ACCF/AHA/HRS/SCAI FLUOROSCOPY CLINICAL COMPETENCE STATEMENT

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

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PREAMBLE

The granting of clinical staff privileges to physicians is a primary mechanism used by institutions to uphold the quality of care. The Joint Commission on Accreditation of Healthcare Organization (JCAHO) requires that the granting of continuing medical staff privileges be based on assessments of applicants against professional criteria specified in the medical staff bylaws. Physicians themselves are thus charged with identifying the criteria that constitute professional competence and with evaluating their peers accordingly. Yet the process of evaluating physicians' knowledge and competence is often constrained by the evaluator's own knowledge and ability to elicit the appropriate information, problems compounded by the growing number of highly specialized procedures for which privileges are requested.

The American College of Cardiology/American Heart Association/American College of Physicians (ACC/AHA/ACP) Task Force on Clinical Competence was formed in 1998 to develop recommendations for attaining and main-

taining the cognitive and technical skills necessary for the competent performance of a specific cardiovascular service, procedure, or technology. These documents are evidence-based, and where evidence is not available, expert opinion is utilized to formulate recommendations. Indications and contraindications for specific services or procedures are not included in the scope of these documents. Recommendations are intended to assist those who must judge the competence of cardiovascular health care providers entering practice for the first time and/or those who are in practice and undergo periodic review of their practice expertise. The assessment of competence is complex and multidimensional; therefore, isolated recommendations contained herein may not necessarily be sufficient or appropriate for judging overall competence.

The ACC/AHA/ACP Task Force on Clinical Competence makes every effort to avoid any actual or potential conflicts of interest that might arise as a result of an outside relationship or a personal interest of a member of the writing panel. Specifically, all members of the writing panel were asked to provide disclosure statements of all such relationships that might be perceived as real or potential conflicts of interest. These statements were reviewed by the ACC/AHA/ACP Task Force on Clinical Competence, were reported orally to all members of the Writing Committee at the first meeting, and were updated at each meeting or as changes occurred. Please see Appendix for the relationship with industry information pertinent to this document.

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I. INTRODUCTION AND BACKGROUND

Both X-ray fluoroscopy and X-ray cinefluorography are core imaging techniques that make invasive cardiovascular procedures possible. Right heart catheterization for hemodynamic monitoring, diagnostic cardiac and vascular angiography, interventional cardiovascular procedures, clinical electrophysiologic studies, temporary and permanent pacemaker, and internal cardioverter-defibrillator placement are among the important cardiovascular procedures that either require or are facilitated by X-ray imaging. Although many patients derive great diagnostic and therapeutic benefit from these procedures, the use of ionizing X-radiation constitutes an associated hazard that must be justified by the procedure's benefits.

In recent years the capability and complexity of invasive cardiovascular procedures have increased substantially. Originally, fluoroscopically guided procedures were principally diagnostic. Currently, many procedures are therapeutic as well. As procedures have become increasingly complex, they may employ greater fluoroscopic durations leading to the potential for greater patient radiation exposure. Refinements in radiologic equipment have improved image quality
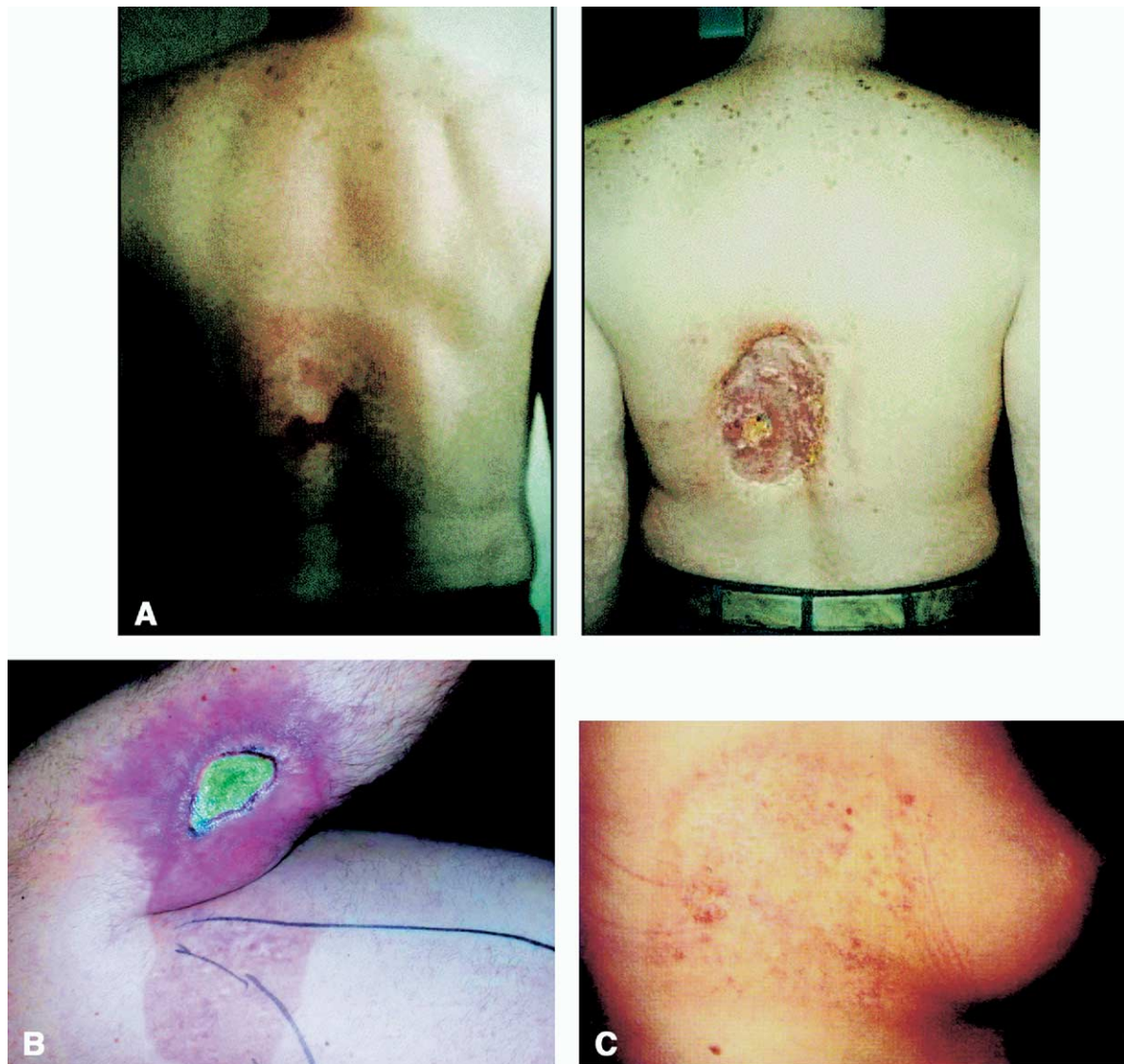
Figure 1. (A) Radiation injury following angioplasty. This was the first reported case of radiation-induced skin necrosis from a coronary angioplasty procedure. The patient underwent three coronary angioplasty procedures, each of which lasted between 1 to 2 h. The last two procedures were performed on the same day, 6 months after the first, and involved about 1 h of fluoroscopy on-time. No data on the number of cine frames is available. Erythema was noted on the patient's back when the patient was removed from the table after the last procedure. One month later the patient reported erythema in the same areal; this persisted. The **image on the left** shows the appearance approximately 5 months after the procedures. The condition progressed into blistering, exudation, ulceration, and necrosis. **The image on the right** shows the wound 22 months after the third procedure (1). **(B)** Radiation injury from an electrophysiologic ablation procedure. A 52-year-old man underwent an ablative procedure for supraventricular arrhythmias. His arm had accidentally been positioned within the radiation field during the 10-h procedure. The estimated dose of radiation was in the range of 15 to 20 Gy (2). **(C)** Chronic radiation-induced skin injury. A 17-year-old girl underwent two electrophysiologic ablation procedures to treat an arrhythmia. The total fluoroscopy time was about 100 min. Erythema was present 12 h after the procedure. At 1 month, the area was red and blistering. At 2 years, the area was described as an atrophic indurated plaque with linear edges, hyperpigmentation and hypopigmentation, and telangiectasia. The patient had difficulty raising her right arm. Because of the close proximity of the breast to the X-ray beam, the scattered radiation resulted in a substantial dose to her right breast, placing her at an elevated risk for breast cancer (3).

while reducing X-ray dose rates. However, even though technologic progress has reduced exposure rates, the greater exposure duration that attends more complex procedures may lead to an increased overall patient and operator exposure accompanied by a greater potential for radiation-induced injury. At present, although many patients derive great benefit from fluoroscopically guided procedures, some suffer radiation-induced injuries as an unintended consequence.

Radiation-induced patient injury takes many forms. Entrance port skin ulceration and necrosis are the most obvious and some of the most attention-getting. This complication consists of a localized area of non-healing skin necrosis at the site of X-ray beam entrance (typically on the patient's back). The shape of the affected area conforms to the shape of the X-ray beam entering the patient and may or may not have sharp borders. Examples are illustrated in Figures 1A to 1C (1–3). Entrance port skin ulceration

causes considerable long-term morbidity often requiring skin grafting.

Complications associated with high doses of fluoroscopy were reported as a theoretical consideration, before they were actually observed and subsequently published in the refereed literature (4,5). By late 1994, the Food and Drug Administration (FDA) had received a sufficient number of reports of injuries to call attention to the problem with an advisory that later appeared on its Web site (http://www.fda.gov/cdrh/fluor.html). Although the first known modern-era event of an induced skin necrosis in the U.S. occurred in 1990, it was not reported in the medical literature until 1996 (1). Subsequent reports in the clinical literature documented that the problem is ongoing (6).

The injuries cited in the literature and to the FDA are likely only a small fraction of the total that actually occur. In addition, it may be suspected that there is the potential for X-ray–guided procedures to cause other less clearly attributable adverse effects, such as neoplasia.

The core principle governing the use of ionizing radiation is ALARA (As Low As Reasonably Achievable). The ALARA principle recognizes that there is no magnitude of radiation exposure that is known to be completely safe. This principle confers a responsibility on all physicians to minimize the radiation injury hazard to their patients, to their professional staff, and to themselves. To practice the ALARA principle, the physician must possess a basic knowledge base in two areas. He or she must know how to operate the X-ray fluoroscopic equipment in a manner that generates optimal image quality with minimal patient and clinical personnel exposure. The physician must also possess the knowledge to recognize patients and circumstances in which the risk of radiation-induced injury is increased. In these circumstances, the physician is responsible for considering that risk in case selection and in procedure conduct decisions.

To meet this responsibility effectively, physicians must possess an understanding of radiation physics, radiation biology, X-ray image formation, and the operation of an X-ray cinefluorographic unit. This knowledge base is well documented, and physicians are responsible for understanding it. Applying it appropriately in the interest of patient and clinical staff protection should be viewed as a standard of care.

This document's purpose is to serve as a resource to physicians who perform X-ray fluoroscopically guided procedures. Although not comprehensive, it contains an introduction to the field written specifically to be accessible and relevant to practitioners. It provides them with an introduction to and an overview of the requisite knowledge base needed to protect patients, clinical staff, and themselves from radiation-induced injury. Additional educational material is available in both the literature and in textbooks (7). It recommends a core curriculum that physicians who perform such procedures should study. The ACC previously published a document summarizing the radiation physics

and biology knowledge base relevant to operator and clinical personnel radiation protection (8). This document is intended to be a companion to that document with a principal focus on patient protection.

II. THE PHYSICS AND NATURE OF X-RADIATION

The Nature of X-Radiation

X-rays are a form of electromagnetic radiation and have many characteristics similar to visible light as well as some important differences attributable to their greater energy content. X-rays are conveniently described in terms of photons—a quantum (discrete packet) of electromagnetic radiation containing a defined amount of energy. A stronger X-ray source produces more photons per unit time than does a weaker source.

An X-ray photon in the diagnostic range contains 5,000 to 75,000 times as much energy as a visible-light photon. A green light photon contains 2 electron volts (eV) of energy. The X-ray photons used for imaging have energies ranging between 10 keV (10,000 eV) and 150 keV. The difference in biologic effects between visible light and X-ray photons is largely attributable to energy content differences.

X-Ray Generation

X-rays are produced in an X-ray tube when high-energy electrons, in an arc created by applying a voltage across a gap, interact with tungsten that forms the X-ray tube anode. (Details of X-ray tube construction can be found in the following text.) When a high-energy electron interacts with a target atom, a variable fraction of its energy is converted into an X-ray photon, and the remainder is dissipated as heat.

X-Ray Spectra

X-rays generated by diagnostic machines contain a spectrum of photon energies that range up to a maximum determined by the voltage applied across the X-ray tube gap. The peak tube voltage (kVp) determines the maximum photon energy (expressed in kilo electron volts [keV]).

