Minimizing Risks from Fluoroscopic X Rays

Bioeffects, Instrumentation, and Examination

Fourth Edition
6th Printing

A Credentialing Program for Anesthesiologists, Cardiologists, Gastroenterologists, Interventionalists, Orthopedists, Physiatrists, Pulmonologists, Radiologists, Surgeons, and Urologists, and Radiographers

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Table of Contents

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FOOD AND DRUG ADMINISTRATION
IMPORTANT INFORMATION FOR PHYSICIANS
AND OTHER HEALTH CARE PROFESSIONALS

September 9, 1994

AVOIDANCE OF SERIOUS X-RAY-INDUCED SKIN INJURIES TO PATIENTS DURING FLUOROSCOPICALLY-GUIDED PROCEDURES

WARNING - FDA has reports of occasional but at times severe radiation-induced burns to patients from fluoroscopically guided, invasive procedures. This communication describes the nature of these injuries and provides recommendations for avoiding them.

(SELECTED SECTION FROM REPORT - COMPLETE REPORT AT www.fda.gov/cdrh)

GENERAL PRINCIPLES AND RECOMMENDATIONS FOR FACILITIES IN WHICH INVASIVE PROCEDURES ARE PERFORMED

1. Establish standard operating procedures and clinical protocols for each specific type of procedure performed. The protocols should address all aspects of the procedure such as patient selection, normal conduct of the procedure, actions in response to complications and consideration of limits on fluoroscopy exposure time.
   - · Include all fluoroscopic system modes of operation used, including image recording.
   - · Strive for clinically adequate images with minimum fluoroscopic exposure.
   - · **Assure appropriate credentials and training for physicians performing fluoroscopy.** (Bold added)
   - · Minimize exposure duration.
   - · Collimate the radiation beam.
   - · Communicate and enforce protocols.

2. Know the radiation dose rates for the specific fluoroscopic system and for each mode of operation used during the clinical protocol.
   - · **All operators of the system must be trained and understand system operation, including the implications for radiation exposure from each mode of operation**. (Bold added.)
   - · Have a quality assurance program for the x-ray system supervised by a qualified medical physicist.
   - · Calibrate and document radiation output.
   - · Record information permitting estimation of the absorbed dose to skin in the patient's medical record.

3. Assess the impact of each procedure's protocol on the potential for radiation injury to the patient.
   - · **Facilities should ensure that physicians performing fluoroscopic procedures have education** so they may, on a case-by-case basis, assess risks and benefits for individual patients, considering variables such as age, beam location and direction, tissues in the beam and previous fluoroscopic procedures or radiation therapy. (Bold added.)
   - · Counsel patients regarding the symptoms and risks of large radiation exposures and address risks from radiation in the consent form.
   - · Justify and limit the use of high dose rate modes of operation.

WARNING!

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by
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Date of activation: 14 February 2011

TEN COMMANDMENTS FOR MINIMIZING RISKS FROM FLUOROSCOPIC X RAYS

#1: Remember, dose rates are greater and dose accumulates more rapidly as patient size and as tissue penetration thickness increases.

#2: Set the dose and dose rate controls for the best compromise in image quality and in radiation dose accumulation.

#3: Keep the beam-on time and the dose accumulation in a single area of the skin to the lowest level commensurate with the benefits of the procedure —The Golden Rule!

#4: Keep the patient at maximum practicable distance from the x-ray tube.

#5: Keep the image receptor as close to the patient as practicable.

#6: Don't overuse geometric or electronic magnification.

#7: If image quality is not compromised, remove the grid during procedures on small patients or when the image receptor cannot be placed close to the patient.

#8: Collimate to the area of interest.

#9: Monitor radiation utilization and maintain a quality control program to assure radiation is managed properly.

#10: Commensurate with their duties, be sure personnel have mastered radiation safety and management.

INTRODUCTION

Medical uses of fluoroscopic x-ray radiation have changed enormously since about 1990. Not only has the number of fluoroscopic procedures increased dramatically since then, but new and more sophisticated applications have been developed. In specialties where fluoroscopy was once only sporadically or never used, it is now indispensable. **However, along with these increased utilizations have come many reports of injuries to both practitioners and patients** (1 - 29). **Since 1990, fluoroscopic radiation has also been suspected as the cause of cancers and cataracts in some physicians**. The primary means of ensuring the safe use of fluoroscopy is through early training and education in its prudent application.

A Short History Lesson

As early as 1902, medical fluoroscopists warned their peers about the irreversible dangers of fluoroscopy and about the importance of good practice in the prevention of its intractable health effects. In the early decades of the 20th century numerous patients and physicians were severely injured by exposure to fluoroscopic radiation (Figs.1 and 2; refs. 30, 31). Many physicians died of radiation-induced cancer. These medical complications to both user and practitioner prompted the medical community to demand safer equipment and improved methods of protection from the rays. The first international conference on protection from radiation was called by physicians who took the first official actions to standardize safe uses (32). This no doubt played a significant role in prevention of many would-be injuries; but injuries, never the less, still occurred. Prompted by the growing evidence of radiation-induced cancers and severe skin reactions, governmental agencies in the 1960's instituted regulations on the design and use of fluoroscopic equipment in medicine. With better controls on equipment design and heightened awareness on the part of practitioners, the number of adverse events declined. **Unfortunately, this has lured generations of practitioners into the false sense of security that regulations and new technologies have rendered fluoroscopic injuries a thing of the past**. ***In fact, some modern instrumentation and medical advances have actually increased the potential for injury to patients and to personnel.***

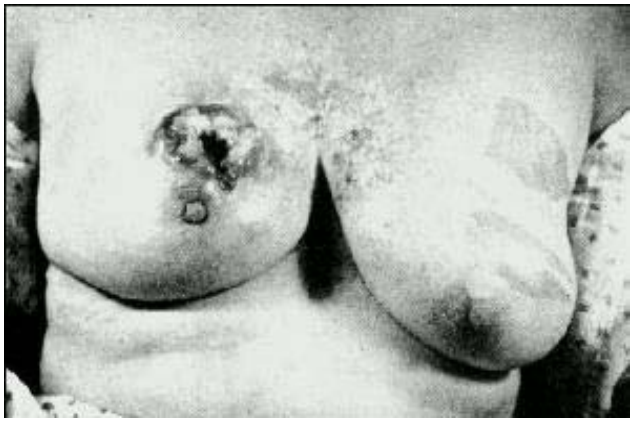

Figure 1. Breast cancer and skin injuries induced by fluoroscopic x rays. (Adapted with permission from reference 30: MacKenzie I. Breast cancer following multiple fluoroscopies. Br J Cancer 1965; 19:1-8)

Since about 1990, hundreds of cases of fluoroscopically-induced dermatitis, including numerous cases of dermal necrosis in patients and physicians have been reported (1-28). The most severe injuries have required skin grafts or myocutaneous flaps. We have personally observed serious radiation injuries in physicians who started using fluoroscopy in their practice around the mid 1990's. Vañó (29) and Haskal (33) have reported on radiation-induced cataracts in physicians and assistants. This increase in injuries is directly related to the burgeoning growth of interventional medical procedures that rely heavily on fluoroscopy for the proper placement of medical devices. Injuries in patients prompted the United States Food and Drug Administration to issue an advisory and warning in 1994 (27) to draw attention to these infre-

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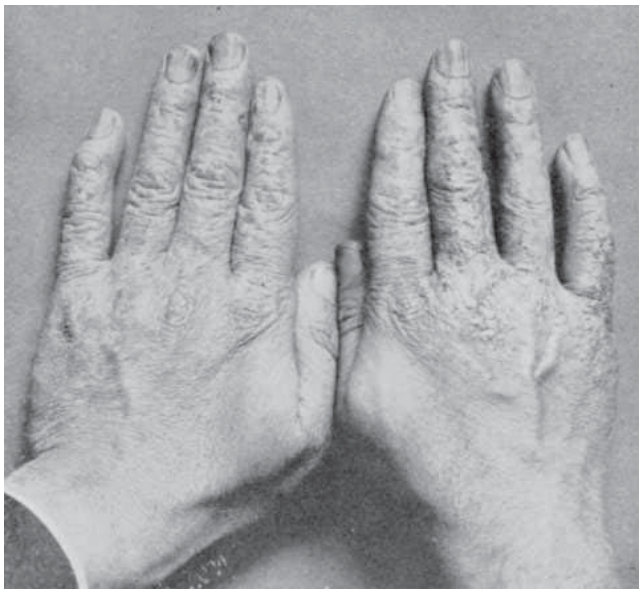

Figure 2a. Hands of Mihran Krikor Kassabian, M.D. after about seven years of direct irradiation from fluoroscopy (age about 33 y). In addition to the chronic radiation dermatitis, the nails are discolored. (From refernce 31: Kassabian MK. Röntgen Rays and Electro-Therapeutics with Chapters on Radium and Phototherapy. Second Edition. Philadelphia: J. B. Lippincott Company, 1910; figure 209A.)

Figure 2b. Deterioration of hands of fluoroscopist in Fig. 2a about six years after image in 2a. Note the brittle, cracking nails and neoplasms. (From: Archives of the American College of Radiology, Reston, VA)

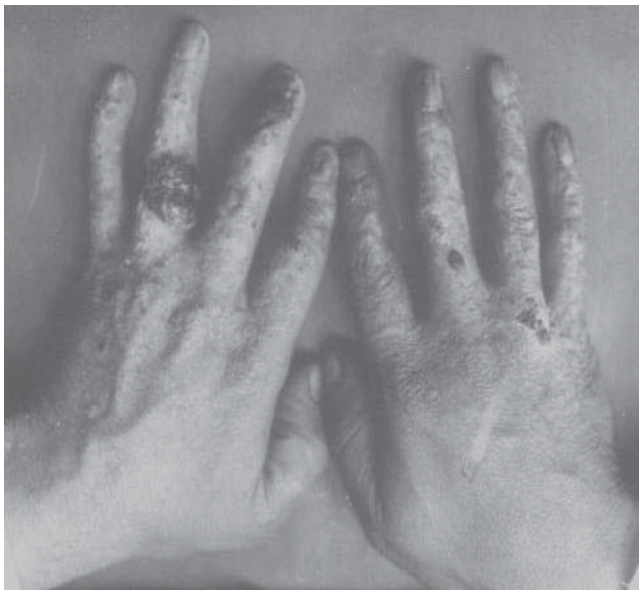

Figure 2c. Further deterioration of hands about one year after condition in Fig. 2b. (From: Archives of the American College of Radiology, Reston, VA)

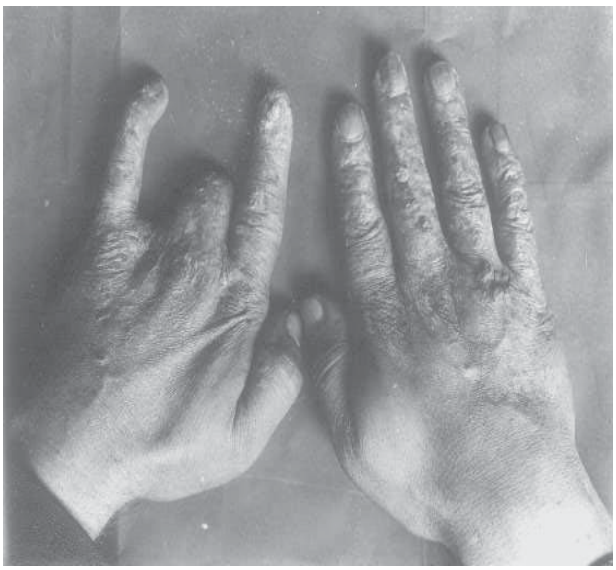

Figure 2d. Amputations and condition of hands five months after picture in Fig. 2c and shortly before death at the age of 40 years. (From: Archives of the American College of Radiology, Reston, VA)

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quent but severe injuries to patients and to make recommendations on steps to be taken to avoid their occurrence. This training course was developed to address, in part, some of their concerns. A brief summary of their advisory is given at the beginning of this monograph.

Responsibilities

X rays are indispensable in medicine and must be applied with a great deal of respect for their potential hazards. Moreover, diagnostic x rays are the principal source of exposure to the general public from man-made ionizing radiations. The responsibilities and the liabilities of the fluoroscopist who uses diagnostic x rays on patients are similar to those involved in dispensing a legally controlled substance. As with drugs, small quantities of x rays can be detrimental to health, but the risk is extremely low. When used in large quantities, the risks are greater and very serious injuries can occur. *For these reasons, only the medical profession is legally permitted to directly and intentionally expose an individual, as a patient, to x rays.* This fact places a serious responsibility on the medical profession to train physicians in the safe, efficient, and economical dispensation of diagnostic-type radiation. This monograph is designed as a concise educational program to help facilities and their physicians meet these goals and to establish a safe working environment for all.

QUALIFIED USERS

The Need for Training

When used under properly controlled conditions, radiation is a safe and indispensable tool in the diagnosis of disease. Radiation applied during fluoroscopically guided interventional techniques is much greater than that needed for simple diagnostic tests of the same organ system, but the increased radiation is well justified by the markedly improved quality of health care. However, it has also been proven that excessive amounts of radiation can be administered by physicians who are not cognizant of how to properly apply radiation (27, 28). Proper application requires training.

This training must involve not only a fundamental knowledge about the proper deployment of radiation for medical purposes, but also knowledge specific to the use of a particular machine, since the configuration of the system control panel and other features usually differ from machine to machine. Most machines have special controls to adjust dose rate and image quality for specific applications. It is essential that users understand the function of and the result of applying each of these controls. An improper choice can result in severe health detriment for patients and practitioners. Since fluoroscopic machines differ markedly in their operation, it is incumbent on the practitioner to understand the nuances associated with various operating modes of a particular fluoroscope. This manual and program deals only with generalities and a complete training program must include a short course on the operation of specific equipment that is not included here.

Before Operating the Fluoroscope

Figure 3 depicts many of the fundamental features of a fluoroscope. Modern fluoroscopes use highly sophisticated technology and are complex machines. Before you operate any medical x-ray equipment, you should know the laws in your state and apply a few common-sense principles to optimize the safe delivery of radiation. As the operator of the equipment you must know:

- How to properly operate the x-ray machine and how to properly use the features specific to that unit (See Table 1),

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- How to properly position the patient and the x-ray system for the procedure,
- How to control image quality (by properly selecting image quality and special dose rate controls, magnification, geometry, use of a grid, collimation, software filters etc.),
- How to minimize radiation levels (by employing the same features as in the previous item),
- How the radiation is distributed in the room,
- How personnel should be positioned for minimum radiation exposure,
- How to properly use shielding devices and personnel-monitoring devices.

Nurses or physician assistants may sometimes be asked, in the presence of a physician, to operate x-ray equipment during procedures. If this is the case in your facility, prudence would dictate that they be trained in its safe and proper operation and in the biological hazards associated with its use. In some localities, regulations may require special training or licensing and prohibit use by untrained personnel. Regardless of who controls the machine, it is the physician who remains responsible for assuring that the x rays are safely and properly applied and that appropriate radiation protection measures are followed.

Table 1. Check-off list for safe operation of fluoroscopic equipment

Which of the following features does your fluoroscopic unit have?

- ☐ Continuous mode fluoroscopy
- ☐ Pulsed mode fluoroscopy
- ☐ Variable pulsed mode fluoroscopy
- ☐ Dose rate (quantum noise) control
- ☐ High-level control
- ☐ Pediatric modes of operation
- ☐ Selectable magnification modes
- ☐ Mechanical filter controls
- ☐ Virtual collimation (permitting collimation control before applying x rays)
- ☐ Virtual table positioning (to permit repositioning of the patient and table without applying x rays)
- ☐ Removeable or retractable grid
- ☐ Variable movement of x-ray tube and/or image intensifier
- ☐ Removeable separator cone
- ☐ Serial imaging modes
- ☐ Stand alone, hanging or other x-ray shields

Do you know

- ☐ How to engage or disengage each option?
- ☐ The advantages or disadvantages of each option for patient dose rate and image quality?
- ☐ The advantages or disadvantages of each option for dose rates to personnel
- ☐ When to employ and when to disengage each option appropriately?

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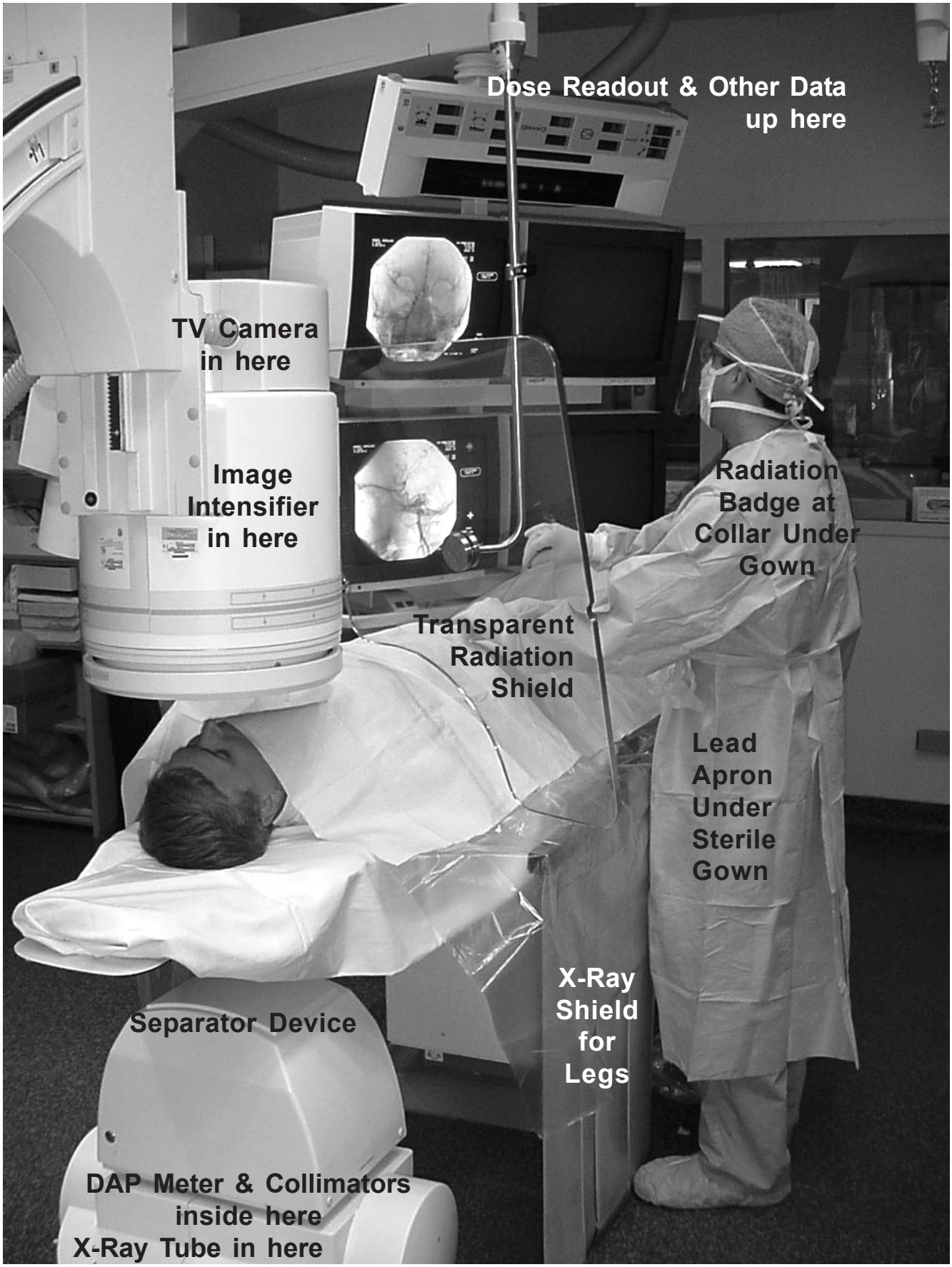

Figure 3. Fundamental Features of the Fluoroscopic Setting

Training on Specific Equipment

For new equipment, an applications specialist from the manufacturer normally provides training. This individual will travel to your facility to instruct staff in the manufacturer's intended operation of the unit. These individuals may or may not be trained in important safety measures or in imaging safety. Larger facilities also employ a medical physicist who evaluates the performance of x-ray equipment. Alternatively, medical physicists act as consultants to smaller facilities. Many medical physicists are board certified and can provide information about equipment, radiation management, safety and biological effects.

PROPERTIES OF X RAYS

X Rays and Light

Ultraviolet light, visible light and **x rays** consist of a multitude of individual particles of radiation called **photons**. Light photons are responsible for human vision. Photon particles are pure energy and have no mass. In open space they all travel in a straight line at the speed of light. All photons are a form of electromagnetic radiation. Ultraviolet light photons, visible light and x rays differ only in the energies of their photons and they have analogous properties:

- Light photons pass through some objects like glass or the cornea and lens of the eye. *X rays are far more energetic and penetrate the body, some passing completely through it.*

- Light interacts with human tissue such as the retina and the skin, effecting vision and a sun tan. *Most x rays interact in the human body and cause changes in molecular structures through ionization.* Some are completely absorbed; others are deflected away from their normal course of travel. Those relatively few x rays that successfully pass through the patient make the radiograph.

- Light that is too intense causes blindness and skin burns. *High exposures to x rays cause cataracts, skin necrosis and other less severe but permanent changes in the skin.* The severity of an effect is related to the amount of energy absorbed by the tissue, i.e., the dose.

- Chronic exposure to ultraviolet light can lead to skin cancer or damage to the eyes. *Any exposure to x rays is thought to have the potential to cause cancer that may develop years later.* Chronic exposure to x rays likewise increases the risk for induced neoplasm and possible malignancy.

- We protect ourselves from intense sunlight by wearing sunscreen or sunglasses. *We protect ourselves from x rays by wearing lead aprons, protective lenses and by using other forms of shielding.*

When x rays interact in a patient, many are scattered in random directions from the exposed volume of the patient. *These scattered x rays are the principal source of radiation exposure to personnel during fluoroscopy.* Since chronic exposure to x rays can lead to increased health risks, ***learning to manage radiation well is an investment in good health—yours, that of your co-workers, and that of your patients!***

RADIATION QUANTITIES AND UNITS

A quantity of x rays can be described in a variety of ways. **The chosen method of quantification depends on what one wishes to communicate about the radiation.** Below, we first introduce the utility of

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each of these concepts. This is followed by an in-depth description of each. Table 2 then summarizes each of these concepts.

1. If the potential health consequences to a specific organ or tissue is the concern, as for example a skin injury, cataract, or a cancer, then **absorbed dose** must be quoted.

2. For comparing carcinogenic or genetically heritable risks for individuals who are exposed to radiation in entirely different ways, as for example a fluoroscopist compared to a nuclear medicine physician**, effective dose** is the appropriate dose descriptor.

3. If the purpose is simply to specify the amount of radiation that exists at a position in space, such as the output of a fluoroscope, then **air kerma** is the quantity of choice*.

4. Equivalent dose is another quantity of interest, but it is not relevant to fluoroscopy. It is relevant only for radiations that have properties markedly different from those of x rays. Since fluoroscopy does not use these other forms of radiation, the concept is functionally irrelevant. Of importance, however, is that this quantity is the quantity quoted in radiation safety reports for exposure to specific body organs and must be recognized by fluoroscopists to ensure proper communication of exposures to personnel.

5. Kerma-area-product (also called Dose-area-product) is quite simply the mathematical product of the area of an x-ray beam and the dose to air in that area (dose to air for fluoroscopy is the same as the air kerma). This term is useful for assessing the total radiation to which a patient is subjected in a procedure. It is principally related to neoplastic and genetic risks. Most modern fluoroscopes measure and report the kerma-area-product for each procedure. It is not directly related to injuries like skin erythema or cataract, but with some manipulation, may assist in assessing that risk.

Absorbed Dose

X rays ionize human tissues and deposit energy. This is the first step in a series of events that may lead to a biological effect. *The concentration of energy deposited locally in tissue is called the* ***absorbed dose*** and provides an important measure of the potential for biological effects. The term "absorbed dose" is often truncated to just "**dose**". Whenever the term "dose" is used without additional modifiers, the concept of "absorbed dose" is to be understood. *Absorbed dose is measured in units of* ***gray (Gy_t) or milligray (mGy_t)***, where we use the subscript "t" to specify the dose as being in tissue. (This distinguishes the unit of dose from that of air kerma as discussed later. This nomenclature is not standard and is provided here as a convenience.) One gray of absorbed dose in tissue is equivalent to an energy deposition of 1 joule in 1 kilogram of tissue mass. A typical fluoroscopic examination of the lower GI tract results in an **entrance skin dose** of about 100 mGy_t (0.1 Gy_t). The dose required to produce desquamation is more than 10,000 mGy_t (10 Gy_t). [Note: **entrance skin dose** is the dose located at the surface where the x rays enter the patient. Dose inside the patient is less and decreases by about a factor of 2 for each additional 4 cm of depth.

*At fluoroscopic x-ray energies, a quantity that is directly related to air kerma is "exposure". As a formal quantity, "exposure" is defined as the number of ions of one polarity produced per unit mass of air. Since energy must be exchanged from the x rays to the molecules of air to produce ions, air kerma and exposure are effectively measuring the same thing; but their units are entirely different. The standard units of "exposure" are Coulmbs per kilogram of air. In the United States, the Roentgen (R) is often used as a unit of exposure and 1 R is equivalent to 8.76 mGy air kerma. The Roentgen is an outdated non-standard unit of measurement and its use is discouraged.

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The **exit skin dose** for a 25-cm thick abdomen (dose to the skin where the x-ray beam emerges from the patient) is only about 1% that of the entrance dose.]

Absorbed dose rate is the rate at which absorbed dose accumulates. It is typically quoted in units of mGy_t/min or mGy_t/h. A fluoroscope typically produces an entrance dose rate to the patient's skin of about 30 mGy_t/min. The dose rate to unprotected tissues of an attending staff member one meter away would be approximately 0.03 mGy_t/min (1.8 mGy_t/h).

An outdated unit of absorbed dose commonly used in the United States is the **rad**. This unit has been replaced by the standard international unit of gray. *One rad is equivalent to 10 mGy_t.* One Gy_t is equivalent to 100 rad.

Effective Dose

Effective dose *is a quantity devised to account for the fact that exposures to people are not typically spatially uniform.* Effective dose is a dose that would produce the same quantitative risk for cancer or heritable effects as the dose actually delivered to a limited portion of the body. For example, the lead apron blocks most of the exposure to the thorax and abdo-

Table 2. Radiation Quantities and Units

Quantity	Units of measurement	What it is - (Definition)	What it measures	Why it's useful
Absorbed Dose	gray (Gy) or milligray (mGy)	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
Effective Dose	sievert (Sv) or millisievert (mSv)	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.
Air Kerma	gray (Gy) or milligray (mGy)	Kinetic energy released in matter	Measures amount of radiation at a point in space	Assesses the level of hazard at the specified location
Exposure (not used in this text)	millicoulomb·kg^{-1}	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
Equivalent Dose	sievert (Sv) or millisievert (mSv)	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
Dose-Area Product	Gy·cm^2, mGy·cm^2, or other similar unit	Product of air kerma and cross sectional area of x-ray beam	Measures how much radiation is employed for a fluoroscopic examination.	Can be used as a quality control measurement to assure that radiation is maintained within acceptable levels.

Adapted with permission from: Hirshfeld JW, et al. ACCF/AHA/HRS/SCAI clinical competence statement on optimizing patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures: a report of the American College of Cardiology/American Heart Association/American College of Physicians Task Force on Clinical Competence. J Am Coll Cardiol 2004;44:2259–82.

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men of fluoroscopy personnel, but the head, legs and arms are unprotected. *Effective dose is a hypothetical dose that would have to be given to your entire unprotected body to produce the same health risk as the nonuniform dose that you received while wearing the apron.* It is quoted in units of **sievert (Sv)** and **millisievert (mSv)**. Because effective dose is essentially a surrogate whole-body risk descriptor that is associated with a nonuniform exposure to radiation, comparisons of risks to individuals from vastly different radiation conditions becomes easier. For example, if one individual is exposed while wearing a lead apron and another is exposed who wore no lead apron, effective dose permits a comparison of their risks, even though their principally exposed organs were quite different.

For radiation protection purposes, regulatory limits on whole-body exposures to personnel are given in terms of effective dose. Effective doses cannot be measured directly. They are extracted from the data generated from film badges or other types of personal radiation monitors. A typical monthly radiation badge reading for a fluoroscopist who wears the badge at the collar outside the lead apron might be about 0.3 to 3.0 mSv (30 to 300 mrem). As a regulatory convenience, the extracted effective dose is sometimes quoted as 1/3 the collar reading, or about 0.1 to 1.0 mSv for our example (10 to 100 mrem). In reality, the true effective dose is less than this. Your monthly effective dose from naturally existing radiation, such as radon gas, cosmic radiation, and naturally existing radioactivity is about 0.3 mSv.

In the United States, effective dose is often quoted in units of rem. The rem is outdated and has been replaced by the sievert. In our example, 0.3 mSv is 30 mrem.

Air Kerma (free-in-air) and Exposure

The quantities used to measure how much radiation is present at a specific position include ***air kerma*** and ***air kerma rate***. These are always assumed to be "free-in-air" unless otherwise stated. "Free-in-air" means that the measurement is done in air away from any surface that might increase the measurement by reflecting or scattering radiation into the area of interest. As x rays pass through air, some of the x-ray photons collide with and ionize the air. This collision process results in an exchange of energy. *At diagnostic energies, "air kerma" is essentially the energy deposited per mass of air or the absorbed dose to air at the position of interest. Air kerma is measured in units of* ***gray (Gy_a) or milligray (mGy_a)***, where the "a" specifies the dose as being in air. [We note that the quantities of **air kerma** and **absorbed dose in tissue**, although measurably different, have the same units – gray (Gy) or milligray (mGy). To distinguish these two quantities and avoid confusion, we put subscripts on the units to identify them as a unit of air kerma (Gy_a or mGy_a) or as a unit of absorbed dose in tissue (Gy_t or mGy_t). This convention is not commonly used and is introduced as a convenience for our readers.] There is no fixed relationship between free-in-air air kerma and the absorbed dose to tissue when the patient is at the same position. However, for usual fluoroscopic field sizes the relationship may be approximated as follows:

Absorbed dose to skin in mGy_t ~

1.4 x free-in-air air kerma in mGy_a

The quantities of **exposure** and **exposure rate**, although outdated, are often used instead of air kerma and air kerma rate. The unit of exposure used in the United States is **roentgen (R)**. *One R of exposure is equivalent to 8.76 mGy_a of air kerma.* See footnote on the previous page.

