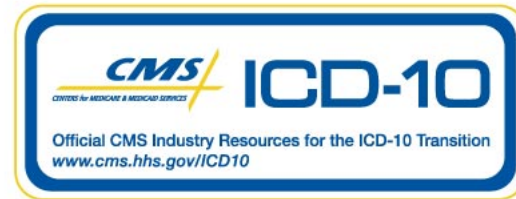


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Radiation Safety in the Practice of Cardiology

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Executive Summary

The medical use of radiation accounts for approximately 90% of the human-made radiation dose to which the U.S. population is exposed. Radiation exposure is a concern for those who participate in many aspects of cardiology practice. Invasive and interventional cardiologists have frequent exposure through fluoroscopy and cineangiography. Electrophysiologists rely heavily on fluoroscopy for procedures. Cardiologists and critical care specialists utilize fluoroscopy for placement of central catheters and temporary pacemakers. Nuclear cardiologists are exposed to radioactive materials. In addition to practitioners, cardiologists-in-training, nurses, laboratory technologists and support personnel are also exposed to radiation in the cardiac laboratory setting and through patients who have been injected with radioactive materials. As the responsible physicians, cardiologists are expected to be knowledgeable about radiation risks and optimal protective methods. They also bear the primary responsibility for the safety and education of cardiologists-in-training.

This document was developed to 1) summarize currently available information regarding risks of radiation exposure during the practice of a variety of cardiology procedures; 2) recommend techniques for reducing radiation exposure in cardiology laboratories in general; and 3) make recommendations for safely conducting procedures, in particular, during times conception is being planned or during pregnancy. The focus of this document is on the health care worker at risk for exposure to radiation during procedures in the catheterization, electrophysiology and nuclear cardiology laboratories. Radiation exposure to patients is not addressed.

Significant levels of radiation exposure pose serious health hazards to medical personnel if standard safety precautions are not taken. These hazards include cancer, cataracts, genetic risks and radiation risks to the fetus during pregnancy. The most important somatic risk of low dose ionizing radiation is cancer induction. While the risk to medical personnel associ-

ated with the acute radiation exposure per case in cardiology laboratories is not of sufficient magnitude to be a major concern, the cumulative risk associated with a lifetime of exposure could become significant, especially if appropriate precautions are not taken.

The advent of complex and prolonged coronary interventional procedures has further increased levels of radiation exposure, although proper procedures and experience can improve exposure rates per case. The use of digital imaging, although potentially capable of reducing radiation dose, requires additional constraints on input dosing, fluoroscopy and personnel exposure. The main differences between cardiac diagnostic and interventional procedures are the increased duration of the procedure and the altered ratio of fluoroscopic to cine time during cardiac intervention, generally resulting in increased duration of fluoroscopy. The estimated annual exposure for those who primarily perform electrophysiologic procedures is lower because of the reduced need for cineangiography and high intensity fluoroscopic imaging. Major concern about radiation exposure in the electrophysiology laboratory generally focuses on ablation procedures because they can require prolonged fluoroscopy time. Data on the occupational exposure of pediatric cardiologists are sparse but suggest that technical limitations in working with the smaller patient may adversely affect radiation exposure to physicians and the medical personnel who assist them. Reductions in exposure can be achieved through training.

Radiation safety concerns also exist for personnel in the nuclear cardiology laboratory, although risks can be minimized by complying with established safety practices. Brachytherapy, the local application of radioactive sources at the coronary endoluminal surface, is a novel and potentially efficacious modality of transcatheter therapy in patients with coronary disease. Should such therapies prove to be effective in large-scale clinical trials, considerable effort must be devoted to the training and credentialing in the use of these isotopes.