Mechanisms of X-Ray Absorption

X-ray photons penetrate tissue to a varying degree. This phenomenon is the basis of X-ray imaging. The attenuation (the degree to which X-ray beam intensity decreases as it passes through an object) of any material is determined by four parameters:

- X-ray photon energy
- The atomic number of the atoms that make up the object
- The physical density (g/cc) of the object
- The thickness of the object

The penetrating power of an X-ray photon increases as photon energy increases. Low-energy photons have insufficient energy to penetrate tissue. Consequently, they do not contribute to image formation, but, as they are absorbed by
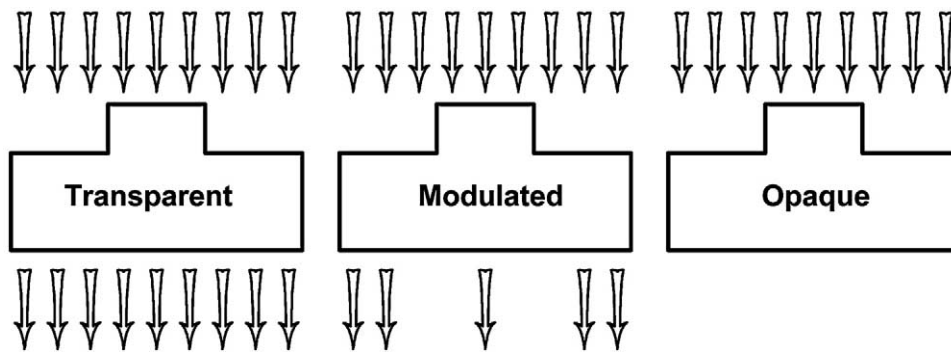
Figure 2. Image contrast. Differential absorption of the X-ray beam by different parts of an object renders its internal structure visible in an X-ray transmission image. X-ray photons are represented as **arrows**. The **left-hand example** shows an object that allows all X-ray photons to pass through it unattenuated. In this circumstance, no image of the object is generated. The **center example** shows an object, different parts of which absorb different fractions of the incident photons modulating the beam intensity and generating an X-ray image of the object. The **right-hand example** is completely opaque to X-ray photons and absorbs all of them. The X-ray image of this object would be a silhouette with no definition of the object's internal structure.

the skin, they contribute to the patient's entrance port skin dose.

Several X-ray absorption processes occur at different photon energy ranges. Two X-ray absorption mechanisms that are important for diagnostic imaging are the photoelectric process and Compton scattering.

The **photoelectric process** occurs when a photon interacts with an orbital electron of an atom (generally the electrons in the K shell). In the photoelectric effect, the X-ray photon is completely absorbed and a free electron is ejected from the atom ionizing it. This process occurs preferentially at low photon energies with high atomic number absorbers. Photoelectric absorption is the principal absorption mechanism that renders iodinated contrast agent and metallic stents visible in X-ray fluoroscopy.

Compton scattering occurs when X-ray energies are much greater than the absorbing material's electron binding energy. The products of a Compton interaction are a scattered X-ray photon of lower energy than the incident photon and a recoil electron. The Compton affect is the main interaction process for diagnostic X-rays in tissue. Most stray radiation in a fluoroscopic laboratory arises from the Compton process.

X-Ray Dose

Radiation dose is delivered by interactions of X-ray photons with the individual atoms that comprise a tissue. These interactions transfer energy from the X-ray photon to the atoms in the tissue. (The term "dose" as used here refers to the "absorbed dose.") "Dose" is a measure of the concentration of energy absorbed by tissue. The formal definition of dose is the amount of energy absorbed from the radiation field by a volume of tissue divided by its mass. Both the absorption of some radiation by the patient and the transmission of a sufficient quantity of radiation through the patient to the image receptor, are necessary to form a radiologic image. Image contrast is produced by partial absorption of the beam (Fig. 2). The dose delivered to a patient during an X-ray fluoroscopic examination is derived from the X-ray photons that enter but do not leave the

patient. The most relevant of the many radiation measurement parameters and their relation to dose are shown in Table 1.

Measurements of Radiation

Radiation levels and doses can be characterized by utilizing a number of different parameters. The measurements are derived from a physical effect evoked by the radiation. The nomenclature has recently been revised. Currently, radiation quantities are expressed in SI (System Internationale) units and are listed and defined in Table 1. For comparison with the older literature, Table 1 also contains the corresponding earlier units shown in brackets (i.e., gray [rad]).

III. PRINCIPLES OF X-RAY IMAGE FORMATION

X-Ray Image Generation

The patient is illuminated with a beam of X-rays. Different structures in the patient absorb different fractions of the incident radiation, modulating the beam intensity (Fig. 2). The modulated beam that exits from the patient is detected by an image receptor. An object is delineated in an X-ray image if its X-ray absorbance is sufficiently different from that of its surrounding structures to produce a different exit beam intensity in that location. For example, an iodine-containing "contrast medium" employed to enhance the visibility of vessels absorbs significantly more of the radiation beam than does the blood it displaces, rendering the contrast-filled vessel visible on the X-ray image.

Parameters That Affect X-Ray Image Formation

X-ray beam penetrating power. To produce an optimally exposed image, the X-ray beam's penetrating power must be appropriately adjusted for the patient's X-ray attenuation. This may be accomplished by varying a number of beam parameters. Ideal X-ray imaging parameters appropriately balance the requirement for contrast (needed to detect the object), the requirement for sharpness (needed to characterize it), and patient dose.

Increasing the kVp of an X-ray beam decreases its

Table 1. Relevant Radiation Quantities

Quantity	Units of Measurement	What It Is	What It Measures	Why It's Useful	Conversion Between Old and New Units
Absorbed dose	gray (Gy) or milligray (mGy) [rad or millirad (mrad)]	The amount of energy locally deposited in tissue per unit mass of tissue	Measures concentration of energy deposition in tissue	Assesses the potential biological risk to that specific tissue	1 rad = 10 mGy
Effective dose	sievert (Sv) or millisievert (mSv) [rem or millirem (mrem)]	An attributed whole-body dose that produces the same whole-person stochastic risk as an absorbed dose to a limited portion of the body	Converts any localized absorbed or equivalent dose to a whole-body risk factor	Permits comparison of risks among several exposed individuals, even though the doses might be delivered to different sets of organs in these individuals	1 rem = 10 mSv
Air kerma*	gray (Gy) or milligray (mGy) [rad or millirad (mrad)]	The sum of initial kinetic energies of all charged particles liberated by the X-rays per mass of air	Measures amount of radiation at a point in space	Assesses the level of hazard at the specified location†	1 rad = 10 mGy
Exposure	millicoulomb·kg^{-1} [roentgen (R) or milliroentgen (mR)]	The total charge of ions of one sign produced by the radiation per unit mass of air	Measures amount of radiation at a point in space	Assesses the level of hazard at the specified location†	1 millicoulomb·kg^{-1} 4 Roentgen (R)
Equivalent dose‡	sievert (Sv) or millisievert (mSv) [rem or millirem (mrem)]	A dose quantity that factors in the relative biological damage caused by different types of radiations	Provides a relative dose that accounts for increased biological damage from some types of radiations	This is the most common unit used to measure radiation risk to specific tissues for radiation protection of personnel‡	1 rem = 10 mSv

*Air kerma can be presented in two separate ways. Incident air kerma is the kerma to air from an incident X-ray beam measured on the central beam axis at the position of the patient and excludes backscattered radiation. Entrance surface air kerma is the kerma to air from an incident X-ray beam measured on the central beam axis at the position of the patient with backscattered radiation included. The two may differ from each other by up to about 40%. †Exposure and air kerma are both used for the same purpose. Exposure used to be the most common measure, but with the switch to international units, air kerma is the preferred unit. ‡For X-rays, gamma rays, and electrons, there is no difference between absorbed dose and equivalent dose, i.e., 1 mGy = 1 mSv. This is not the case for neutrons and alpha particles, but these radiation types are not relevant to X-ray exposure. The important issue is that cardiologists recognize that for their interests there is no practical difference between a measurement of mGy and that of mSv.

absorption, enabling the penetration of dense body parts, and reduces patient exposure by reducing the fraction of the beam absorbed by the patient. However, as kVp increases, the difference in the relative absorption of different tissues decreases. This decreases beam modulation and reduces image contrast. Therefore, optimal X-ray imaging requires a compromise kVp that produces the best balance of penetration power, image contrast, and patient dose.

Increasing the total electrical power applied to the X-ray tube, without changing kVp, can also increase the number of X-ray photons that penetrate the patient. This generates a greater number of X-ray photons of the same penetrating power. This strategy maintains image contrast at the cost of greater patient dose and greater X-ray tube loading. The gain from this strategy is an image with less noise, greater contrast, and better definition (see the discussion of image noise in the following text) at the cost of greater subject exposure and a greater X-ray tube loading. Another potential downside of this strategy is that the increased loading may require a larger X-ray tube focal spot, which will reduce

image sharpness. In most modern cinefluorographic units, these parameters are set automatically by programs installed in the system. The programs are user-configurable if desired. It is important that physician users understand the operation and the patient exposure implications of choosing among the different selectable programs.

X-ray beam filtration. Because low-energy X-ray photons have very limited penetrating ability, they deposit their energy in a patient's superficial tissues, exposing these structures without contributing to image formation. Thus, it is desirable to remove (filter) low-energy photons from the X-ray beam. Aluminum has appreciable photoelectric absorption at low photon energies. Its attenuation decreases with increasing photon energy. Placing an aluminum disk on the output port of the X-ray tube preferentially removes low-energy photons from the beam, thus reducing the dose absorbed by the patient (Fig. 3). This process is called "hardening the beam." Increasing beam hardness increases the fraction of the beam's photons that successfully penetrate the patient and that contribute to the image. This
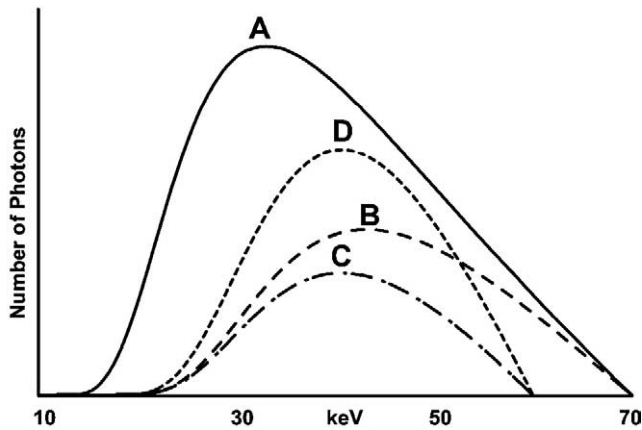
Figure 3. X-ray beam filtration. Plots of the X-ray photon energy composition of a typical beam of diagnostic X-ray produced at 70 kVp. The number of X-ray photons is plotted on the ordinate, and the photon energy is plotted on the abscissa. The original X-ray beam e **(curve A)** contains photons with multiple energies including many with energies below 30 keV that are of no diagnostic value. Intercepting the X-ray beam at the exit port with copper filters **(curve B)** preferentially absorbs low-energy photons. This reduces skin dose but also image contrast. Decreasing kVp to 60 while employing copper filtration **(curve C)** improves contrast but decreases beam intensity. Increasing the X-ray tube current increases the total number of photons produced and restores beam intensity (at the expense of additional X-ray tube loading) **(curve D)**. The X-ray spectrum represented by **curve D** provides the same image quality as that provided by curve A at much a reduced dose to the patient.

means that less radiation must enter the patient in order to produce a given exit dose. Thus, if the beam is hardened, overall patient exposure is reduced even though the dose that reaches the image detector is the same. Many newer cardiovascular fluoroscopic systems use combinations of high-power X-ray tubes equipped with copper filters (producing a higher photoelectric absorption than aluminum) and special system regulation curves to produce even greater beam hardening while maintaining image contrast and

quality. The effect of beam hardening on the distribution of X-ray photon energies is displayed in Figure 3.

Scattered radiation. Scattered radiation is produced when the X-ray beam interacts with the patient. Scattered radiation that reaches the image receptor constitutes noise and reduces image contrast. Scattered radiation is also the principal source of exposure to both the patient' body parts that are outside the field of the primary X-ray beam and to the laboratory staff. The amount of scatter increases with increases in the size of the X-ray field and the intensity of the X-ray beam (Fig. 4). All measures that reduce patient dose commensurately reduce the dose of scattered radiation that exposes both the patient and the operator and clinical personnel.