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The term "exposure" has two meanings. The first meaning is that of a defined quantity of charge released per unit mass of air as a result of the interaction of the radiation with air. The second is a generic use of the word to mean that an individual was present when radiation was also present, i.e., the person was exposed to radiation. The two should not be confused.

Equivalent Dose

Equivalent dose *is a tissue dose that accounts for the different ionizing properties of forms of radiations that are not of concern to fluoroscopy*. However, for radiation protection purposes, regulatory dose limits to specific body sites, such as hands or lens of the eye, are quoted in units of equivalent dose. The units are **sievert (Sv)** and **millisievert (mSv)**. When used for fluoroscopy and diagnostic radiology, an absorbed dose in mGy_t is the same quantitative value as an equivalent dose in mSv, i.e., 1 mGy_t = 1 mSv.

In the United States, a unit of equivalent dose that is often used is the **rem**. This outdated unit has been replaced with the international standard of sievert. *One rem is equal to 10 mSv. One Sv is the same as 100 rem.*

Kerma-Area (Dose-Area) Product

Kerma-area product (KAP) is more commonly called the **dose-area product** or **DAP**. The "dose" in this case is actually the absorbed dose to air, not to tissue, and can therefore be misleading.

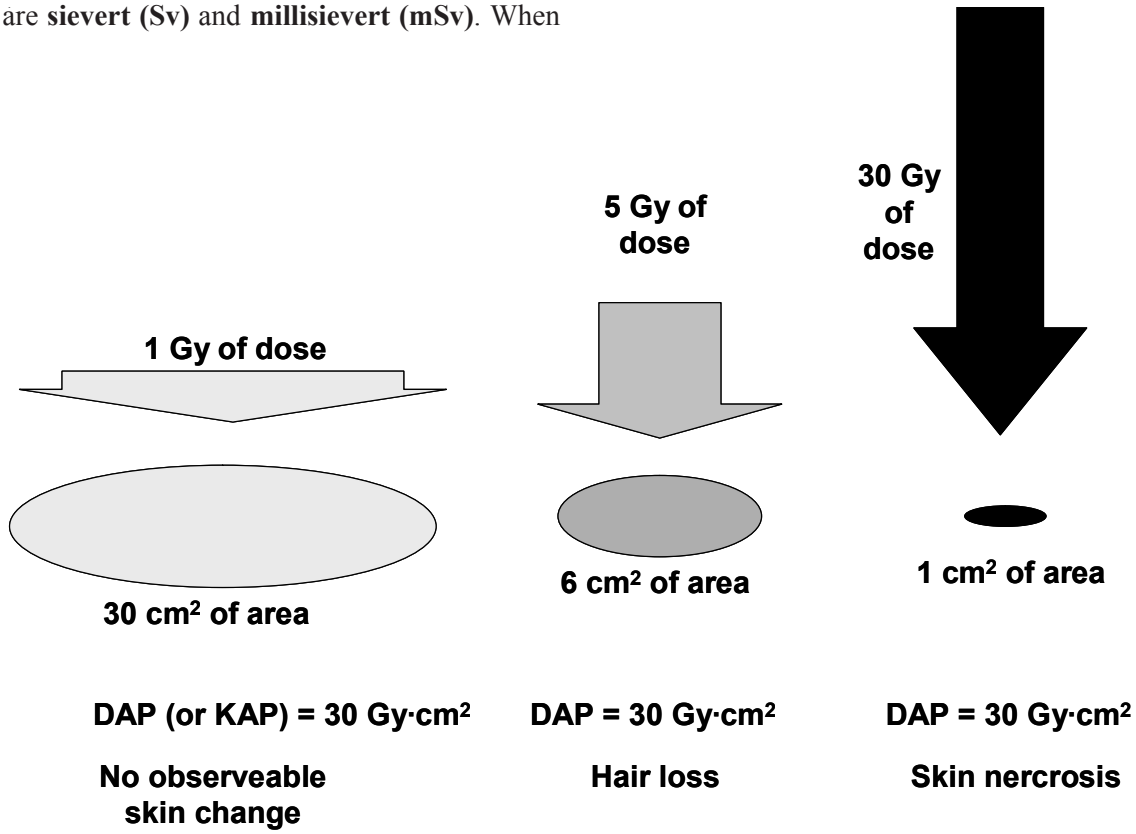

Fig. 4. Three examples of Kerma-Area Product (which is the same thing as Dose-Area Product or DAP). In all three cases the DAP is the same, but the dose is very different. By itself DAP cannot be used to assess risk for injury to skin. DAP is used to assess total radiation delivery, which is related primarily to the potential carcinogenic risk. DAP is useful as a performance improvement tool. (Note, all units of Gy in this diagram reflect the dose to air or the air kerma.)

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The overall carcinogenic risk to a patient depends on the amount of radiation to which they are exposed and the amount of tissue exposed. Recall that air kerma is the quantity that best reflects the amount of radiation at a point in space. It does not tell us how big the radiation field is. Kerma-area product (KAP), on the other hand, depends directly on area since it is obtained by multiplying the dose in air (i.e., the air kerma) times the area of the beam. KAP (or DAP) thus refers to the concentration of energy imparted to a cross sectional area of air. Note that this quantity increases with increasing beam area (field size), even if the air kerma remains unchanged (Fig. 4). DAP reflects carcinogenic risk better than absorbed dose because it includes the size of the exposed area. For the same air dose, narrower beams result in lower DAP and less risk because a smaller amount of tissue is exposed.

DAP may be used to monitor radiation output from radiographic machines, including fluoroscopes. Typically the device used to measure DAP is placed near the x-ray source before the beam enters the patient (Fig. 3). The measurement is usually provided in units of $\mathbf{Gy_a \cdot cm^2}$ or $\mathbf{mGy_a \cdot cm^2}$. To obtain a measure of the risk for injury to the skin where the beam enters the patient, absorbed dose can be derived by dividing the DAP measurement by the area of the beam at the skin. This yields the air kerma at the skin, which can be converted to tissue dose through the equation described on page 19. Using DAP to monitor radiation usage is discussed further under commandment #9.

BIOLOGICAL EFFECTS

Potential biological effects of radiation are classified as either **stochastic** or **deterministic**. Stochastic effects include neoplasm and heritable changes in reproductive cells. Deterministic effects include radiation-induced epilation, erythema, and necrosis. The differences in these two categories result from the fact that changes in a single cell are sufficient to cause stochastic effects but deterministic effects cannot be induced unless there are changes in many cells.

Lesson learned #1: X rays are a carcinogen and any dose of x rays has the potential to cause cancer. Fluoroscopists must diligently exercise sound radiation management to minimize risk to patients and to personnel.

Ionizing radiation can induce a change in the genetic material of a single cell that might initiate development of a neoplasm, a stochastic event. Theoretically, this could occur at any dose level. However, at low doses the likelihood of inducing those precise changes necessary to cause the effect is very small. This probability increases with increasing dose because more interactions occur and thus the likelihood of inducing the necessary changes in one cell increases. *Thus, for stochastic effects, the effect might be produced at any dose and the probability of inducing the effect increases with increasing dose. The severity of the effect is independent of dose.*

For deterministic effects, changes must occur in many cells before the effect, such as erythema, manifests itself. For these events to occur, a certain dose level must be reached. This is known as the threshold dose since the effect cannot be induced at lesser doses. As dose increases above the threshold the likelihood and the potential severity of the effect increases. *Thus, for deterministic effects, a threshold dose exists and the likelihood of the effect occurring, as well as its severity, increases as dose increases beyond the threshold.*

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Radiation-Induced Cancer

Interactions of x rays in tissues cause ionization and a subsequent breakdown of biomolecules. The biomolecular components may chemically interact with other biomolecular material, causing further changes. Following low-dose exposure to x rays, these events are likely to be inconsequential to the tissue due to repair mechanisms that nullify induced changes. However, it is always possible that permanent changes in the genetic material of one cell may be induced. These changes could be passed on to future generations of cells. The possibility exists that specific changes in the genes may initiate carcinogenesis. The **latent period** between irradiation and diagnosis may be as short as two years or as long as many decades. *It is hypothetically possible that any dose of radiation, no matter how small, could induce cancer.* Because the frequency of such an occurrence would be very low, it is not possible to test this hypothesis. However, doses in excess of 200 mGy_t have been shown to induce cancers with the likelihood increasing as dose goes up. For an entire-body absorbed dose of 200 mGy_t the risk might be in the range of 0.2% to 1.6%.

Cancers in patients

Figure 1 shows a breast cancer diagnosed in the early 1960's but which was induced in the early 1950's (30) by extensive fluoroscopy. There is always a long delay between exposure and diagnosis and it is not possible to biologically distinguish a radiation-induced cancer from a cancer of other etiology. Therefore, it is very difficult to identify a radiation-induced cancer. This case represents the rare instance wherein the historical circumstances strongly point to previous fluoroscopies as the cause of this cancer. In this case, the patient underwent fluoroscopy of the lung more than 200 times with her breasts facing the x-ray tube. The cumulative absorbed dose to the patient's breast probably exceeded 40 Gy_t. ***Small doses from modern equipment might induce cancers***, but the frequency of induction would be too low to detect. *Because radiation at any level has the potential to cause cancer, fluoroscopy must be used with considerable discretion.*

Cancers in medical workers

Physicians who performed radiography and fluoroscopy in the first half of the 20th century died of cancer at a rate exceeding that of other physicians (34 - 36). With the implementation of sound radiation protection, this excess rate fell in fluoroscopists practicing later in the century. However, some cancers, such as multiple myeloma, were still found to be slightly in excess. Because radiation-induced cancers are a potential risk to any employee exposed occupationally to radiation, the only sensible approach is to learn how to minimize one's risk by minimizing exposure. There are no levels of exposure thought to be completely safe, but sound practices will keep the risks at acceptably low levels.

Radiation-Induced Heritable Effects

It also may be possible that heritable changes in the genome of reproductive cells will affect descendants (37). The likelihood of this occurring in humans is extremely low, and has never been unequivocally demonstrated in any human. In fact, some humans have been rendered temporarily infertile by radiation only to recover and later parent normal children. The daughter of one such person is now a medical doctor.

All estimates of radiation-induced heritable risk in humans are derived from studies in animals. The only way to minimize this potential risk is to minimize the dose to as low as reasonably achievable. (The acronym "ALARA" is used to denote the philosophy of

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"as low as reasonably achievable"). For patients, gonadal shields can be used to minimize dose to reproductive organs when they do not interfere with the intended diagnostic or interventional result. For personnel, use of proper radiation protection equipment, such as protective apparel, shields, and personal radiation monitors, is effective. These are discussed in detail later under commandment #10.

Radiation-Induced Injuries

If the dose from x rays is very high, cell damage is extensive. Repair mechanisms are overloaded. Cell death and tissue breakdown can occur. Figures 2 and 5 - 14 demonstrate this effect for medical radiation. ***X rays of sufficient intensity to cause such effects do not typically cause any sensation during the irradiation. Furthermore, unlike a thermal burn, x-ray injuries typically develop slowly.*** Visual evidence of induced erythema may perhaps become apparent soon after the fluoroscopy **but usually does not occur until days or weeks later**. If the dose exceeds certain levels, tissue degeneration **will develop over many months into ulceration and dermal necrosis**. Some single delivery (non-fractionated) threshold doses for certain effects are given in Table 3. While these thresholds are based on current information, the reader should realize that they apply mostly to people with healthy skin, apply only to doses delivered in a very short period of time, and that there may be a wide variation of sensitivities among individuals. These thresholds should be used as guidelines, not as absolute boundaries.

Table 3. Potential Effects in skin from fluoroscopy. (Adapted from Ref. 38 and revised according to information provided in private communication with J. W. Hopewell, 1999.)

Effect	Single-dose threshold (Gy_t)	Onset
Early transient erythema	2	~2 – 24 h
Main Erythema	6	~10 d
Temporary epilation	3	~3 wk
Permanent epilation	7	~3 wk
Dry desquamation	14	~4 wk
Moist desquamation	18	~4 wk
Secondary ulceration	24	>6 wk
Late erythema	15	8 -10 wk
Ischemic dermal necrosis	18	>10 wk
Dermal atrophy (1st phase)	10	>12 wk
Dermal atrophy (2nd phase)	10	>1 y
Induration (invasive fibrosis)	10	
Telangiectasia	10	>1 y
Dermal necrosis (late phase)	> 12?	>1 y
Skin cancer	None known	>5 y

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Injuries to practitioners

Figures 2a – 2d are a self-portrait series of a physician's hands years after intense exposure to fluoroscopic x rays (31). The physician, Mihran Krikor Kassabian, MD, took these photographs to encourage prevention of such injuries. Dr. Kassabian died of radiation-induced cancer in 1911 at the age of 40. This text is dedicated to his message of prevention.

Figure 5 demonstrates a wound on the finger of a dentist who routinely exposed his hand to x rays while holding the dental films during examinations. The cumulative damage over time resulted in ulceration. *This occurred in the late 1980's and demonstrates how small doses of radiation delivered repeatedly can accumulate to erode the skin.*

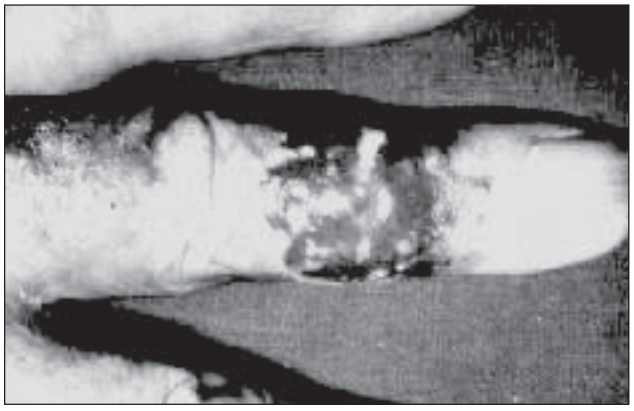

Figure 5. Dentist's finger after chronic exposure to x rays. (Courtesy of J. G. B. Russell)

Lesson learned #2: Fluoroscopists must avoid chronic irradiation of their hands by knowing how to orient the fluoroscope in relation to themselves and to the patient and by avoiding direct irradiation of their hands, except under the rare instance when patient care requires it (commandment #10).

Injuries to hands – true vignette #1

Injuries to hands of fluoroscopists still occur. In 1997, a physician showed his hands to one of the authors. Radiation dermatitis was visible from the knuckles to the fingertips. The skin appeared scaly and discolored with no hair in the affected areas. The fingernails had brown striations. Similarities to Fig. 2a, although not as severe, were striking. The physician frequently put his hands in the direct x-ray beam to place needles and catheters into the spinal canals of patients lying prone on the examination table. Contrary to advice in this monograph, he was instructed that it was appropriate to use the machine with the x-ray tube above the patient. This x-ray beam orientation and his frequent hand exposure led to years of excessive skin dose. Radiation dermatitis was diagnosed about 3.5 years after commencement of his duties.

Injuries in patients

Figures 6 - 14 depict the severe consequences of high dose rates and long exposure times that result in large radiation doses to patients. The notion that radiation injury is not possible today due to improved fluoroscopic equipment is not true. The fluoroscopic injuries illustrated here occurred between the years 1990 and 2004. Although wounds of this severity are rare, doses required to produce them can be readily achieved with modern equipment. There are two very important facts about radiation-induced effects: 1) there is **no sensation of temperature rise** at the time of irradiation to forewarn an exposed individual about the adverse event, and 2) a **long delay** almost always occurs between irradiation and manifestation of the effect. Therefore, unlike heat from fire that alerts an individual about the danger of getting too close, there is

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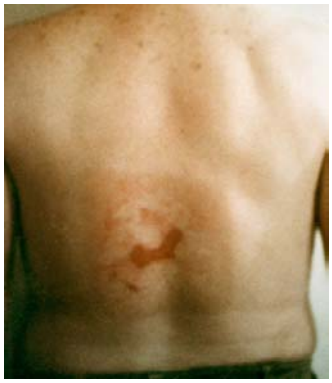

Figure 6a. Erythema several months after angioplasty.

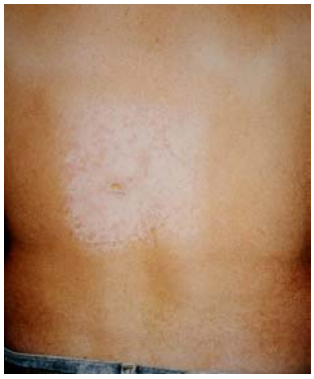

Figure 6b. Healing of injury in Fig. 6a five months after procedure.

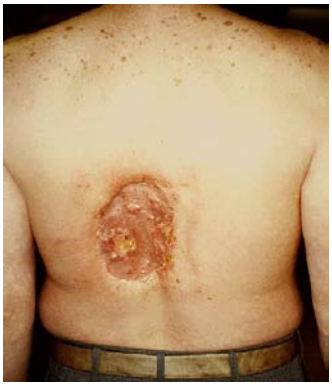

Figure 6c. Wound in patient of Fig. 6a at 22 months after angioplasty.

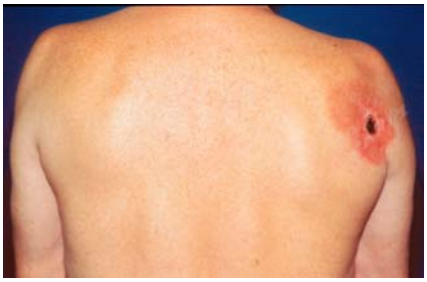

Figure 7. Fluoroscopically-induced ulcer. (Adapted with permission from: Wolff D and Heinrich KW. Strahlenschäden der Haut nach Herzkatheterdiagnostik und –therapie: 2 Kasuistiken. Hautnah derm 5: 450-452, 1993.)

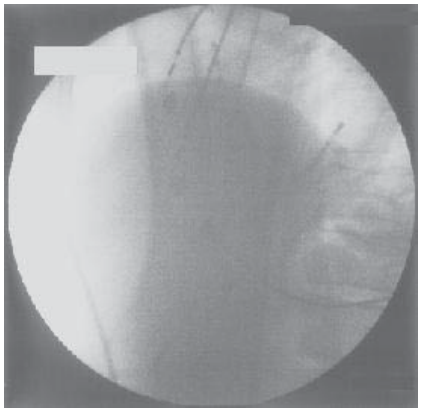

Figure 8a. EP catheter ablation, fluorograph with humerus in the field-of-view.

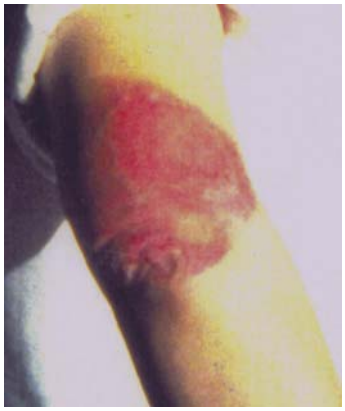

Figure 8b. Erythema about 3 weeks.

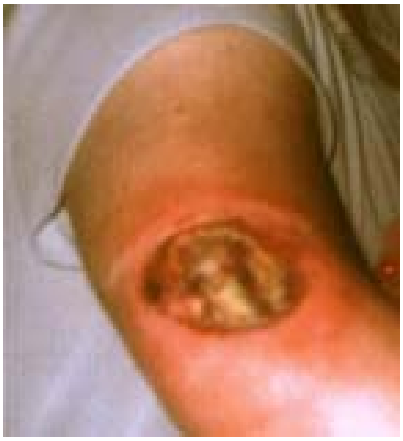

Figure 8c. Ulcer about 5 months after procedure in Fig. 8a.

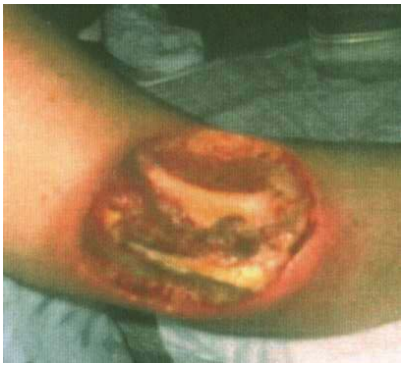

Figure 8d. Extent of injury with humerus visible about 6.5 months after procedure in Fig. 8a.

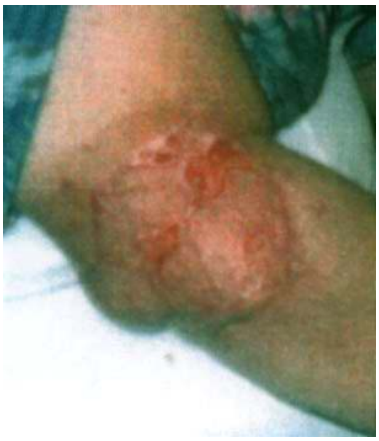

Figure 8e. Surgical flap about 10 months after procedure in Fig. 8a.

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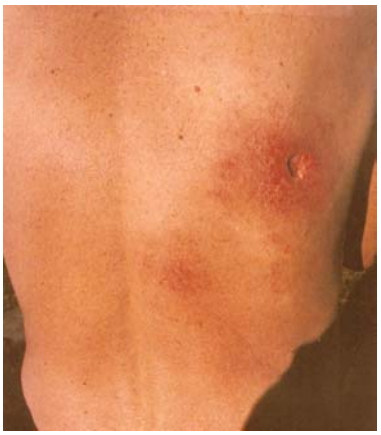

Figure 9a. Two regions of erythema about one year following PTCA procedures with rotational atherectomy and stent placement. Open area of wound probably due to skin biopsy.

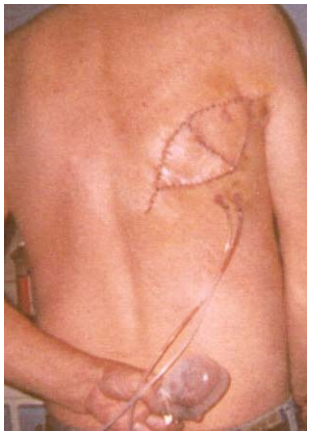

Figure 9b. Graft of wound in Fig. 9a about 2 years after procedures. (Figs. 9a and 9b reproduced with permission from Koenig TR, et al. AJR 2001; 177: 13-20.)

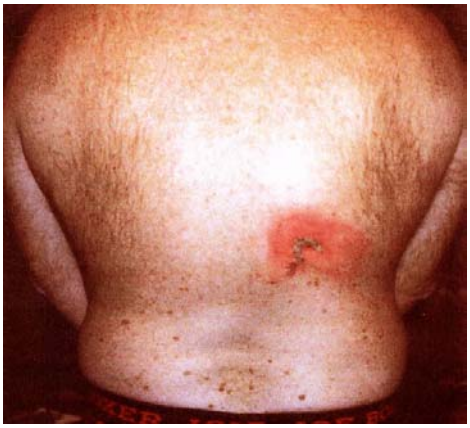

Figure 10. Well-demarcated ulcerating wound in patient following angioplasty of right coronary artery and stent placement. (Reproduced with permission from Wagner L K and Medical Physics Publishing, ref. 23.)

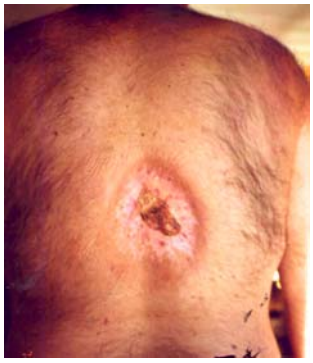

Figure 11a. Patient who underwent three procedures for TIPS placement. Wound six months after procedures.

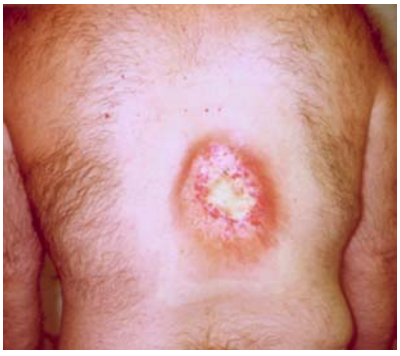

Figure 11b. Wound of patient in 11a at 10 months. (Figs. 11a through 11d reproduced with permission from: Koenig TR, et al. AJR 2001; 177: 3-11.)

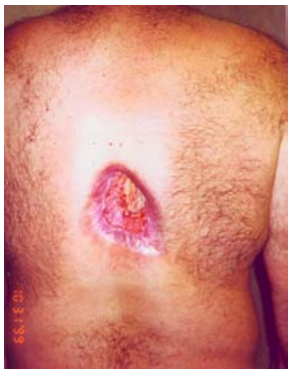

Figure 11c. Wound of patient in 11a at 22 months.

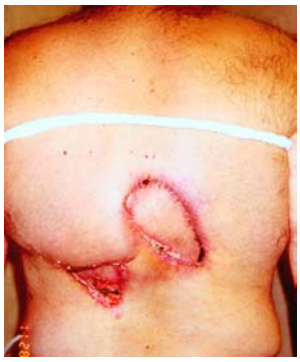

Figure 11d. Patient in 11a at 23 months after musculocutaneous skin graft.

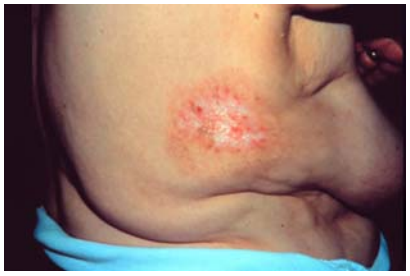

Figure 12. Poikilodermic area subsequent to ulceration in 75-year-old woman, 11 months after PTCA with ~42 minutes of fluoroscopy. (Reproduced with permission from: Wolff D. (1998). Research thesis, private communication. See also Koenig TR, et al. AJR 2001; 177: 3-11.)

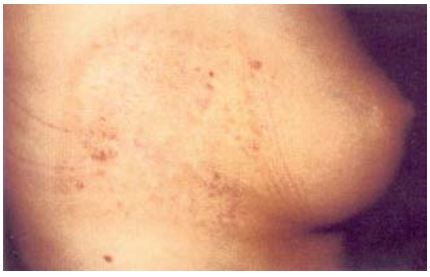

Figure 13. Skin changes on right side of thorax and breast following two attempts at cardiac ablation procedure in 17-year-old patient. Dose ~ 11 – 15 Gy_t. Patient has difficulty raising right arm. (Reproduced with permission from: Vañó E, et. al. BJR 1998; 71, 510-516.)

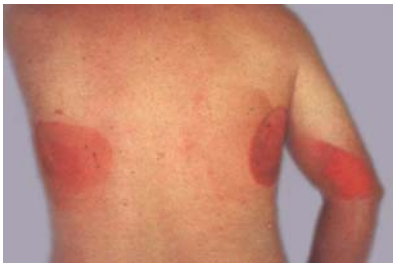

Figure 14. This patient had three bi-plane electrophysiological and ablation procedures within about 4 months with a cumulative total of 372 minutes of fluoroscopy. The lesions on the back healed, leaving a discolored scarred area. The arm required grafting. (Reproduced with permission from Vlietstra RE, et al. J Interven Cardiol 2004; 17: 131-142.)

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no preventative sensation from fluoroscopy that skin damage or a cancer is being induced. *Thus, in the absence of any warning signals, keeping radiation dose below thresholds for injury is the responsibility of the operator*. (In very rare instances, some patients have complained of pain late in a procedure after radiation buildup has occurred. Pain has also been reported in radiation therapy accidents where enormous doses were delivered in a very short time.)

Figure 6 depicts a radiation-induced injury in a patient who had three angioplasty procedures. An erythema appeared promptly after the third angioplasty and was evident after several months (Fig. 6a). In Fig.6b the area of exposure appears to be healed, but there is a notable lack of skin tone due to the destruction of melanocytes. Figure 6c shows the deep necrosis that later developed as a result of radiation damage to the vascular system of the dermis. Figure 7 shows a similarly protracted development of a necrosis in a different patient following cardiac angioplasty (24). Erythema developed after 14 days with progression into ulceration and poor healing. The wound is shown about 12 months after the procedure.

Figures 8a – 8e depict a radiation injury induced in the right arm just above the elbow of a patient who underwent radiofrequency cardiac catheter ablation for arrhythmia. The inferior aspect of the right humerus of the patient is visible in the fluorographic image of 8a. The arm of the patient was positioned in the direct beam very near the port of the x-ray tube. The separator cone was removed (the separator cone is discussed in commandment #4). The skin of the arm was therefore about 20 - 25 cm from the source. In order to penetrate the extra soft tissue and bone the automatic brightness control increased the x-ray intensity to a very high level . These factors produced dose rates at the arm that likely exceeded 0.5 Gy_t per minute (50 rad/min). If the high dose rate mode was engaged, the rates could have been in excess of 1.8 Gy_t per minute (180 rad/min). The total fluoroscopy time was about 20 minutes. The dose to the arm probably exceeded 25 Gy_t (2500 rad). Fig. 8b is a photograph of the erythema that occurred about three weeks after the procedure. Necrosis is evident 5 months later (Fig. 8c). The extent of the injury is demonstrated at 6½ months in Fig. 8d, which shows the exposed humerus. A surgical flap is in place at 10 months (Fig. 8e). The flap remained intact at 18 months after the ablation procedure. No further follow-up is available.