Medical personnel may be concerned about their exposure to radiation if they are not appropriately protected during pregnancy because of the risks of fetal death, malformations, growth retardation, congenital defects, mental retardation and cancer induction. Exposures within the recommended limits (0.5 rem per pregnancy, 0.05 rem/month of pregnancy) are not thought to impart a significant risk for the pregnant worker or her unborn child. A woman who chooses to continue working in the cardiology laboratories may do so when pregnant or planning conception as long as appropriate protection and monitoring practices are followed. However, if a pregnant worker chooses to limit her exposure during pregnancy, her decision should be supported without repercussions. Appropriate planning will permit the pregnant cardiologist-in-training to meet all procedural requirements, even if she limits exposure during pregnancy.

The ALARA principle, which emphasizes utilizing techniques and procedures to keep exposure to a level *as low as reasonably achievable*, should be followed to minimize the risk of radiation exposure to medical professionals. Personnel shielding options (e.g., two-piece wraparound aprons, thyroid shields and eye protection) should be used to effectively attenuate scatter X-ray levels. Two monitoring badges are recommended to be worn during X-ray exposure (one inside the lead apron at the waist level [which also serves as a "fetal" monitor for the pregnant worker] and one outside the lead apron at the collar). Angiographers, especially those who perform peripheral angiography, should consider the use of sterilizable ring badges to monitor hand exposure. Workers in the nuclear cardiology laboratory should wear a badge at the waist or chest level and also a ring badge when handling radioactive doses. When radiation badges or reviews of personal exposure history indicate that exposure exceeds recommended (or personally acceptable) limits, it is vital that critical reviews of equipment performance and laboratory and individual practices be conducted, in addition to a possible temporary reduction in the number of cases.

Given the large number of cardiac procedures involving radiation being performed in the United States by an increasing number of workers, the principles for reducing and monitoring radiation exposure should be known and followed by every practitioner, trainee and assistant in every laboratory. Many steps, as detailed in the tables in this article, can be taken to minimize radiation exposure to the worker in the cardiology laboratories. When properly applied, the combination of limiting radiation exposure and following optimal practices, which include appropriate equipment selection and use, maintaining distance from X-ray sources and using shielding, will prevent excessive exposure in every operator, regardless of caseload and complexity.

I. Preamble

The present document is an expert consensus. This type of document is intended to inform practitioners, payers and other interested parties of the opinion of the American College of

Cardiology (ACC) concerning evolving areas of clinical practice and/or technologies that are widely available or are new to the practice community. Topics chosen for coverage by Expert Consensus Documents are so designated because the evidence base and experience with the technology or clinical practice are not sufficiently well developed to be evaluated by the formal ACC/American Heart Association (AHA) Practice Guidelines process. Thus, the reader should view Expert Consensus Documents as the best attempt of the ACC to inform and guide clinical practice in areas where rigorous evidence is not yet available. Where feasible, Expert Consensus Documents will include indications and contraindications. Some topics covered by Expert Consensus Documents will be addressed subsequently by the ACC/AHA Practice Guidelines process.

II. Introduction

To date, there has been a lack of widely distributed recommendations to limit radiation exposure and its potential biological risks in cardiovascular practice. Hospitals may provide instruction and establish limitations for personal exposure, but less is provided for individuals considering conceiving a child or for women who are pregnant. Few training programs and hospitals have well developed policies regarding radiation risk and exposure recommendations, particularly for pregnant women. A survey of diagnostic radiology residency programs revealed that 87% of the 53% responding to the survey had a written policy regarding parental leave and radiation safety. Of those, 44% addressed the possibility of adjusting rotation schedules to avoid angiography and 42% to adjust fluoroscopy rotations during pregnancy (1).

In 1996, the ACC Ad Hoc Committee on Women in Cardiology conducted a Career Development and Professional Life Survey of all women and a sample of men in the ACC (ACC Professional Life Survey, 1996). Included in the questionnaire were the following questions:

- Have you altered your training or practice focus to reduce the risk of occupational radiation exposure? In what way?
- Women only—Have you performed procedures requiring fluoroscopy or angiography while pregnant?
- Women only—Where have you obtained information regarding risk of radiation exposure due to cardiac procedures during pregnancy?