Image noise. A radiographic image of a uniformly dense object will have point-to-point variations in brightness. These random fluctuations, which are an inherent property of the X-ray beam, are called *image noise*. Noise is due to the quantum nature of the X-ray beam and increases as the X-ray dose decreases. Noise reduces the ability to detect low contrast structures. Increasing the dose suppresses noise and increases the ability to resolve structures. Image noise in an X-ray fluoroscopic image appears as a speckling of the image that is also commonly referred to as "quantum mottle." Image noise should be readily apparent in fluoroscopic images if X-ray equipment is properly calibrated. Fluoroscopic doses should be deliberately set at low levels to minimize total patient dose accumulation during the portion of the procedure that requires lesser image quality while reserving higher-dose (and lower noise) imaging for circumstances when image clarity becomes more critical. (It is important to point out that many current digital image processing algorithms are intended to decrease an image's apparent noise. Thus, the smooth appearance of an image
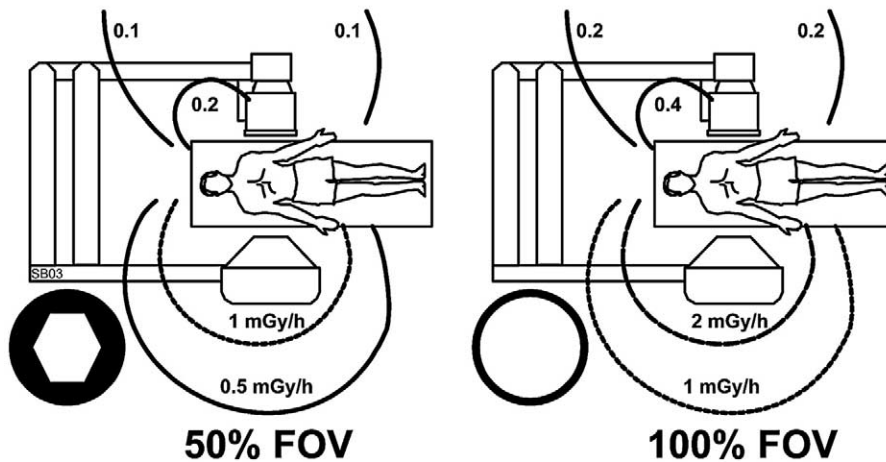
Figure 4. The intensity of scattered radiation as a function of exposed field size. For the same magnification mode of the image intensifier, scatter intensity increases everywhere in the room as the collimator is opened. Doubling the beam area doubles the scatter dose rates. The **left-hand image** illustrates the scatter field from a 60 left anterior oblique projection at a height of 100 cm from the floor with the collimator partially closed to allow exposure of only the central 50% of the field. The scattered radiation dose rates (which expose both the patient and the operator) are indicated by the isodose lines. The **right-hand image** illustrates an identical X-ray system position except that the collimator is fully open, exposing the entire field. Note that at any location, the intensity of the scattered radiation doubles. FOV = field of view.
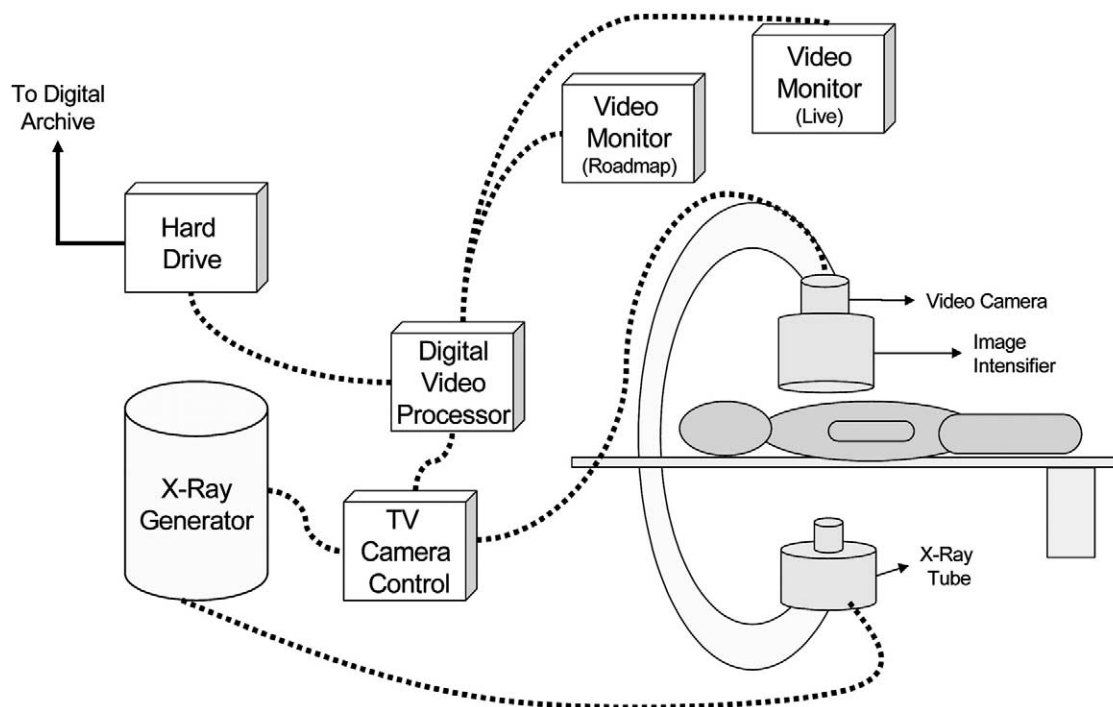
Figure 5. Block diagram of a filmless X-ray cinefluorographic unit. The unit consists of a patient positioning system, an X-ray source, an X-ray image detector, and a digital video image processor, recorder and display system. X-rays are produced in the X-ray tube from highly controlled electrical power that is applied by the X-ray generator. X-rays that penetrate the patient form an X-ray image that is detected and converted to a visible light image by the image intensifier. The visible light image is detected by the video camera and converted to a digital video signal that is processed and displayed as a visible light image on video monitors. Feedback circuitry from the digital video processor communicates with the X-ray generator. This enables modulation of X-ray output to achieve appropriate subject penetration by the X-ray beam and, accordingly, proper image brightness. X-ray systems that have flat panel detectors rather than image intensifiers do not have video cameras as the flat-panel detector produces a digital video image directly without the intermediate visible light stage.

acquired on a current digital system does not necessarily mean that the image was acquired at a high dose.)

IV. THE OPERATION OF AN X-RAY CINEFLUOROGRAPHIC UNIT

Overview

The main functions of an X-ray cinefluorographic system are to produce a collimated X-ray beam of appropriate intensity and quality, to project that beam through the patient at a desired angle, to detect the modulated X-ray beam after it passes through the patient, and to transduce the modulated X-ray beam into a usable visible light image. X-ray production is regulated by feedback loops from the image receptor. These components are schematically illustrated in Figure 5.

X-Ray Generation

The X-ray generator controls and delivers electrical power to the X-ray tube. It applies a high voltage across the gap between the X-ray tube cathode and anode and electrically heats the tube's filament. This causes the emission of electrons from the filament. The cathode current (expressed in milliamperes [mA]) determines the number of electrons liberated at the cathode. The voltage applied across the gap (expressed in kilovolts-peak [kVp]) accelerates the liberated

electrons across the gap from the cathode filament to the anode and determines the energy with which they strike the anode material. The accelerated electrons interact with the metallic anode of the tube. A small portion of the energy carried by the electrons is transformed into X-rays. Thus, the cathode current (mA) determines the number of X-ray photons produced, and the tube voltage (kVp) determines the energy of the X-ray photons produced. The essential elements of a medium power X-ray tube are shown in Figure 6.

X-ray generation is inefficient from the standpoint of energy transformation. Less than 1% of the electrical energy applied to the tube is converted to X-rays; the remainder is deposited in the tube as heat. This creates an important heat dissipation challenge for X-ray tube design. Current tube designs are capable of dissipating several times as much heat as those of the early 1990s. Thus, these tubes can deliver significantly more radiation to patients without overload than was possible a decade or so ago.

For optimal imaging, the X-ray beam should emanate from an infinitesimally small point. This requires minimizing the size of the anode focal spot (the area on which the electron beam impinges) to as small a size as possible. However, the high power of the electron arc (approximately 100 kilowatts) limits the ability to reduce focal spot size because the power density at the focal spot would exceed the
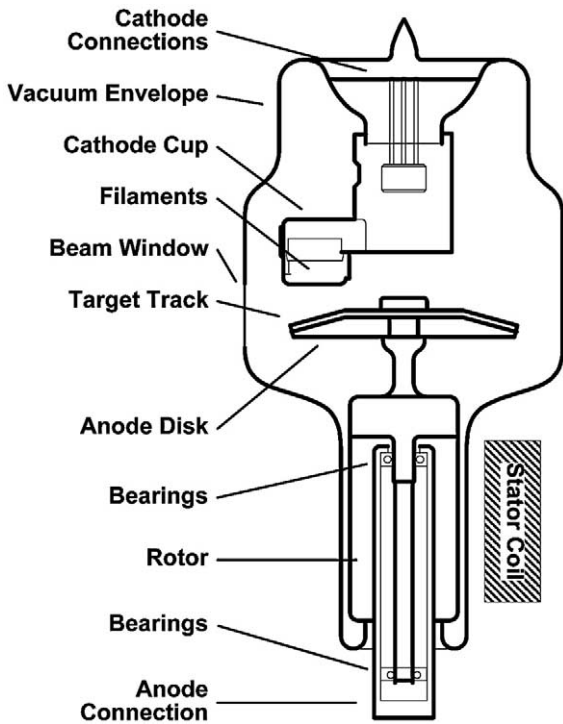
Figure 6. Medium power rotating anode X-ray tube. The entire apparatus is enclosed in an evacuated glass envelope. Electrons are emitted from the cathode filament cathode cup. They are accelerated across the tube by the application of high-voltage (kVp) and impinge on the anode disk target. A small portion of the electron beam's energy is converted to X-rays upon impact with the anode. The majority of the energy heats the focal spot. Rotating the anode disperses the heat along a long track rather than concentrating it in a single spot. This enables the X-ray tube to generate a higher power beam. Reprinted with permission of Wiley-Liss, Inc., a subsidiary of John Wiley & Sons, Inc. Balter S. Physics and Technology: X-Ray Generation and Control. Catheter Cardiovasc Interv 1999;46:92–7.

anode material's ability to absorb and dissipate the energy. As a result, the anode target would melt and destroy the tube. Therefore, at least two focal spot sizes are available on X-ray tubes: a large one, generally about 1 mm in size, and

a small one of about 0.5 mm. The small size provides better image definition, but the X-ray output is limited and not sufficient for all tasks. The large size provides less definition, but permits a greater X-ray output when the task requires it.

Electrical current can be applied to the tube either continuously or in a pulse train (Fig. 7). This produces either continuous or pulsed X-ray output. Continuous irradiation causes images of moving objects to be blurred and leads to greater exposure. For this reason, virtually all present-day systems operate in a pulsed mode. The video frame rate is usually an exact multiple of the X-ray pulse rate in order to maintain synchrony between the X-ray pulses and the video acquisition. In the U.S., the standard video frame rate is 30 frames per second. Thus, typical X-ray pulse rates are 30, 15, and 7.5 pulses per second. The X-ray pulse rate determines the image sequence's temporal resolution. More rapid pulse rates provide greater temporal resolution and are useful for imaging rapidly moving structures, albeit at the price of a greater X-ray exposure. When the pulse rate is less than the video frame rate, the video chain presents the frame acquired during the pulse repeatedly (once for 15 pulses per second and three times for 7.5 pulses per second) until the next pulse is delivered. This eliminates flicker that would be caused by alternating bright and dark frames. However, it does not eliminate motion "jerkiness," which attends slower pulse rates. For most modern units used in pediatric cardiology, rates of up to 60 frames per second are available. These more rapid frame rates are needed to capture the rapid movement that occurs in small children's cardiovascular systems.