Figure 9 shows the back of a patient who underwent two procedures separated by four months (5), both involving atherectomy and stent placement. The fluoroscope was in a left lateral oblique orientation with the second procedure also employing a cranial tilt. The first procedure involved 172 minutes of fluoroscopy (cine use is not known). The second included 73 minutes of fluoroscopy and over 2000 frames of cine. Two areas of erythema are apparent. The lower area healed without intervention. The upper area necrosed and required grafting, Fig. 9b. The ulcerated area seen in the upper wound of Fig. 9a is probably the result of a skin biopsy that resisted healing due to the radiation injury.

Figure 10 shows an ulcerating skin injury that developed after a coronary angioplasty and stent placement of the right coronary artery. Using a left oblique orientation with cranial tilt of the fluoroscope , the beam entered at the lower right section of the back and projected through to the upper left side of this large-chested gentleman. Fluoroscopy time was 63 minutes with nearly 5000 frames of cine (~2.5 minutes of cine). The machine was routinely tested and found to be in compliance over the period during which this procedure was performed. Note that the borders of the collimator are well demarcated, indicating that the x-ray beam was fixed in this position for most of the procedure. About a month afterwards the individual reported

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pain associated with a reddened area in his lower right back. A full-thickness ulcer developed 3 – 4 months after the procedure and grafting was required.

Fig. 11 is an image of skin injury following two transjugular intrahepatic portosystemic shunt procedures (TIPS) and one attempted TIPS, all within one week of each other (4). The procedure times summed to a total of about 12 hours (the x-ray-on time was much less but unknown). Weeks later the patient developed an irritating rash on his back that progressed over time into a deep necrotic wound (Fig. 11c). Although the patient had sought medical care from several physicians, the diagnosis as to the etiology of this injury was not made until 10 months after the procedure.

Fig. 12 shows a poikilodermic area following ulceration on the right side of a patient about 11 months after PTCA that involved more than 42 minutes of fluoroscopy (24). In a separate female patient, Fig. 13 illustrates a large area of telangiectasia and other skin changes following two attempts at ablation for arrhythmia that resulted in approximately 100 minutes of fluoroscopy on-time (20). Approximately 12 hours after the second attempt, an erythema developed in the right axilla. At one month the area was red and blistering. At two years the area was described as an atrophic indurated plaque, 10- x 5-cm with lineal edges, hyper- and hypopigmentation, and telangiectasia. The patient was described as having difficulty raising her right arm. The absorbed dose in this case was estimated to be perhaps in the range of 11-15 Gy_t. In both cases the radiation dose to the right breast was substantial. The woman in Fig. 13 was 17 years old while the woman in Fig. 12 was 75 years of age. Radiation-induced breast cancer is much more likely to develop in women exposed prior to the age of 20 years.

Figures 14 show three areas of erythema in a patient who had undergone an electrophysiological and ablation procedure for his WPW syndrome. A total of three procedures were performed within about four months. Each procedure involved about two hours of fluoroscopy, roughly one hour for each plane of this biplane procedure. The areas of erythema are shown about 8 days after the third procedure. The lesions on the back cleared over time without surgical intervention. The lesion on the arm did not heal and required grafting. Figure 15 demonstrates this biplane configuration with insets of this and another arm injury from similar circumstances. Note that the x-ray beam on the patient's right side is intercepted by a portion of the patient's arm. Since the arm is closer to the x-ray source than the patient's back, the dose to the skin of the arm is considerably higher than that to the back. This explains in a large part why the arm received the greater injury. The fact that the arm was in the beam also means that an unnecessary amount of extra tissue is in the beam and this causes the x-ray unit to further increase

Lesson learned #3A: Radiation-induced skin injury in a patient is possible and can be severe. It can result from a single long procedure or from doses accumulated over multiple procedures. *Radiation dermatitis is delayed, from weeks to years after the exposure. A conscientious effort should be made to avoid prolonged exposure to the same area of the skin.*

Lesson learned #3B: *No body parts other than those essential for the completion of a procedure should be in the field-of-view during fluoroscopy or fluorography*. Exposure rates to the patient can be extremely high if any part of the patient is in close proximity to the source, especially if the separator cone is removed.

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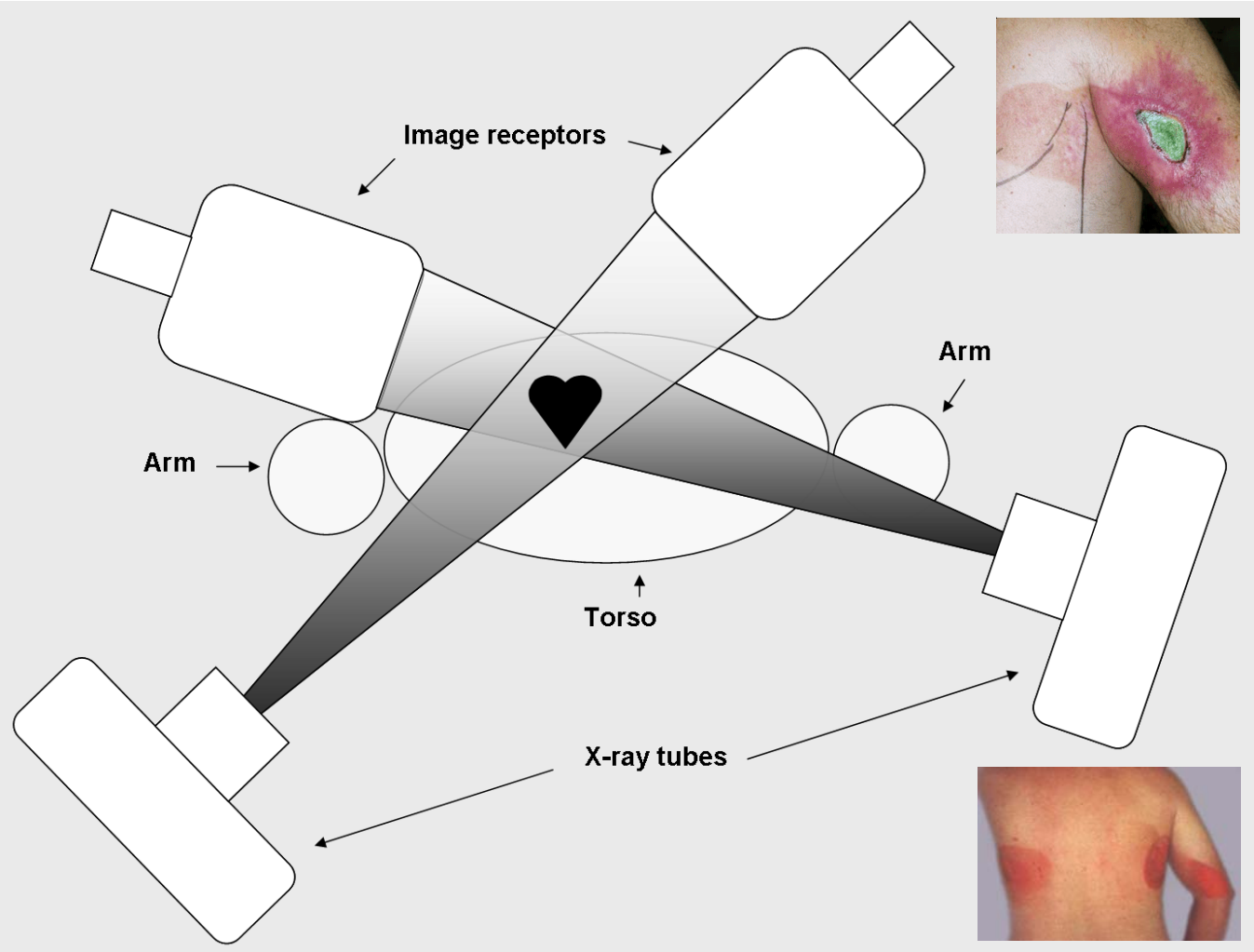

Fig. 15. Two cases of injury to right arm for separate patients undergoing fluoroscopically guided ablation procedures for arrythmias. The diagram depicts a bi-plane fluoroscopic configuration illustrating how arms inadvertently placed in the x-ray beam can be seriously injured. (Image in upper right reproduced with permission from: Wong L, Rehm J. Radiation injury from a fluoroscopic procedure.N Engl J Med. 2004 Jun 17;350(25): e23 (copyright 2004 Massachusettes Medical Society; all rights reserved). Image in the lower right reproduced with permission from: Vlietstra RE, Wagner LK, Koenig T, Mettler F. Radiation burns as a severe complication of fluoroscopically guided cardiological interventions. J Interven Cardiol (Blackwell Publishing) 2004; 17: 131-142.)

radiation output. A diligent effort must be exercised to keep arms comfortable and out of the direct beam during fluoroscopy (Lesson learned 3B).

As these figures indicate, extreme levels of fluoroscopic radiation results in very severe effects that develop over extended periods of time. The injuries cause permanent disfigurements in the patients.

The number of reported injuries to the skin of patients, who have had high-dose fluoroscopy and fluorography, continues to increase (e.g., refs. 1 and 2). At least 200 cases of injuries are known. Only sound radiation management practices will reduce these events. Sound practices include use of equipment appropriately designed for the application, proper management of the patient, proper application of the radiation, and a quality management program that includes dose monitoring and quality control of the equipment.

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Radiation-Induced Cataract

Radiation-induced cataract has recently come under greater scrutiny than previously examined. Historically, radiation-induced lens opacities that are visible under a common slit-lamp microscope occur only after acute doses in excess of about 1 Gy_t. The threshold for low-dose-rate chronic exposure is higher. Obvious vision impairing cataracts are likely to occur at doses in excess of 5 Gy_t. However, with increasing technology that permits the detection of previously unidentifiable cataracts, the presence of lesions in the posterior pole of the lens have been observed in interventionalists thought to be exposed under the previously believed threshold for cataract induction(33). The effects that these subtle changes might have on vision is not well defined, but they are of a concern for individuals whose professions rely critically on excellent vision. So, while a threshold exists for obvious visual impairment, no threshold is known for these subtle effects of unknown significance regarding vision. In adults the time from exposure to development of a cataract is on the order of a year or more. Because doses necessary to cause visually impairing cataracts are high, they need not be a major concern for patients as long as simple precautions are employed (see discussions under commandment #8). However, to keep even extremely subtle changes at a minimum, the principle of ALARA should apply. The same is true for physicians. When not followed, the potential for inducing cataract becomes very real. In 1998, Vañó et. al. (29) reported cataracts induced in physicians and assistants who participated in interventional procedures using equipment with the x-ray tube mounted above the table, contrary to advice in this program. This configuration caused large doses to accumulate over many years to the eyes of the individuals concerned.

FLUOROSCOPY

Fluoroscopy is the production and display of serial x-ray images for the purpose of observing real-time motion of internal anatomic structures. X rays are produced in an x-ray tube and spread out (fan out) from their point of origin. The tube and its housing are designed to allow those x rays that travel toward the patient to escape their enclosure while the others are blocked from leaving the housing (Fig. 16). Those that are permitted to escape the housing form a well defined nearly uniform field of x rays that enters the patient (Fig. 17). As they penetrate through the patient, most of the x rays are absorbed by the patient or they are scattered and relatively few (typically ~1% for an average adult) completely penetrate through the body. As the x rays penetrate deeper into the patient, the field becomes nonuniform, assuming a new distribution that creates the image. Those few that are transmitted through the patient generate the image, which is captured in an image receptor. The image receptor converts the nonuniform x-ray field into a visible image that is typically observed on a video monitor. The image receptor can be a flat panel digital device or an image intensifier (Fig. 18). Image intensifiers are, at the time of this writing, the most common type of image receptor, but the digital panels are expected to increase in use and dominate the market as the technology improves.

When Do X Rays Exist?

X rays are produced by the rapid deceleration of high velocity electrons (Fig. 16). This is achieved in the x-ray tube by accelerating electrons in a vacuum across a very high voltage and then abruptly stopping them in a heavy metal tungsten target. *X rays are present only when the switch that controls the high voltage is engaged by the operator!* This switch is usually a foot pedal, but hand switches are also used.

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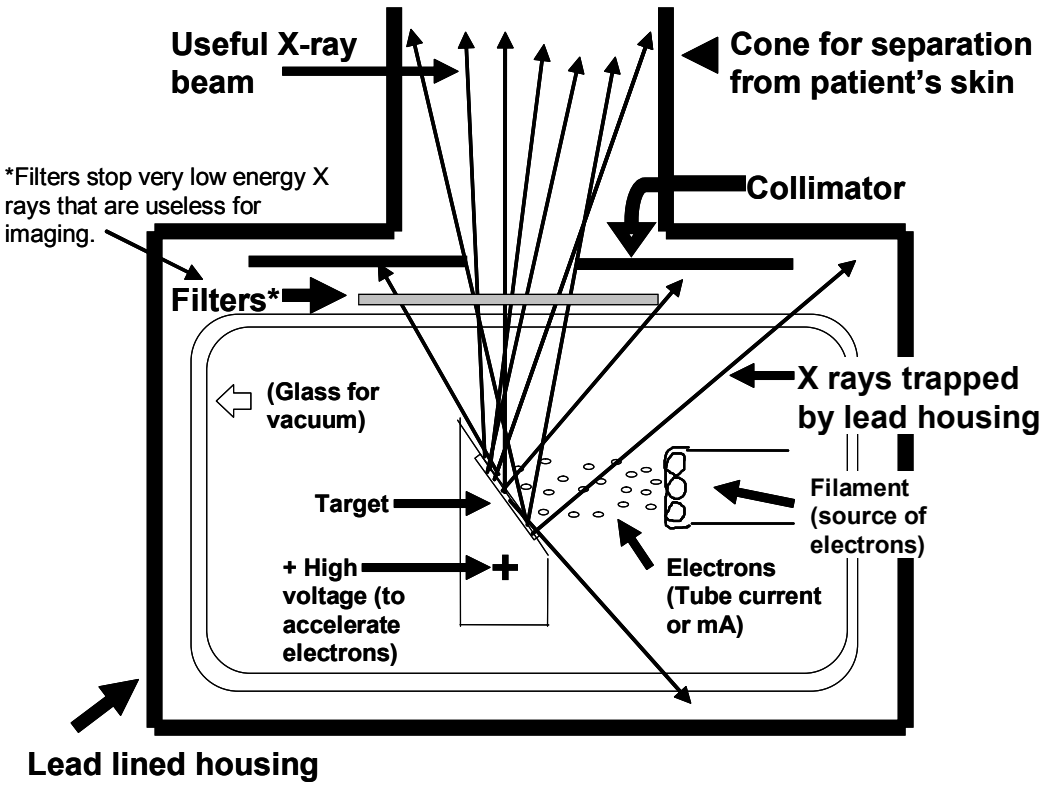

Fig. 16. The x-ray tube and components related to radiation safety and x-ray beam management.

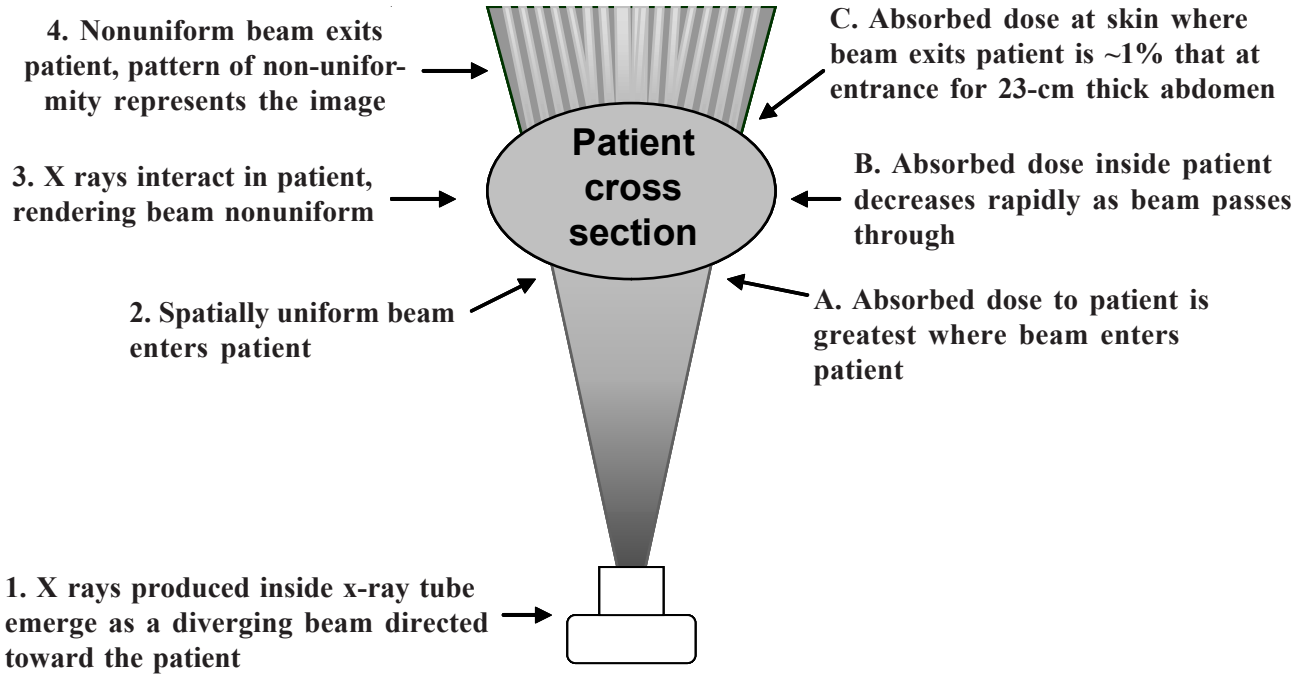

Fig. 17. Radiographic image formation and patient absorbed dose.

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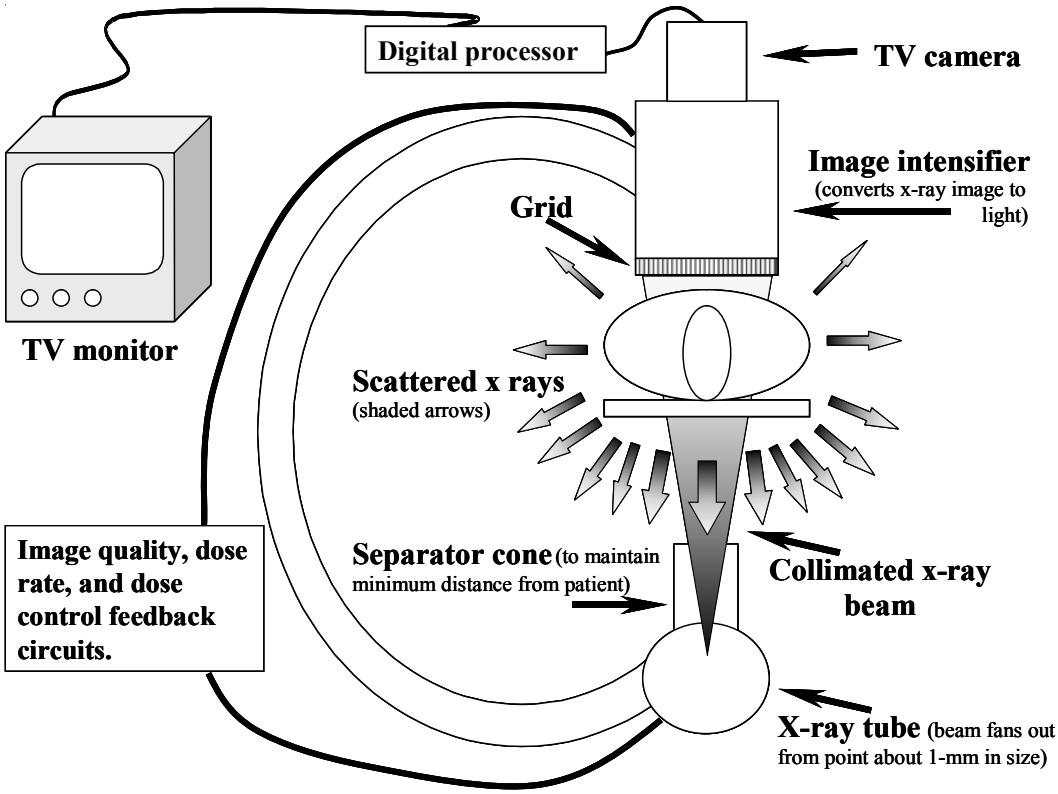

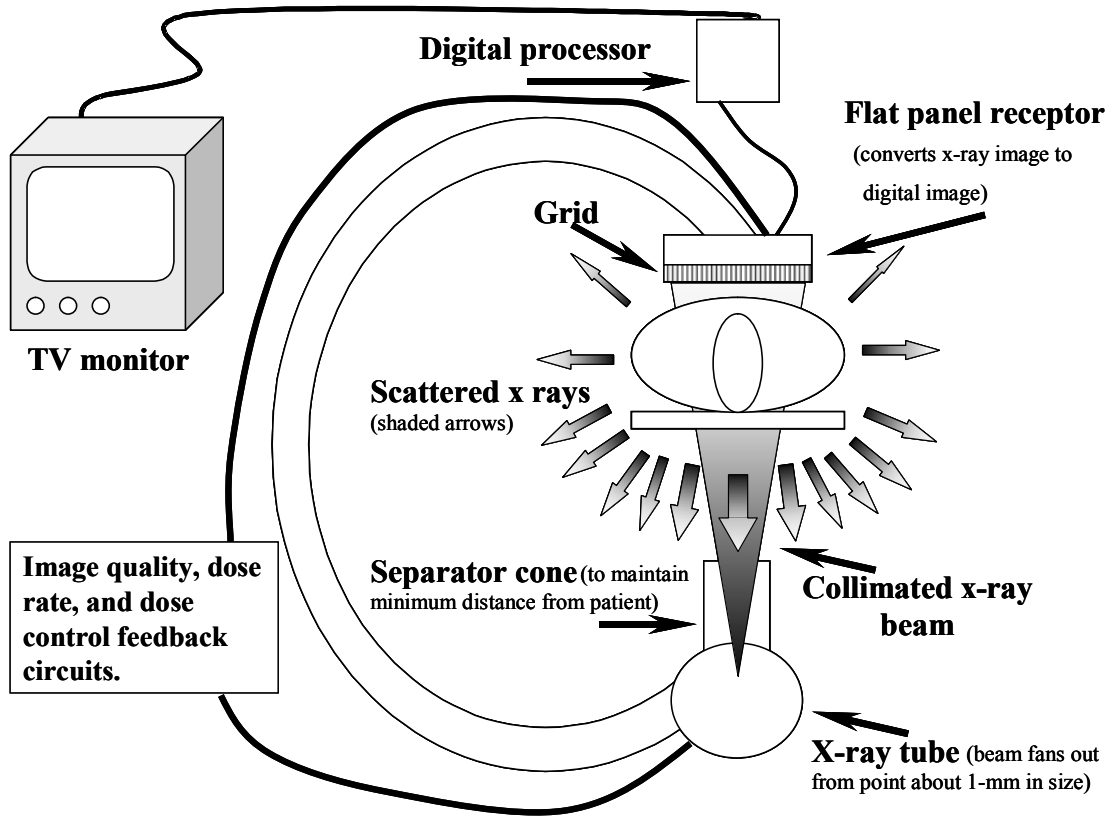

Figures 18. Fluoroscopy can employ an image-intensifier (upper drawing) or a flat-panel direct-digital imaging device (lower drawing). Both systems employ radiation in a similar manner.

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It is required by regulation that the switch be continually pressed in order to maintain x-ray production. Once the switch is released, the x rays are automatically turned off and vanish from the environment. The switch is sometimes called a "dead man" switch because if the operator releases the switch for any reason, even if the operator dies, x-ray production ceases. Circumventing the operation of this switch, as for example by placing an object on it to keep it depressed without human activation, is a violation of regulation and represents a serious disregard for safety. ***The golden rule of radiation management in fluoroscopy is to keep the amount of beam on-time to the least practicable for the procedure. Judicial use of the switch is a most important aspect of sound radiation management.***

About Dose Rates and Dose

X-ray dose rate to the patient is greatest at the skin where the x rays initially enter the patient (Fig 17). *Fluoroscopic dose rates at the skin may vary from less than 10 mGy_t/min up to and exceeding 500 mGy_t/min*. Therefore, a very long examination involving 40 minutes of on-time fluoroscopy could result in a dose of less than 400 mGy_t or more than 20000 mGy_t (20 Gy_t), depending on the operation of the equipment. *While a dose of 400* mGy_t *will produce no apparent effect, 20* Gy_t *can cause severe skin effects that develop slowly and may take months to heal, probably requiring surgery.* Dermal atrophy may develop after several months and become more severe after a year. Dermal necrosis may slowly evolve over many months. It is therefore extremely important that physicians know how to minimize radiation doses to patients in order to avoid short-term (< 2 years) radiation injuries (e.g., burns) and long-term (>2 years) harm (e.g., cancer).

Fluoroscopic Control of Dose Rate

Although discretionary use of the off-on switch is the golden rule, minimizing radiation output while the beam is on is also an important axiom. Understanding how you as an operator of the fluoroscope can control the rate of x-ray production is essential.

Output control: Tube current (mA)

Electron flow in an x-ray tube is expressed in ***milliamperes (mA)*** *and is called the* ***tube current*** (Fig. 16). *The tube current (mA) controls the rate at which x rays are produced without changing other properties of the beam.* (Important point: do not confuse the number of x rays that are **produced** with the number of x rays that are **actually used** in the examination. Many x rays that are produced are undesirable because they only serve to increase dose to the patient without contributing to the imaging process. Eliminating these unwanted x rays from the useful beam is a major component of equipment design and is discussed later.) In general, higher tube currents proportionately increase the x-ray intensity, lower currents reduce it. To illustrate the importance of tube current, the common film-based radiograph is acquired with tube currents in the range of 100 to 800 mA. The duration of the exposure is short, typically on the order of 10 to 500 milliseconds. This results in a very high dose rate to the patient but for only a very brief period of time. *Fluoroscopy, on the other hand, is a long-duration dynamic x-ray imaging process that must be performed at reasonably low x-ray dose rates to prevent the accumulation of excessive radiation dose in the patient.* Controlling tube current is only one of the ways to manage dose rate under fluoroscopy.

In the modern setting, the operator of the fluoroscope does not consciously manipulate the tube current. Rather this is done indirectly by changing fluoro-

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scopic settings that tell the machine to alter tube current (as well as a host of other factors). For purposes of instruction it is essential that the operator understand that tube current manipulation is a primary factor in the control of image quality and radiation output. The following discussions provide examples of how tube current manipulation can affect image quality and radiation output. This is designed to help the reader understand that tube current is just one factor that is used to indirectly control image quality and radiation output.

Conventional fluoroscopy

Originally, fluoroscopic units were very simple devices, composed of an x-ray tube and a fluorescent screen. X rays were engaged continually while the physician viewed a very dim image on the screen. The introduction of image intensifiers brightened the image considerably, but the image was very small. Television was then coupled to the image intensifier to produce a large bright image, but the spatial resolution was degraded by the television system and the dynamics were restricted by television design. This system was used for much of the last century and is called "conventional" fluoroscopy. In this design, the average tube current during this type of operation is simply reduced to very low levels, on the order of a few mA, to maintain low radiation output.

When viewing a motion picture on television or in a movie theater, the perception of continuous motion is created by flashing thirty still-frame images on the screen every second (25 images per second in Europe). In conventional fluoroscopy, each image on the TV monitor represents 1/30th of a second. But because the x rays are continuously produced, each image is actually a smear of the action in the 1/30th of a second interval (Fig. 19A). Due to the pulsating motion of blood vessels and the vibrating motion of a catheter wire, the image of the catheter wire in the vessel during the 1/30th of a second interval can be significantly smeared, or blurred. Conventional fluoroscopic equipment is still in use, but it is rapidly becoming obsolete due to major advances in x-ray tube design and digital imaging techniques that enhance image quality. All or nearly all modern machines no longer employ continuous fluoroscopy as the default method of operation. Instead the "continuous" mode is actually produced as 30 pulses per second.

Pulsed fluoroscopy

Pulsed fluoroscopy enhances image quality by acquiring 30 images per second but each image is acquired with a very short pulse of x rays followed by an interval during which no x rays are produced. For example, if the pulses are only 1/100th of a second long in each 1/30th of a second interval, then the motion blur (or smearing) is much reduced and the image resolution for that frame is enhanced. This is illustrated in Fig. 19B where 30 consecutive stop-action images of a galloping horse are shown during a 1-second interval. If each snapshot image of the galloping horse were flashed in front of us at 30 sequential images per second, we would perceive the motion as continuous and sharp.

To maintain image quality in 30-frame pulse imaging, the same number of x rays as were used in the 1/30th second interval of conventional fluoroscopy must be employed for each image. To compensate for the fact that there are no x rays produced during the interval between pulses, the tube current during the short pulse in our example must be enhanced by a factor of 3.3. The **average** tube current, or average mA, does not change, and so the dose rate to the patient does not change. *The result is improved image resolution with no change in dose rate.*

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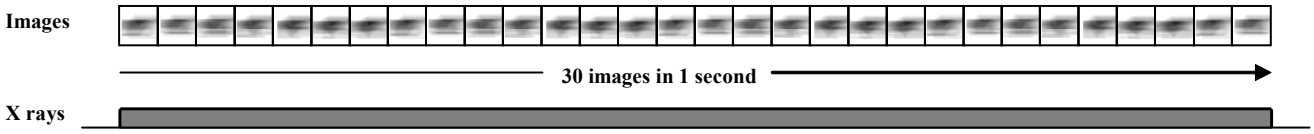
A. Continuous fluoroscopy

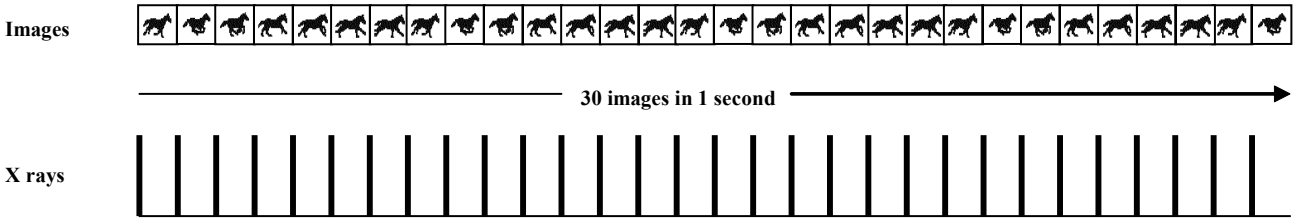
Blurred appearance of motion with continuous x-ray production because exposure time lasts the full 1/30th of a second for each image interval



Continuous stream of x rays produces blurred images in each frame

B. Pulsed fluoroscopy, no dose reduction

Sharp appearance of motion because each of 30 images per second is captured in a pulse (snapshot) of 1/100th of a second; exposure is the same as in A.



