulative air kerma is reported. The *air kerma area product* is the integrated x-ray intensity over the field of view. It can be approximated as the product of the air kerma and the x-ray field area. Because the x-ray beam size is generally constant for cardiovascular procedures, air kerma and air kerma area product provide equivalent indicators of patient radiation burden. However, neither is a good indicator of actual patient skin dose, and neither should be used as such. Converting these metrics to an estimate of skin dose is an area of active academic research and implementation by the manufacturers (Fig. 7.5).[21] The newest interventional x-ray systems may offer advanced features that approximate actual patient skin dose during a procedure, thereby providing the operator some guidance to help avoid radiation skin injury during complex procedures. Traditionally, x-ray fluoroscopy time was used to monitor patient radiation burden. However, fluoroscopy time has important limitations for use as a dose metric. Specifically, it does not account for exposure from acquisition imaging or variation of fluoroscopy dose rate. Therefore fluoroscopy time is a poor indicator of patient radiation burden or skin dose and should not be used as a primary dose metric. Fluoroscopy time can be considered a useful secondary dose metric as a surrogate for procedure complexity or operator proficiency.

Best Practices for Patient Dose Management

Before starting a procedure, the patient record should be reviewed for prior instances of radiation exposure that could contribute to increased risk of radiation skin injury. No standard period of time exists over which the look-back should occur. Cellular injury from radiation commences immediately upon exposure, and repair mechanisms begin shortly thereafter.[22,23] If the radiation dose is sufficiently high, tissue damage can manifest over a period of several hours to several weeks after exposure.[5,24,25] Both cellular and tissue repair occur in the minutes, hours, days, and months following high exposure. When possible, multiple potentially high skin-dose procedures should be scheduled at least several weeks apart to minimize the potential for cumulative skin effects. When clinically necessary, repeat exposures over a period of a few days should be performed judiciously and should assume that the potential for radiation skin injury is cumulative.

Modern interventional x-ray systems include many features designed to result in a relatively low patient skin dose while still providing a clinically adequate image quality. System optimization for dose should be a collaborative effort between the clinical practice and the x-ray equipment manufacturer and should include a combination of a low detector-input dose, use of x-ray beam spectral filters, and a low frame rate.[26,27] Most invasive cardiac procedures can be performed using 7.5 fps fluoroscopy and 15 fps acquisition imaging. Operational modes should be created specifically for the variety of clinical tasks encountered in the invasive cardiology labs. Specific modes should be used for adult cardiac catheterization and ablation procedures, recognizing that the dose from catheterization procedures has approximately equal contributions from fluoroscopy and acquisition imaging and that the dose from ablation procedures is nearly entirely from fluoroscopy. Specific pediatric modes should be created with reduced detector input dose and should specify removal of the antiscatter grid for small patients (<20 kg).[28,29] System configuration and clinical use should recognize that some portions of procedures may require improved image quality. For these instances, it is useful to provide an operational mode that includes a higher radiation dose rate. As a matter of routine, the x-ray system should default to the lowest reasonable radiation dose rate mode, and the operator should be provided the option to temporarily switch to a higher dose-rate mode when improved image quality is required. Strategies for optimizing x-ray system settings to minimize patient radiation dose are summarized in Table 7.2.

For all x-ray imaging, it is important to minimize the time the x-ray beam is on to minimize the dose. Activate fluoroscopy only when necessary, and cease as soon as the live imaging is no longer needed clinically. For most cardiac operational modes, the dose rate associated with acquisition imaging is 10 to 20 times greater than that for fluoroscopic imaging. One method to reduce patient dose is to preferentially use and store fluoroscopic images obtained at a relatively low radiation dose rate, rather than acquisition imaging, when high-quality images are not required. Importantly, never use acquisition imaging to overcome poor fluoroscopic image quality.

If fluoroscopic image quality is clinically inadequate, switch to a fluoroscopy mode with a higher radiation dose rate.

Especially for large patients, use of relatively shallow (postero-anterior) x-ray projection angles can help minimize the x-ray path length through the patient and thereby reduce the dose rate.[31,32] To help minimize skin dose, ensure that the patient's skin is positioned as far as reasonably possible away from the x-ray source and that the image receptor is positioned as close as reasonably possible to the patient (minimize the "air gap" between the patient and the image detector; Fig. 7.6). For patient safety, it is particularly important to ensure that the patient's arms are not in the x-ray beam.