Within the X-ray tube housing, X-rays leave the anode in all directions. The X-ray tube housing incorporates lead shielding that absorbs all X-rays except those emanating from its exit port. This defines the maximum diameter of the beam. In addition, a collimator is incorporated into the X-ray tube port to adjust the beam size to the minimum
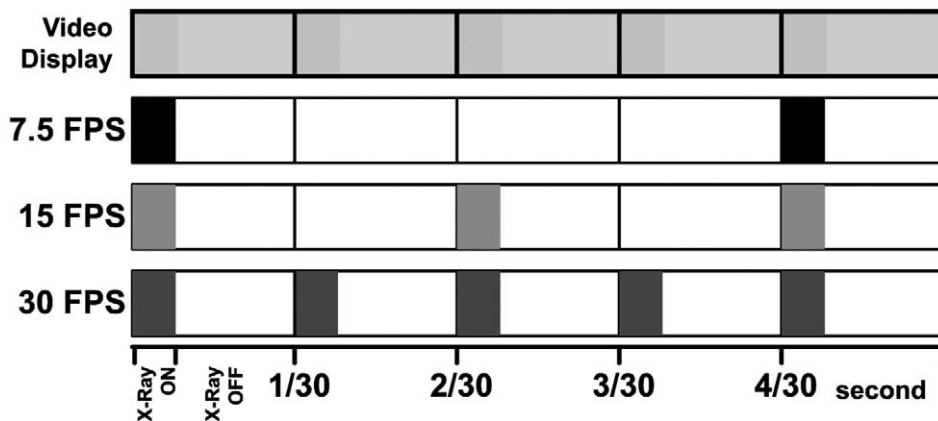
Figure 7. Fluoroscopic pulsing X-rays are produced during a small portion of the video frame time **(colored blocks)**. The pulse rate may be reduced by skipping video frames with the constraint that the video frame rate must be an exact multiple of the pulse rate to retain synchrony between the X-ray pulses and the video frame acquisition. In the U.S., the video frame rate is 30 frames per second. Thus, X-ray pulse rates of 30, 15, 7.5 frames per second are feasible. The temporal relationships between X-ray pulsing and video framing are shown. Visual flicker would be apparent at pulse rates below 30 pulses per second. This phenomenon is reduced by repeatedly displaying the last image at the full video frame rate (30 frames per second). FPS = frames per second.
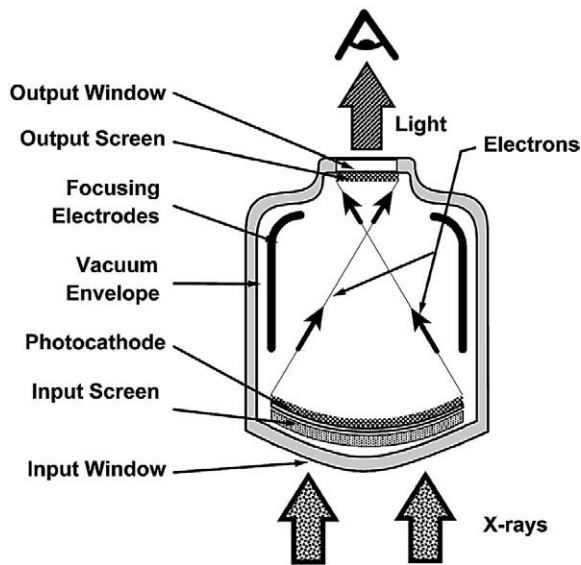
Figure 8. Diagram of an X-ray intensifier. The X-ray image passes through the input window and interacts in the input screen, converting the X-rays to a visible light image. The photocathode converts this light image to an electron beam image. The electrodes focus and accelerate the electrons that strike the output screen, producing the amplified light image of a much reduced size.

required for the imaging task. This beam collimation is necessary to confine the radiation to the imaged area of the patient, thus reducing exposure to other patient body parts. Collimation also reduces scatter radiation to clinical personnel.

X-ray image capture. Currently, two X-ray image capture systems are in active clinical use: image intensifier/video camera systems and flat-panel detectors.

Image intensifier-video camera systems. The X-ray image intensifier is a vacuum tube that converts the X-ray image into a visible light image that is brighter than that achievable by a simple fluorescent screen. Figure 8 is a schematic sagittal section of a single-mode X-ray image intensifier. The visible light output of the image intensifier is transmitted to a visible light image receptor such as a digital video camera for image display and recording.

Flat-panel detector systems. The image intensifier/video camera combination is currently being superseded by integrated direct digital image receptors (flat panel detectors). These detectors incorporate a charge-coupled device visible light detector in direct contact with the input phosphor. Thus, they generate a direct digital video signal from the original visible light fluorescence without requiring the intervening stages. Figure 9 schematically illustrates the structure and operation of a typical flat-panel detector.

X-Ray Exposure Modulation

The X-ray beam is attenuated as it passes through tissue. The degree of attenuation varies with tissue density and other factors such as the projection angle and the distance between the X-ray tube and the image receptor. In image intensifier systems, feedback circuits measure the brightness of the image generated by the image receptor. This feedback signal is used to modulate the output of the generator in response to changes in patient density and position. This is accomplished by an automatic dose rate control circuit designed to maintain a constant brightness level of the image intensifier output signal. X-ray intensity is increased if the detector measures a signal that is too dim and it is decreased if the signal is too bright. Similar feedback circuits are used in flat panel detector systems using the digital video output signal level as the source. Subject attenuation increases as overall tissue thickness increases. This means that the patient entrance port skin dose increases substantially when compound projection angles with cranial or caudal skewing are employed (Fig. 10).

Video Image Capture

Cameras and displays are the conduit between the image receptor and the observer's eye; they also serve to record the image permanently for later review and archiving. Various
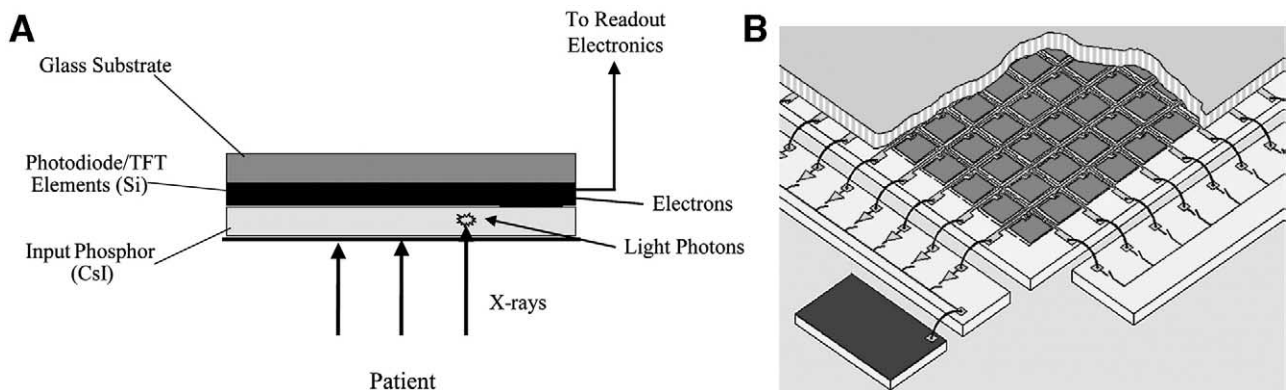
Figure 9. Flat-panel detector (scintillator type). **Panel A** depicts a cross-sectional diagram of a flat panel detector showing its components. **Panel B** depicts a highly magnified view of a corner of the detector showing the individual charged-coupled array detector elements in contact with the cesium iodide scintillator and their connections to the readout electronics. The X-ray image interacts in the cesium iodide input screen, converting the X-rays to a visible light image. The input screen is in direct contact with a charged-coupled array detector that directly produces a digital output signal that is transmitted to the X-ray system video chain. Reprinted with permission of Wiley-Liss, Inc., a subsidiary of John Wiley & Sons, Inc. Holmes Jr., et al. Flat-panel detectors in the cardiac catheterization laboratory: revolution or evolution—what are the issues? Catheter Cardiovasc Interv 2004;63:324–30.
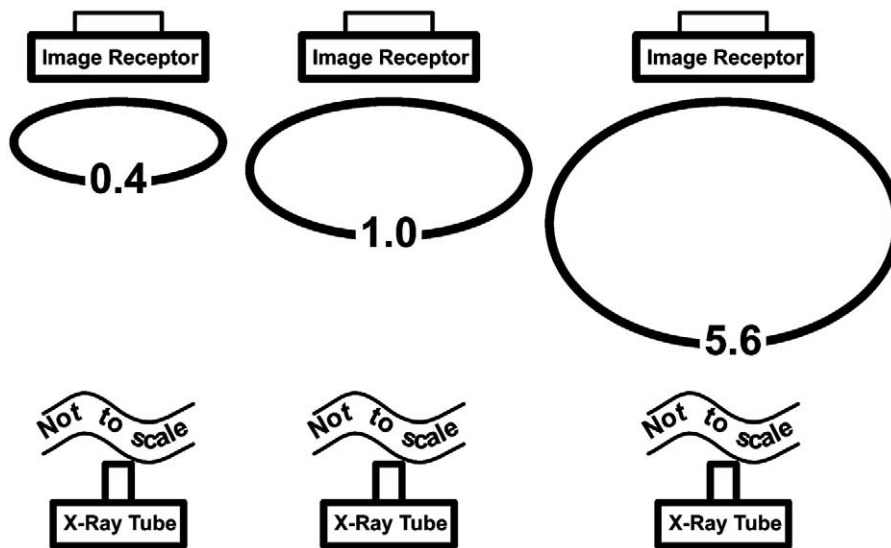
Figure 10. Effect of tissue thickness on entrance skin dose. Entrance skin dose increases rapidly with modest increases in the length of the radiation path in the patient. The causes are tissue attenuation and displacement of the patient's entrance surface toward the X-ray tube. Path length increases with compound beam angulation as well as with patient size. For a fixed geometry C-arm in this figure, the relative skin dose increases from 0.4 to 5.6 (14:1) as the path length increases from 12 to 36 cm (3:1). This example is for a mobile C-arm fluoroscope with fixed source-image distance and the patient is as close to the image receptor as possible. The actual relative values will differ for different types of equipment. Maximum fluoroscopic dose rates are limited by FDA regulations. There are no regulatory limits on cinefluorographic dose rates. Skin dose always accumulates far more rapidly in large patients (or with the use of compound angulation) than for non-compound views of thin patients.

camera technologies have been used over the years. Initially, photographic film was the primary image-recording medium. However, the refinement of video cameras and digital image processing has led to the universal adoption of direct electronic video image recording. In image-intensifier–based systems, the amplified light image is monitored by a video camera. The video image is captured as a digital video image file. Flat-panel X-ray detector systems internally convert the X-ray image into a digital video signal. After processing, the image is displayed on a high-quality television monitor.

Image Display and Processing

Digital images are usually processed before display or storage. Image processing alters the image with the intent of making it easier to interpret. All image-processing techniques involve compromise of some other aspect of image quality. Image-processing techniques include gray scale transformations to change contrast level; image smoothing to reduce the appearance of noise (at the expense of sharpness); and edge sharpening (at the expense of increasing the visibility of noise).

Image processing can also include combining multiple images. This reduces the effective noise level at the expense of blurring moving objects. Another image-processing technique involves subtracting one image from another to display differences between the two images (at the expense of increasing effective noise).

Cardiac cinefluorographic images are often acquired at a matrix size of 1024 × 1024 pixels. They are usually displayed in the laboratory at that resolution. Most cine archive systems (electronic or CD) downscan the images to a 512 × 512 matrix before storage. This is done to reduce data storage requirements and to reduce network data transmission times. Typically, downscanned images are re-upscanned to a 1024 × 1024 matrix size when they are displayed. This restores some but not all of the resolution of the original image. Thus, image resolution when viewed in the laboratory is somewhat better than when the image has been recalled from storage.

Imaging modes. The X-ray cinefluorographic units operate in two modes: fluoroscopy and acquisition (or image recording). The purposes and X-ray generator operating parameters of the two modes are different, particularly in terms of the input X-ray dose delivered. As a result, differences exist in image quality between these two modes. Figure 11 illustrates the differences in image noise between a single digital fluoroscopic frame and a single digital cine frame.

FLUOROSCOPY. Fluoroscopy provides a real time X-ray image when it is not necessary to record it. Fluoroscopy does not require the same level of image quality as does acquisition recording for diagnostic interpretation. Because these images are seen in motion, the neuropsychology of vision effectively integrates several frames—effectively reducing the perceived image noise. Thus, greater image noise can be tolerated and fluoroscopic X-ray input doses can be lower than doses used for acquisition. As the fluoroscopic dose rate decreases, image noise increases, degrading image quality.

Fluoroscopic dose rates should be set at the lowest input dose rate needed to generate a usable image. Current fluoroscopic systems have two or more operator-selectable dose rates. The higher dose rates provide less image noise, thus enabling the delineation of greater detail at the cost of greater patient and operator exposure.
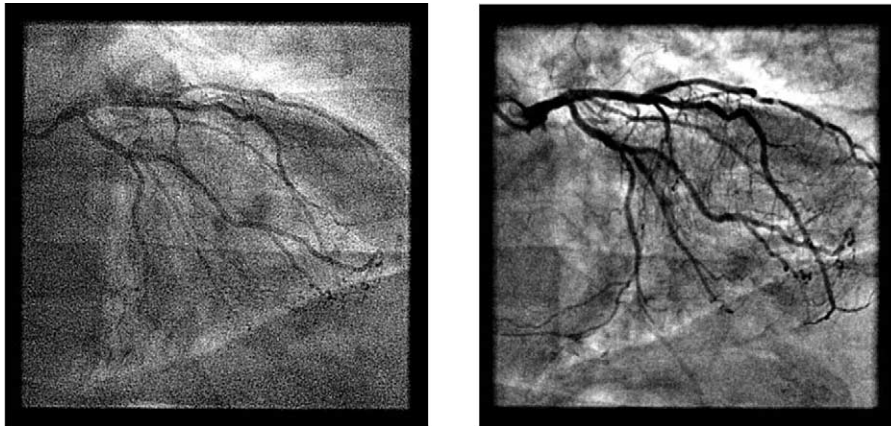
Figure 11. Comparison of single fluoroscopic and fluorographic images. The **left-hand image** is a single frame acquired at a fluoroscopic level input dose. The **right-hand** image is a similar frame from the same patient recorded in the same projection, but acquired at an acquisition level input dose. Note that the **left frame** is noisier because a lower dose was used than for the acquisition frame.