Each x-ray pulse shown above has greater intensity than continuous mode, but lasts for only 1/100th of a second; no x rays are emitted between pulses; dose to patient is same as that in A.

Fig. 19. Schematic video display of a horse galloping left to right across a TV monitor. The principles of pulsed fluoroscopy are evident if we imagine that the horse is the opaque tip of a catheter that is threaded through a vessel. In A (upper drawing), the movement appears as a blurred object moving left to right because with continuous fluoroscopy there is no stop-action imaging. In B (lower drawing), a short pulsed fluoroscopic output captures 30 stop-action images per second and the video displays these sharp images in sequence to produce the sensation of motion. The result is the perception of motion with finer detail.

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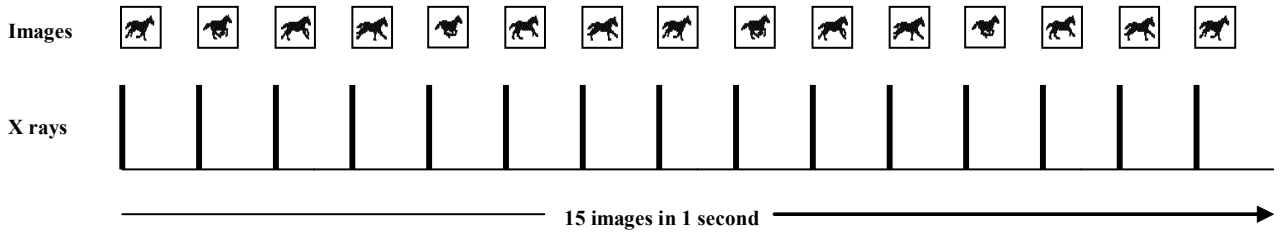
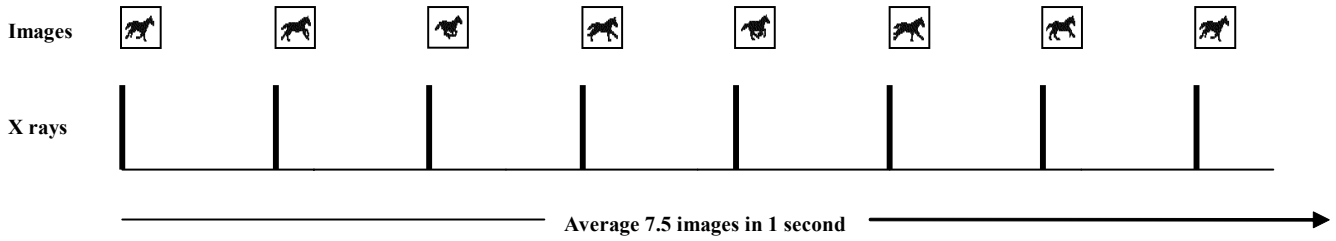
A. Pulsed fluoroscopy, dose reduction at 15 pulses per second

Sharp appearance of motion captured at 15 images per second in pulsed mode. Dose per pulse is same as in Fig. 19B, but only half as many pulses are used, thus dose is reduced by 50%. The tradeoff is a slightly choppy appearance in motion



B. Pulsed fluoroscopy, dose reduction at 7.5 pulses per second

Pulsed fluoroscopy at 7.5 images per second with only 25% the dose of that in Fig. 19A or 19B.



C. Pulsed fluoroscopy, dose reduction at 3.75 pulses per second

Pulsed fluoroscopy at 3.75 images per second with only 12.5% the dose of that in Figs. 19A or 19B.

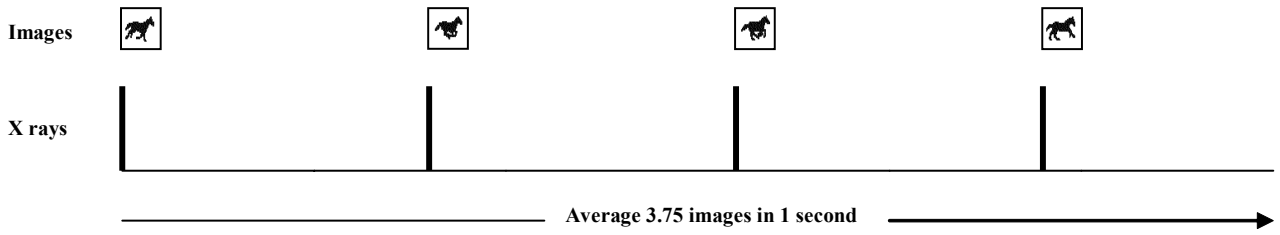


Fig. 20. Dose savings from variable pulsed fluoroscopy. In A, images are captured only 15 times each second. Since only half as many images are acquired as in Fig. 19B, the patient dose is reduced by half! The tradeoff is that the image sequence appears to have a choppy motion. In B, the image rate is again halved. This produces an even choppier image motion, but the dose is again halved. In C, the image rate is even less with parallel effect and even more dose reduction.

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Note: Tube current (mA) for pulsed fluoroscopy no longer has the same meaning as in continuous fluoroscopy because of the pulsed nature of the beam. Tube current is often quoted as the mA during the pulse, not the average mA. Since the length of the pulse can vary, the relationship of pulsed tube current to dose rate is not easily discerned. Pulsed tube currents can therefore be unusually high and produce low dose rates due to a short pulse duration or produce high dose rates due to a long pulse duration. The actual dose rate can only be known if there is a dose rate monitor to measure the output directly.

Output control: Variable pulsed fluoroscopy

Variable pulsed fluoroscopy is a selectable feature that many manufacturers now incorporate into their systems to reduce patient dose or to enhance image quality. In variable pulsed fluoroscopy, the operator can select the number of pulses per second from a range of options. Typical values for equipment manufactured in North America are 7.5, 15, 30, and 60 pulses per second. Normally, dose rates with variable pulsed systems are lower with lower pulse rates. [This, however, is not always the case. See "warning" in next section for details.] A further understanding of these concepts is necessary to appreciate the opportunity for improving image quality and reducing dose during fluoroscopic procedures.

Dose savings from variable pulsed fluoroscopy

Dose savings can be achieved by reducing the number of pulses per second (the "variable" factor). While 30 images per second may be necessary to watch a ballerina move gracefully across the TV monitor, that many images per second is usually unnecessary to watch the advancement of an invasive medical device, as, for example, a catheter along a lumen. Usually about 15 images per second, or less, will capture the motion necessary for medical care (Figs. 20A and 20B). Therefore, *in variable pulsed fluoroscopy only 15 or 7.5 pulses of x-rays per second may be necessary to adequately capture the clinical information. With each pulse a distinct image is flashed on the screen. Low image rates will yield a slightly choppy motion.* Reducing the pulse rate from 30 per second to 15 or 7.5 per second theoretically reduces the dose by a factor of 2 to 4, respectively. In practice, the dose savings are not always the same as the theoretical factor because the pulse intensity or duration may be additionally enhanced to reduce "noise" or "snow" in the image. The dose savings are, however, usually very substantial. Reducing the number of pulses to less than 7.5 per second (Fig. 20C) will further reduce dose rate, but the dynamic motion becomes very choppy. ***The least number of pulses necessary to properly perform the procedure should be used.***

A warning

Different manufacturers implement pulsed fluoroscopy in a variety of ways. While many manufacturers have "pulsed fluoroscopy", not all manufacturers implement it with dose savings or image enhancing methods. In some cases the dose rates may even increase, rather than decrease, because the pulse intensities and durations are adjusted to increase x-ray output. This might be done to reduce image noise, for instance. Prior to using any "pulsed fluoroscopy" system, it is important that the fluoroscopist verify through independent testing how the pulsed modes function. How the equipment manages dose for each pulse mode can and should be verified by a medical physicist.

Last-image hold

Most modern fluoroscopes have digital technology in which the last frame or last few summed frames of the fluoroscopic image can be stored in memory

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and displayed for continual visualization after the beam is turned off (***last-image hold***). This feature can be used to allow the physician time to study the progress of the procedure without using live fluoroscopy. ***Considerable savings in dose to the patient and to personnel can be realized by prudent application of last-image hold.***

Output control: Tube potential (kVp)

The energy of the x rays is controlled by the tube voltage, which is about 500 to 1000 times higher than standard electrical outlet voltage. The energy of x rays plays an essential role in patient dose rate and image quality. The **high voltage** is expressed as **kilovolt peak (kVp)** and usually ranges from about 60 up to about 125 kVp. The kVp affects both the penetration and the intensity of the x rays. *Higher kVp x rays are more penetrating and more intense. Doses to patients would increase at higher kVp except for the fact that fluoroscopic tube currents at higher kVp's can be markedly reduced due to the increased penetrability. When the mA is appropriately reduced, increasing the kVp results in reduced exposure rate to the patient.* But higher kVp's also reduce image contrast. *In general, high kVp and low mA is employed to keep entrance skin dose rate at a minimum, especially in large patients. The trade-off for this reduced dose rate is reduced image quality. Therefore, kVp depends on patient size and is a compromise between image quality and patient dose rate.* The kVp is usually controlled by the fluoroscope, but the operator may have some specific control over kVp (see commandment #2).

Output control: Filtration

Not all x rays are alike. Just as visible white light is composed of a spectrum of different energies of photons that we perceive as different colors, so too fluoroscopic x rays have a wide spectrum of energies. *The very low energies are detrimental to the patient because they contribute only to patient dose with no imaging value.* Filtration hardware removes most of the very low energy x rays from the beam before they exit the x-ray tube housing. **Filtration** of an x-ray beam refers to the metal foils or plates that cover the exit port of the x-ray tube (Fig. 16). Typical filtration is 3 mm of aluminum but most modern units also employ copper or other types of metal filtration (e.g., 0.2 mm copper or more). On many modern units, different filters are available so that the imaging process and the dose rate control can be tailored to the type of patient and the type of study or task. Copper filtration removes dose-enhancing low-energy x rays more effectively than aluminum filtration. To maintain optimal contrast, these special heavily filtered fluoroscopes may also operate at lower tube potentials than might otherwise be used (e.g., less than 70 kVp). The result is reduced x-ray exposure to the patient with no loss in image contrast.

The one drawback of using copper or other metal filters is that they also reduce the intensity of the desired x rays. This means that higher tube currents must be employed to produce an intensity that will penetrate the filters adequately to result in a useful beam. Average currents of 10 to 30 mA are frequently employed for this type of filtration scheme. Specially engineered x-ray tubes are built to sustain such currents for fluoroscopy. These types of currents would be unusual if only 3-mm aluminum filters were used. Differences in filtration among machines are examples of major individual differences that can exist among fluoroscopes. With some fluoroscopes, the operator can control the set of filters used for a particular examination. This monograph discusses the general principles and trade-offs of various filtration schemes, but the specifics on how a particular machine should be operated must be learned for each machine. *Therefore, physicians must know if their equipment has selectable filtration, know how it is activated, and know when it is en-*

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gaged. Not understanding these features might lead to persistent application of excess radiation.

Automatic Dose Rate Controls

The image receptor converts x rays into an electronic image that can be displayed on a video monitor. The quality and brightness of the image depend on the quality of the receptor and on the quality of the unprocessed x-ray image that is presented to the receptor. To maintain proper image quality, the operator can control several features, such as real-time software image processing and the field-of-view (magnification mode). But many image quality operations are controlled in real-time by the fluoroscopy system. These operations are passive to the operator but markedly affect radiation use. For example, for any modern system with **automatic brightness control (ABC)**, the brightness of the x-ray image is adjusted in real-time by the machine. The machine does this by measuring the brightness of the image and adjusting some factors up or down in real-time to keep that brightness at a predefined level. The feedback circuit to achieve this is illustrated in Fig. 18. Adjustment of the kVp and mA are two of the parameters most frequently managed automatically by the machine as part of this brightness control. *Adjustments of the kVp and the mA of the x-ray tube affect the contrast and brightness of an image*[1] *as well as the dose rate to the patient. The* system that automatically adjusts kVp and mA is called the **automatic dose-rate control (ADRC)** and is part of the **automatic brightness control (ABC)**.

The brightness of the image depends on the unprocessed x-ray image that is presented to the receptor. This, in turn, depends on how much tissue the x rays had to penetrate to reach the receptor. The amount of tissue traversed depends on the anatomical area being imaged, the size of the patient and the orientation of the beam. The machine adjusts kVp and mA automatically to produce a sufficiently penetrating beam that will result in adequate image quality and brightness. Therefore, dose rate to the patient depends markedly on patient size, beam orientation and beam position. The automatic adjustments of the kVp and mA by the machine frequently go unnoticed by the physician.

In addition to image brightness, the ADRC may also respond to other changes in the system, such as a change in **source-to-image-receptor distance (SID)** if the machine has this capability. The ABC might adjust other factors to accommodate the changes in dose rate and image brightness. For example, for image intesified systems TV gain or the f-stop of the optics might be adjusted. ***For your purposes it is important that you know how use of the machine affects dose rate and image quality. The intent is to produce the necessary image quality at the lowest adequate dose rate for the procedure.***

Fluoroscopy Versus Fluorography

The relatively low dose rates used in fluoroscopy produce an image quality that is substantially inferior to that of conventional radiography. However, these low dose rates are necessary to keep cumulated radiation dose to patients at reasonably safe levels. **Fluorography** is the use of the fluoroscopic apparatus to acquire and digitally record a series of higher quality static images. Conventional film imaging, called radiography, may also be used for acquisition, but this method is essentially obsolete. The quality of digital fluorographic images is similar to radiographic images**.**

[1]The contrast and image brightness discussed here are due to changes in how the x rays interact in the patient. They are not related to the contrast and brightness controls on the TV monitor. The controls on the TV monitor only affect the electrical conditions inside the monitor and they must be properly adjusted prior to x-ray application.

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Dose rates from fluorography are typically about 10 to 60 times greater than those from fluoroscopy. Therefore fluorography should be used only for short-duration high-quality imaging.

Fluorographic modes include **digital angiography** (**DA**), **digital subtraction angiography** (**DSA**) and **cineangiocardiography** (**also called cine fluorography or just cine**). The relative contributions regarding radiation dose to the patient from fluoroscopy versus fluorography depend on the application. The range is from almost all fluoroscopy and no fluorography in orthopedic procedures to approximately 30% from fluoroscopy and 70% from fluorography for some complex neuro- and cardiac interventions. *The physician's prudent use of fluorography is a major component of radiation management, especially for the patient. Physicians must not allow the superior-quality images to lure them into the unnecessary application of these elevated-dose-rate techniques*.

For fluoroscopy and fluorography, the following are the principal factors that control image quality, radiation dose rate, and total radiation dose to the patient and to personnel:

1. **The size of the patient**
2. **Equipment dose rate and dose settings**
3. **Beam-on time and dwell time**
4. **Proximity of the x-ray tube to the patient**
5. **Proximity of the image receptor to the patient**
6. **Image magnification**
7. **Grid utilization**
8. **X-ray field collimation**
9. **Dose monitoring**
10. **Personnel mastery of radiation safety**

For each of these ten factors, a key point is summarized later in this text. These key points comprise **ten commandments** for controlling risks. A summary of these discussions can be found in Table 8.

An operator's control panel of a mobile C-arm fluoroscopy unit is shown in Fig. 21. Although other control panels will look quite different from this one, this operator's panel demonstrates some of the fundamental controls for managing radiation output and image quality. Shown are displays/controls for tube current, kVp, image magnification, collimation, beam-on time, variable pulsed fluoroscopy, and dose rate control. Other controls and indicators are also present.

In the *manual mode* of operation, the operator controls everything except item #1, the size of the patient. The kVp and mA are set at the controls indicated in Fig. 21. In the *automatic mode*, the machine assumes control of the tube current (mA) and kilovoltage (kVp). How the machine adjusts the mA and kVp will depend on several factors, including the manufacturer's choice of design and operator selectable criteria. The x-ray tube filtration that is employed may or may not be selectable by the user. Other selectable options may include different dose rate control modes and establishment of the initial kVp (sometimes called the kVp "floor"). The control panel will indicate changes in kVp and mA. *Thus, the operator must understand how to set the operational controls of the fluoroscope in order to maximize image quality and reduce doses to the patient and personnel.*

To help ensure proper function of the ADRC, ABC, collimation, pulsed fluoroscopy, etc., it is essential that the machine be routinely checked by a medical physicist and serviced by qualified personnel.

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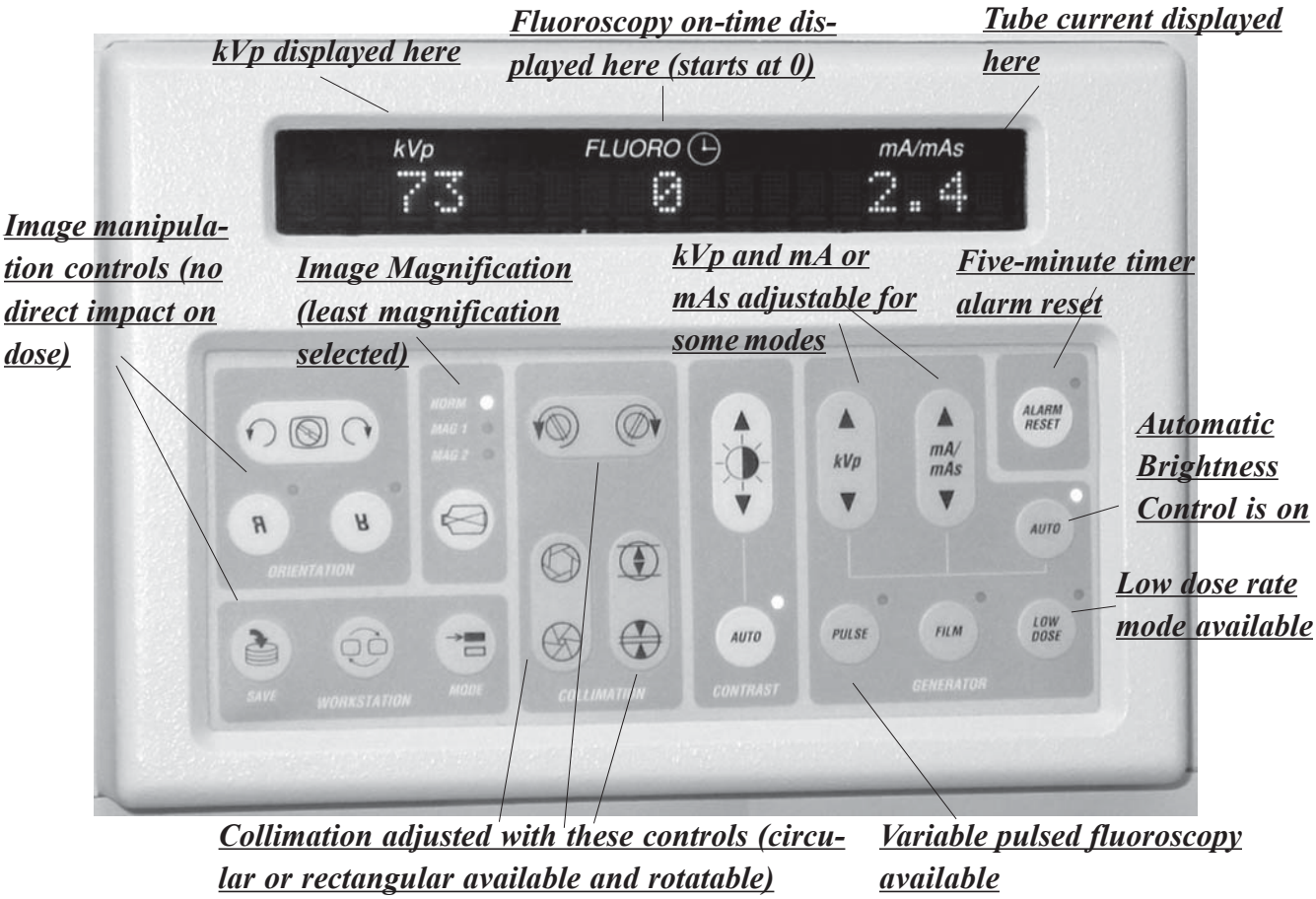

Fig. 21. A control panel.

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TEN COMMANDMENTS FOR CONTROLLING IMAGE QUALITY, DOSE, AND DOSE RATE

Commandment #1: Remember, dose rates are greater and dose accumulates more rapidly as patient size increases and as tissue penetration thickness increases.

#1. The Size of the Patient

Factors affecting dose rate

Fluoroscopic x rays do not readily penetrate thick tissue masses! The dose rate to a large patient can exceed that of a thin patient by a factor of ten or more! For example, less than 1% of radiation that enters a 23-cm thick mediastinum or abdomen actually penetrates through the patient to form the image. For a 28-cm thick anatomy this decreases to less than 0.5%; but for a 15-cm thick patient, about 5% gets through. Therefore, as the fluoroscopic beam is positioned over thicker or denser areas of a patient, the transmission of x rays through the patient decreases markedly. This reduced transmission decreases the brightness and the quality of the image. To maintain a sufficiently bright and clear picture on the monitor it is usually necessary to increase radiation output by adjusting the kVp and mA upwards. Since continually manipulating the kVp and mA would be a distracting and an unnecessary activity for the operator, the machine automatically increases tube current (mA) and kilovoltage (kVp) through the ABC and the ADRC, as discussed previously. Increasing mA increases **only the intensity**, not the penetrability of the x-rays. Thus, increased mA maintains image quality but at the expense of rapidly increased dose rate to the patient. On the other hand, increasing kVp increases both the **penetrability** and the **intensity** of x rays at the skin entrance. Despite the increased intensity with increasing kVp, because the penetrability is also increased the mA can be reduced considerably. Increased kVp combined with appropriately reduced mA results in a net decrease in entrance skin dose rate. The down side is that increased kVp reduces image quality. Nevertheless, increased kVp is necessary to appropriately manage skin dose rate. Thus the machine is designed to automatically adjust kVp and mA to maintain a satisfactory compromise between image quality and skin dose rate for the particular task.

Another very important factor plays a role in increasing skin dose rate to larger patients. Because of their size or due to a steep beam angle, the patient's skin is often closer to the x-ray source. Dose rate rapidly increases as the patient is moved toward the x-ray tube as explained in commandment # 4. Fig 22 illustrates how changing patient size and beam orientation affects entrance skin dose rate. In Fig. A the entrance dose rate to the skin of a thin patient is typically 20 - 40 mGy_t per minute of on-time. When the patient is large and the beam is angled as in Fig. B the radiation output increases to the near maximum allowed by regulation. This dose rate is further increased by the fact

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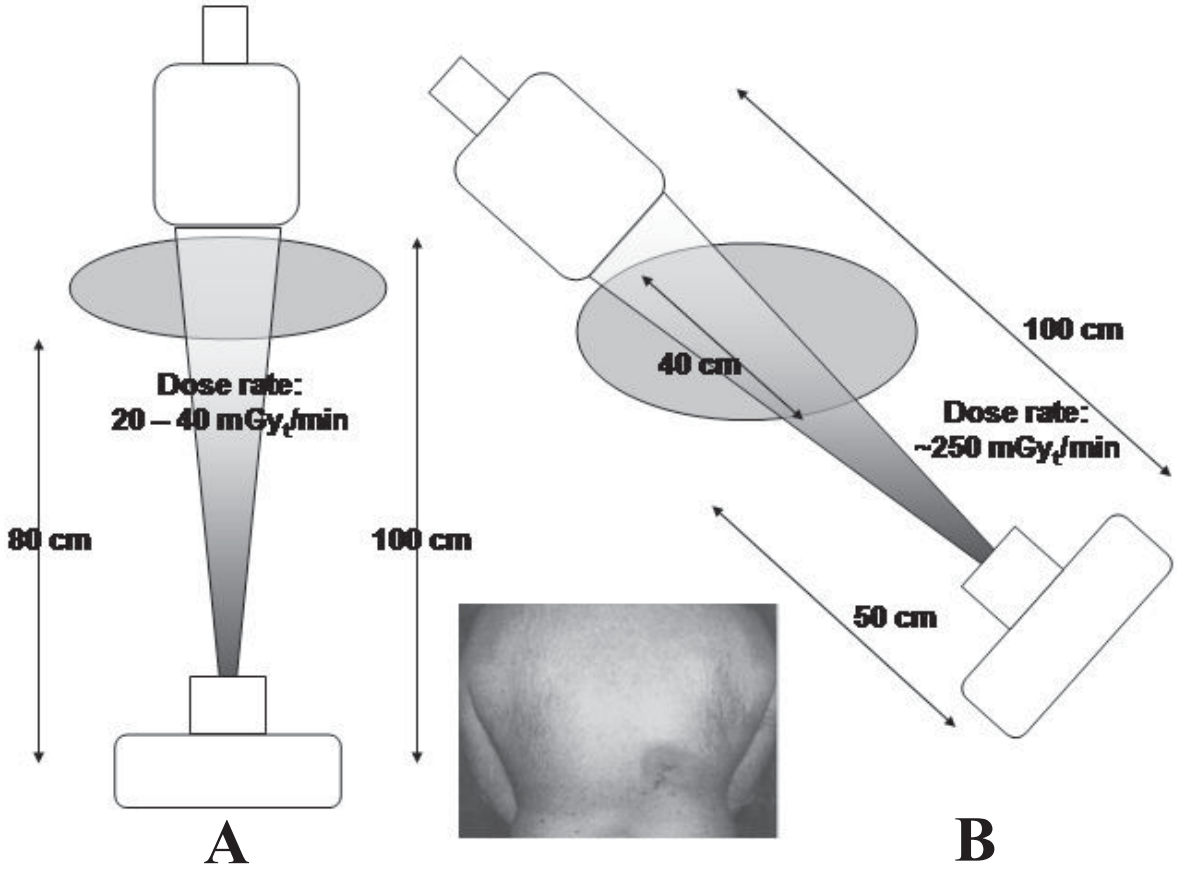

Fig. 22. How patient size and beam orientation affect absorbed dose to the patient. (Reproduced with permission from reference 23.)

that the skin of this large patient is necessarily closer to the source due to size and beam orientation. In the case shown, the entrance dose rate to the skin is nearly 250 mGy$_t$ per minute of on-time, an increase of about a factor of 10! The injury shown in the inset was associated with this type of beam angulation and is discribed in the discussion of Fig. 10. ***Large patients must be managed carefully to avoid an unnecessary accumulation of dose.***

Patient size is one important factor that has lead to radiation-induced skin injuries in patients (1, 3, 5). Figs. 6 - 14 are cases of injuries in patients who underwent fluoroscopy through thick body masses. ***Long exposure times through the same thick section of the patient can result in dangerous cumulated dose levels.*** In some cases, severe injury has occurred in less than 20 minutes of fluoroscopy time. This appears to result from physicians sometimes resort to high-dose-rate modes of machine operation in large patients because image quality in the normal mode is poor. While the machine takes the control for adjusting kVp and mA on a continuing basis, how it makes the adjustments depends on how the operator sets the controls of the unit. These special modes boost the normal output and can result in extremely rapid buildup of dose to the patient. ***Knowing the operation of these types of high-rate modes and understanding the factors that lead to potentially dangerous dose rates is essential to proper patient management.*** Dose management factors that can reduce risks in large patients are discussed in commandments 2 through 9.

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Other than controlling the beam orientation relative to the patient, which controls the thickness of tissue mass that must be penetrated, there are at least two other instances when it is possible to control the amount of tissue that intercepts the direct beam. One is the well-known practice of draining ascites prior to shunt placement in the liver of patients with portal hypertension. The other is a common problem that faces nearly every fluoroscopist — ***keeping arms and other extraneous anatomy out of the beam.*** Arms, and especially their bones, unnecessarily attenuate x rays and increase the apparent thickness of the patient, which causes the automatic dose rate control to drive to higher levels. Several cases of severe injuries to arms have been reported (Figs. 8, 14, 15). In the three cases presented, the right arm was directly in the field; and, in the case of Fig. 8, was apparently resting on the port of the x-ray tube. In the case of Fig.14 the arm was not fully in the beam, but was partially blocking the edge of the field (see Fig. 15), resulting in increased dose rates at the surface of the arm. This latter situation is a more difficult circumstance to control because the arm might not be obvious in the fluoroscopic image. Physicians must ensure that the arms of the patient are not inadvertently placed in the radiation field. Ancillary staff should watch the patient and the image monitor and notify the physician if the arms drift into the field. This rule applies to both arms, regardless of whether they are on the x-ray-tube side or the image-receptor side of the beam.

Another organ that less commonly can be manipulated to be out of the direct beam is the female breast. It is particularly important that direct irradiation of the female breast be avoided, if possible, in order to control the risk for breast cancer in female patients. Radiation-induced breast cancer is a known risk when fluoroscopy doses are high (refs. 30, 39 and Fig. 1).

Because the presence of unnecessary body mass degrades image quality and increases dose rate to the patient, keeping arms and any unnecessary body part out of the beam is an essential aspect of radiation management.