Particularly for complex procedures, including structural heart and ablation procedures, there is often a clinically preferred x-ray beam projection angle that is conducive to visualization of the anatomy. This can lead to high localized skin dose. When clinically possible, the effect can be reduced by using multiple x-ray projection angles such that the dose is distributed over a larger skin area. In this case, the projection angle must be changed enough (~15 degrees) to avoid overlap of the irradiated skin areas.

By default, x-ray systems are typically configured to modify the patient entrance air kerma rate with changes to the size of the primary field of view (magnification mode). Smaller fields of view (higher magnifications) are associated with increased patient skin-dose rates. Systems should be configured to operate using the most clinically useful x-ray beam size. This is typically a 20-cm diagonal field of view (at the image detector) for catheterization procedures and a 25-cm or larger field for structural heart and ablation procedures. Magnification modes should be used sparingly as necessary to support the clinical procedure. The operator should be familiar with and should use secondary collimator control. Secondary collimators reduce the x-ray beam area and thereby reduce patient dose and x-ray scatter to the operator and to the image receptor. Particularly for large patients, x-ray scatter to the image receptor contributes to reduced image contrast; therefore decreasing the size of the x-ray beam area with the secondary collimators can result in a notable improvement in image quality. Furthermore, systems equipped with a large-screen monitor may be configured to use the wide display mode for increased dose optimization. By using a larger field of view with collimation and zooming the image to a wide display, the use of magnification mode can be avoided.[33] Strategies to minimize patient radiation dose during a procedure are summarized in Table 7.3.

Active monitoring of the cumulative air kerma should be incorporated into the clinical practice for all procedures. Intra-procedure announcement of air kerma starting at 3 Gy and then in increments of 1 Gy thereafter is recommended.[10] After the procedure, air kerma and air kerma area product values should be included in the patient record for future reference. Each practice should routinely audit patient radiation dose metrics to recognize trends in patient dose and to facilitate relevant

TABLE 7.2 Strategies for Optimizing X-Ray System Settings to Minimize Patient Radiation Dose

Decrease frame rate	For at least most fluoroscopic imaging, 7.5 fps is adequate; for acquisition (cine) imaging, 15 fps is adequate.
Decrease detector target dose	Work with the x-ray system manufacturer to specify a lower dose target at the image receptor.
Increase use of x-ray spectral filtration	Ensure that both fluoroscopy and acquisition programs use x-ray beam spectral filters. A minimum of 0.1 mm copper should be used for acquisition imaging to reduce skin dose while maintaining image quality.[30]

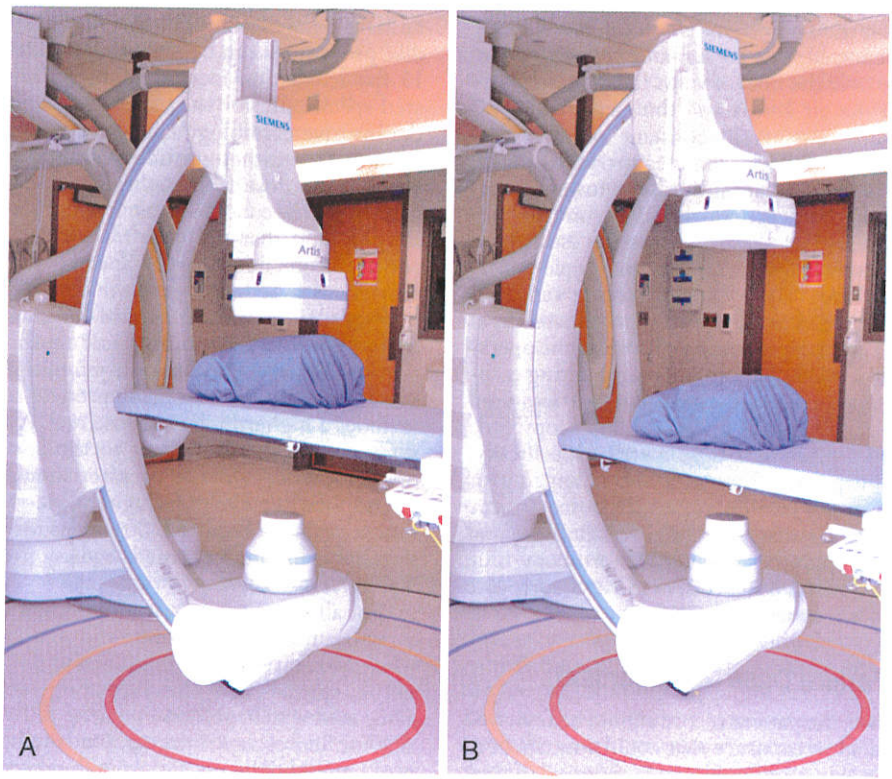

Fig. 7.6 (A) Good imaging geometry with the table elevated and a small air gap (<10 cm). (B) Poor imaging geometry with a short distance between the x-ray tube and patient (table too low) and a great distance between the patient and image receptor (air gap). (Photographs courtesy Mayo Clinic, Rochester, MN.)