ACQUISITION (CINE). Acquisition mode generates higher resolution images suitable for diagnostic interpretation (including single-frame viewing) and archiving. Acquisition images are obtained at higher X-ray input doses in order to reduce image noise and optimize clinical visualization. Most X-ray cinefluorographic units are calibrated such that the per-frame dose for acquisition is approximately 15 times greater than for fluoroscopy. Thus, a single frame acquired in acquisition mode delivers about the same patient dose as 1 second of fluoroscopy. Figure 11 illustrates a comparison of single-frame images acquired at fluoroscopic and acquisition doses.

The optimal acquisition mode input dose per frame is that which achieves the best balance between image noise and image quality. The dose rate is also directly proportional to the acquisition frame rate. As with fluoroscopy, digital gap-fill can achieve flicker-free image displays at any frame rate. However, as frame rate decreases, image presentation becomes increasingly jerky despite gap-fill. As overall delivered dose is directly related to frame rate, the optimal frame rate is that which is just fast enough to capture clinically important transient events. A typical acquisition frame rate for adult studies is 15 frames per second.

Optimizing the Exposure Parameters That Determine Image Quality

The three main image-quality parameters—sharpness, contrast, and noise—are interdependent. The need to minimize patient exposure requires that dose be reduced to the minimum level that will generate an image with an acceptable degree of noise. The goal is to produce a usable image, not a perfect one.

For example, ideally an image would be acquired using a low kVp exposure to maximize image contrast and a large dose rate to minimize image noise. However, this would deliver a large patient exposure. Increasing kVp reduces patient exposure but decreases image contrast. Decreasing image receptor input dose reduces patient exposure but increases image noise. Thus, for a given patient density,

there is an optimal compromise set of exposure parameters that preserve diagnostic quality image contrast at an acceptable image noise level while minimizing patient dose.

Fluoroscopy Dose Management Issues

Several features are available that facilitate patient dose reduction during fluoroscopy:

- **X-ray beam collimation:** beam collimation restricts the size of the beam, enabling the operator to control the size and shape of the irradiated field. This provides an important exposure-limiting capability. The collimator should always be adjusted so that only the immediate field of interest is exposed to the X-ray beam, thus sparing the surrounding tissue from direct irradiation (see "Beam Collimation" in Section V).
- **Last image hold:** This feature presents the last acquired fluoroscopic frame on the video monitor, thus providing an opportunity to study the image without continuing the exposure.
- **Pulsed fluoroscopy:** This provides brief, several millisecond, X-ray pulses to generate images that are electronically processed by the digital video chain in order to furnish a continuously presented image. The pulse rate is operator selectable and ranges from 30 frames per second downward. As the pulse rate decreases, the patient exposure rate decreases (at the cost of increasingly jerky-motion presentation). Within limits, pulse rate reduction can produce images of acceptable quality for the purpose of the examination while minimizing dose rate. (Not all machines reduce dose rate with lower pulse rates. The dose-saving function of pulsed fluoroscopy can be assessed by a medical physicist.)
- **Virtual collimator and semitransparent diaphragm control:** Current X-ray units have the ability to generate a virtual display of collimator and semitransparent diaphragm positions. This enables the operator to position these devices as desired without using fluoroscopy.

- **X-ray stand position memory:** Current units are able to store multiple stand positions in memory and can automatically move to a selected position on command. This enables the operator to avoid the use of fluoroscopy to achieve a desired stand position.

There is a limit to which dose and frame rates can be reduced in cardiovascular applications. The neuropsychology of vision provides a degree of integration that decreases perceived visual image noise and jerkiness. In addition, digital image processing permits the digital equivalent of integration by a process called "recursive filtering." Application of recursive filters reduces the impression of noise at the expense of blurring objects that are moving. Fifteen frames per second is an optimal compromise frame rate. Rates below 15 frames per second may degrade the image presentation sufficiently to interfere with intricate device manipulation procedures, but may be adequate for less demanding tasks.

The dose rate often increases as the degree of electronic magnification of the image increases. For an image intensifier, the dose rate is roughly inversely proportional to the input area of the image detector. This relationship was obligatory for older film-based X-ray units as image-intensifier light output was directly related to input field size. For example, if the acquisition mode input dose for a 23-cm image intensifier is 100 nanograys (nGy) per pulse, the corresponding input doses when that intensifier is operated in the 17-cm and 13-cm modes are 183 and 313 nGy per pulse, respectively. For current fully digital image intensifier units, this relationship is no longer necessarily true as the light requirements of the video chain can be changed to require different amounts of light input at different image-intensifier field sizes. Similarly, the relationship between dose rate and active field-of-view for a flat-panel detector can be adjusted for different input field sizes. In general, both image-intensifier detector and flat panel detector dose rates are programmed to increase somewhat as the size of the field-of-view decreases, but these dose increases are required principally to reduce the image noise increase that would otherwise be noticeable at greater degrees of magnification (Fig. 11).

Acquisition Dose Management Issues

The acquisition mode is employed when images need to be reviewed and archived, and analysis of a static single frame or series of frames is necessary. The optimal acquisition mode input dose per pulse is that which achieves the best balance between image noise and patient dose. When moving objects are imaged, image sharpness is also determined by pulse width, with briefer pulses yielding greater sharpness. As with fluoroscopy, digital gap-fill can achieve flicker-free image displays at any acquisition pulse rate. The dose rate is also directly proportional to the pulse rate. The optimal pulse rate is that which is just fast enough to capture the transient moving events being examined. Thus, for adults it is now common to acquire images at 15 frames per second. Higher pulse rates are generally needed to image small children. Substantially lower pulse rates are usually appropriate for the peripheral vasculature. Image sharpness is related to the pulse width not the frame rate.

Digital Image Subtraction

A digital subtraction image is obtained by subtracting one image from another. This electronically removes information that is identical in two images. The resulting image is a display of the difference between the two images. In angiography, the first image (mask) is obtained before the injection of contrast. The second image is acquired during the angiographic run. The computed resultant image contains the difference between the two acquired images and emphasizes the contrast-opacified structures. Because the subtraction process accentuates image noise, it is necessary to counter this effect by acquiring each of the original images at a substantially (as much as 20-fold) higher dose per frame. The increased dose per frame may be partially offset by the ability to employ slower frame rates. However, studies that use digital subtraction imaging generally employ larger aggregate doses than do studies that employ unsubtracted cinefluorography.

V. DETERMINANTS OF PATIENT X-RAY DOSE

Patients undergoing invasive cardiac procedures do not receive uniformly distributed whole-body radiation. The delivered radiation is mostly concentrated in a confined area of the thorax. The effect of the patient's exposure is related to the dose received by each directly or indirectly exposed structure.

Measurements of Patient Dose

Two parameters of dose—the dose at the interventional reference point (IRP) and the dose-area product (DAP)—are useful for characterizing patient exposure. Currently available interventional fluoroscopic equipment determines real-time estimates of the instantaneous and cumulated values for these dose factors. The unit's indication of these cumulated values provides valid indicators of a patient's dose and consequent risk for radiation-induced effects.

Dose (Air Kerma) at the IRP

The IRP is located on the X-ray beam axis 15 cm from isocenter on the X-ray tube side (Fig. 12). For an interventional cardiologic procedure, this location approximates the location of the skin at the beam entrance point when the heart is located at isocenter. Thus, the air kerma at this point is an indicator of skin dose. Although quantitatively not an exact measure of skin dose, the estimate provides a measure by which an assessment can be rendered regarding the risk of injury to the patient's skin.
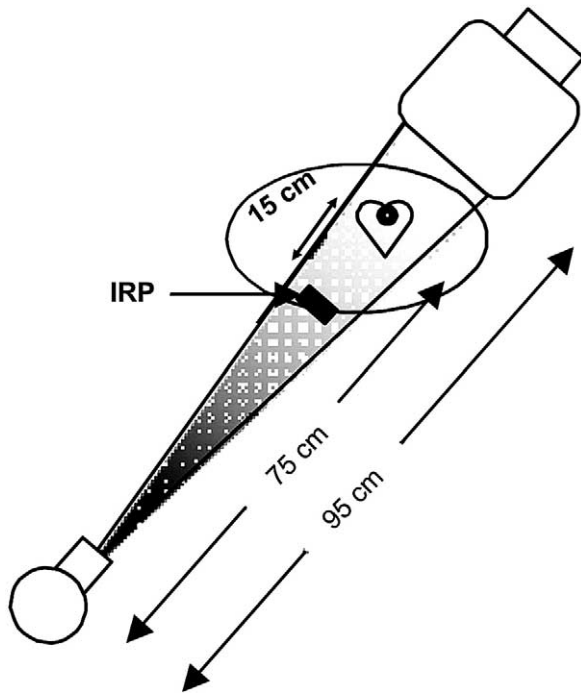
Figure 12. The interventional reference point (IRP). The IRP is located 15 cm from isocenter on the X-ray tube side of a fluoroscope, as shown in the diagram. This approximates the location of the patient's skin in cardiologic procedures. As is obvious, for conditions other than the one illustrated here, the IRP might be located many centimeters away from the skin surface. This might occur for non-isocenter settings, larger or smaller patients, or different beam orientations. Therefore, air kerma measurements at the IRP must be used for guidance purposes and not considered to be true skin dose.

DAP

The DAP is the absorbed dose to air (air kerma) multiplied by the X-ray beam cross-sectional area at the point of measurement. It is expressed in $Gy \cdot cm^2$ or some variation thereof. The cumulated DAP for a procedure is a surrogate measurement for the total amount of X-ray energy delivered to the patient. Consequently, it is a measure of the patient's risk of a stochastic effect (see Section VI).

Contrary to the measurement of dose at the IRP, the value of the DAP of an unattenuated X-ray beam does not depend on the distance from the X-ray source. This is because, although the dose decreases with distance from the X-ray source, the beam area increases commensurately. The DAP is usually measured by means of a transmission ionization chamber placed in the X-ray tube assembly. It may also be calculated from generator and collimator settings. A typical beam cross-sectional area at the IRP is between 30 and 100 cm^2. Thus, the DAP at the IRP might numerically be 100 to 300 times the air dose at the IRP.

Value of Dose Monitoring

Estimated values for air kerma at the IRP are calculated and displayed by modern X-ray units. Typically, the system measures the DAP using an ionization chamber placed in the X-ray tube's exit port. As discussed previously, this

parameter is constant at all distances from the beam. The system calculates the dose at the IRP from DAP data and the known position of the X-ray tube collimator leaves.

However, the values that the system displays, nonetheless, are estimates and have a margin of error that may be as much as a factor of two or greater. Thus, the measure, therefore, must be interpreted with some discretion. For example, a calculated IRP air-kerma dose of 2 Gy is very unlikely to represent an actual skin dose of 6 Gy (the approximate threshold dose for delayed skin erythema). Conversely, if the calculated IRP dose is 4 Gy, it is more likely that the erythema threshold may have been crossed. Thus, patients who receive an IRP dose greater than 4 Gy should be advised that they might develop a skin rash, along with instructions on what to do in the event that one is observed.

Dose levels at the IRP and DAP are influenced by many variables, not all of which are under the operator's control. Nonetheless, assessment of these parameters provides a measure of a physician's radiation management performance. Factors not under the operator's control include patient size and disease complexity. However, other variables, such as X-ray system position, collimator position, and appropriateness of beam-on time, are affected by the operator's attention to radiation safety practices. Thus, although the relationship of DAP to patient injury is indirect, monitoring DAP is a valuable part of overall quality assurance monitoring. The DAP tracking for all procedures provides a measure of appropriateness of patient radiation protection practices.

Dose at the IRP Monitoring

The dose at the IRP has a direct relationship to the risk of patient skin injury. Real-time intraprocedural monitoring of the dose at the IRP may be employed to make decisions about procedure conduct. If a large dose has been delivered before completion of non-critical aspects of a procedure, it may be appropriate to abbreviate that procedure with plans to reassess the patient's condition at a later date. This would permit skin examination to determine whether or not any injury is apparent as well as some time for the skin to recover from the previous exposure. In addition, if feasible, the radiographic projection can be altered so that the dose is distributed over more than one skin entrance port. Knowledge of the dose parameters also permits the physician to advise the patient who has received a large dose to be vigilant for signs of skin injury and about what to do if one occurs.