Image quality in large patients

Image quality in large patients is inevitably poorer than that in thin patients. This is due to the increased scatter radiation that degrades the image and reduces perceptibility of detail. Additionally, kVp often must be increased to improve penetrability of the beam at the expense of image quality.

Patient size and dose rates to personnel

Dose rates to personnel increase with larger patients because more radiation of a higher energy is needed to penetrate through the patient and larger patients scatter a larger proportion of these x rays into the room. The presence of unnecessary body parts in the beam also increases scattered radiation. Furthermore, since image quality usually decreases in larger patients, procedures tend to take longer, increasing radiation on-time and dose to personnel.

Concise summary #1: As patient size (mass of irradiated tissue) increases, image quality decreases, patient dose increases, and exposure rates to personnel increase.

Quiz #1: What measures can be taken to reduce radiation dose and dose rate in large patients?

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Commandment #2: Set the dose and dose rate controls for the best compromise between image quality and radiation dose accumulation in the patient.

#2. Establishing Appropriate Dose and Dose-Rate Settings

Settings for fluoroscopy

Fluoroscopy units today are highly sophisticated and versatile machines. All modern units provide for automatic management of certain operating parameters while other features are under the control of the operator. How these features work is different for different models of equipment. An understanding of the versatility designed into a machine's dose management controls is essential if the operator is to appropriately employ them. Properly setting these options is essential to minimizing dose and optimizing image quality. Activation of the fluoroscope without appropriately setting the machine's dose rate management features is likely to result in unnecessary dose to personnel as well as to the patient. If there are questions on how to use these controls, consult with a representative of the company or a medical physicist before proceeding.

There are at least four operational factors for the fluoroscopy mode that must be considered to properly manage radiation dose rates before stepping on the pedal to produce x rays. These are:

1. Fluoroscopic pulse rate
2. Beam filtration
3. Dose rate setting
4. kVp floor

For completeness, two other fluoroscopy settings, manual and recorded fluoroscopy, will be briefly discussed.

Older generation machines have none of the above options while more modern machines usually have several. These features sometimes are not obvious to the operator because manufactures might give special names to the feature that do not reflect the dose rate characteristics or they design the features into a software package that requires some facile computer navigation. For many low dose-rate options, image quality is noticeably poorer. However, a medical task does not necessarily need superior quality. **Physicians should learn to use the image quality that is compatible for efficacious completion of their procedures.** Quality should never be so poor as to unnecessarily prolong a procedure because of the difficulty of visualizing detail; but alternatively quality should not be excessive so as to unnecessarily deliver high doses to the patient and personnel. Physicians must understand the appropriate level of quality needed to strike the proper balance with low dose rate options.

Fluoroscopic pulse rate

Most modern machines have options to adjust pulse rate during fluoroscopy. As previously discussed, lower pulse rates result in a choppier motion but can greatly

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reduce the dose rate to the patient, and collaterally to personnel. Use pulse rates that suit the task at hand. For coarse work involving slowly moving objects, low pulse rates of just a few pulses per second may be satisfactory. For moderate motion, pulse rates of 7.5 per second are likely adequate. For coronary work in adults, pulse rates of 15 frames per second are commonly employed with the 30-pulse-per-second mode reserved for difficult situations. Pulse rates of 60 per second are reserved for cardiac procedures in young children where the rapidly beating heart places severe demands on dynamic resolution. Fortunately, because children are much smaller than adults the dose rates at these pulse rates need not be high.

Use of variable pulse rates can be problematic because manufacturers can manipulate the pulses by increasing the pulsed tube current or the pulse duration. Therefore it is the responsibility of the operator to understand how any particular machine changes dose rate as pulse rate is adjusted. If the machine lowers dose rates in an appropriate manner with lower pulse rates, the savings in radiation use can be very substantial.

Beam filtration

Most modern fluoroscopy units employ some form of heavy beam filtration, well in excess of regulatory requirements, to tailor the x-ray spectrum for improved skin-dose management. Some of these machines provide multiple filter options and automatically control the filter used for a particular task. Other machines require that the operator choose in advance which filter combination or combinations be used. This is usually a simple selection and might be called "level 1", "level 2" and "level 3" dose modes. They might have other names. Regardless of their moniker, the operator should understand these modes and the effects they have on image quality. **Set the system in the mode that provides the lowest dose rate with acceptable image quality.**

Dose rate setting

Many modern units permit the operator to adjust dose rate with different automatic dose rate control settings. Typically, the lowest dose rate setting provides an image that appears "noisy", analogous to trying to observe motion in a rain storm (Fig. 23). Image quality is improved by increasing the dose rate setting, reducing the level of the noise ("rain"). For many procedures, or many portions of a single procedure, these low-dose-rate settings are perfectly adequate and should be employed whenever possible.

Some machines allow the operator to choose from at least two types of dose rate options. For convenience, we describe them as "high-level" options and "non-high-level" options. For a **high level** option, a special means of activation is required and a special audible signal is necessary to indicate high-level engagement. For this mode, dose rates can be enhanced well beyond the standard regulatory levels (the standard regulatory limit is about 90 mGy_a/min at a compliance testing point that roughly simulates patient skin entrance). **Non-high-level** modes can be engaged with the usual foot or hand switch button and no special audible tone is required. Dose rates in this mode must not exceed the standard regulatory limit, but they are slightly higher in the higher dose-rate mode than in the lower dose rate setting.

*Fluoroscopic units with **high-dose-rate** capability (also known as high-dose level, high-dose control, or high-level control options) can be operated with high to extremely high levels of dose rate to the patient.* (This special fluoroscopy mode must not be confused with record modes of operation. For this mode, recording is optional.) The commercial name assigned to this mode of operation varies among

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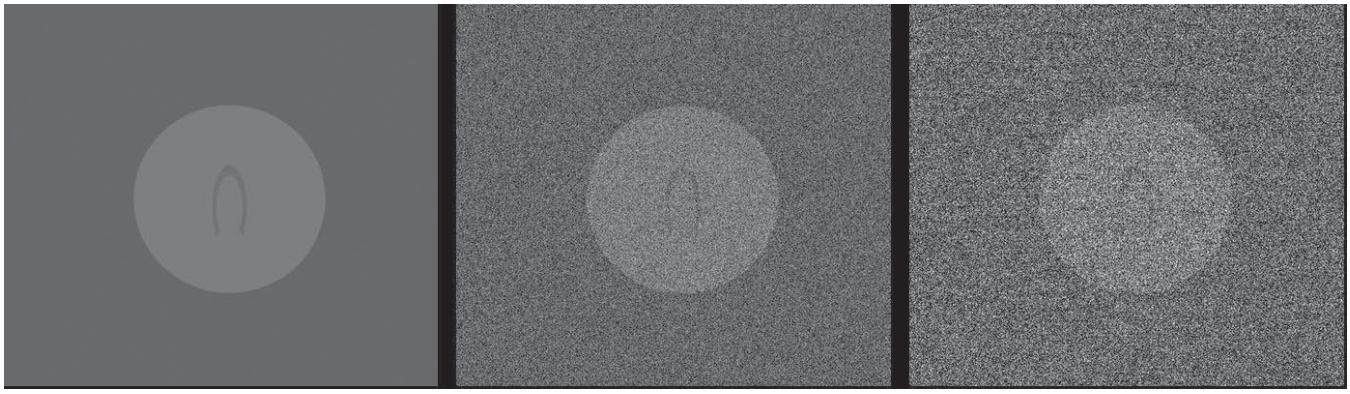

Fig. 23. From left to right the noise in these images increases, simulating the effect of lower dose rates on image quality. The fluoroscopist must decide on the best compromise in dose rate and image noise when choosing a dose-rate setting.

manufacturers. Even though entering this mode requires that the method of engagement be different from that of the normal mode, sometimes this is a subtle difference, such as using a different foot pedal or depressing a different switch. In this mode the machine adjusts the mA, kVp and possibly the pulse width upward, resulting in fluoroscopic dose rates that exceed conventional regulatory limits. A continuous audible tone indicates when this mode is engaged, but in many circumstances this tone is inaudible to the operator due to other noises in the room. ***This can be a particularly dangerous mode for units manufactured prior to May 19, 1995.*** Machines built before this date may operate without limit in this mode. The FDA has placed restrictions on the maximum dose rate permitted in this mode for machines manufactured after May 19, 1995. ***Regardless of date of manufacture, this high-dose-rate mode should be used only briefly*** to perceive detail that cannot be discerned otherwise. While it is repetitious, it is worthwhile reiterating the tenet: **"always use the lowest dose-rate setting necessary to efficaciously complete the procedure"**.

The kVp floor

Some units provide for the capability of defining a minimum kVp, below which the fluoroscopic mode will not operate. This is called the kVp floor. In general the machine will begin to operate at a kVp close to the floor in order to keep contrast as high as possible. Only when the dose rates at the kVp floor approach the regulatory limit does the kVp increase. As the kVp floor is increased, x-ray production and the penetrability of the x rays increase while contrast decreases. For most fluoroscopy systems in use today, the user does not have to define a kVp floor and the automatic dose-rate control (ADRC) and automatic brightness control (ABC) establish the kVp and mA according to predefined methods. For those machines that do have this option, proper selection is critical to proper dose management. In general, higher kVp's are required in larger patients to keep the dose rates at an acceptable level while maintaining adequate image brightness. *Typically, a higher kVp with low mA will result in a lower dose rate than a lower kVp with a high mA.* Operating at too low a kVp floor will result in unnecessary dose to the patient and to personnel (40). In general, in order to keep dose rates at levels as low as reasonable, select the highest kVp consistent with the image quality necessary to appropriately complete the procedure.

Systems under manual control

Manually controlled systems are rarely used anymore. Such units are outdated and probably should be replaced. For completeness we offer this brief review of their operation. For manually operated machines,

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the operator should establish a low tube current (~1 mA or less) and adjust the kVp upwards as needed to obtain a sufficiently bright image (See Fig. 21). Higher kVp's will result in lower image contrast. If the image does not contain sufficient contrast for the fluoroscopic procedure, then the kVp should be lowered slightly with appropriate increases in mA. This should be continued until a satisfactory combination of image contrast and image brightness is achieved.

Recorded fluoroscopy

The United States Food and Drug Administration does not regulate fluoroscopic exposure rates when dynamic imaging is recorded. The intent of this rule is to permit the physician to record and review high quality serial imaging, when necessary, to benefit the medical care of the patient. This mode is not intended to be used as a fluoroscopy mode! In some instances, fluoroscopic equipment has been outfitted with video tape recorders or other image recording methods with the explicit purpose of legally boosting dose rates beyond the regulatory fluoroscopic limits with no intent to use the recording for medical purposes. This is a regulatory loophole that permits physicians to perform fluoroscopy at unnecessarily high dose rates (too high a mA) but which provides greatly improved image quality over conventional fluoroscopy. *This circumvention constitutes abuse of the regulatory intent.* Cumulated exposures to patients and to personnel are excessive under these circumstances. If the fluoroscopic system produces inferior image quality, it should be serviced or replaced with better equipment that can produce higher quality imaging at dose rates within the regulatory standard. If higher dose rates are periodically necessary to view fine detail, a high dose rate unit should be purchased and properly employed for those procedures. However, the quality of many modern machines is so good that high level control is probably unnecessary. **Bypassing the regulatory limit by employing the indiscriminate use of recorded fluoroscopy must be strictly forbidden.**

Fluorographic imaging

Cineangiocardiography and the cine loop

In typical adult cine runs, the skin-dose rate to the patient may be on the order of 5 mGy per second to many tens of milligray per second. The actual rate depends on the amount of tissue to be penetrated and on the equipment setup. Some equipment allows for capture of cine images (**cineangiocardiography or cine)** at different selectable dose rates, or frame rates, to accommodate different needs during a procedure. If dose rate can be reduced for certain applications, considerable savings in radiation usage will be realized. This is done by adjusting the tube current, kVp and exposure time per frame. Frequently, an intermediate dose rate mode is perfectly adequate for clinical purposes and should be used in place of full-dose-rate cine, especially for discardable runs.

Digital fluorography

Average dose rates from serial digital fluorography, DA and DSA, are typically much less than that of cine fluorography, which reflects the lower frame rate acquisition. However, doses per frame are usually higher than that in cine, rendering a higher quality sequence of static images. Unlike conventional film imaging, digital fluorography can be acquired using a wide range of techniques [kVp, tube current and exposure time (mAs)] and still produce adequate image quality. Doses per frame of imaging from **digital angiography (DA)** and **digital subtraction angiography (DSA)** are on the order of 3 to 5 mGy_t in a typical adult run using good beam positioning. Since 1 to 6 frames per second are typically acquired, the resulting dose rates to the patient are about 200 to 1800 mGy_t

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per minute. Techniques exceeding that necessary for appropriate image quality result in unnecessary dose to the patient. The physician should work with their technologists and representatives of the manufacturer to establish the appropriate techniques and dose settings per frame of imaging.

Machine settings and doses to personnel

Dose rates to personnel in the room depend markedly on decisions by the operator regarding dose rate management for the patient. If image quality is improved by increasing the dose rate to the patient, the dose rate to personnel in the room will also increase.

Concise summary #2: Dose-management features of a fluoroscopy unit are varied and depend on the design of the equipment. A proficient understanding of these features is essential for proper dose management.

Quiz #2: Cite at least two compromises that a fluoroscopist must make when choosing an appropriate operating setting for dose management and image quality.

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Commandment #3: Keep the beam-on time and the dose accumulation in a single area of the skin to the lowest level commensurate with the benefits of the procedure —The Golden Rule!

#3. Beam On-Time and Dwell Time

Fluoroscopic on-time

Control over beam-on time is almost always the most important aspect of radiation management. ***The Golden Rule to minimize risk from fluoroscopic radiation is "keep the beam-on time to as low as reasonably achievable".*** Exposure time may be controlled either by a button on the control panel or by a foot pedal. X rays are present only while the switch is engaged. When disengaged, x rays vanish from the room. Keeping fluoroscopic beam-on time and the number of image acquisitions for an examination to a minimum will prevent unnecessary radiation dose the patient, operator, and other personnel. In the past, excessive use of x rays during a single procedure was controlled by the fact that the x ray tubes were not capable of sustained operation. Today, technology has created x-ray tubes that can endure extremely prolonged use. Thus, the restraining features in fluoroscopy and fluorography have been essentially removed. This places greater responsibility on the operator to manage the radiation application appropriately by restricting its use to only that which is essential.

It is essential to disengage fluoroscopic exposure whenever the image on the monitor is not being used. Avoid long durations of continuous fluoroscopy. Intermittently use the radiation to complete the procedure. Avoid the temptation to keep the x-ray beam on while studying the image. ***For foot pedals, practice tapping the x-ray control and then use the last-image-hold to maintain a picture of the image while contemplating the procedure. Absentmindedly leaving the x rays on while viewing other factors associated with the procedure, such as direct observation of the patient or communication with other personnel in the room, must be strictly avoided.***

Fluoroscopy timer

All fluoroscopic units have a **timer** (Fig. 21). While fluoroscopy is on the timer remains silent for five minutes and then gives off a warning tone that is silenced only after being reset. This cycle is then repeated. *The purpose of this timer is to help the physician keep track of fluoroscopic duration*. The cumulative fluoroscopy time should be reviewed as an effective quality improvement tool. A logbook can be maintained to record cumulative times. The reasons for times exceeding the norm should be reviewed and adjustments made in future procedures when indicated.

Beam dwell time

Avoid prolonged fluoroscopy time over the same skin site! Even when procedures are prolonged (e.g., more than 30 minutes) it still may be possible to reduce risk associated with skin dose by moving the beam to a different orientation, thereby avoiding over irradiation of a single skin site. While this may not be an optimal choice for efficiently completing a procedure, it might be a worthwhile consideration in some unusually prolonged procedures.

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Excessive on-time - true vignette #2

The switch used to engage fluoroscopy requires a continuous pressure and it automatically disengages when released. This is a safety feature that applies to hand controls as well as to foot controls. (The switch is called a "dead-man" switch because it shuts down if the operator falls dead.) The intent of the dead-man switch is to ensure that x rays are applied only when needed by the physician (commandment #3). The authors of this manual were personally involved in one circumstance where a surgeon used a heavy object to keep the foot switch continually engaged during his procedures. His excuse was that it was a distraction to have to repeatedly engage the fluoroscope. Such behavior constitutes abuse of a safety device and is justification to revoke fluoroscopic privileges.

Fluorography on-time

Digital fluorography

Serial digital fluorography is a major component of many procedures. While used much less frequently than fluoroscopy, doses to the patient from serial fluorography are substantial and can contribute more dose to the patient than fluoroscopy in some procedures. Typically, 1 – 6 frames per second are acquired and the resulting dose rates to the average patient are about 200 – 1800 mGy_t per minute. Using only the necessary frames per second and terminating the run promptly after the necessary information is acquired can result in a substantial savings in dose to the patient. ***The temptation to acquire more images because of the ease at which they can be collected must be strictly avoided.***

Cine and the cine loop

Cine uses a recording medium (e.g., digital disk) to capture movement dynamics. This technique plays an essential role in interventional cardiology. Recording the dynamic loop of the cardiac cycle permits replay for review. *These high-quality recordings are often captured using much higher dose rates than used for fluoroscopy.* Unless required for permanent documentation as part of the patient's medical record, these images are reviewed and then sometimes erased when the next run is recorded. Although the ease of digitally recording multiple runs has increased the value of cine, the ease of activation also makes this feature susceptible to overuse. Cine must be selectively used on a limited and intermittent basis to study the progress of a procedure. Since the dose savings realized by eliminating unnecessary cine runs will be substantial, the physician must make a conscious effort to avoid non-essential runs.

Because of these high dose rates, all cine fluorography must be used judiciously for only short imaging sequences. In digital **cine**, image dynamics are captured at rates of about 7, 15 or 30 frames per second to resolve the temporal motion of the beating heart. Entrance skin doses per image of cine are about 0.3 – 0.6 mGy_t, rendering high dose rates on the order of 140 - 1100 mGy_t per minute, but they can be higher, depending on many factors such as patient size, magnification, air gap, oblique imaging, etc. Poorly tuned equipment or poor techniques also contribute to markedly increased dose rates. A mere 2 seconds of run time can result in a skin dose of 7 – 60 mGy_t. If 30 runs occur during a procedure, this represents additional skin dose of 0.21 – 1.8 Gy_t. If it is possible to shorten the runs by 2 seconds, a substantial savings in

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skin dose is realized. Attention to these details becomes critical in interventional work when use of fluoroscopy and cine fluorography over the same skin area may be prolonged. Five to ten minutes of cine at the higher rates will cause serious skin injury. Less time is needed if conditions boost rates to even higher levels. ***Over-use of cine as a substitute for fluoroscopy results in excessive doses to personnel and can cause serious injury to the patient.*** The temptation to use cine when fluoroscopy will do must be strictly avoided.

Aids to reduce beam on-time

For specific procedures in radiology, orthopedics, pain management, and other specialties, there are numerous techniques that can be applied to reduce the need for fluoroscopy while introducing and positioning invasive devices. Some are as simple as applying markers on the skin of the patient or using a forceps or other similar devices to mark a position. Forceps might be used to move objects in the field while the x rays are engaged. Still other devices use laser beams to orient the position and help direct the introduction of surgical tools and devices. These guidance techniques and instruments can reduce the use of fluoroscopy by significant amounts and we encourage their use whenever practicable.

Beam on-time and doses to personnel

Managing beam-on time to the least practicable also keeps dose to personnel at the least practicable.

Concise summary #3: Managing beam-on time to the least practicable for both fluoroscopy and fluorography is the "Golden Rule" for proper dose management.

Quiz #3: Cite several technological aids that can help the fluoroscopist reduce beam-on time for an examination.

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Commandment #4: Keep the patient at maximum practicable distance from the x-ray tube.

#4. Proximity of X-ray Tube to Patient

X rays originate and emanate from a small area inside the x-ray tube. This area is about 1-mm wide and is called the "focal spot". As the distance from the focal spot increases, the intensity of x rays rapidly decreases. This is analogous to heat from a lighted match. The flame produces an extremely intense heat in a very small area close to the match, but the heat diminishes rapidly with distance. The potential for skin injury is very high if one is near the flame but is reduced markedly as the distance from the flame is increased. Similarly with x rays, ***as one increases the distance between the patient's skin surface and the source of x rays, the x-ray intensity is reduced and the potential for skin injury is decreased***.

In procedures involving lateral and oblique fluoroscopy (or isocentric fluoroscopy as used in special cardiologic or neurologic procedures), the geometry of the examination places an important limitation on the maximum distance that the source can be maintained from the patient. For example, when viewing the patient in a lateral or an oblique position, the x-ray source is usually much closer to the skin surface than it would be for a anteroposterior or posteroanterior views. *As a result, in lateral and oblique orientations the entrance dose rates at the patient's skin can be much higher*. Recent articles have reported patients with severe skin burns as a result of too much radiation dose in the oblique and near lateral orientations during cardiologic procedures (Figs 7, 9, 10, 12-14; refs. 1, 5, 20, 23). Therefore, *it is important in all procedures to keep the patient's skin surface at maximum practicable distance from the x-ray source.*

Some units have the capability to move the x-ray tube and the image receptor independently. The distance between the x-ray source and the image receptor can vary between about 85 cm and 130 cm. However, when the distance from the x-ray source and the image receptor becomes too great, the machine finds it difficult to increase output to accommodate the distance. The kVp in this case may be driven too high and image quality (i.e., contrast) degrades. If this is inadequate for the procedure, the physician must draw an appropriate compromise between source-to-image distance and image quality, while maintaining an appropriate distance of the source from the patient. Typically, the source-to-image distance is maintained between 90 cm and 110 cm.

Sometimes, increases in SSD to reduce dose rate result in increases in kVp and/or mA that enhance radiation output. In these cases the dose reduction through increased SSD should outpace the elevation in dose rate caused by changes in kVp and mA, resulting in a net decrease in skin dose rate (see question #4 for further details).

The separator cone (or spacer device)

The United States Food and Drug Administration (FDA) requires that fluoroscopic x-ray machines be designed so that the patient's skin is at least a specified fixed distance from the x-ray source. All fluoroscopy machines are designed with the x-ray source behind a device that forces a minimum separation of the source from the skin of the patient. This minimum source-to-skin distance depends on the type of fluoroscope and the date it was manufactured. In conven-

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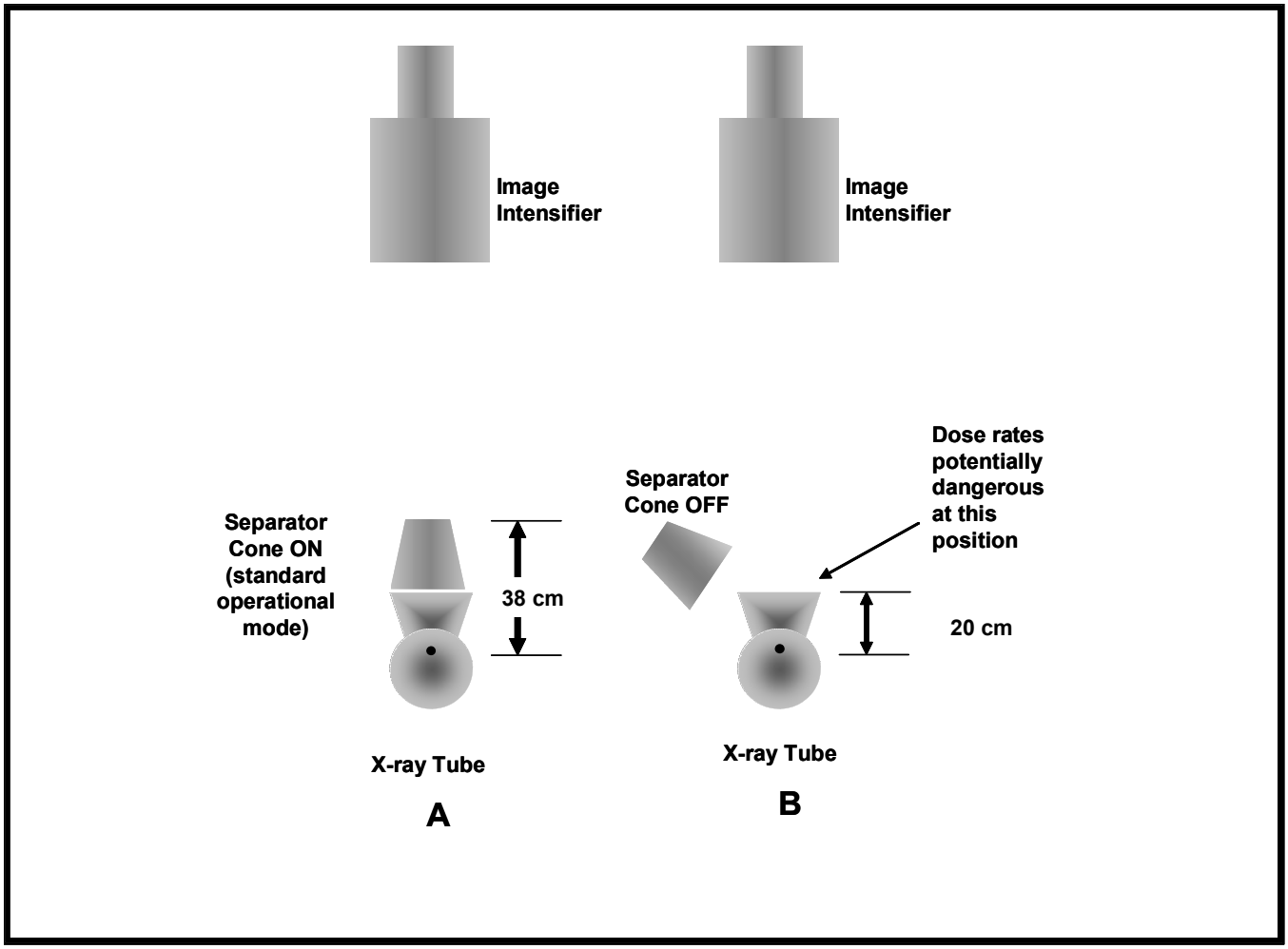

Fig. 24. Diagram of fluoroscopic system with separator device on and off. Fig. A depicts the standard configuration with the cone on. Fig. B is a nonstandard configuration with the potential for much higher dose rates at the port of the x-ray tube housing. Use in this mode should be discouraged except in cases where the cone might become detrimental to the procedure.

tional fluoroscopy, such as that used in gastrointestinal work, the source is located under the table and at a fixed distance from the patient. C-arm type units have plastic cones or other devices that serve as spacers to maintain a minimum separation (Figs. 3, 16 & 24). *The purpose of this regulation is to prevent the dangerous situation in which the intense beam emerging from the x-ray source is too close to the patient's skin.* For modern machines that are fixed in a room, a minimum distance of 38 cm between the source and the end of the spacing device is required. For mobile units this distance is 30 cm. However, for some procedures this physical constraint makes it difficult to maneuver the C-arm around the patient. To provide some flexibility, the FDA permits machines to be designed with removable spacers (Fig. 24). For diagnostic procedures the device is to remain attached to the x-ray source. For special surgical procedures, the device may be removed and the minimum distance can be as short as 20 cm. *This creates a potentially dangerous situation and the physician should make special efforts to maximize the distance of the x-ray tube from the patient's skin.* ***No body parts should ever be in contact with the port of the x-ray tube during fluoroscopy or fluorography.***

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Once special surgical procedures are completed, the spacer device is to be reattached to the x-ray source. However, too often these devices are removed and never reattached. The danger of the close source can only be avoided if the physician is conscientious about maximizing the distance between the x-ray tube and the patient. **Dose rates at short distances can be extreme (greater than 0.5 Gy_t per minute) and the thresholds for epilation, erythema, and severe injuries can be reached in a matter of minutes.**

The fact that regulatory agencies place restrictions on the radiation output of fluoroscopes is common knowledge. However, this restriction is too frequently misinterpreted. For example, the restriction that the output of the common fluoroscope may not exceed 87.6 mGy_a/minute at the compliance testing point (10 R/minute in the U.S.A.) does not mean that the entrance skin dose to the patient cannot exceed 87.6 mGy_t/minute. In fact, the entrance skin dose rate can readily reach 200 – 250 mGy_t/minute. This is due to radiation that is scattered back to the skin surface from the tissues inside the patient and because the x-ray source is often closer to the patient than the compliance testing point. These two factors elevate the dose rate to well beyond the compliance limit. This is illustrated in Figure 22. Rates are even higher for high-dose-rate modes and fluorography.

This commandment is designed primarily for the safety of the patient***. It serves mostly to minimize the concentration of x rays at the skin surface***.

SSD and dose to personnel

When SSD is increased, the amount of radiation scattered into the room will depend on how collimation and the distance between the x-ray source and the image receptor (SID) change. *If collimation remains confined to the area of interest, scatter in the room usually doesn't change much and might be reduced.*

SSD and image quality

When maximizing source-to-skin distance, image quality might change because the size of the image is reduced. This change in image size is due to the change in position of the patient relative to the x-ray tube and image intensifier. Also, as distance is increased, kVp might increase, resulting in reduced image contrast.

Concise summary #4: Keeping the patient's skin as far away from the x-ray source as practicable will minimize dose rate to the skin. If collimation is confined to the area of interest, scatter in the room either decreases or doesn't change much. Image quality depends on image size which is slightly reduced and on kVp which might be increased.

Quiz #4: For an x-ray source with distance adjustment independent of the image intensifier, you notice that the mA increases as you move the x-ray tube from 40 cm to 60 cm from the patient's skin (see diagram in the appendix). The collimators are fully open to the input area of the image intensifier. Why does the patient's skin dose rate decrease and dose rates to personnel not change much? (See Appendix for answer.)

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Commandment #5: Keep the image receptor as close to the patient as practicable.