quality improvement. Detailed recommendations for a facility's quality assurance–peer review (QA-PR) process and recommendations for administrative practices for the evaluation of known or suspected radiation injuries can be found in the reference section.[34]

Patients for whom the air kerma exceeded 5 Gy should receive post-procedure instruction and appropriate follow-up. Informing such patients that they received a substantial dose of radiation and asking them to have a family member check their back in 1 month are simple and effective first-level assessment steps. The patient should report the appearance of a red patch the size of a hand to the physician who performed the procedure. The physician should then arrange to see the patient to continue evaluation and management. Physicians should also consider prospectively contacting patients who received a substantial dose 1 to 2 months after the procedure. Physicians should regard any such signs as being of radiogenic origin until an alternative diagnosis is established.

Straightforward procedures, including diagnostic procedures, are typically not associated with a high skin dose that could lead to skin injury. However, it is important to practice low-dose radiation techniques during all procedures to master the skills necessary to maintain low skin dose during difficult procedures. It is important that all procedure room staff understand radiographic imaging and radiation safety principles, and physicians should foster a collaborative effort to ensure patient radiation safety.

STAFF RADIATION PROTECTION

Studies that report measurements of staff radiation dose during cardiac catheterization procedures show that high levels are possible.[35] Particular concern has been noted with regard to radiation doses to the lens of the eye,[36] the hands,[37] and lower extremities[38] of the operator. Recent reports have detected acute radiation-induced DNA damage in blood lymphocytes of physicians performing interventional fluoroscopy procedures.[39,40] It is possible for personnel to reduce occupational radiation exposure with careful attention to their actions during the procedure; such actions include knowledge of the sources of radiation exposure and methods that can be used to decrease exposure levels.

TABLE 7.3 Intraprocedure Strategies to Minimize Patient Radiation Dose

Default to low-dose-rate fluoroscopy.	Configure the x-ray system to use the lowest reasonable fluoroscopy dose rate. Table-side controls provide access to modes with a higher dose rate when a higher-quality fluoroscopic image is required.
Be attentive to x-ray geometry.	Maintaining a long x-ray source–patient distance and a short patient–image receptor distance can substantially reduce patient skin dose.
Activate x-ray imaging judiciously.	Activate x-ray only when clinically indicated, and cease irradiation immediately after clinical utility has passed.
Use moderate x-ray beam angles.	When possible, use less x-ray beam angulation to decrease the path length through the patient, thereby decreasing x-ray attenuation and reducing dose rate.
Use secondary collimators.	The patient will receive less radiation, operator dose from scatter will go down, and the quality of images of large patients will improve.
Never use acquisition imaging to overcome poor fluoroscopic image quality.	Acquisition dose rates can be as much as 20 × greater than for fluoroscopy. When necessary to improve image quality, temporarily switch to a higher dose rate fluoroscopy mode.

Occupational Dose Monitoring

Radiation monitors are worn by personnel who work in fluoroscopy procedure rooms to determine their individual occupational exposure level. In order to provide an estimate of personnel radiation risk when protective aprons are worn, the use of two radiation monitors is recommended.[10] One monitor is worn under the apron at the waist or chest level, and a second monitor is worn outside the apron at the neck. The values from both monitors are used to estimate effective dose, and the neck monitor provides an estimate of the dose to the lens and thyroid if protective glasses and a thyroid shield are not worn. Because the exposure reading under the apron will be much lower than the reading at the neck, it is essential that the monitors be clearly labeled to avoid accidental exchange.