Of 505 women respondents, 44% indicated they had altered their training or practice to reduce risk of radiation exposure, compared to 17% of 539 male respondents. Women indicated that they most frequently selected a career/training track with minimal radiation exposure (53%) while 50% planned conception/pregnancy during a time of nonradiation exposure and 4% chose not to have children (more than one answer could be selected). The most frequent references for information regarding radiation risks were medical texts or journals (33%), consulting a physicist knowledgeable about medical radiation (27%), consulting an obstetrician (18%) or consulting radiologists or cardiologists (15% each). Only 19% referred to

Table 1. Radiologic Quantities*

Radiation Quantity (conventional term)	Description of Quantity	Conventional Units (abbreviation)	SI Units (abbreviation)	Symbol	Equivalent Expressions—Relationship Between Quantities
Exposure	Amount of ionization per mass of air due to X and gamma rays	Roentgen (R)	coulombs/kg (C/kg)	X	$1R = 2.58 \times 10^{-4} \text{ C/kg}$
Absorbed dose	Amount of energy imparted by radiation per mass	Radiation absorbed dose (rad)	Gray (Gy)	D	1 rad = 100 erg/g 1 rad = 10 mGy 100 rad = 1 Gy 1 J/kg = 1 Gy
Kerma	Kinetic energy released per unit mass	Radiation absorbed dose (rad)	Gray (Gy)	K	$K(\text{mGy}) = 3.39 \times 10^{-4} \times X(\text{C/kg})$
Dose equivalent	A measure of radiation-specific biological damage in humans	rem	Sievert (Sv)	H	$H(\text{Sv}) = W_R \times D (\text{Gy})$ $H(\text{rem}) = QF \times D (\text{rad})$ 1 rem = 10 mSv 100 rem = 1 Sv
Effective dose equivalent	A measure of radiation- and organ system-specific damage in humans	rem	Sievert (Sv)	H _E	$H_E(\text{Sv}) = \sum W_T H_T(\text{Sv})$ $H_E(\text{rem}) \sim \sum W_T H_T(\text{rem})$
Activity	Amount of radioactivity expressed as the nuclear transformation rate	Curie (Ci)	Bequerel (Bq)	A	1 Ci = 3.7×10^{10} Bq 1 Bq = 1 s ⁻¹ (dps) 37 kBq = 1 μCi 37 MBq = 1 mCi 37 GBq = 1 Ci

*Data from Bushberg et al. (58). dps = disintegration per second; H_T = equivalent dose to organ or tissue; QF = quality factor; W_R = radiation weighting factor; W_T = tissue weighting factor; 1 erg = 10⁻⁷ joule.

hospital or training program policies and 29% never obtained any information (ACC Professional Life Survey, 1996).

Of the 87 men indicating they had altered their training or practice focus to reduce risk of radiation exposure, 47% indicated that they selected a career/training track with minimal radiation exposure and 15% planned conception during a time of nonradiation exposure (ACC Professional Life Survey, 1996).

Many young practitioners, particularly women, select a specific area of cardiology that limits radiation exposure in training and practice, based on what is likely an inadequate knowledge of actual risk (ACC Professional Life Survey, 1996). Whether talented individuals are choosing not to pursue any form of career in cardiology because of perceived risks due to radiation is not known. A summary of existing knowledge regarding personal and fetal risks would be valuable for trainees and program directors to enable individuals to make informed career decisions as well as to reduce risk during laboratory procedures. Therefore, the purpose of this document is 1) to summarize currently available information regarding risks of radiation exposure during the practice of a variety of cardiology procedures; 2) to recommend techniques for reducing radiation exposure in cardiology laboratories in general; and 3) to make recommendations for safely conducting procedures, in particular, during times conception is being planned or during pregnancy. Although there is often a direct relationship between reduction in radiation exposure to patients and reduction in exposure to workers, this document will focus on the health care worker at risk for exposure to radiation during procedures in the catheterization, electrophysiology and nuclear cardiology laboratories. This document will not address radiation exposure to patients.