#5. Proximity of Image Receptor to Patient

To reduce radiation dose to the patient, the image receptor should be as close to the patient as practicable. For a fluoroscopic system with fixed distance between the x-ray source and the image receptor, entrance dose to the patient decreases either as the patient is moved closer to the image receptor or as the image receptor is moved closer to the patient.

If the x-ray source and the image receptor move independently, then after the patient is positioned at the appropriate table height, move the image receptor as close as reasonable toward the patient. [Note: the x-ray tube should, of course, be as far away as is practicable.] When the image recptor is independently moved closer to the patient, the production of x rays decreases because of the shorter distance between it and the x-ray source. *Since in this particular instance the source-to-skin distance is not changed, placing the image receptor as close to the patient as practicable yields a lower dose rate to the skin where the beam enters the patient.*

Keeping the image receptor close to the patient minimizes the concentration of x rays at the skin surface where the beam enters the patient. Whether scatter in the room decreases depends on how collimation and the distance between the source and image receptor change. If collimation remains confined to the area of interest, scatter in the room is reduced, otherwise it doesn't change much. One other advantage for the operator may be that the image receptor acts as a shield when it is close to the patient because it absorbs x rays scattered off the exit-beam surface of the patient. When placing the image receptor close to the patient, the size of the image is reduced and image quality might change. This change in image size is due to reduced geometric magnification.

Neuroradiologic procedures are usually performed with an *isocentric configuration* (i.e., no matter how the C-arms are oriented around the patient, the anatomy of interest remains in the center of the image) and the image receptor is intentionally separated from the patient. Cardiologic procedures might also employ an isocentric configuration. The image receptor may be separated from the patient to accommodate difficult angulation or to ease the maneuverability of the C-arm around the patient. Some invasive procedures require a large gap between the patient and the image receptor to provide an appropriate working space for the invasive devices. This is true for many surgical procedures and in pain management. If circumstances mandate that fluoroscopy be done with a large air gap of more than 25 cm between the patient and the image receptor, then the physician should consider removing the grid, if possible (see commandment #7). This should reduce patient dose without loss of image quality because scatter radiation is not likely to interfere with image contrast. Otherwise, particular attention must be paid to other means by which to reduce dose rate and cumulative dose to the patient.

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The Combined Importance of Commandments 4 & 5

Patient dose and position of fluoroscope

Figure 25 demonstrates how the positioning of the C-arm can dramatically affect radiation dose to the skin of the patient. Figures 25A to 25D depict differences in the proximity of the x-ray tube to the patient's skin. In all cases the distance of the x-ray tube from the image intensifier is 110 cm and the kVp, tube current, fluoroscopic time, and magnification mode of the image intensifier are assumed to be unchanged. Only the geometric magnification changes (see commandment #6). Figure 25 and Table 4 provide an example of a prolonged TIPS (transjugular intrahepatic portosystemic shunt) procedure to demonstrate how the different geometries can have a tremendous effect on dose to the patient and on biological response. There is more than a factor of five difference in dose between the geometry of Fig. 25A and Fig. 25D. *This can easily mean the difference between no noticeable skin reaction and a serious injury*. *Differences in geometry of as little as a few centimeters can have a major impact on dose to a patient's skin.* For example, the difference in dose between a source-to-patient distance of 70 cm and 65 cm is 0.8 Gy_t (80 rad) for the TIPS example of Table 4.

Patient dose and physician height

Tall physicians may have no difficulty in maintaining good geometry, as depicted in Fig. 26A (no invasive devices present) or 26B (invasive devices present). Physicians who are "vertically challenged" may find that a geometry more like Fig. 26C may be necessary. Note that the table is lower to accommodate the physician's height. However, when the table is low, the floor may prevent the physician from moving the tube appropriately away from the patient. At one institution a platform was built to assist a "vertically challenged" physician. Although platforms can reduce this disadvantage, we advise caution in their use because they may create a hazard, resulting in injury to personnel or even the patient. If the position of the image intensifier is independently adjustable, the physician can and should control dose to the patient by moving it as close to the patient as possible. Figs. 26C and 26D show how the dose is reduced by about 30% simply by moving the image intensifier 20 cm closer to the patient, all other conditions remaining the same (note: the mA will be adjusted by the ABC). If the image intensifier can be moved closer, the dose would be further reduced. If not, the physician might consider removing the grid, if this option is available. Removing the grid is likely to reduce the dose by another 30% or more. [In some machines, SID control might provide adjustments to the ABC that maintains the entrance exposure rate at a level different than those that don't have SID control.]

Patient dose and invasive devices

During certain invasive procedures, placing the image intensifier close to the patient would restrict the physician's working area. Syringes, catheters, or other devices may be protruding from the patient (e.g., from the back at the spine). For reasons discussed in commandment #10, the preferred orientation for protection of personnel is to keep the image intensifier above the patient and the x-ray tube below. An adequate distance between the patient and the image intensifier (Fig. 25B) must be maintained to provide working space for manipulation of invasive devices and to prevent collisions when moving the C-arm. Since the image intensifier and the x-ray tube are fixed in opposing orientations, the constraints on the image intensifier may also place severe constraints on how far the x-ray tube can be positioned from the patient. While not recommended, the separator cone is sometimes removed from the x-ray tube to allow for freedom of movement of the C-arm around the patient. For large patients,

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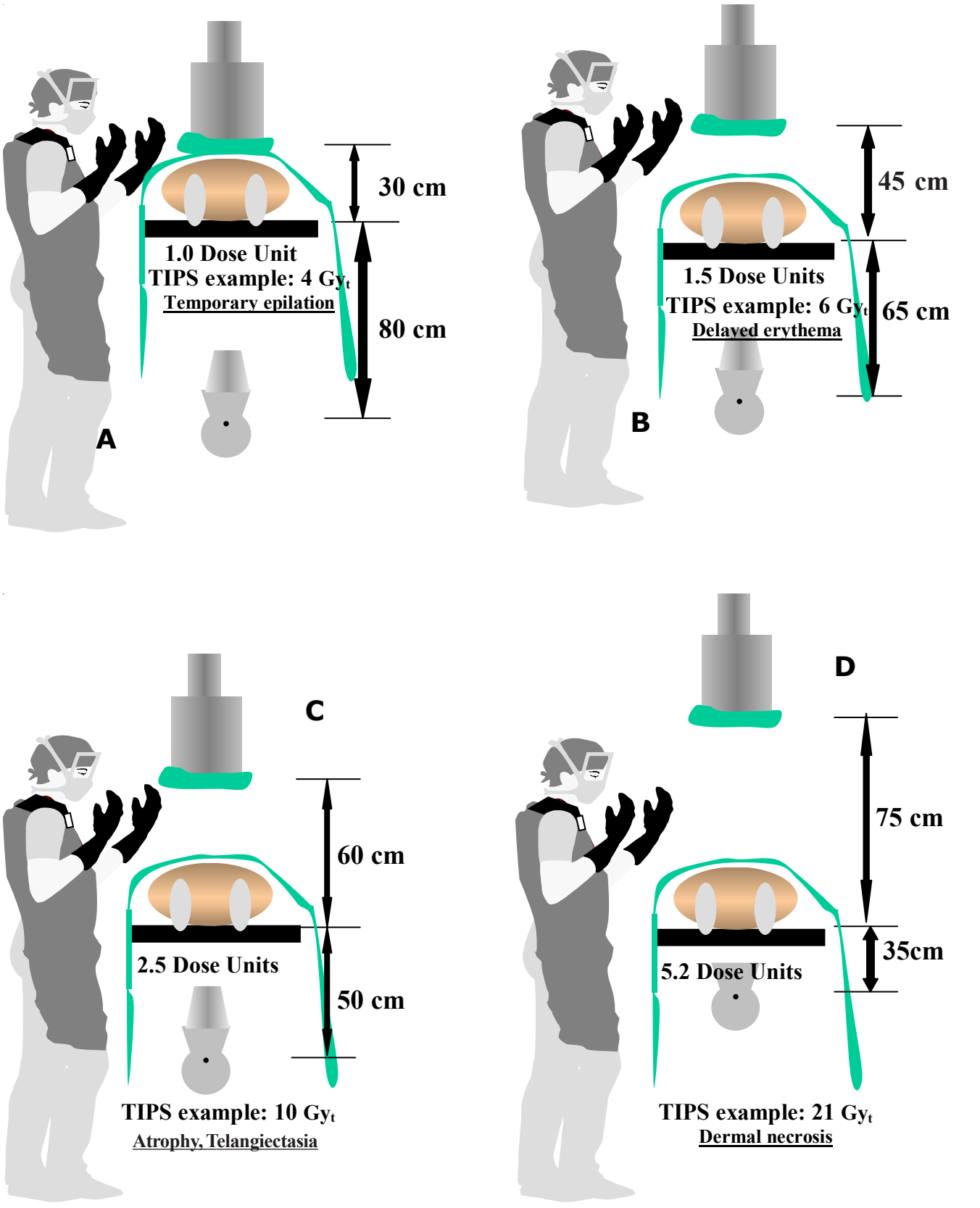

Fig. 25. Effects of different fluoroscopic geometries on absorbed dose rates to the patient .

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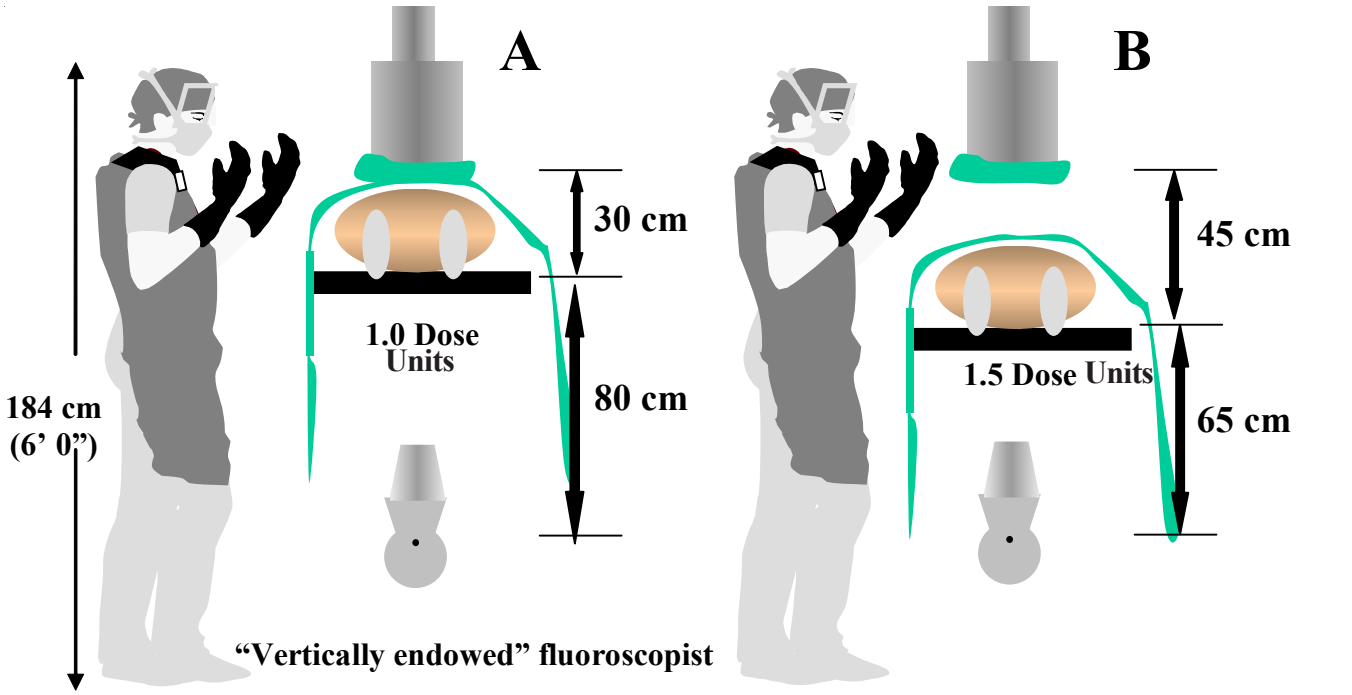
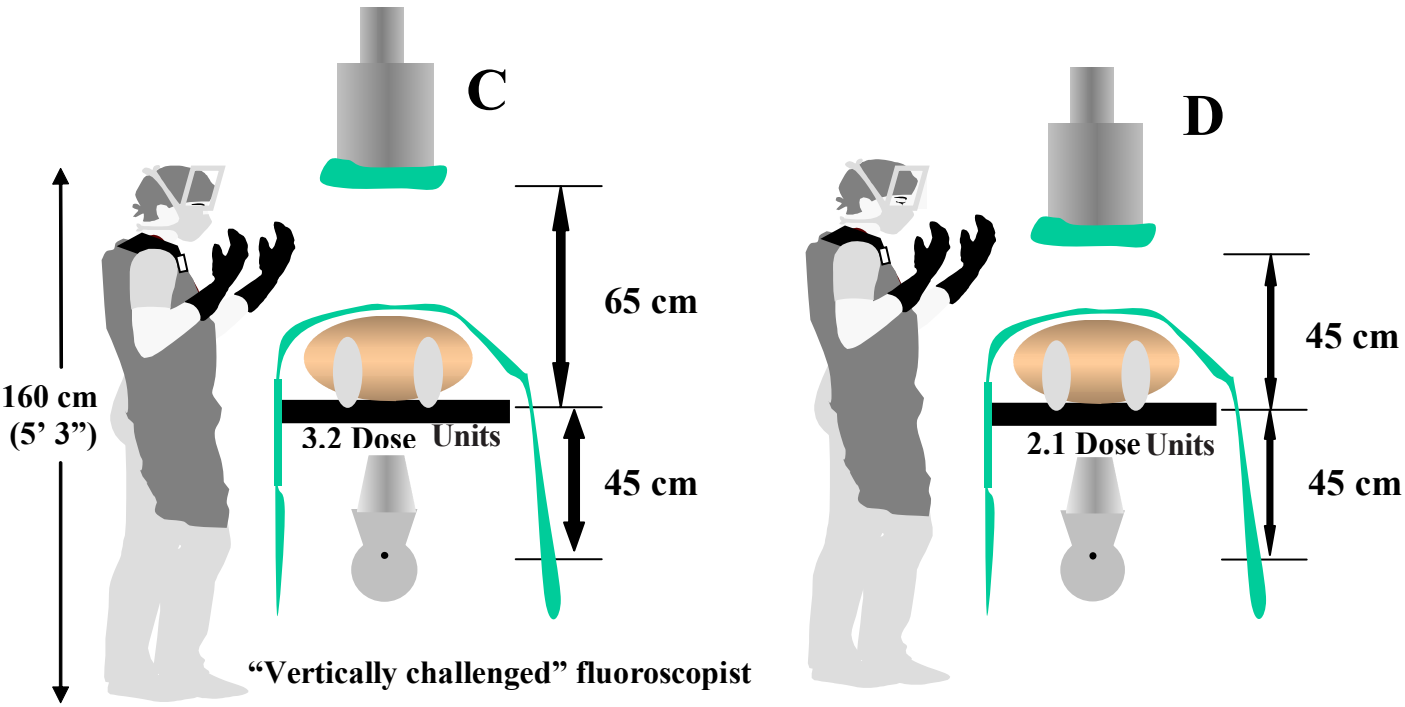


Fig. 26. The "vertically endowed" fluoroscopist has the advantage here. Fig 26A is the ideal geometry, but may not be practical either because of the fluoroscopist's height or because the area fluoroscoped may have invasive devices protruding from the patient. Geometry depicted in Fig 26B is more typical when a gap is required between the patient and the image intensifier. Fig. 26C shows the case of a "vertically challenged" fluoroscopist. Fig 26D shows that keeping the image intensifier close to the patient can reduce some of the disadvantage in shorter physical height.



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Reference figure	Distance of x-ray source from patient	Skin dose relative to Fig. A	Skin dose to patient for prolonged TIPS procedure	Potential delayed skin reaction	Difference in dose between reference geometry and ideal geometry of A
25A	80 cm	1.0	4.0 Gy_t	Temporary epilation	0.0 Gy_t
Not shown	70 cm	1.3	5.2 Gy_t	Temporary epilation	1.2 Gy_t
25B	65 cm	1.5	6.0 Gy_t	Erythema	2.0 Gy_t
25C	50 cm	2.6	10 Gy_t	Atrophy, telangiectasia	6.0 Gy_t
25D	35 cm	5.2	21 Gy_t	Necrosis	17 Gy_t

Table 4. The effects of geometry on skin dose.

the port of the x-ray tube may actually come into contact with the patient's skin. As discussed previously, if the separator cone has been removed and the port is close to or in contact with the skin, the potential for a injury is maximum. ***Extreme caution is advised and this configuration should be diligently avoided!***

The standard geometry used for fluoroscopy of areas where invasive devices are inserted (Fig. 25B) serves to increase dose rates to patients because commandments 4 and 5 are difficult to implement. For these procedures, particular attention must be given to other measures to reduce doses to patients, such as short exposure times and removal of the grid, if this option is available. Use of good collimation will ensure that scatter does not degrade image quality (see commandment #8).

Concise summary #5: Keeping the image receptor close to the patient minimizes entrance skin dose rate. If collimation is confined to the area of interest, scatter in the room decreases. The effect on image quality depends on image size, which is reduced.

Quiz #5: Why does keeping the image receptor closer to the patient decrease dose rate to the patient?

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Commandment #6: Don't overuse geometric or electronic magnification.

#6. Image Magnification

While magnification of the image improves the visibility of detail and is often useful and necessary during fluoroscopy, it frequently results in increased dose rate to the patient. Magnification can be achieved in two ways: electronically and geometrically. Electronic magnification controls the focus of the image intensifier and is an option that the physician can choose by pushing a button. In flat panel detectors electronic magnification is achieved by software adjustment to the display matrix. Geometric magnification is achieved by changing the position of the patient relative to the x-ray tube and image receptor. The advantages and disadvantages of each are discussed below.

Electronic magnification (field-of-view size)

Some image intensifiers have only one field size; a typical size is 9-inch (23-cm) diameter. Others are designed for multiple field-size viewing (field-of-view or magnification modes) and may include two, three, or four modes of different imaging diameters. These different field sizes are the electronic magnification options of the fluoroscopic system. Magnification is achieved by making the usable x-ray field smaller and displaying this smaller field over the full viewing area of the monitor. Some standard modes of operation from greatest to least magnification are 4 inch (10 cm), 6 inch (15 cm), 9 inch (23 cm), and 12 inch (30 cm). The fluoroscopic unit in Fig. 21 has three field sizes that are selectable as "Normal", "Mag1", and "Mag2".

The entrance dose rate is often related to the magnification selected. *The mode of least magnification (largest field) usually delivers the lowest dose rate.* How the dose rate to the skin of the patient changes when magnification is employed depends on how the system is designed by the manufacturer. For some designs, the dose rate does not change. More frequently, it increases. This increase may be as much as a factor of two or more for each magnification increment. A medical physicist should be consulted if there is a question on how the system works.

In the United States the maximum dose rate for fluoroscopy must not exceed the maximum permitted by regulation, regardless of the magnification mode of the image intensifier. For the most part, this means that the maximum rate may not exceed 87.6 mGy_a/min at the compliance testing point (note: this is about 120 mGy_t/min). There are other regulatory limits for some machines.

If the manufacturer has designed the system to maintain the same entrance dose rate, regardless of electronic magnification mode, then the physician can operate in the magnification mode of choice. However, typical systems will increase dose as magnification increases. For these types of systems the operator must be aware of some important dose-management concerns. If a physician is not certain how the fluoroscope works, then the following principle should be heeded: *To optimize overall radiation management, use the least magnification consistent with the goals of the procedure and reduce the irradiated volume of the patient by employing collimation (commandment # 8).*

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When electronic magnification is employed, dose rates to personnel in the room might increase, but could decrease or not change much. What happens depends on how collimation, kVp, and tube current respond to the change in electronic magnification. If collimated field area is unchanged, dose rates in the room still usually go up because kVp and tube current usually go up.

Geometric magnification

Geometric magnification is achieved by increasing the distance between the patient and the image intensifier or by decreasing the distance between the x-ray tube and the patient. This is achieved by moving either the patient or the machine. Increasing the distance of the image intensifier from the patient is contrary to commandment #5(keep the image intensifier as close to the patient as possible). Decreasing the distance of the x-ray tube is in opposition to commandment #4 (keep the patient at maximal practicable distance from the x-ray tube). However, geometric magnification has some advantages from a procedural point of view. Examples include those using an isocentric configuration or those that require fluoroscopy of the area where invasive devices are introduced. Two things are of note regarding dose rates when using this technique. *First, dose typically increases with the square of geometric magnification.* That is, if magnification increases by a factor of two, dose rate increases by a factor of four. *Second, maximum dose rates in this configuration may exceed the regulatory limit, resulting in skin dose rates of more than ~120 mGy$_t$ / min.* This is because compliance dose rates are tested only at a point representing conditions of low geometric magnification (patient closest to the image intensifier as in Fig. 25A). When the patient is positioned for geometric magnification, dose rate to the patient's skin increases. The increases in dose shown in Fig. 25 are a direct result of the changes in geometric magnification.

Dose rates to personnel in the room might increase with increased geometric magnification, but this depends on how tube current, SID, and collimation are adjusted with magnification.

Concise summary #6: Magnification almost always results in increased dose rate to the patient's skin. The least magnification consistent with the goals of the procedure should be used in conjunction with collimation to manage radiation properly. Electronic magnification, rather than geometric magnification, is less likely to result in too high a skin dose rate. Image quality under magnification fluoroscopy usually improves. Dose rates to personnel in the room may increase or not change much as magnification increases.

Quiz #6: Many fluoroscopes adjust dose rate under electronic magnification according to the square of the magnification factor. How does dose rate to the patient change as one shifts from a 24-cm field of view (no magnification mode) to a 12-cm field of view (magnification mode)? (See Appendix for answer.)

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Commandment #7: If image quality is not compromised, remove the grid during procedures on small patients or when the image intensifier cannot be placed close to the patient.

#7. The Grid

*A **grid** is a flat plate device that improves image contrast by selectively shielding the image intensifier from scattered x ray*s (Fig. 27). It is positioned in front of the image receptor to improve image clarity, although this causes the radiation dose rate to the patient, as well as scatter to personnel, to increase. Many GI fluoroscopic units have an automatically retractable grid that can be removed by the press of a button during fluoroscopy. In some C-arm units, the grids are manually removable. Grids should not be removed if not designed for that purpose. If the grid is removed, the radiation dose rate to the patient decreases, sometimes by a factor of 2 or more. However, image contrast might be compromised (Fig. 27B). (It is also very important that removable grids be handled with great care to prevent nicks or dents that could ruin their effectiveness. **Grids are fragile and costly devices.**)

Two circumstances in which it is advantageous to remove the grid include the following:

1) Pediatric patients or small adults generate very little scatter. It may be possible to perform fluoroscopy without the grid for these patients.

2) For procedures that employ a large space between the patient and the image intensifier, very little scatter reaches the image intensifier (Fig. 27C). Good collimation further minimizes the image-degrading effects of scatter. The grid serves little purpose in this case. The fluoroscopist should consider removing the grid if the image intensifier cannot be positioned closer than about 25 cm to the patient. This occurs, for example, in many pain management procedures and during neuroangiographic work. Söderman et al. (41) have demonstrated that removal of the grid during neuroangiography reduces dose to the patient by about 34%, with no noticeable affect on image quality.

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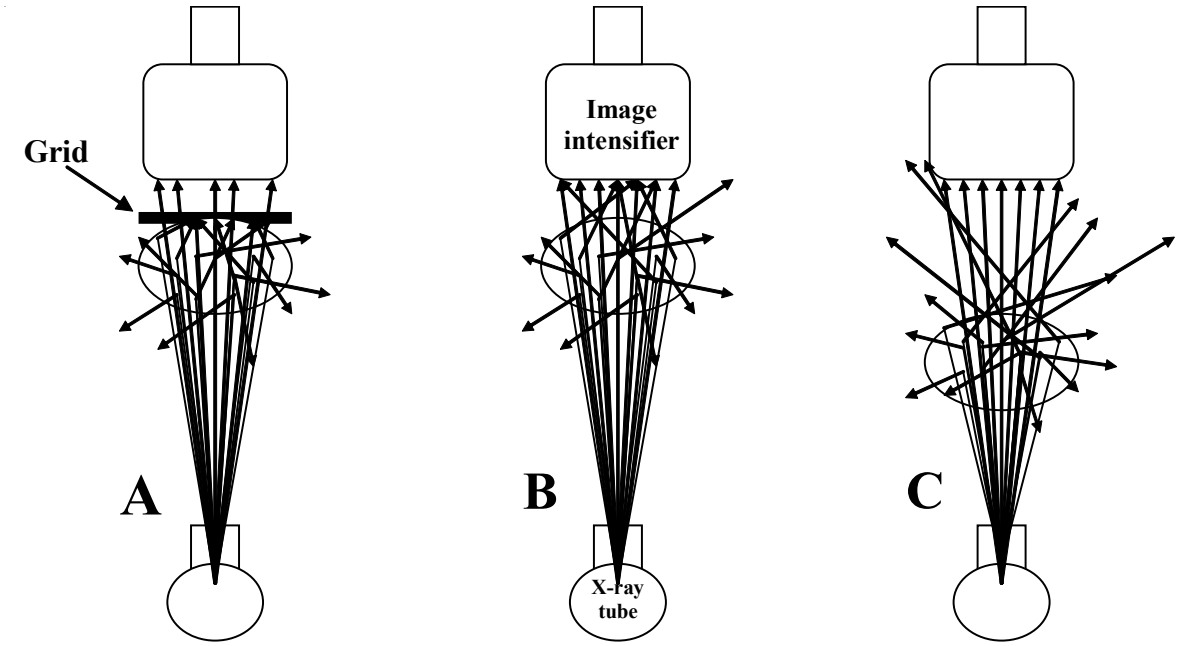

Figure 27. The grid and scatter. In A, the grid is in place and effectively stops image-degrading scatter radiation (bent arrows) from reaching the image intensifier. (The remaining scatter goes into the room, but this scatter does not affect the image.) The grid permits most, but not all, of the image-forming x rays to pass through to the image intensifier (straight arrows). In B, the grid is removed. Scattered x rays now reach the image intensifier, reducing image contrast. This is usually unacceptable for medical tasks. With the grid removed, all image forming x rays enter the image intensifier. In C, the air gap provides enough space so that the scattered x rays now pass out of the range of the image intensifier. This scatter no longer degrades image quality. If such an air gap is used, the grid serves no purpose and removing it permits all the image-forming x rays to be used. Removing the grid in this case lowers dose rate to the patient without degrading the image quality.

Concise summary #7: A grid improves image quality by removing scatter radiation. The use of a grid increases patient dose and doses to personnel in the room.

Quiz #7: Why is the use of a grid more important for fluoroscopy in adults than it is for fluoroscopy in infants? (See Appendix for answer.)

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Commandment #8: Always collimate down to the area of interest.

#8. X-Ray Field Collimation

Collimators are x-ray blockers that are located just outside the x-ray tube (see Figs. 3 and 16) and are used to define an opening through which the x rays can pass. The collimators' blades can be manually adjusted to reduce or enlarge the area of the visible image, and thus reduce or enlarge the area of the patient that is exposed. They are adjusted from the operator's control panel (Fig. 21). The shadows of the collimators' blades should be minimally visible on the TV image when the blades are fully open. *Using the collimators to reduce the x-ray field to the areas of interest has the following advantages:*

1) it reduces radiation detriment to the patient by reducing the volume of tissue exposed;

2) its reduces the scattered radiation in the room because less radiation is used;

3) it improves image quality by reducing scatter in the image;

4) it can be helpful in managing skin dose to the patient because there will be less likelihood of overlap of entrance beam areas when the x-ray system is rotated to a slightly different beam angle.

As the collimators open to expose a larger area of the patient, more image-degrading scatter radiation is produced (Fig 28). Collimating down to the area of interest reduces scatter radiation and this improves image quality. Reducing the field-size by collimation also reduces the risk to the patient because the carcinogenic risks are proportional to the volume of tissue exposed. Controls to adjust the collimators are shown in Fig. 21. (Note: Sometimes closing the collimators too much will result in an overly bright image, unusually high tube current (mA), or other unusual effects. This occurs because the blades block part of the area used by the ABC to control brightness. Just open the collimators slightly and the image should return to normal.)

Collimation does not reduce entrance dose rate to the skin of the patient. While collimation reduces the area of the exposed skin, the absorbed dose rate to the skin that remains exposed is likely to increase. This is due to the fact that the automatic brightness control responds to all radiation striking the image receptor. Since collimation reduces scatter radiation, the scatter that would otherwise strike the receptor is reduced. The ABC then responds to this decrease by increasing output.

One of the biggest problems in implementing collimation is that, for many x-ray units, the x rays must be on so that the operator can watch the blades move to the desired positions. Some manufacturers provide a software preview of collimator adjustment that requires no engagement of x rays to position the blades. The area defined by the blades appears as a computer simulated rectangle overlying the last image hold. This feature has proven very useful in reducing unnecessary fluoroscopy time and in improving the utility of the collimators.