Dose limits to personnel are set by regulatory agencies to prevent tissue reactions and to limit the risk of stochastic effects. Table 7.4 lists the current National Council on Radiation Protection and Measurements (NCRP) dose limits for occupational workers. When attention is paid to radiation safety and optimal work habits practices, a fluoroscopy operator's effective dose is likely to be between 2 and 4 mSv/year.[41]

Fluoroscopy operators should take special note of dose limits for the lens of the eye. Until recently, it has been generally accepted that radiation-induced cataracts do not form below a threshold lens dose of 2 to 5 Gy. This threshold provided the basis for the maximum permissible dose of 150 mSv/year for the lens. However, new data on the radiosensitivity of the eye indicate that the threshold dose may be significantly lower, and the International Commission on Radiological Protection (ICRP) has recommended a lower lens-dose limit of 20 mSv/year averaged over 5 years, with no single year exceeding 50 mSv.[42] Also, the NCRP has recently recommended an annual dose limit of 50 mSv.[43] Although U.S. regulatory agencies have not adopted a lower lens-dose limit, careful attention to radiation protection of the eye is warranted to minimize cataract risk. Protective shielding to reduce radiation exposure to the eye from scatter includes leaded eyewear and ceiling-suspended upper body shields. Additional information on lens-dose reduction is included later in this section.

For pregnant personnel, a lower dose limit is applied to minimize radiation exposure of the embryo/fetus. To monitor

TABLE 7.4 Occupational Dose Limits

Dose Quantity	Dose Limit
EFFECTIVE DOSE	
Annual[a]	50 mSv
Cumulative[a]	10 mSv × age in years
EQUIVALENT DOSE (ANNUAL)	
Lens of the eye[b]	50 mSv
Skin, hands, and feet[a]	500 mSv
Embryo and fetus, equivalent dose (monthly) once pregnancy is known[a]	0.5 mSv

[a]National Council on Radiation Protection and Measurements (NCRP). *Report 116: Limitation of Exposure to Ionizing Radiation*. Bethesda, MD: NCRP; 1993.

[b]National Council on Radiation Protection and Measurements (NCRP). *Commentary No. 26: Guidance on Radiation Dose Limits for the Lens of the Eye*. Bethesda, MD: NCRP; 2016.