DAP Benchmarking Data

Because DAP is determined both by physician-operator behavior and by variables that are not under the operator's control, it is impossible to identify a value for DAP that denotes a boundary between appropriate and inappropriate practice. Few data are available that permit benchmarking for these parameters. Of the data available, recent European

Table 2. Factors Affecting Dose in Interventional Procedures

Equipment Design and Settings
  Movement capabilities of C-arm, X-ray source, image intensifier
  Field-of-view size
  Collimator position
  Beam filtration
  Fluoroscopy pulse rate and acquisition frame rate
  Fluoroscopy and acquisition input dose rates
  Automatic dose-rate control including beam energy management
    options
  X-ray photon energy spectra
  Software image filters
  Preventative maintenance and calibration
  Quality control
Patient Factors
  Patient body weight and habitus
Physician Procedure Conduct
  Positioning of image intensifier and X-ray source relative to the
    patient
  Beam orientation and movement
  Detector field-of-view size
  Collimation
  Acquisition and fluoroscopic technique factors on some units
  Fluoroscopy pulse rate
  Acquisition frame rate
  Use of variable beam filtration
  Total fluoroscopy time
  Total acquisition time

experience (9) suggests that procedure DAP values in excess of 100 Gy·cm^2 for a routine diagnostic coronary angiogram should be evaluated for appropriateness as part of a quality assurance review. However, the appropriateness of the 100 Gy·cm^2 value, or any other value, should be considered in the context of the type and complexity of the procedure as well as patient characteristics.

Factors That Influence Patient Absorbed Dose

Three groups of factors affect the dose delivered to the patient during an invasive cardiovascular procedure:

1) equipment-related factors
2) patient-related factors
3) procedural-related factors

These are itemized in Table 2 and are discussed in detail by Limacher et al. (8).

Equipment-Related Factors

Equipment-related factors include equipment features and selectable operational modes that provide control over X-ray dose rates. The list of factors in Table 2 is not necessarily complete, because equipment design continually evolves. The availability of these features must be considered when selecting equipment to ensure that it includes the necessary features that can adjust patient dose rate appropriately for the intended applications.

Depending on the design and features of a particular X-ray unit, different equipment-related dose management factors will be operator selectable. The operating physician must know the location and function of these controls. He or she should understand the unit's dose reduction features and employ them as needed to assure minimal patient and personnel exposure. Common operator-selectable features include fluoroscopic pulse and dose rates and acquisition frame rate. Other features may or may not be under the operator's control. These include acquisition dose rate, X-ray beam energy (kVp), and beam filtration.

Studies have demonstrated that small variations in equipment operation factors can alter the patient radiation entrance exposure rate substantially. This can mean the difference between an inconsequential skin dose and a dose that can cause deep dermal necrosis over a large area (10).

Patient-Related Factors

The principal patient-related factor is patient size. As patient size increases, the input dose of radiation required for sufficient penetration to the image detector increases in an exponential manner. Thus, large-chested and, particularly, obese individuals require much greater levels of radiation input than do thin-chested subjects.

Image quality deteriorates as patient size increases. Large patients generate more scattered radiation. This degrades image contrast and signal-to-noise ratio. Large patients also require X-ray beams with higher kVp that yield lower image quality because of reduced subject contrast and increased radiation scatter. The reduced image quality in a large patient may increase the procedure's technical difficulty, potentially prolonging it and consequently requiring a greater radiation input.

Procedure Conduct Factors

Procedure conduct factors characterize how the physician applies the radiation. These factors are influenced by patient and disease characteristics. The general principles for minimizing patient dose that apply to most equipment configurations and clinical situations are listed in the following text. They are discussed in greater detail in Section VIII. Although patient dose is greatly affected by the X-ray unit's configuration, capabilities, and calibration, it is also importantly affected by physician conduct, which is governed by the physician's knowledge and judgment.

Many of the physician conduct factors are itemized in Table 2. It is important that physicians understand how the various conduct factors affect patient exposure and know how to manage them. The following factors are the important variables directly or indirectly under the physician's control that affect the dose to the patient.

Exposure duration. One of the most important procedure conduct factors is exposure duration, or "beam-on time," over a single skin entrance site. Physicians must learn to use beam-on time wisely to ensure that dose accumulation in the skin is well managed and kept as low as reasonably achievable. In prolonged procedures, when practical, the physician should consider changing the fluoroscopy projec-
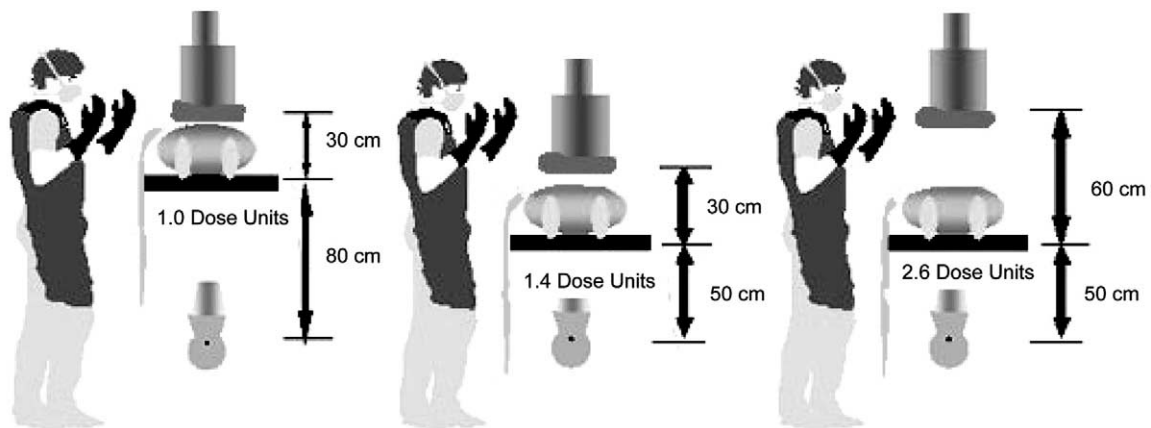
Figure 13. On the **left**, the physician performs the procedure with the patient table elevated and the image intensifier close to the patient (total distance from the X-ray tube to the detector = 110 cm). In the **center**, the physician employs a lower table setting but maintains the image intensifier close to the patient's chest (total distance from the X-ray tube to the detector = 80 cm). Because of the closer proximity to the X-ray tube, the dose rate to the patient at the beam entrance port will be about 40% higher. On the **right**, the physician employs a low table height but has elevated the image intensifier (total distance from the X-ray tube to the detector = 110 cm). The skin dose to the patient on the **right** is 260% that of the patient on the **left**. (The image generated by the configuration on the **right** is 40% to 50% larger owing to geometric magnification caused by the elevated image intensifier.) If the procedure on the **left** required a 3 Gy skin dose, the same procedure employing the center configuration would result in a 4.2 Gy dose, whereas the one performed employing the configuration on the **right** would result in 7.8 Gy. Adapted with permission from Wagner LK, Archer BR. Minimizing Risks from Fluoroscopic X-Rays. R. M. Partnership, The Woodlands, Texas 2000.

tion angle so that the beam entrance site is altered, thus reducing the dose to any given area of skin.

Positioning of the image receptor and X-ray tube. A very important conduct variable that is directly under the operating physician's control is how the X-ray system is positioned with respect to the patient. For similar examinations in terms of total fluoroscopy and acquisition time, the way the physician positions the X-ray system can substantially affect the X-ray dose delivered to the patient. Elevating the image receptor above the patient's body can increase the input dose substantially—by as much as a factor of 4. Figure 13 illustrates an example in which positioning the image receptor excessively far from the patient increases the dose by a factor of 2.6. Failing to minimize the distance between the patient and the image receptor not only increases entrance port dose, it also increases the scattered dose to the physician operator and other in-room personnel. Also, placing the X-ray tube too close to the patient's body can greatly increase the dose to the skin. Each of these factors can importantly affect the radiation output and dose absorbed by the patient.

The operating physician must balance multiple considerations when positioning the patient and the X-ray system. For example, it is convenient to perform a coronary interventional procedure with the target lesion located at the fluoroscopy unit's isocenter. This strategy minimizes the need to reposition the patient when the X-ray projection angle is changed. However, this strategy often shortens the distance between the X-ray tube and the patient, increasing the patient's entrance port skin dose. In contrast, positioning the X-ray tube too far from the patient entrance may require an excessive increase in beam kVp, potentially degrading image quality.

Beam Collimation

The net effect of beam collimation to limit exposed field size on patient exposure is complex. Collimating to the area of interest reduces exposure by reducing the volume of tissue that is irradiated. As a result, it also reduces scattered radiation within the patient and in the procedure room, reducing both patient and personnel exposure. In addition, it improves image contrast by reducing scattered radiation at the image intensifier. Conversely, beam collimation does not reduce entrance port radiation dose rate and may actually increase it. How the dose rate is affected by beam collimation depends on the design of the particular X-ray unit's automatic brightness control system.

Input Dose and Frame Rate

Images generated with lower input dose rates or at lower frame rates are generally of lower quality than higher dose or frame rate images. Thus, the physician must understand the safety value of low dose rate and low frame rate operations. The physician is responsible to employ the lowest dose rate that does not compromise image quality. This strategy maximizes patient protection without undermining procedure efficacy.

VI. PATIENT EFFECTS OF X-RAY EXPOSURE

Ionizing radiation, although a very beneficial aid to invasive procedures, can be harmful. When used in small amounts the risk of a harmful reaction is very small. As dose increases, risk increases. Above certain threshold levels the risk can be substantial, causing severe patient injury. Physicians who apply radiation to patients must employ a risk-benefit decision process much like that used when

Table 3. Adverse Effects of Radiation

Deterministic Effects
   Skin injury and hair loss
      Thresholds
      Dose-response relationships
      Progression of injury
   Eyes
      Other organs
Stochastic Effects
   Neoplasm
      Incidence and mortality risks
      Risk models for low-dose effects
      Latent periods
      Heritable genetic effects

Table 4. Threshold Skin Entrance Doses for Different Skin Injuries

Single-Dose Effect	Threshold (Gy)	Onset
Early transient erythema	2	Hours
Main erythema	6	Approximately 10 days
Late erythema	15	Approximately 6–10 wks
Temporary epilation	3	Approximately 3 wks
Permanent epilation	7	Approximately 3 wks
Dry desquamation	14	Approximately 4 wks
Moist desquamation	18	Approximately 4 wks
Secondary ulceration	24	Greater than 6 wks
Ischemic dermal necrosis	18	Greater than 10 wks
Dermal atrophy (1st phase)	10	Greater than 14 wks
Dermal atrophy (2nd phase)	10	Greater than 1 yr
Induration (invasive fibrosis)	10	*
Telangiectasia	10	Greater than 1 yr
Late dermal necrosis	Greater than 12?	Greater than 1 yr
Skin cancer	Not known	Greater than 5 yrs

Gy = Gray. *No estimate available. Data derived from references 1,4,10–12.

prescribing prescription drugs. To make informed decisions, the physician must understand the relationship between an exposure to radiation and the potential consequences to health. Radiation effects fall into two classes: deterministic effects and stochastic effects.

Deterministic effects are predictable dose-related phenomena. They have a threshold dose below, which the effect does not occur. The threshold is variable, depending on the nature and condition of the exposed tissue. For doses in excess of the threshold, both the probability and the severity of deterministic effects increase with dose. Examples of deterministic effects include radiation-induced epilation, erythema, and necrosis of the skin.

Stochastic effects are probabilistic in nature, and their severity has no relationship to dose. The likelihood of inducing a stochastic effect increases with dose, but there is no identifiable threshold for the effect. The exact functional relationship with dose is unknown. Guidelines exist regarding the risk potential. Examples of stochastic effects include radiation-induced neoplasm and heritable genetic defects.

For all effects there is a delay between the irradiation and the appearance of the effect. The delay may be hours to months for some deterministic effects and years to decades for others. Because of the delay, in some circumstances the connection between the effect and the prior radiation exposure may be ambiguous.

Table 3 lists adverse health effects of radiation that can occur as a result of exposure from invasive cardiac procedures.

Deterministic Effects

Dose relationships. The threshold dose for deterministic effects depends on the time course of the radiation delivery. Threshold doses are generally expressed in terms of a single acute dose. Dose fractionation (delivery over multiple sessions) changes this relationship, enabling a tissue to tolerate a greater total accumulated dose. However, significant previous exposure lowers the single-dose threshold for an effect in a subsequent exposure. Thus, if a patient receives a total dose that exceeds the single-dose threshold in multiple sessions that are separated significantly in time, the effect is less likely to occur than if the same dose were administered

at a single session. As a result, a patient who undergoes multiple invasive cardiac procedures over several years may not develop an effect even if the total cumulated dose exceeds the single-dose threshold. Conversely, the patient who has undergone multiple procedures may develop an effect following a later procedure even though the dose delivered during that particular procedure was below the single-dose threshold.

Skin injuries. Radiation-induced skin injury is the most common deterministic effect that occurs as a consequence of fluoroscopic procedures. The skin is an actively dividing tissue. Consequently, it is moderately radiosensitive. The skin at the site where the fluoroscopic beam enters the patient receives the largest radiation dose and, accordingly, is the organ at greatest risk (4).