Radiation dose to personnel in the room is caused by scattered radiation. The volume of tissue irradiated strongly influences the amount of scatter that is generated. This is demonstrated in Fig. 28. If the field

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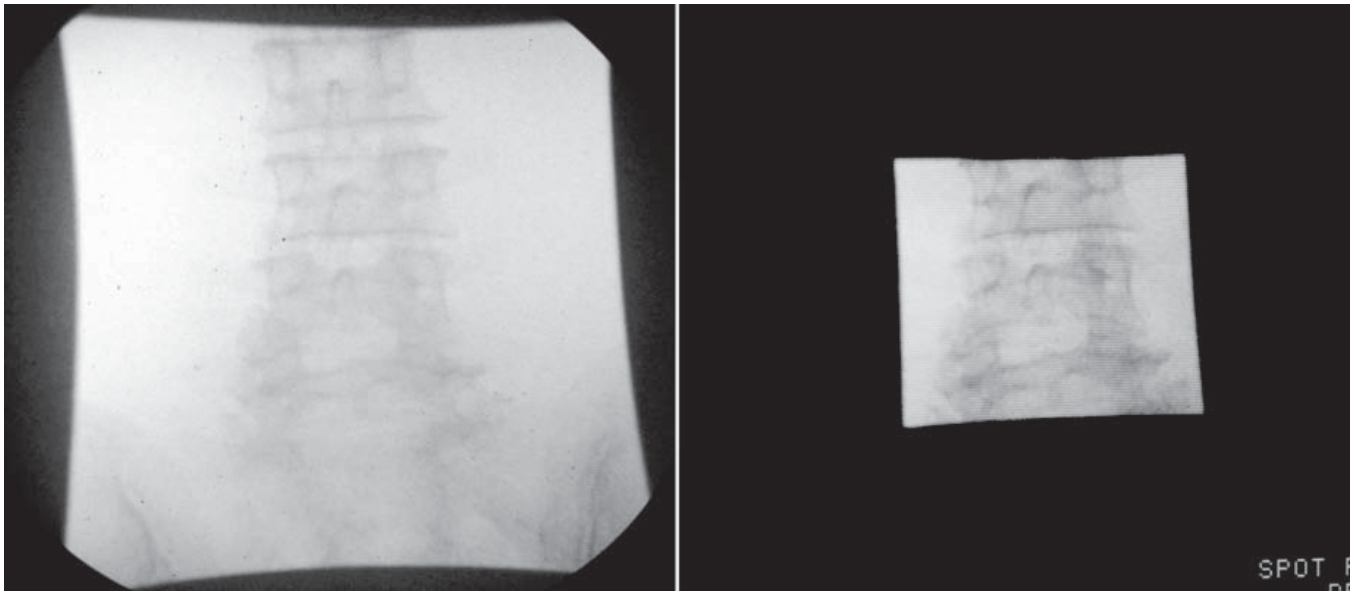

A B

Figure 28. The effects of collimation are illustrated in Figs. A and B for viewing the lumbar spine (a human spine imbedded in a plastic manikin is used for demonstration.) In Fig. A the field-of-view is about four times larger than in Fig. B. Irradiation in Fig. A exposes four times more patient tissue than in B, and therefore puts four times more tissue at risk for radiation-induced effects. Scatter radiation to personnel in the room is also four times greater. Collimation in B reduces risk to the patient, to personnel, and improves image quality by reducing scatter in the image.

dimensions are increased by a factor of 2 by opening the collimators, then the volume of exposed tissue increases by a factor of about 4. Thus the dose to personnel in the room also increases by a factor of 4. *Large reductions in dose rate to personnel in the room can be realized if the radiation field is manually collimated to the area of interest.*

Practical applications:

1. For some invasive procedures a large air gap between the patient and the image intensifier is used to accommodate invasive devices. This air gap greatly reduces the image-degrading effects of scatter. Collimating to the area of interest further reduces scatter. This can render the functionality of the grid superfluous. If the grid is removable, removing it will result in a lower dose rate to the patient and there is not likely to be any significant loss in image quality. Lower dose rates also reduce risks to personnel, especially to the physician's hands.

2. Lateral fluoroscopy of the spine with the patient prone on the table is a common projection employed in some procedures, such as in pain management. In this orientation the part of the laterally projecting x-ray field that is above the back of the patient is unattenuated and strikes the image intensifier with its full intensity. This produces an intensely bright area in the image just above the spine. The operator should rotate the collimators so that the blades are parallel to the surface of the back. *With this orientation, closing down the collimators to block the unattenuated beam is an effective way to improve image quality and reduce risks to the hands if manipulation of interventional devices is required*.

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3. Cataracts are a potential risk for patients undergoing high-dose interventional procedures in the head. The threshold for radiation-induced cataract is about one Gray. For interventional procedures, such doses to the side of the head are relatively common. The primary source of radiation exposure to eyes originates from direct exposure from the lateral x-ray beam. *The physician can reduce such exposure by shielding the eyes on the lateral side. This is most easily achieved by using collimation.* The collimator must be closed down to shield a large portion of the orbit that is closest to the x-ray tube. *(The frontal view should be performed with the x-ray tube posterior to the head and the image intensifier anterior.* This ensures that the eyes receive only the much reduced exit-beam dose and not the much higher entrance dose. *If performed with the x-ray tube anterior, the potential for cataractogenic doses is greatly increased.)*

Concise summary #8: Applying collimation improves image quality by reducing scatter, lessens the radiation burden to the patient by reducing the volume of tissue exposed, and reduces dose to personnel in the room by reducing scatter.

Quiz #8: After applying collimation you notice that the tube current increases. Is this normal and what should be done about it?

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Commandment #9: Monitor radiation utilization and maintain a quality control program to assure radiation is managed properly.

#9. Monitor Dose to Patients

Monitoring the amount of radiation that is used to complete procedures is an important exercise to help ensure that radiation is being used efficaciously. As a quality control measure fluoroscopy use should be reviewed periodically. Unusually high-use procedures should be reviewed to ascertain the reasons for the unusual events and to decide whether or not modifications to procedures are warranted. As a patient management tool, dose monitoring will help physicians in their decisions about the progression of a procedure when doses become very high. There are four important parameters used to monitor radiation use:

- fluoroscopy beam on-time
- dose area product
- cumulative air kerma at a fixed reference point
- cumulative peak dose at a site in the skin

Fluoroscopy on-time is an easy and useful parameter to monitor for procedures that typically employ less than 20 minutes of fluoroscopy on-time. Because of the short duration of use, the radiation dose delivered to the skin during routine diagnostic fluoroscopy is not usually measured. Instead, the general practice is to have the equipment periodically tested to ensure compliance with standards of performance. Other than this, the physician controls the application of radiation and should have sufficient training to keep the use to a minimum. However, the physician should keep track of fluoroscopic on-time as a quality control measure. For example, diagnostic barium contrast studies of the alimentary canal typically require about 2 – 3 minutes of fluoroscopy time. Individual procedures that use more than twice that should be reviewed for appropriateness. If the average time is 5 – 6 minutes, a review should be initiated to ascertain whether or not this is acceptable and actions taken to address any problems that are disclosed. For most routine diagnostic studies, this should be sufficient to assure safety.

Fluoroscopy on-time does not monitor radiation use from fluorography nor does it monitor how effectively a physician uses collimation. Dose-area product (DAP) does both of these and therefore is a more effective quality control measure. DAP is the air kerma multiplied by the field area. Most modern fluoroscopy units have a dose-area product meter. In some countries, it is common to record the dose-area product for fluoroscopic procedures. Use of DAP meters is increasing in the United States. The real-time monitoring of this quantity might be useful because it fosters good radiation management habits. This quantity is minimized by reducing the dose and dose rate to the patient as well as by reducing the field size, which encourages good collimation. Comparing the cumulative DAP results of one physician's studies to those of a physician who performs similar studies is also useful in identifying deficient radiation management habits.

For some procedures, e.g., complex interventional work, very high doses of x rays to the patient might be required. In these cases, **measurement of the absorbed dose to the skin is necessary** *to assure that it is at an acceptably low level for the procedure***.** The United States Food and Drug Administration has recommended that this be monitored for patients whose skin dose might exceed 1 Gy_t

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(100 rad) or at a level that the facility decides is appropriate for patient care (27). Many devices are available to monitor doses without interfering in the proper completion of the procedure. The most effective real-time readout devices are computerized dose monitors that keep track of the dose distribution throughout the skin. Unfortunately very few systems are equipped with such a dose mapping device. However, most modern new isocentric units used for fluoroscopically guided interventions provide a cumulative monitor of the air kerma (air dose) at a point 15-cm from the isocenter and toward the x-ray tube. This location is known as the interventional reference point (IRP, Fig. 29). Monitoring dose to this point is not as accurate as the skin dose mapping monitor. This is because cumulative dose at the IRP does not account for changes in skin dose that result from changes in beam positioning, differences between patient skin location and the IRP, or collimation. The diagram of Figure 29 demonstrates a few of these points. Nevertheless use of this cumulative dose to monitor radiation risk to the patient can be very beneficial because it forewarns a physician when cumulative doses are reaching levels of concern. Some considerations on use are given in Table 5.

On older equipment that has not been equipped with a real-time dose monitor, other options are available. One company offers an add-on computerized dose monitoring system that monitors cumulative dose at a reference point much like the dose at the IRP. It must be installed by the company.

A self processing film-like monitor is very easy to use and measures in real-time the peak skin dose to a patient. An example is provided in Figure 30. The "film" is simply placed on the fluoroscopy table under the

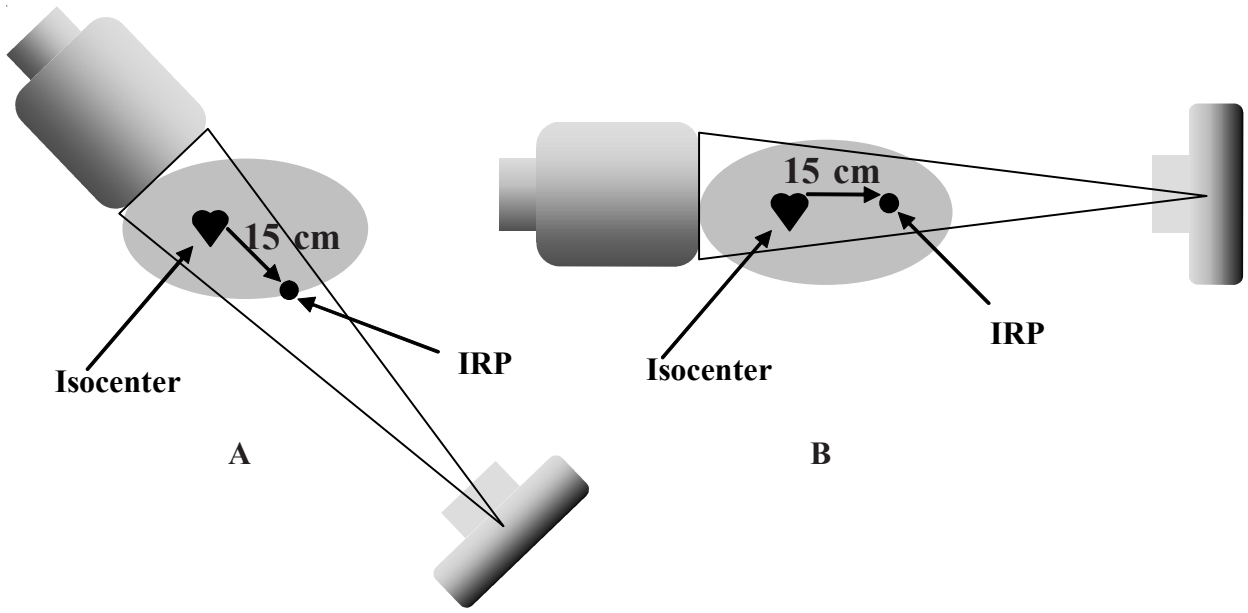

Fig. 29. The IRP is the interventional reference point which is fixed at 15 cm from isocenter in the direction of the x-ray tube, regardless of beam orientation. Sometimes the IRP is at the skin surface as in A. In other orientations it might be inside the patient, as in B. With still other orientations and patient sizes, it might outside the patient.

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Table 5. Examples of use of air kerma at IRP in dose management for the patient

Air kerma at the IRP (Gy_a)	Action
2	Advise physician that IRP air kerma is 2 Gy_a so that he/she can assess the benefit/risk pace of the procedure.
4	Advise physician that IRP air kerma is 4 Gy_a and that the threshold for erythema might have been reached, depending on how the beam is oriented and how often it has been rotated. Consider moving the projected view to a different skin site.
6	Advise physician that IRP air kerma is 6 Gy_a and that the threshold for moderate to severe skin effects might have been reached, depending on how the beam is oriented and how often it has been rotated. Consider moving the projected view to a different skin site.
8	Advise physician that IRP air kerma is 8 Gy_a and that beyond this point there is a potential for severe skin effects, depending on how the beam is oriented and how often it has been rotated. Benefit-risk depends on how critical the patient's condition is.

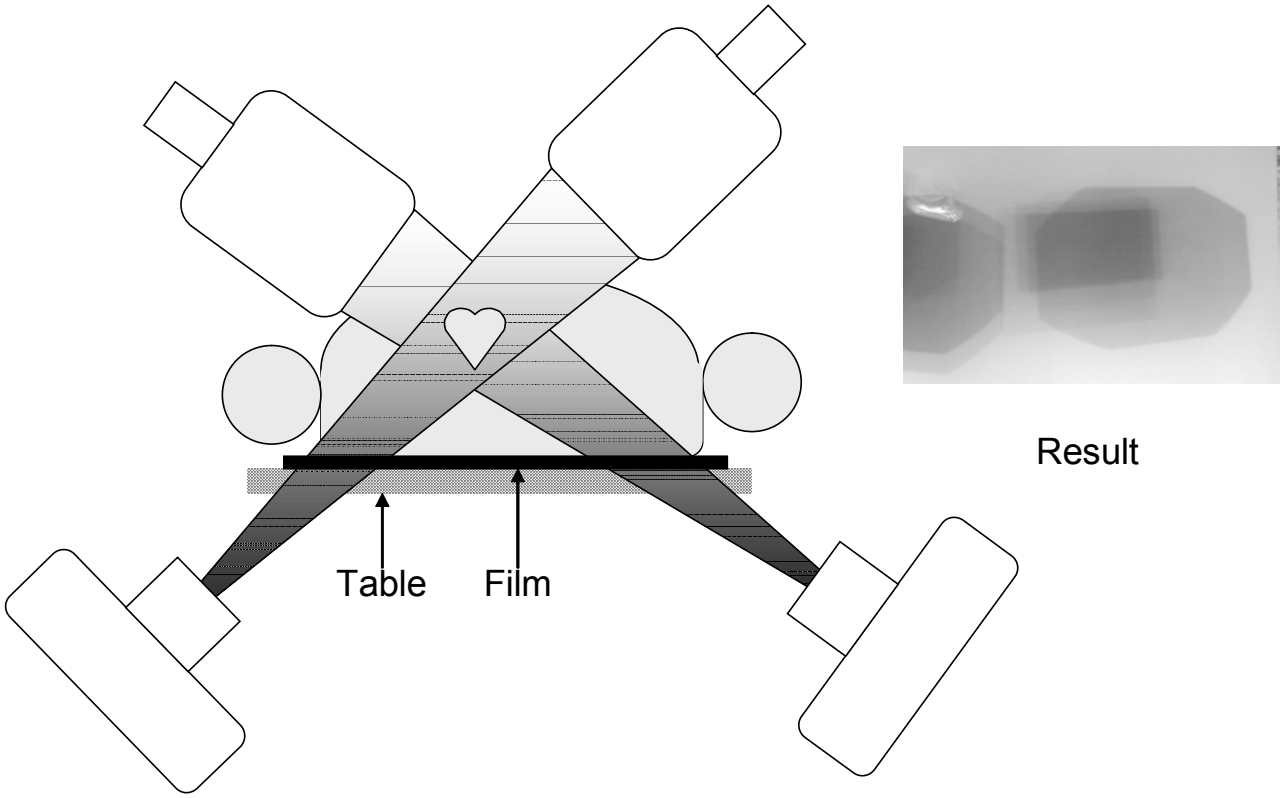

Fig. 30. Use of special dosimetry "film" to monitor skin dose in patients. The example shown is a biplane procedure. The film is placed flat on the table at the level where the beam will enter the patient. We find it helpful to place the film inside an envelope or plastic bag to protect it from fluids. The film self-develops as x rays strike it. The inset shows the result of such an examination. Note the different shapes of the fields, demonstrating changes in collimation and beam angle during the procedure. Note also the different darkness levels, indicating differences in skin dose with different locations. The field on the left was off the edge of the film, but it still provides useful data.

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patient where the beam will be directed and it turns darker as dose increases (International Specialty Products, New Jersey). The "film" is not visible in the x-ray image. If a procedure becomes unusually extended, the "film" can be removed to see if the dose is reaching critical levels. If necessary, the degree of film darkening can be compared to a pre-exposed calibration film to assess the actual skin dose in Gray.

In special circumstances a DAP meter can be used to assist in skin-dose evaluation, but this requires some special considerations (see Fig.4).

Use of any one of these devices is likely to require some assistance by a knowledgeable individual, such as a medical physicist. Some will require more assistance than others.

Dose monitoring for pregnant patients

Sometimes, it is necessary to perform a fluoroscopic examination on a pregnant patient. In these unusual circumstances it is helpful to monitor how much radiation the conceptus of the patient receives. To do so some facilities set aside a group of radiation "badges" for this and other purposes. Placing badges posteriorly and anteriorly on the patient at the level of the uterus is an effective way to monitor the radiation delivery. The monitors can be sent to the vendor's laboratory for emergency readout and the results obtained in about a week. Real-time personnel monitors might also be used for this purpose, but care must be exercised in their use. Some of these devices are specifically designed for very low dose rate use and will not read correctly if they are placed in the direct beam.

When to monitor

In addition to monitoring fluoroscopic on-time, we recommend that physicians consider radiation dose monitoring as follows:

- for any procedure that may utilize more than 20 minutes of fluoroscopy;
- for any procedure that potentially involves irradiation of the torso of a pregnant patient;
- periodically to assure that radiation doses are within acceptable norms;
- for training purposes.

Concise summary #9: Radiation delivery to the patient may be monitored in a variety of ways. Select a method compatible with the manner in which radiation is used, maintain a quality control program to review unusual events. Modify procedures as necessary.

Quiz #9: Cite at least three ways to monitor radiation dose to patients and discuss their relevance with regard to patient care. (See Appendix for answers.)

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Commandment #10: Commensurate with their duties, be sure personnel have mastered radiation safety and management.

#10. Mastery of Radiation Safety

While the principal source of radiation for the patient is the x-ray tube, the principal source for the operator and other personnel is scatter from the patient. A secondary source is the leakage of some x rays through the shielding of the x-ray tube. Leakage is usually much less of a concern than scatter from the patient.

As soon as the x-ray switch or pedal is disengaged, x rays cease to exist in the room and the patient is no longer a source of scatter radiation. The operator has full control over x-ray production. While the x rays are on, the most important means by which physicians can reduce dose to themselves and personnel is by using shielding and by properly positioning personnel relative to the patient and the fluoroscopic equipment. Monitoring radiation exposure to personnel provides the means to measure the effectiveness of shielding and positioning.

Protective aprons

All personnel who are not positioned behind a radiation barrier must wear a protective apron during procedures. We recommend that this apron have shielding characteristics equivalent to that of 0.5 mm of lead which will shield the protected areas of the operator from approximately 90% of the scattered radiation. The lead equivalencies are usually printed on a tag located on the apron. The apron should fit well, covering the torso from the shoulders to at least the mid-thigh level and around the sides. The apron should fit snugly around the sides of the upper chest, especially in women to ensure protection of the breasts. For C-arm fluoroscopy, a wraparound apron can be effective in reducing exposure to the posterior. The backside of the apron should use lighter lead, at least 0.2-mm equivalent. Lead aprons should be properly stored on a hanger and handled with care because the protective lining can be damaged and this may compromise their shielding characteristics. Aprons should be checked at least annually for holes, cracks or other forms of deterioration.

Radiation monitoring for personnel

Unless protected by a radiation barrier, personnel who perform fluoroscopic procedures are usually required to wear a personal radiation-monitoring device, typically a badge containing a stimulable luminescent dosimeter. The purpose is to ensure that radiation exposure is properly managed. We recommend that personnel wear these monitors anteriorly on their collars outside the lead apron to measure the dose to the unprotected head and neck. If this dose is kept within our guidelines, the dose under the apron will be very low and very acceptable. If the monitor is worn under the apron, dose to the head and neck will be unknown. This is unacceptable. (See vignette #3.) Badge readings should be reviewed by personnel with the radiation safety officer. Table 6 provides our recommendations for actions associated with monthly readings on collar badges. These recommendations are more con-

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Radiation mis-monitoring – true vignette #3

One of the authors received an inquiry from an individual who wanted to know if 200 mSv, accumulated over 20 years of work in a cardiac catheterization laboratory, was a large amount of radiation. Upon further discussion, it was learned that this was the dose reported on a cardiologist's radiation badge. He only wore the badge some of the time and it was usually worn under the lead apron (contrary to advice in commandment #10). The true radiation exposure was therefore unknown, but could have been hundreds of times higher to his face and head. As the conversation continued, the author learned that the middle-aged physician had brain cancer. The ultimate question was whether the radiation exposure received over twenty years could have caused the cancer.

While radiation has been weakly associated with cancers of the central nervous system (primarily in children), there can be no definitive answer to the caller's question. What is known is that there was poor radiation management for twenty years. Had the physician been properly monitoring his radiation exposure, he would have known the conditions of the working environment and corrective action could have been initiated early on. Because of the unknown etiology, it cannot be asserted that this would have prevented the cancer, but radiation as a likely agent would have been essentially eliminated.

Table 6. Recommended actions for monthly collar badge readings

Typical monthly reading in mSv (mrem)	Recommended actions
<1.0 mSv (< 100 mrem)	**No actions** recommended, continue safe practices.
1.0 – 4.0 mSv (100 – 400 mrem)	**Evaluate** work habits to reduce dose if possible, **consider** using extra shielding.
> 4.0 mSv (> 400 mrem)	**Investigate** causes, **evaluate** work habits, **add** shielding and **implement** other dose reducing actions.

servative than regulatory limits and represent what the authors feel are reasonably achievable goals.

Real-time monitors, that produce an audible signal to inform the wearer about elevated exposure rates, are available. These devices warn physicians when their working habits result in exposures that require precautionary action. They also serve as an effective training tool for beginners. Physicians who perform two or more procedures a day may find them of considerable benefit for encouraging good working habits.

Using distance as a shield

The distribution of stray radiation in a procedure room during lateral fluoroscopy is illustrated in Fig. 31 (42). Note that the scatter is higher on the side where the beam enters the patient. This same distribution of scatter tends to follow the x-ray system as it is rotated

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around the patient, i.e., the scatter is highest where the beam enters and lowest on the opposite side.

Increasing the distance of personnel from sources of radiation can markedly reduce their radiation dose. The rule that relates distance with dose reduction is known as the **"inverse-square law"**. This "law" says that dose rate drops precipitously as distance from the radiation source (e.g., the patient) increases. Specifically, the dose rate decreases by the inverse square of the relative increase in distance. For example, the rate at 2 meters is 1/4th that at 1 meter. At 3 meters it's 1/9th that at 1 meter. In Figure 31 the relative kerma decreases from a value of 4.0 next to the patient on the x-ray tube side to a value of 1.0 when distance from the patient is doubled. *Physicians should develop a habit of taking one step back from the irradiated area before they engage fluoroscopy.* This will markedly reduce their overall exposure, particularly that to their head, arms, hands, neck and legs.

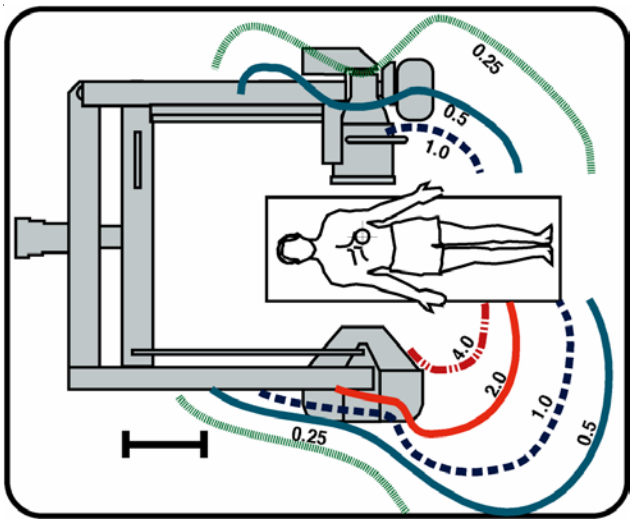

Fig. 31. Distribution of stray radiation around a laterally positioned fluoroscope. Relative air kerma levels are shown for 150 cm (~5') above the floor or roughly at head level. The distance bar at the bottom left represents a 0.5 m scale. (Reproduced with permission from: Balter S. Stray radiation in the cardiac catheterization laboratory. In: Nickoloff EL, Strauss KJ. Categorical Course in Diagnostic Radiology Physics: Cardiac Catheterization Imaging, Radiological Society of North America, 1998, 222-230.)

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Leaded eye wear, thyroid shields, and upper body shields

Leaded eye wear and **thyroid shields** are recommended if monthly collar badge readings exceed 4 mSv (400 mrem). While their use is generally optional, they are effective at all dose levels and will prevent large lifetime accumulations to the thyroid and eyes. Protective eye wear may be the apparatus most likely to be required for regulatory compliance in a high-dose environment. Recent evidence indicates that subtle changes in the optical lens might be induced at doses lower than originally thought. The effects of these changes on vision are as yet unknown. Eye protection should therefore be considered, especially by high-use individuals. *To be effective, eye wear must be equipped with side shields to reduce dose from the lateral direction.* Leaded goggles will also serve as a protective splash shield.

Upper body shields (Fig. 32) are transparent shields that are usually suspended from the ceiling. They protect the entire face, neck, part of the upper torso and are designed to be easily accessible in the fluoroscopic environment. Figure 3 demonstrates the use of another form of ceiling-suspended shield (McMahon Medical, Inc., San Diego, CA). This shield is contoured so that it can be positioned around the torso of a patient between the irradiated anatomy and the operator. This effectively stops the bulk of the scattered x rays as they leave the patient. For mobile or fixed room fluoroscopy, shoulder mounted face shields will have the same protective value if they are available. Otherwise the combination of protective eye wear and a thyroid shield may be used to protect the head and neck.

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Mobile and lower body barriers

Flat panel mobile shields (Fig. 32) are very effective whole- or partial-body shields. Usually they are designed as stand-alone roll-away shields or as shields mounted at the side of the patient table. They must be placed between personnel and the source of radiation, i.e., the irradiated area of the patient and the x-ray tube. They are recommended for the operator and all ancillary personnel who must be in the room but who are not performing patient-side work.

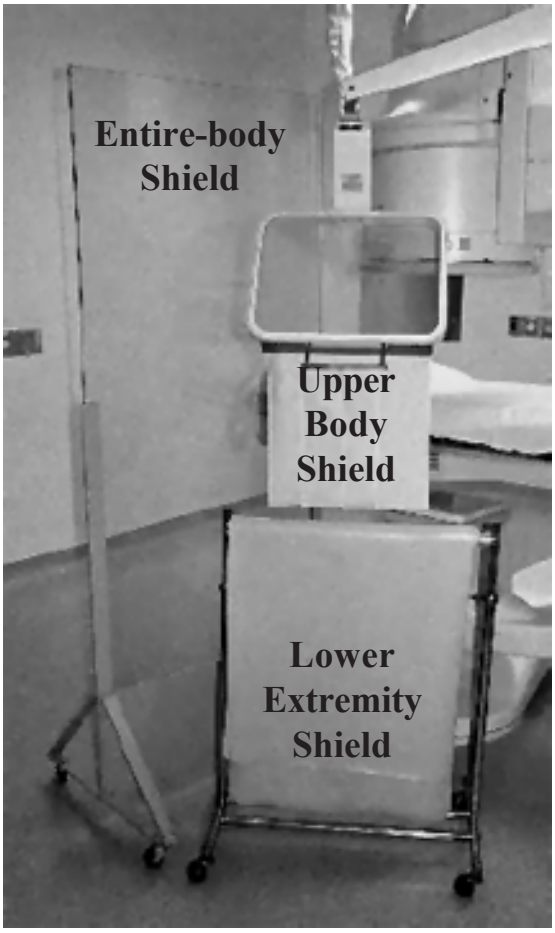

Figure 32. Variety of shields for protection during fluoroscopy. Suspended from the ceiling is a shield for the head and neck area. The tall standup shield is used for whole body protection and the shorter shield protects the legs from radiation scattered under the table from the patient.

Physicians or assistants located at tableside may accumulate large radiation doses to their legs if they spend long hours performing fluoroscopy. This is because the x-ray tube is usually below the table and backscatter off the patient is most intense under the table. Lower-extremity shields (Figs. 3 & 32) can be used to shield the legs and feet of operators (see Fig. 3 for a lower-extremity shield mounted at tableside).

Hand protection

We personally have observed dermal atrophy of the forearm and hands in one physician and radiation dermatitis in the hands of two other physicians who performed fluoroscopy for several years. These effects occurred in the mid-1990's. Radiation dermatitis in physicians' hands is demonstrated in Fig 2a.

General concern over radiation exposure has convinced some physicians to wear special **hand shields** or sterile **x-ray attenuating surgical gloves**. The gloves are thin to provide tactility and they come in sterile packaging. Hand shields are thicker protective covers that do not interfere with finger movement. ***However, physicians should be warned that such devices are not likely to protect hands if placed fully into the beam.*** When placed fully in the x-ray field, gloves and shields add to the attenuation of the beam. This reduces image brightness. On most fluoroscopes the automatic brightness control (ABC) detects this and radiation output is increased to penetrate the "protective" gear. The net result is no significant reduction in hand exposure and increased patient exposure. The gloves themselves also tend to produce a large amount of scatter radiation that is not seen in the image but which does irradiate the hand. For these reasons**, *physicians must not be lured into a false sense of security and mistakenly rely on gloves as their principal means of protection during fluoroscopy*.**

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Protective hand gear can be relied on only to protect against radiation outside the field of view of the ABC. Some gloves reduce the scattered radiation to the hands by about 35%, others by much less. To protect hands during fluoroscopy, we recommend the following:

1. K*eep hands out of the beam as much as possible.* If the image of your fingers or hands appears on the monitor, they are being directly exposed. *Hands should be pulled back from the imaged area and away from the image intensifier unless physical control of invasive devices is required for patient care during fluoroscopy.* Use remote handling devices when possible, such as forceps or other specially designed instruments.