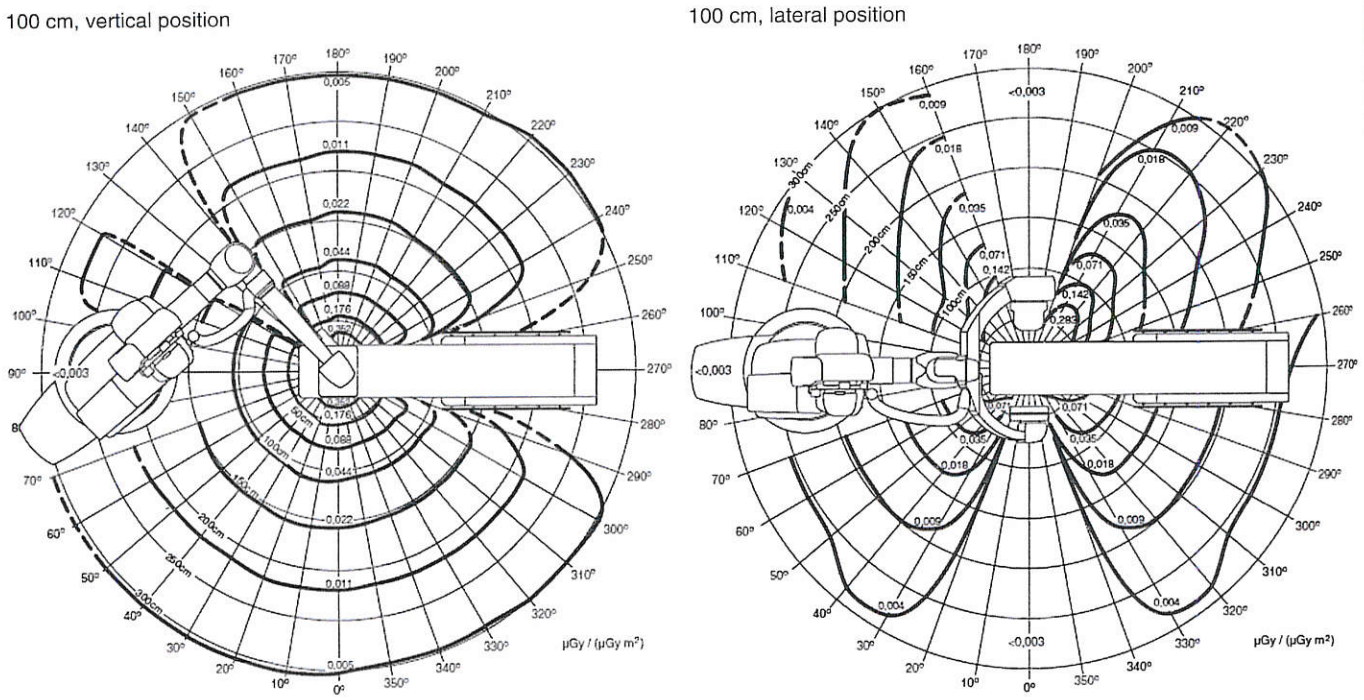

Fig. 7.7 Scatter isodose curves for a fluoroscopic system. Scatter levels at a height of 1 m is shown for a vertical *(left)* and lateral *(right)* orientation. Isodose lines are in units of μGy per μGy m^2 of patient air kerma area product as reported by the x-ray system. (Courtesy Siemens Medical Systems.)

the conceptus dose, a radiation monitor is provided when a worker has declared her pregnancy. This monitor is worn at the waist level under a protective apron and is exchanged on a monthly basis. Because current data do not suggest a significant increased risk to the fetus of pregnant personnel in the cardiac catheterization laboratory, it is not necessary—nor is it legal—to restrict pregnant workers from working in fluoroscopy procedure areas.[44] However, additional radiation safety precautions and monitoring of radiation exposure among pregnant personnel are warranted.

Sources of Personnel Radiation Exposure

Radiation exposure during fluoroscopy procedures comes from three sources: (1) the primary x-ray beam, (2) scattered x-rays, and (3) x-ray tube leakage x-rays. Occupational exposure to the *primary beam* may occur when the operator manipulates devices positioned within the imaging field of view. Dose rates in this region are in the range of 5 to 20 mGy/h at the surface, where the x-ray beam *exits* the patient during fluoroscopy. Dose rates to the operator's hands when they are placed in the unattenuated x-ray beam (patient-entrance side) can exceed 100 mGy/min for fluoroscopy and 2000 mGy/min for cine mode. *Scattered x-rays* are produced when tissue is exposed to the primary x-ray beam, and the rays travel in all directions from the point of origin. Scatter dose rates are typically 1 to 10 mGy/h at the operator's position. The third source of radiation is from *leakage x-rays* emitted from the x-ray tube in areas other than the primary beam port.

In general, scatter levels decrease in proportion to the inverse squared distance from the irradiated patient tissue volume. However, it should be noted that the radiation distribution surrounding the patient is not uniform. Fig. 7.7 shows a typical scatter isodose plot for a C-arm. For a lateral x-ray beam, note that radiation intensity is concentrated in the area near the x-ray tube. This distribution is caused by higher levels of scattered x-rays produced at the primary beam patient-input port. Forward scattered rays from the first few centimeters of tissue depth are heavily attenuated by the rest of the patient tissue, which results in higher radiation levels in the direction back toward the x-ray tube.

Personal Protective Equipment

X-ray scatter from the patient is the primary source of radiation dose to in-room personnel, and it should be minimized to reduce the likelihood of long-term health effects. Occupational radiation dose can be minimized through a combination of radiation safety devices and practices. These may be summarized by the concepts of reducing patient *dose rate*, reducing *time* duration of exposure, increasing *distance* from the scatter source (the patient), and use of *shielding* to block x-ray scatter. In addition, it is important to recognize that the occupational radiation dose *rate* that originates from the patient is directly proportional to dose rate to the patient. A primary step to reducing occupational dose is to reduce patient dose. For most interventional cardiac lab personnel, the amount of time spent in the procedure room is determined by the number and type of procedures performed and is not readily controlled on an individual basis. The inverse square law dictates that the intensity of radiation decreases in proportion to the square of the distance from the source. When the x-ray beam is on, personnel should position themselves as far as reasonably possible from the patient. It is recognized, however, that patient care necessitates that some personnel remain close to the patient during exposure. Therefore the most important concept for personnel radiation dose reduction is shielding.

Shielding refers to placement of any device between the patient and personnel with the purpose of absorbing x-ray scatter. All in-room personnel are required to wear a protective garment over the trunk of the body. A typical 0.5 mm lead-equivalent garment blocks about 98% of the x-ray scatter