When skin doses exceed certain thresholds, the radiation injures numerous cells and the biological response in skin is readily detectable. Severe skin injuries are illustrated in Figure 1. Proposed thresholds for various effects in healthy skin are listed in Table 4. These "thresholds" and their temporal patterns of development should be viewed as approximations for reasons discussed in the previous text. Because the doses that cause these injuries are large, they are rare complications of invasive cardiac procedures. However, long and complex invasive cardiac procedures can deliver entrance port skin doses that exceed the threshold and all of the injury stages that have occurred. These phenomena are thoroughly reviewed in the references in Table 4.

Skin injuries pose particularly severe problems because of difficulty in diagnosis and challenges to their management. Diagnosis is often difficult and initially missed because the problem generally presents two to three weeks following the causative exposure. Both the patient and the patient's physicians frequently fail to connect the developing skin

lesion to the earlier radiation exposure. The lesion is typically located on the patient's back and may interfere with sleeping. Some skin ulcerations require skin grafting.

Radiation-induced skin injury can usually be identified by the temporal pattern of development in relation to the time of irradiation and by the location of the injury at the beam entrance site (6) (John Hopewell, oral communication, 1999). If the beam is positioned over a single skin site for a prolonged period of time and the collimation is not changed, the lesion will be well demarcated with a shape consistent with that of the collimated beam.

The patient's state of health may modify the normal response of skin to radiation (6,11). Data suggest that collagen vascular disease (particularly scleroderma, discoid lupus erythematosis, and mixed connective tissue disease), diabetes mellitus, and hyperthyroidism make the patient more susceptible to injury. Patients homozygous for ataxia telangiectasia are known to be more sensitive. Various chemical and pharmaceutical agents have also been associated with increased risk for skin injury. In addition, patients who have previously undergone fluoroscopically guided procedures or radiation therapy may have a lower threshold for radiation injury in subsequent procedures.

Cataract

Radiation-induced cataract has a threshold dose of 1 to 2 Gy for a single acute exposure. As the eyes are not in the primary beam during cardiac procedures, this dose should never be delivered during a cardiac procedure. The minimum latent period between exposure and diagnosis is approximately 1 year (12).

Stochastic Effects

Induced neoplasm. Epidemiologic data indicate a linear dose-response relationship between ionizing radiation exposure and induction of solid tumors. A recent analysis of the low-dose data from atomic bomb survivors (13) demonstrated a small but detectable increase in cancer incidence at an estimated total body absorbed dose as low as 100 mGy (10 rad) and perhaps less. Statistical models indicate a fatal cancer risk increment range of 0.04% to 0.12% for a whole-body exposure of 10 mSv (1 rem) (14). The 0.04% figure applies to low-dose-rate delivery, assuming that repair mechanisms under these low-level conditions can ameliorate the radiocarcinogenic process. The 0.12% figure is the upper 90% confidence limit for the risk. Based solely on these numbers as applied to the adult patient, the risk of mortality from a malignancy induced during a typical cardiologic intervention with a DAP of 200 Gy·cm^2 is less than 1%. For patients over the age of 50 years, the risk is considerably less than this figure (13,14).

The minimum delay between radiation exposure and diagnosis of an induced cancer is 2 years in the case of

leukemia. The risk of leukemia is very low beyond 25 years after an exposure. Solid cancers have a minimum latent period of about 5 years and the risk extends for many decades.

Female breast cancer is one of the best-documented examples of X-ray–induced cancer. Between the 1930s and 1950s, fluoroscopy was used to monitor and assess the adequacy of an artificially induced pneumothorax for treatment of pulmonary tuberculosis. Women who received this treatment suffered a substantial increase in the frequency of breast cancer (15,16). Because the female breast can reside in the direct X-ray beam, it is important to avoid direct entrance beam exposure to the breast or breast buds, to the extent possible, and to eliminate other unnecessary direct exposures to the female breast by carefully applying beam orientation, collimation, and breast positioning.

Risk of neoplasm in children. Radiation risk management in children is different from that for adults. Radiogenic neoplasm is importantly related to age at exposure and is gender dependent (14,17). Sensitivity declines with increasing age. Newborns are estimated to be 10 to 30 times more sensitive than middle-aged or older adults. The risk for mortality in newborn males is about 0.12% to 0.15% per 10 mSv (1 rem). Females are more susceptible than males, because of greater breast and thyroid sensitivity. Additionally, because of smaller body size, a greater portion of a child's radiosensitive tissues is in close proximity to the X-ray beam during cardiologic procedures. Fortunately, because of small body size, radiation penetrates children more readily, and dose rates are kept low as a result. The risk of inducing a cancer in a child from an interventional cardiovascular procedure that delivers 60 min of fluoroscopy and a comparable dose from fluorography is likely to be on the order of tenths of a percent to 1%, depending on the system dose efficiency.

Heritable abnormalities. Atomic bomb survivors are the largest population that has been studied. A small but statistically not significant increase in birth defects occurred in first-generation offspring of atomic bomb survivors (18). Animal data suggest that the risk is greatest in the first 2 months after exposure and then declines.

Interventional cardiac procedures should not expose the gonads to significant direct beam radiation. The dose delivered to the gonads by scatter when the primary beam is focused on the thorax is very small and is not affected by external shielding. However, pelvic procedures place the gonads directly in the X-ray beam and may deliver significant doses to the reproductive cells. The risk for radiation-induced heritable effects on the reproductive cells of exposed individuals is estimated to be approximately 0.01% affected offspring per 10 mGy (1 rad) absorbed dose to the gonads (14). Because this risk applies only to actively reproductive patients and as the gonads receive little direct irradiation in the majority of procedures, this risk is extremely small in the population of adult patients undergoing cardiac procedures. Besides the obvious factor of keeping exposure duration

Table 5. In Utero Effects

Deterministic Effects
   Central nervous system functional effects
   Malformations
   Dose-response
Stochastic Effects
   Types of risks (neoplasm, heritable)
   Dose-response
   Gestation dependence

times to a minimum, the most effective way to manage exposure to the gonads during pelvic radiography is to collimate to the area of interest.

Although the risk for transferring effects to new generations may be small (and is 0 for patients who are no longer reproductive), the principle of ALARA still applies and is the best protection for future generations. It is advisable to wait 6 months after doses to the gonads in excess of 100 mGy before attempting conception (12).

Pregnancy: a special case. Radiation risks associated with pregnancy are thoroughly reviewed elsewhere and are summarized in Table 5 (19). For low doses to the conceptus, the principal risk is radiation-induced cancer. The risk for childhood cancers (principally leukemias) from in utero exposure is about 0.06% per 10 mSv (1 rem), but the risk for long-term adult development of induced cancers is not known. Because solid cancers are about seven times more prevalent than induced leukemias and occur much later, the lifetime risks following in utero exposure are likely to be similar to the newborn risk (see the previous text).

Doses to the conceptus in excess of 50 to 100 mGy place the child at risk for growth retardation, malformation, resorption, or miscarriage. Actual risk of such events depends on dose and stage of development. The specific types of risk depend on the gestation age of the conceptus. Tissues principally at risk are those of the central nervous system. See other texts for a complete discussion (12,19,20).

The relationship of dose to the patient and dose to the conceptus is frequently misunderstood. Pregnancy need not be an absolute contraindication to a fluoroscopically guided procedure. Interventional procedures in the head or the chest do not necessarily (and are probably not likely to) deliver dangerous doses to the conceptus, and in emergency care such procedures are likely to be justified. Even during critical developmental stages (gestational weeks 1 to 12), procedures that involve structures above the diaphragm are unlikely to deliver doses capable of inducing deterministic effects (malformations) to the conceptus because direct irradiation of the conceptus can be maintained at minimal or negligible levels. In the most critical developmental stages, the conceptus is very small and remote from the diaphragm.

The uterus only receives radiation scattered from the irradiated area, and this is only a small fraction of the dose delivered to the directly irradiated site (typically much less than 2%). A commonly held misconception is that a fetus can be protected from radiation exposure by shielding a pregnant woman's abdomen and pelvis. This will be ineffective for procedures in which the chest or head are the principally exposed body regions. In these circumstances, fetal exposure is caused by scattered radiation emanating from the directly exposed structures. Lead shielding applied externally to the pelvis and abdomen will not intercept this scattered radiation. Taking pains to avoid direct radiation exposure to the abdomen and pelvis and collimating the field to the area of interest ensures that exposure to the fetus is minimized. Therefore, the risk for these types of effects from irradiation above the diaphragm should be negligible for most well-managed procedures. Only in extended procedures would the dose to the uterus exceed 50 mGy. The principal potential risk to the fetus is radiation-induced neoplasm. The importance of this risk must be weighed in relation to the anticipated clinical benefits to the mother.

VII. RADIATION RISKS FROM TYPICAL INVASIVE CARDIOVASCULAR PROCEDURES

Clinical Risk-Benefit Ratio

The appropriateness of exposing a patient to a potential procedure hazard requires that the procedure's expected benefit justify the probable risk. Radiation-induced injury is one of the hazards attending invasive cardiovascular procedures; it must be considered in the risk-benefit decision and also must be minimized through procedure conduct decisions.

The presence of known or suspected cardiovascular disease in a patient affects the balance of risk versus benefit. One simple guideline for diagnostic investigations of individual patients is the expectation that the outcome of the procedure will have a positive effect on the patient's cardiovascular health. It is helpful to remember that a negative study can be a very important factor in a patient's life.

Regarding interventional procedures, it is helpful to quote from the older literature:

> "We may safely expect that damage suits for Roentgen ray burns, caused during diagnostic exposures, will become more and more infrequent. But with the employment of the rays for therapeutic purposes, burns have now become a rather common accident. . . . Where cosmetic considerations alone are concerned, such heroic therapy is injudicious" (21).

This century-old admonition is applicable to current issues in invasive cardiovascular procedures. The choice to use or to continue to use radiation during a therapeutic procedure needs to be carefully considered. Considerations include the necessity for the procedure, the availability of alternative strategies, the availability of appropriately calibrated equipment, and operator proficiency. The overall risk-benefit balance may change as the procedure progresses and the patient's total radiation exposure accumulates. The operator has the responsibility to end the procedure before the balance of risk to benefit becomes unfavorable. In contrast,

abruptly terminating an incomplete clinical procedure simply because a predefined radiation dose threshold has been exceeded is seldom in the patient's best interest. Continuing evaluation of the evolving clinical situation and all of the patient's risk factors, including radiation, will optimize results.

General Considerations for Deterministic Risk

Evidence in the interventional literature shows chronic skin changes associated with multiple procedures irradiating the same portion of a patient's skin (Fig. 1). It is also known from radiation oncology that the same dose of radiation delivered over time (fractionation) usually produces less of a biological effect than the same dose delivered in a single session. Clinical management of unwanted skin injuries was an important part of radiotherapy prior to the 1960s. Unfortunately, much of this knowledge has been lost in the last four decades. Generally, it can be said that fractionation has an incomplete radioprotective effect regarding deterministic injury.

General Considerations for Stochastic Risk

Patients who require an invasive cardiovascular procedure often have chronic disorders. It is commonplace for a patient to require multiple procedures over his or her lifetime. The risk of radiation injury is related both to the immediate exposure and to the total lifetime accumulated dose.

The estimated effective dose range attributable to invasive cardiology procedures is between 1 and 10 mSv. The effective dose delivered by diagnostic cardiac radionuclide procedures in an adult is in the range of 15 to 35 mSv. The annual effective dose delivered to an individual in the U.S. by natural background radiation ranges between 3 and 4 mSv. There are several areas in the world in which the natural background contribution exceeds 10 mSv/year. Thus, broadly speaking, an invasive or radionuclide cardiac procedure presents the same stochastic radiation risk as about 2 to 3 years of natural background radiation.

Multiple Procedure Considerations

Although dose fractionation clearly reduces the deterministic risk of a given total radiation dose, the linear no-threshold model of stochastic injury indicates that stochastic radiation risk depends on the total dose accumulated by a patient during his or her lifetime. Thus, the cancer risk increases with the number of procedures. Splitting a procedure offers no practical protection against radiogenic malignancy.

VIII. PHYSICIAN RESPONSIBILITIES TO PATIENTS

The physician who performs invasive cardiovascular procedures is responsible for conducting the procedure safely and for effectively balancing the importance of the procedure with the need to minimize the patient's radiation injury

hazard. This responsibility encompasses both case selection and procedure conduct.

To meet this responsibility, the physician must understand the patient characteristics that determine risk, the basic principles for minimizing patient dose, and the equipment's dose-control features. This knowledge base must be integrated and applied to decisions regarding patient selection, procedure conduct, and equipment operation. Thus, the physician must possess both fundamental knowledge and machine-specific training in order to control radiation utilization optimally. In addition, the physician is responsible for conducting appropriate communication with the patient concerning the risk of radiation injury.