2. *Work on the exit-beam side of the patient whenever possible.* **For an adult abdomen, exit radiation is only about 1% the intensity of the entrance radiation.** For vertical projections the x-ray tube should be below the table. For oblique and lateral beams, it is best to stand on the side of the patient where the image intensifier is located. If proper collimation is always employed, working on the exit-beam side near the image intensifier ensures that the exposure to your hands is from exit radiation only. One simple way to assure that the beam is properly confined within the boundaries of the image receptor is to make sure the shadows of the edges of the collimator blades are visible in the image.

Figure 33. The ring badge for monitoring dose to the hands. The white sensitive area is turned inward on the hand to measure exposure from the beam that is directed upward from beneath the patient.

For some procedures the logistics of positioning the x-ray machine, sterile trays, and medical personnel dictate that the physician must work on the x-ray tube side of the patient. Extra care must be exercised in this situation to ensure that hands are only rarely, if ever, exposed to the direct beam. *While the occasional exposure to the hands will not result in any noticeable effect, repeated exposures with this geometry can quickly elevate dose to the hands beyond recommended limits*. [See practical application 2 under commandment #8.]

Table 7. Recommended actions following monthly hand-dose monitoring.

Monthly ring dose	Action	Continue monitoring?
< 3 mSv	Dose sufficiently low to discontinue monitoring.	Discontinue for now; repeat in one year.
3 mSv - 10 mSv (300 mrem - 1 rem)	Efforts to reduce dose are recommended.	Yes.
> 10 mSv (1 rem)	Immediately adjust habits to reduce dose.	Yes.

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3. *Wear a ring badge to measure your hand exposure* (see Fig. 33). This should be done monthly for a period of several months. The ring detects radiation only at the base of the finger. Dose at the fingertips may be significantly higher. The ring should be worn on the dominant hand on the finger closest to the beam. This is usually the middle or the index finger, but wearing it on the ring finger might be more comfortable. The sensitive badge area should be turned to face the oncoming beam (see Fig. 33). Refer to Table 7 for guidance on monitoring. These recommendations are designed to assure that dose to the hands remains within the commonly recommended maximum annual limit of 500 mSv. Ring dosimeters can be sterilized if necessary (contact the supplier for recommended methods).

Equipment design safety features

Conventional GI fluoroscopy

For fluoroscopy of the gastrointestinal tract, the equipment is usually designed with the x-ray tube permanently mounted underneath a fixed table and the image intensifier positioned over the patient. The sides of the table contain shielding and the units are equipped with leaded drapes at the side of the image intensifier that absorb radiation scattered at right angles from the patient. The image intensifier itself is shielded to provide an extra measure of protection from x rays that scatter inside the image intensifier. At the side of the table and below the tabletop, there is an open slot that permits free movement of the cassette tray. A shielded flap or hinged bar should cover this slot during fluoroscopy. *This entire configuration is chosen in order to optimize radiation protection to personnel in the room*.

The leaded drapes are designed as separate strips so that a physician can insert his or her hands to perform a procedure without removing the drapes. The physician should very rarely, if ever, fluoroscope with hands in the beam. If the drapes are an impediment to the proper completion of a procedure, then they can be removed, but they must be replaced for use in other procedures.

All personnel not immediately involved with patient care, should step back a suitable distance from the patient, wear lead aprons, or step behind a radiation shield.

Remote control fluoroscopy

In some forms of remote control fluoroscopy the x-ray tube is positioned above the patient with the image intensifier under the table. In this situation the radiation reflected off the patient is at a high intensity and it is not appropriate for physicians to perform in-room procedures with these machines unless some extra special precautions are taken for the operator and other personnel in the room. In general, *these devices are designed for remote control use where the operator and all assistants will position themselves in a shielded booth while remotely manipulating the machine for acquisition of the images.* No protective aprons need be worn in this setting. *Fluoroscopy should never be performed in-room on a remote control unit unless there is special consultation with the radiation safety office.* [Radiation–induced cataracts have been reported in individuals who performed in-room fluoroscopy with these types of machines without using special precautions (29).] As always, it is recommended that fluoroscopists and technologists wear radiation badges whenever x-ray-producing devices are used.

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C-arm fluoroscopy

In C-arm fluoroscopy there are no shielded drapes, no shielded table, and the examinations are usually performed in the room, not remotely. ***In these configurations it is very important that the operator pay attention to radiation management practices specific to these devices.***

With the C-arm oriented vertically, the x-ray tube should be located beneath the patient and the image intensifier above. This configuration makes use of the patient as a shield to reduce radiation exposures to personnel, especially to the physician's hands if they are in the beam.

When using lateral and oblique projections, radiation levels are least intense on the exit beam side (image intensifier side) of the patient. Figure 31 illustrates how stray radiation levels are distributed around a lateral C-arm. For example, in the lateral orientation scatter is frequently about four times greater on the x-ray tube side than on the image intensifier side. This ratio may be more or less depending on the size of the patient and section of the body irradiated. Therefore, for the purposes of radiation protection, standing on the image intensifier side of the patient is the best choice. (This assumes the x-ray tube is appropriately aligned with the image intensifier and that collimation is properly employed. This alignment of the fluoroscope should be checked at least annually. As a simple real-time assurance of this requirement, the edges of the collimators should be adjusted so that they are seen on the monitor.)

If assistants to the procedure must be positioned on the x-ray tube side, they should be provided with extra shielding, such as a mobile barrier or head shield. *All individuals who are in the procedure room and who are not behind a shielded barrier must wear a radiation monitoring device (e.g., a radiation "badge") and a protective apron (we recommend an apron of 0.5 mm lead-equivalency).* Personnel not immediately involved in the procedure should position themselves behind a radiation shield or maximize their distance from the patient while wearing a lead apron.

In many situations the physician is required to work on the x-ray tube side. For example, cardiologists often stand next to a laterally projecting x-ray tube located on the right side of the patient. The left arm and left side of the cardiologist's body are closest to the irradiated area of the patient and can accumulate a high radiation exposure over time. *If it is necessary to stand on the x-ray tube side, physicians and other assistants should wear lead aprons that cover their exposed side.* ***We also strongly recommend ceiling suspended radiation shields to reduce exposure to the head and neck*** (see vignette #2 and Fig. 3). To best monitor radiation exposure, radiation badges should be worn outside the apron on the left side of the collar or attached to the left side of the thyroid shield. Face shields, thyroid collars, and/or protective eye wear may also be of benefit. When the tube is located obliquely on the physician side under the table, a large amount of radiation can be scattered toward the legs. Stepping away from the patient during fluoroscopy or using leg shields is recommended for those fluoroscopists who perform numerous procedures in this configuration. (Minor skin changes in the legs of some cardiologists and radiologists, such as hair loss and slight increases in pigmentation, have been personally communicated to the authors.)

Invasive devices and doses to patient and staff

Fluoroscopy with x-ray tube under table

Fluoroscopy at the area of the patient, where medical devices are inserted, poses a particularly difficult problem for radiation management. This is demonstrated in Figs. 34A and 34B. Figure 34A, with the

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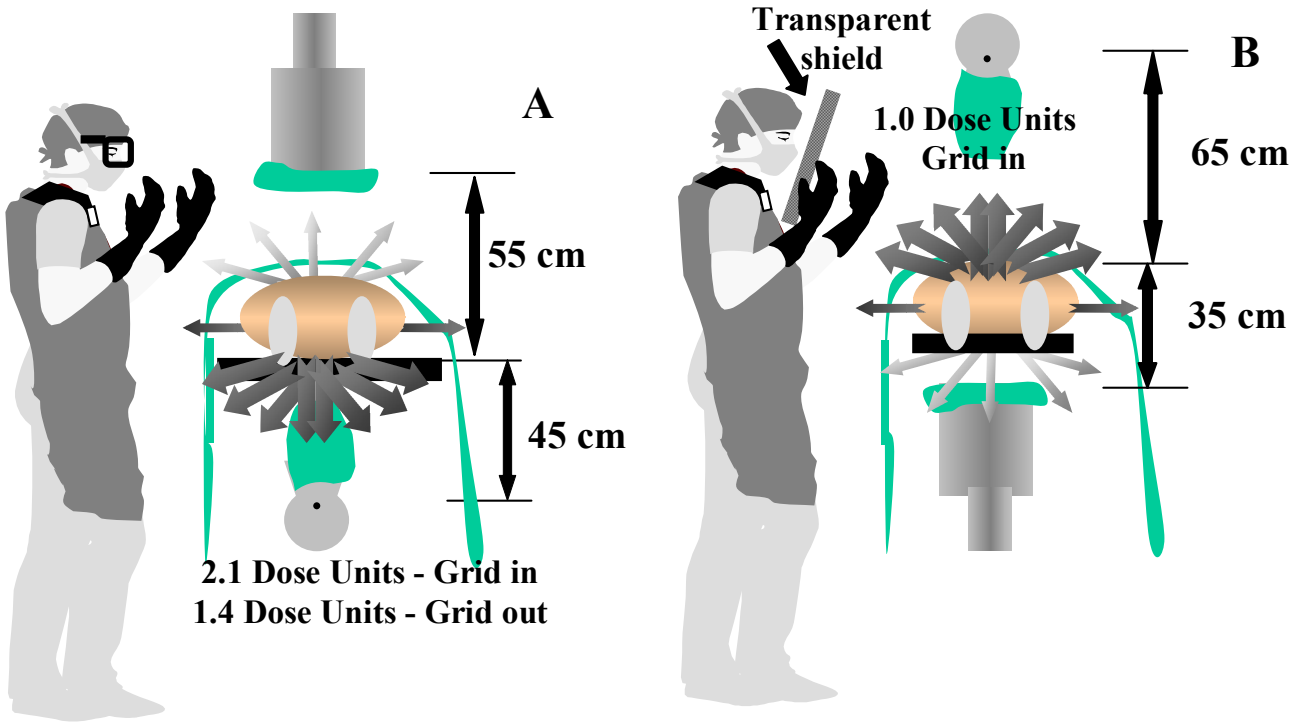

Fig. 34. Comparison of under-table and overhead geometries. Although dose to the patient is lowest with the x-ray tube above the patient as in B, doses to personnel are lowest with the x-ray tube below the patient as in A. Configuration A is generally recommended.

x-ray tube under the patient, is the configuration preferred for the protection of personnel. In this configuration the patient is a shield to the face and hands of personnel, protecting them from the more intense x-ray field that enters the patient. However, because a large gap is required between the patient and the image intensifier, the entrance skin dose to the patient is not ideally managed. This is because the x-ray source is closer to the patient than in the ideal case and the image intensifier is away from the patient. When procedures are unusually long or exposure rates unusually high, the risk for a skin injury is higher than that with ideal geometry. However, the grid is unnecessary because the function of the grid is effectively achieved by the air gap. If the grid can be removed, this may help mitigate patient dose without undo loss in image quality, particularly if tight collimation is used.

Due to the large amount of scatter under the table, using leg shields or stepping away from the patient during fluoroscopy is recommended for fluoroscopists who perform most of their work in this configuration. Removal of the grid will also help prevent excessive irradiation from under-table scatter by simply reducing the input dose rate to the patient.

Fluoroscopy with x-ray tube over table

The configuration in Fig. 34B (tube over table) is preferred by some because the physician can easily create a large working space between the patient and the x-ray tube. Note that the image intensifier is close to the patient and the grid is in place. While this geometry has the potential advantage of minimizing the dose to the skin of the patient, it is decidedly more difficult to manage exposure to personnel. *The hands of personnel who attend the patient may be exposed to the full intensity of the direct beam* (see vignette #1). *This configuration also exposes the head of the operator to the most intense scatter from the patient.* We have personally observed monthly exposures to the face and hands of a few tens of mil-

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Radiation management upside down – true vignette #4

Upon reviewing reports of radiation badge monitoring for their facility, the Radiation Safety Officer (RSO) noted that the film badge readings of several fluoroscopy staff were consistently high. However, the pain-management physician had minimal readings. This peculiar finding prompted an investigation.

The practitioner, it turns out, never wore his radiation badge (contrary to advice in commandment #10), which explained his low readings. When asked about his use of the fluoroscope, he proudly demonstrated that he always kept the x-ray tube under the patient and as far away as possible. He also trained other physicians to use this setup. Unfortunately, the physician had confused the image intensifier with the x-ray tube and, in fact, had been keeping the x-ray tube above the patient and too close to the patient, all contrary to commandments # 4 and 5. A close look at the physician's hands revealed chaffing, discoloration and epilation, clear signs of radiation dermatitis from inappropriate use.

When the RSO asked the physician and staff to demonstrate the use of the collimators, a series of blank stares ensued. No one knew that the unit even had a collimating system, contrary to commandment #8.

In addition to this, the RSO had noted that the low dose rate options on the unit had had their buttons taped over in such a way as to render them unusable, contrary to commandment #2.

This vignette demonstrates well that the use of the fluoroscope in unqualified hands can lead to health consequences.

Radiation management that works – true vignette #5

A physician, who was involved in a heavy workload of pain management, was concerned about her personal radiation-badge readings, which were about 10 – 20 mSv per month. The badge was worn at the collar outside the lead apron and represented the dose to her head and neck. In order to improve radiation management, her fluoroscopic habits were analyzed. The physician was orienting the fluoroscope correctly with the source under the patient, but she was unaware that she could employ a lower dose rate mode (see commandment #2). Upon reduction of the dose rate, the physician noted that the images were of a lesser quality but were perfectly adequate for patient care. In addition, the physician found that it was possible to step back from the patient before engaging fluoroscopy, without jeopardizing patient safety (commandment #10). With these two changes the monthly radiation-badge readings dropped to 0.2 – 0.5 mSv/month. Her diligence at wearing her radiation monitor caught the problem early in her career, saving her a lifetime of high-dose exposures.

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lisieverts (a few rems) for physicians who use this geometry. *Since this configuration may result in unacceptably high exposures, it is not recommended for routine use* (see Vignette #4). Radiation-induced cataracts have been reported in personnel who have used this configuration (29). We only recommend its use in special situations wherein it expedites the procedure, avoids excessive dose to the patient, and is performed under the supervision of expert radiation safety guidance (see, for example, our discussion on thoracic fluoroscopy in women). Radiation management precautions should include:

1. *Move the x-ray tube away from the skin as far as practicable (commandment # 4).*
2. *Move the image intensifier as close to the patient as practicable (commandment #5).*
3. *To protect the head and neck area, use a transparent shield with sterile covers, if necessary; or step back from the patient before engaging fluoroscopy.*
4. *Have assistants use extra shielding or stand well back from the patient (more than 2 meters is recommended).*
5. *Hands must routinely be pulled back from the field of view during fluoroscopy. Insertion of hands in the field should only be on those rare occasions when patient care critically depends on it. Monitor hand dose as described in Table 7.*
6. *Use collimation to control image quality and reduce scatter (commandment # 8). The collimator blades must be visible in the image and closed down to the appropriately small area.*
7. *Keep the beam-on time of the study as short as possible (commandment # 3).*

Pregnant personnel

Pregnant women may continue to work in fluoroscopic areas, but they should wear an extra radiation monitor at the level of the abdomen underneath the lead apron. This serves as a monitor for the dose to the conceptus. Some choose to change abdominal badges every two weeks to maintain a frequent update of the dose to the conceptus. Others prefer to change the badges on the normal monthly schedule. Monitoring at intervals greater than one month (e.g., quarterly) is not recommended. Some find special real-time personnel monitors useful. A record of the dose to the abdomen should be maintained to ensure that the dose is within recommended standards. The under-apron badge should not measure more than 0.5 mSv (50 mrem) in any one month. Remedial action should be taken if the reading is in excess of 0.3 mSv (30 mrem). [These should not be construed as dangerous levels, they are merely levels chosen to ensure compliance with recommended limits.] Some physicians choose to monitor before they become pregnant to correct potential problems before pregnancy.

A wraparound apron with 0.5-mm lead equivalent in front and about 0.2 mm in back is recommended. Special lead aprons with a 1-mm lead-equivalent patch over the pelvis have been used to provide extra protection for the conceptus or a small lap apron can be worn underneath the regular apron to provide the same effect.

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Concise summary #10: Proper use of protective equipment is essential to radiation management for personnel. Knowing how to position the fluoroscope around the patient and how to position oneself for minimum radiation dose is critical to minimizing one's long-term exposure to radiation. Special precautions are recommended for pregnant women.

Quiz #10: Cite the two most important rules for minimizing radiation dose to the operator's hands. Cite two ways, other than the use of protective gear, to minimize your overall exposure to radiation. (See Appendix for answers.)

Other Methods to Protect Patients

Patient management

Detailed medical records can be very effective in managing radiation exposures to patients who receive multiple studies or who may require radiation therapy later. For procedures that involve a lengthy amount of fluoroscopy (about 20 minutes or more) or a known high dose to the skin, a record carefully identifying the area of exposed skin will alert other physicians about the need to be attentive about limiting irradiation of the same area. A record of the estimated skin dose would also be helpful (see commandment #9). It is additionally advisable that patients who have prolonged procedures be followed about 2 – 3 weeks later for potential development of any skin changes, unless the dose was monitored and found to be less than about 3 Gy_t. Documentation of any delayed reactions will assist in future care and will provide information that alerts physicians of the need to pursue dose minimization in the future.

If a patient has a previous irradiation history from an intervention, then prior to any additional lengthy procedure the physician should examine the skin area to look for changes, such as telangiectases, epidermal thinning, dermal atrophy, or changes in pigmentation that are indicative of previous high exposures. Positioning the C-arm to a slightly different angulation might be a practical way to avoid overexposure of a specific area when procedures are prolonged. [Lichtenstein et al. (12) also suggest that the use of topical radioprotectors, such as leukotrienes and prostaglandins, might be considered when doses are high. These protectors must be applied before the procedure to be effective. However, there is no experience on their effectiveness in patients undergoing extended fluoroscopic procedures.]

Informed consent

For extended procedures where the fluoroscopic dose to the skin or eye is likely to exceed 2 Gy_t (more than about 30 minutes of standard fluoroscopy), the physician may wish to counsel the patient on the potential radiation effects as outlined in Table 3. (See FDA recommendations at the beginning of this monograph).

Diseases that render patients radiosensitive

Some diseases may render patients sensitive to radiation and they may be at greater risk for adverse reaction from high doses received from interventional

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procedures (4, 25, 26). These include patients with ataxia telangiectasia, connective tissue diseases (collagen vascular disease), and diabetes mellitus. Such patients should be counseled about potential adverse reactions in the case of high doses to the skin. One patient with mixed connective tissue disease and diabetes mellitus experienced severe dermal necrosis after a transjugular intrahepatic portosystemic shunt procedure (25). Other conditions, such as homozygousity for ataxia telangiectasia, are known to make individuals extremely sensitive to the adverse affects of ionizing radiation.

Pregnant patients

The possibility of pregnancy in any woman of childbearing age should be considered a potential contraindication to a fluoroscopic study of the abdomen or pelvis unless the situation is a life-threatening emergency (43, 44). Irradiation of the abdomen or pelvis of a potentially pregnant woman should be performed only after careful examination of the benefits and risks. If a patient of childbearing potential is thought to be pregnant or has not had a menstrual period within the previous 4 weeks, special consideration should be given prior to proceeding with a fluoro-

Table 8. Summary of commandments 1 – 10. How individual factors affect radiation management. (An ↑ means the factor increases, ↓ means the factor decreases.)

Operational Factors	Radiation Management Factors		
	Image Quality	**Radiation Skin Dose to Patient**	**Radiation Dose to Staff**
1.) Patient Size ↑	↓	↑	↑
2.) Dose rate controls ↑	↑	↑	↑
3.) Beam On-Time ↑	***No Change***	↑	↑
4.) Source-to-skin distance ↑	(Depends on magnification and image size)	↓	(Depends on how collimation is adjusted in response to change)
5.) Image Receptor to Skin Distance ↑	(Depends on magnification and image size)	↑	(↑ if SID ↑ or if collimators open wider, otherwise no significant change)
6.) Image Magnification ↑ (electronic or geometric)	(Usually ↑ but depends on focal spot size)	(Usually ↑ but depends on system design)	(Usually ↑ , but depends on system design and how collimation, kVp, and tube current respond.)
7.) Grid used	↑(for image receptor close to adult patient)	↑	↑
8.) Collimator Opening ↑	↓	(Skin dose is about the same but more tissue is exposed)	↑
9.) Monitoring patient dose ↑	***No Change***	↓(due to physician education)	↓(due to physician education)
10.) Personnel Safety ↑	***No Change***	***No Change***	↓

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scopic examination. For all procedures that involve extensive fluoroscopy of the pelvis, a pregnancy test is advisable unless there is no reproductive potential. Potential risks to a conceptus will depend on the gestation age and radiation dose. These potential risks (and the most vulnerable period) include radiation-induced loss of pregnancy (0-2 weeks postconception), small head size (2-15 weeks postconception), intellectual deficit and mental retardation (8-15 weeks postconception), and induced childhood cancer, particularly leukemia (entire gestation). A consult with a radiation effects expert should be sought before proceeding in such circumstances.

Many options are available to help optimize benefit and minimize risk. Critical developmental periods might be avoided, patient position might be changed to reduce dose, the examination might be otherwise modified, and the dose can be monitored.

Use of a lead-apron shield for the patient is likely to provide an indirect message to the patient that you are taking every measure to protect her child; but, in fact, shielding is not likely to be of much benefit. The lead apron must not be placed in the direct beam since the additional attenuation will only cause the ABC to increase radiation output in order to penetrate the shield. The shield will not protect much against scatter because scatter is generated inside the patient, not external to her. The best way to protect the conceptus is to use good collimation and keep the beam-on time as short as possible.

Shielding with a lead apron might help prevent the inadvertent direct irradiation of the conceptus by creating a radio-dense boundary that warns the physician of the proximity of the conceptus during panning of the fluoroscope. If shielding is used, ***it is important that the shield be positioned on the x-ray tube side of the patient*** under the pelvis but out of the way of the area to be fluoroscoped so that the beam is intercepted before it enters the patient. If placed on the image intensifier side, the conceptus will still be directly irradiated because the shield does not block the beam before it enters the patient. However, the image will give a false impression of protection because the shield will block the beam before it enters the image intensifier. Thus the image misleads the observer into believing the patient is protected.

Thoracic fluoroscopy in women

Breast cancer has been induced in women who had thoracic fluoroscopic evaluation for the treatment of tuberculosis (Fig. 1). Some of these women were positioned with their breasts facing the x-ray tube. This might occur with today's procedures if the x-ray C-arm is oriented for an oblique view through the thorax, perhaps to view the spine with the patient prone on the table. *This orientation of the x-ray c-arm and the patient may result in a situation where the breast is directly in front of the x-ray port. Outputs at the port can be very intense due to the close proximity to the source.* Intensities of more than 0.5 Gy_t per minute are possible, depending on the equipment and the size of the patient. There are a few considerations, compromises and actions to help the physician abate this breast exposure and the concomitant cancer risk. Consider any of the following:

1. *It may be reasonable to turn the c-arm over so that the x-ray tube is above the back of the prone patient* (Fig. 34B). The breast would receive only the much reduced exit dose. This violates the standard principles of good radiation management for personnel (Fig. 34A). However, this configuration is preferred to deliver less dose to the patient's breast. The precautions discussed under commandment #10 for this geometry should be followed.

2. *Position the beam so that the breast is not in direct line with the x rays or consider using support materials to move some of the breast*

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out of the direct beam. Remember to maximize the distance of the x-ray port from this area.

Dose management for prolonged procedures

Even though increases in dose rate may be relatively small due to one less-than-ideal application of a commandment, small changes in many of the dose-management techniques can result in a very large increase in dose rate. Fig. 35 shows the skin dose to a patient who undergoes a prolonged procedure for placement of an intrahepatic portosystemic shunt, using a fluoroscope from a major manufacturer. Each bar represents the dose under different fluoroscopic conditions. The patient was very large with a 280-mm thick abdomen (see commandment #1). The unusually long procedure required 90 minutes of fluoroscopy and 100 fluorographic images (DA and DSA). The "standard" technique employed pulsed fluoroscopy at 7.5 frames per second (see commandment #2), a magnification mode using a field-of-view of 280 mm (see commandment #6), negligible air gap between the patient and the image intensifier (see commandment #5), and a 700-mm source-to-skin distance (see commandment # 4). Skin dose from this "standard" procedure is demonstrated by the clear bar. The gray bars demonstrate the skin dose when only one of the operating factors is altered for the procedure. The new setting of the operating factor is listed under the bar. These doses are modestly increased over the "standard". The largest single-factor change in dose results from the use of continuous-beam fluoroscopy rather than the 7.5 frames per second pulsed mode. This change causes the dose to increase by a factor of 2.6. The black bar represents the dose when all the gray applications are simultaneously used in the procedure. The difference in the doses between the standard and the combined technique (black bar) is 8.8 Gy! The dose to the skin from the "standard" technique would not be expected to cause any serious skin effect. From the combined technique erythema and dermal atrophy are anticipated.

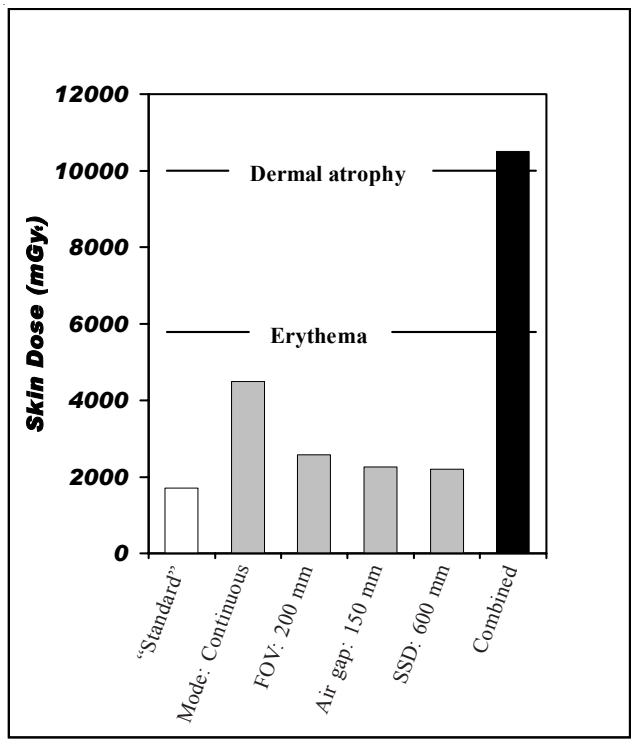

Fig. 35. Comparison of skin dose from prolonged fluoroscopic procedure using various operating parameters in a large patient (40). (See text.)
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The lessons of this exercise are twofold. First, *effective application of dose-reducing techniques as described in the commandments can result in very large savings in dose to the patient (as well as to personnel*). Second, the *application of dose-reducing pulsed-fluoroscopy results in a very large savings in dose to the patient and to personnel*. (Caution: as previously indicated, not all pulsed-fluoroscopy modes result in dose-savings. Consult with the manufacturer or a medical physicist if there are questions related to your equipment.)

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Regulations

All fluoroscopy equipment marketed in the United States must meet radiation control design specifications as mandated by the FDA. These include specifications on shielding, collimator function, source-to-skin distance, limits on x-ray intensities and many other features of design. These requirements have markedly reduced the potential for radiation injury from medical x-ray equipment. ***However, no regulation on design can guarantee safe use***. *Almost all fluoroscopic machines can expose patients to unacceptable and dangerous levels of radiation. Operator training in the safe use of radiation is essential for good medical practice.*

Once equipment is put into service at a medical facility, the radiation control department of each state is responsible for enforcement of regulations. Compliance is enforced by inspectors who perform surveys at facilities. Although regulations may vary from state to state, most states have some common rules. The reader is cautioned that some state laws may be stricter (or less strict) than those specified here.

1. Most regulations state that *no occupationally exposed person may receive an effective whole-body dose of more than 50 mSv per calendar year as a result of incidental exposure to radiation in the work place*. An annual dose of this level is exceptional and should not be considered routinely acceptable. We recommend that the annual effective (whole-body) dose not exceed 10 mSv (refer to Table 6 for our recommended monitoring guidance).

Your radiation badge measures the dose you receive. To ensure an accurate dose reading, badges should be changed monthly or bimonthly, depending on type of work. You should review your exposures periodically to ensure that they are within limits acceptable for your practice. The radiation safety officer (RSO) is required to inform you if your badge readings exceed regulatory limits. (Note: Your effective whole-body dose may not match your badge reading because of shielding afforded during fluoroscopy by your protective apron. The relationship between your badge reading and your whole-body effective dose can be explained by your RSO. This relationship may have a regulatory interpretation that differs from state to state.)

2. In normal practice the monthly exposure to the conceptus of a pregnant woman employee should not exceed 0.5 mSv. This can be verified with an abdominal monitor that is worn under the lead apron at belt level.

3. *There are no regulatory limits on the cumulative amount of radiation a patient may receive from diagnostic or interventional medical procedures*. The physician is the individual who has full control over and responsibility for this exposure.

4. *Members of the general public, excluding patients, are not permitted to receive more than 1 mSv of radiation per year as a result of incidental exposure to ambient radiation generated by the use of medical x-ray equipment.*

Moving Forward

The FDA has issued an advisory on the harmful effects of x rays to patients and has noted that some prolonged uses of fluoroscopy have resulted in radiation injury, ranging from erythema to dermal necrosis

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and worse. The advisory recommends that physicians be trained in the safe uses of x rays. This monograph was designed to help meet this goal. Your enforcement of the principles outlined in this document will be a major step in assuring the responsible medical use of x rays.

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Index

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