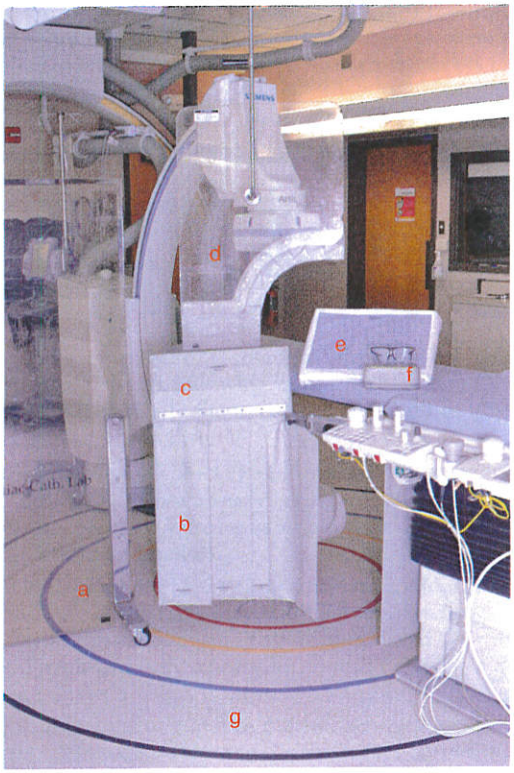

Fig. 7.8 Personnel radiation safety devices: *a,* portable leaded-glass shield; *b,* lower body shield; *c,* vertical extension to lower body shield; *d,* upper body shield with patient contour extensions; *e,* sterile, disposable radiation-absorbing drape; and *f,* leaded-glass safety glasses. The lines on the floor *g* indicate distance from the patient corresponding to 2× changes in scatter dose rate, providing a visual reminder of the protective effects of increased distance from the scatter source. Mandatory lead-equivalent garments and thyroid shield are not shown. (Photograph courtesy Mayo Clinic, Rochester, MN.)

incident upon it. For a 0.35 mm lead-equivalent garment, attenuation is approximately 94%. Radiation shields or drapes attached to the patient table provide excellent protection of the lower body (Fig. 7.8). Shields are needed on both sides of the table when operators simultaneously work from both sides. Use of optional vertical extension of these drapes provides additional protection to the operator's midsection for femoral-access procedures, but they interfere with the patient for radial-access procedures. Ceiling-mounted, leaded-glass upper body shields can provide up to 80% protection of the upper body, including the otherwise unprotected neck and head.[20,45] For femoral artery–access procedures, the upper body shield should be positioned nominally perpendicular to the patient head-foot direction, tight to the patient abdomen, and just superior to the access point to minimize the angular size of the gap in protection under the shield occupied by the patient. For radial-access procedures, the upper body shield is best positioned nominally parallel to the patient's head-foot direction and close to the patient's arm. For upper body shields, flexible extensions attached to the bottom of the leaded-glass shield provide a soft and contoured contact between the shield and patient. A good guideline for use of the upper body shield is that the operator should have to look through the shield to see the volume of the patient being irradiated. Floor-mounted mobile shields should be available for protection of in-room personnel, particularly nursing staff. Physician operators should wear leaded glasses to reduce the dose to the lens of the eye and thereby minimize lifetime risk of radiation-induced cataracts.[40,46] Glasses with a large surface area, including side shields, are most effective.[47]

Disposable radiation-absorbing towels or drapes can provide up to 60% upper body protection in situations where the upper body shield cannot be readily used, including in the hybrid operating room.[20,48] These must be thoughtfully positioned to maximize protection. Other novel radiation protection devices are commercially available and may also be considered.[49,50] Generally, these novel systems are floor mounted or suspended and are designed to provide whole-body protection, thereby removing the weight burden of a protective garment.[51–53] Other novel technologies, such as robot-guided interventional systems, provide an opportunity for both operator radiation protection and ergonomic comfort.[54,55] Strategies to reduce occupational radiation dose are summarized in Table 7.5.

TABLE 7.5 Strategies to Reduce Occupational Radiation Dose

Reduce patient dose.	Occupational radiation dose is proportional to patient dose. Efforts to reduce patient dose will positively affect occupational dose.
Use x-ray shields judiciously.	*Operators:* When properly used, the ceiling-mounted upper body shield can substantially reduce operator dose. *Nursing staff:* Remain behind a lead barrier when possible.
Wear your radiation monitoring badge.	Consistent use of the radiation monitoring badge is the best way to know how well your occupational dose-reduction efforts are working.
Maintain situational awareness.	*Operators:* Do not activate the x-ray unnecessarily when a nurse or technologist is tending to the patient. *In-room staff:* When possible, step back from the patient when the x-ray beam is on.
Wear leaded glasses.	Operators should wear leaded glasses with large side shields to reduce the dose to the lens of the eye and thereby reduce the lifetime risk of developing cataracts.

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Additional references available online at expertconsult.com.