Patient Education and Consent

There is no current standard of practice for obtaining informed consent for the risk of a radiation-induced injury. When obtaining informed consent for invasive cardiovascular procedures, it is customary to outline the known serious complications in detail and the more frequent, but less severe, complications in general. For most patients and procedures, the risk of radiation-induced injury is sufficiently small that it does not merit specific mention as part of the informed-consent process. However, it may be appropriate to include radiation injury when obtaining informed consent from a patient who is at increased risk. Such patients would include those who will undergo a particularly long and complex procedure, a patient who has had multiple recently performed fluoroscopic procedures, or a patient who is extremely obese. In addition, as radiation injury presents late following the procedure and may be difficult to diagnose, there is a role for warning a patient about the possibility of radiation-induced injury if the procedure used more than 50 min of fluoroscopy time (with modern, well-calibrated equipment) or delivered more than 4 Gy to the interventional reference point. The threshold for such a warning should be reduced to 30 min if the patient is obese or if the procedure was done utilizing an older (greater than 5 years) X-ray unit. In such circumstances, arrangements should be made for appropriate follow-up 1 and 3 months' post-procedure to ascertain whether there is any evidence of a radiation-induced injury.

Procedural Dose Management

The best practice that minimizes the patient's risk of radiation injury follows three basic principles that underpin the ALARA principle:

- there is no known absolutely safe dose of ionizing radiation
- the smaller the dose, the less the risk of an adverse effect
- incremental radiation exposures have cumulative effects

Adherence to these principles requires attentiveness to radiation protection and, on occasion, making operational compromises. Most of the practices that minimize the dose delivered to the patient also minimize the dose to the operator and clinical personnel. Thus, practices that protect

the patient also protect others. The operating physician is responsible for understanding these variables and for applying these considerations when determining the operational strategy for conducting a procedure (6).

The basic principles of minimizing radiation exposure include:

1. **Minimize beam-on time, both for fluoroscopy and acquisition.** The fluoroscopic beam should be on only when the dynamic information from the fluoroscopy image is being actively utilized. Never irradiate the patient unless the primary operator's eyes are on the monitor. The last image hold feature can be used to study many anatomic details without the need for ongoing radiation exposure. The number of acquisition runs should be held to the minimum consistent with accurate diagnosis and effective conduct of a therapeutic procedure.

2. **Use optimal beam collimation.** Collimation, should be used actively to limit the X-ray beam size to the minimum area needed for effective procedure conduct. Fluoroscopy with the collimator leaves wide open delivers unnecessary radiation to both the patient and to clinical personnel.

3. **Position the X-ray source and image receptor optimally.** The X-ray system should be positioned so that the distance from the patient to the image detector is minimized. It is usually clinically desirable to position the patient's heart near the imaging system's isocenter. Given this constraint, the distance between the X-ray tube and patient should be practicably maximized (some designs permit the independent control of this distance, while others do not).

4. **Use the least degree of image magnification required for accurate interpretation.** For X-ray systems that use conventional image intensifiers, the dose generally increases substantially with increasing magnification. Depending on operating parameters, flat-panel detector systems may have a smaller dose increment with magnification. The least degree of image magnification that is consistent with accurate interpretation should be used.

5. **Understand and utilize the X-ray dose-reduction features provided by the X-ray unit.** Employing a sophisticated unit's dose-reduction features can substantially reduce dose. Use the slowest fluoroscopy pulse rate and the lowest fluoroscopy dose rate that will produce satisfactory images. Use high-dose fluoroscopy only when the enhanced image quality it provides is absolutely necessary. Use the slowest acquisition frame rate that is adequate for diagnosis. Employ beam-hardening filters whenever feasible.

6. **Vary the site of the radiation entrance port.** During procedures that require long fluoroscopy times, if clinically feasible, change the radiographic projection so as to minimize the dose to any particular portion of entrance port skin.

7. **Record the estimated dose delivered to the patient.** Current X-ray systems provide calculated estimates of entrance port doses. The dose at the IRP is a measure of deterministic risk. The DAP delivered to a patient during a procedure is both a measure of stochastic risk and a potential quality indicator. Physicians should be made aware of the exposures they deliver to their patients and how they compare to established norms. For older units that do not provide this function, the total fluoroscopy and acquisition times should be recorded. The purchase of accessory dose monitors should also be considered for such equipment.

8. **Maintain X-ray equipment in good repair and calibration.** A qualified medical physicist should periodically check equipment calibration (both radiation levels and image quality factors). Patient input doses for both fluoroscopy and acquisition should be set at the lowest values that are consistent with satisfactory image quality. A qualified medical physicist should periodically verify dose and image quality performance for fluoroscopy and acquisition as part of the laboratory's quality assurance program. These settings will produce images with detectable noise. Operators should recognize that a good image contains a degree of noise and should not request calibrations that produce completely smooth images. Aging image intensifiers have reduced light output for a given X-ray input dose. Thus, an aging image intensifier will automatically require the X-ray system to deliver an increased dose. Such image intensifiers should be replaced.

9. **Select X-ray units with sophisticated dose-reduction and monitoring features.** The International Electrotechnical Commission (IEC) has published a standard (22) defining the minimum necessary safety equipment for interventional fluoroscopes. At the time of this writing, the FDA has proposed adding most of these elements to all newly manufactured fluoroscopic units. Additional radiation and other patient or staff safety components may be available. Their use is encouraged.

IX. RECOMMENDED RADIATION SAFETY CURRICULUM FOR PHYSICIANS WHO PERFORM INVASIVE CARDIAC PROCEDURES

The potential for radiation-induced harm to patients and clinical personnel is substantial. Consequently, to optimize patient and personnel safety, physicians who operate X-ray fluoroscopic equipment must possess a basic knowledge of radiation physics and radiation safety/protection. This Committee makes two operational recommendations:

1. Individual catheterization/electrophysiology laboratories should establish polices for radiation safety and

Table 6. Basic Radiation Physics and Safety Curriculum for Cardiovascular Specialists Who Perform Fluoroscopically Guided Critical Care Unit Procedures

Imaging Physics and Technology
1. X-ray dosimetry concepts
   X-ray production and feedback control
   Image formation
   Fluoroscopic systems
   Image handling
Patient and Staff Radiation Management
2. Radiation risks including pregnancy and heritable concerns
   Patient selection, consents, history, physical examinations, follow-up procedures
   Review of radiation injury cases
   Distance–time–shielding
   Situational awareness
   Pregnant staff
Operational Certification for Each Fluoroscope Used in the Laboratory Approximately 15 Minutes Per System Using the Target System
3. Location and function of key controls
   Available clinical modes and their associated dose rates
   Available radiation-shielding devices
Certification Examination
4. Written certification examination with constructive review of responses

This curriculum is recommended for all cardiovascular medicine specialists. (Each topic is recommended for approximately 1 hour of instruction or study.)

fluoroscopic training by utilizing this publication and other appropriate sources as guides.

2. Institutions that have X-ray fluoroscopic equipment should employ a credentialing process to authorize physicians to operate it. The process should establish required knowledge thresholds that physicians need so as to be authorized to perform fluoroscopically guided procedures. This will assure optimal patient and staff

Table 7a. X-Ray Production and Imaging

Each of the following topics is recommended for 1 hour of presentation or study.
X-Ray Generation and Control
1. Bremmstrahlung and X-ray properties
   X-ray generators, filters, collimators, brightness, and exposure rate controls
X-Ray Dosimetry
2. Radiation dosimetry, units, and measurement
   Image Formation
3. Effects of dose, kVp, geometry, and focal spot size on image contrast, spatial resolution, and noise
Image Acquisition
4. Image intensifier and flat panel receptors
   Pulsed fluoroscopy (pulse duration, intensity, frame rate)
   Serial imaging
Image Processing and Management
5. Basic aspects of the digital image (matrix size, bit depth)
   Digital image processing (subtraction, recursion)
   DICOM and PACS
Imaging Laboratory—Demonstrations in the Cardiovascular Laboratory
6. Radiation-measuring instruments
   Effects of changing physical parameters on image quality
   Basic quality assurance testing

Advanced radiation physics and safety curriculum for individuals training to perform fluoroscopically guided angiographic, interventional, and electrophysiologic cardiovascular procedures (approximately 12 hours of instruction or study).

Table 7b. Radiation Biology, Safety, and Protection

Radiation Effects
7. Stochastic risk (including sensitivity factors)
   Deterministic injury: skin, hair, eye, etc.
   Pregnancy and heritable concerns
Patient Dose-Management Fundamentals
8. Clinical dose monitoring (dose @ IRP, DAP, IEC cumulative dose)
   Consents, history, physical examinations, follow-up procedures
   Effects of different operating modes on patient dose and image quality
   Geometry factors and patient factors
   Intraprocedural radiation benefit-risk evaluation
   Review of radiation injury cases
Staff Radiation Safety
9. Distance–time–shielding
   Situational awareness
   Badges
   Beam orientation effects
   Pregnant staff
Safety Laboratory—Demonstrations in the Cath Lab
10. Effects of patient size and imaging geometry on patient dose
    Scatter radiation fields—intensity and orientation
    Properties and use of radiation protection accessories
Professional Standards and Regulatory Requirements (1/2 lecture)
11a. Professional standards of practice (e.g., ACC, AHA, HRS, SCAI)
    FDA
    State
    JCAHO
Miscellaneous and Review (1/2 lecture)
11b. Other topics of current or local interest
Final Examination
12. Written certification examination

Advanced radiation physics and safety curriculum for individuals training to perform fluoroscopically guided angiographic, interventional, and electrophysiological cardiovascular procedures.

safety and optimal quality diagnostic/interventional imaging.

Currently, there is already considerable movement toward this goal. The JCAHO had previously published proposed credentialing standards relating to fluoroscopy (23). Although these particular standards do not appear in the current JCAHO manual, they remain excellent guidelines. These include initial didactic training, operational training on individual fluoroscopes, and fluoroscopic continuing medical education. The State of California requires all fluoroscopists to qualify for a state permit.

This document proposes a curriculum that covers the basic knowledge of radiation physics, radiation biology, radiation safety, and radiological imaging that should be held by practitioners who perform X-ray fluoroscopically guided invasive cardiovascular procedures. The curriculum proposed in this document conforms to the JCAHO elements. It specifies topics to be included, but does not specify any minimum number of clock-hours needed to complete the curriculum. Other authorities suggest training times in the range of 2 to 20 clock-hours (23–25).

This curriculum specifies the knowledge that a qualified physician should possess in order to be credentialed to use X-ray fluoroscopic machines. There are two different curricula—basic and advanced. The basic curriculum is out-

lined in Table 6, and the advanced curriculum is outlined in Tables 7a and 7b. The necessary knowledge could be acquired through didactic courses, self-study, or computer-based instruction. Physicians who have completed training should be able to demonstrate that they possess the knowledge specified by the curriculum by passing an appropriate certifying examination.

The necessary knowledge depth varies depending upon the types of fluoroscopically guided procedures a particular physician performs. The basic curriculum is appropriate for physicians who perform fluoroscopically guided critical-care unit procedures such as right heart catheterization, temporary pacemaker placement, and intra-aortic balloon pump placement. This includes understanding the basic elements of X-ray imaging, the biological effects of radiation, and the elements of patient and staff radiation safety. The Committee recommends that the basic curriculum be incorporated into cardiovascular training programs and be presented to all trainees in cardiovascular medicine.

The advanced curriculum is appropriate for physicians who perform angiographic, interventional, and electrophysiologic procedures that employ greater amounts of radiation in more complex circumstances with different purposes and a greater attendant risk of patient and personnel injury. The Committee recommends that the advanced curriculum be incorporated into interventional cardiology and clinical electrophysiology training programs.

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Appendix 1. ACC/AHA/HRS/SCAI Writing Committee to Develop a Clinical Competence Statement on Fluoroscopy: Relationships With Industry

Name	Consultant	Research Grant	Scientific Advisory Board	Speakers' Bureau	Steering Committee	Stock Holder
Dr. John Hirshfeld, Jr.	None	None	None	None	None	None
Dr. Stephen Balter	None	None	None	None	None	None
Dr. Jeffrey A. Brinker	None	None	None	None	None	None
Dr. Morton J. Kern	None	None	None	None	None	None
Dr. Lloyd W. Klein	None	None	None	None	None	None
Dr. Bruce D. Lindsay	None	None	None	None	None	None
Dr. Carl L. Tommaso	None	None	None	None	None	None
Dr. Cynthia M. Tracy	None	None	None	None	None	None
Dr. Louis K. Wagner	Radiation Management, Ltd., Co. (partner)	None	None	None	None	None

This table represents the relationships of committee members with industry that were reported orally at the initial writing committee meeting and updated in conjunction with all meetings and conference calls of the writing committee during the document development process. It does not necessarily reflect relationships with industry at the time of publication.