III. Background

A. What Is Radiation?

Both ionizing and nonionizing radiation are used in medical practice; however, ionizing radiation is of primary concern to cardiologists because of its risk of producing biological injury. Ionizing radiation is any electromagnetic or particulate energy capable of producing ions by interaction with matter and includes X-rays from X-ray producing equipment and gamma rays from radioactive material. Whereas X-ray units only produce radiation when they are energized, radioactive material used in nuclear cardiology emits radiation continuously. Nonionizing radiation (which will not be discussed in this document) includes ultrasound, magnetic resonance imaging (MRI), and radiofrequency electromagnetic radiation, which in turn includes laser beams and microwaves.

B. Radiation Quantities and Units

The basic radiation quantities and units are summarized in Table 1. Throughout this document, units will be expressed in traditional units, followed by the International System of Units (SI) in parentheses.

Exposure is a measure of the amount of ionization produced in a unit mass of air and is proportional to the quantity of X or gamma photons incident upon the air mass. In traditional units, the roentgen (R) is the unit of exposure and is a defined amount of electric charge collected in a unit mass of air. The SI term for exposure is coulombs/kilogram:

$$1 R = 2.58 \times 10^{-4} \text{ coulombs/kilogram of air.}$$

The *absorbed energy per unit mass of material* is expressed as the rad (radiation absorbed dose) in traditional units or gray (Gy) in SI units.

$$1 \text{ rad} = 100 \text{ ergs/gram};$$

$$1 \text{ Gy} = 1 \text{ joule/kilogram} = 100 \text{ rad};$$

$$1 \text{ rad} = 0.01 \text{ Gy}.$$

The amount of energy absorbed by different materials for the same exposure of X or gamma radiation varies depending on the energy of the radiation and atomic number of the absorber. *Dose Equivalent* is the term used for purposes of radiation protection and expresses on a common scale the radiation effects from different types of radiation. Some types of radiation produce more biological damage per unit dose than other types of radiation. The Dose Equivalent is expressed as rem in traditional units and as sievert (Sv) in SI units. A rem (or sievert) is equal to a rad (or gray) multiplied by a quality factor (QF) and other modifying factors. Since the quality factor of X-rays and beta/gamma rays is 1, quantitatively, 1 rem = 1 rad, for the procedures involved in cardiology practice.

The *activity* of a radioactive substance is expressed as the number of nuclear disintegrations per unit time. The Curie (Ci) is the traditional unit of radioactivity, defined as 3.7×10^{10} nuclear disintegrations per second (dps). The Becquerel (Bq) is the SI unit of radioactivity and is defined as one disintegration per second (Table 1).

There are three main characteristics of radionuclide materials: 1) physical, biological and effective half-life; 2) level of energy, expressed in kiloelectron volt (keV); and 3) type of radiation emission, i.e., alpha, beta, gamma or positron. The *physical half-life* of a given radioisotope is defined as the time required for one-half of the original number of atoms in a sample to decay. Physical half-life is not affected by temperature, atmospheric pressure or chemical composition. The *biological half-life* is defined as the time required for the body to eliminate 50% of any administered radioactive dose through biological processes. *Effective half-life* is defined as the time required for the body to eliminate 50% of any administered radioactive dose through a combination of biological processes and physical radioactive decay. This parameter takes into consideration both the biologic elimination and the physical radioactive decay. It is the effective half-life that is used in dosimetry in nuclear cardiology. The level of energy emitted and type of emission are unique to each radionuclide. An overview of X-ray production is presented separately in Appendix I.

C. Regulatory Agencies and Advisory Groups

National and international groups of radiation scientists have reported the effects of radiation dose and made recommendations for limiting radiation exposure. The National Council on Radiation Protection and Measurement (NCRP) is the national advisory body whose recommendations are fol-

lowed in the United States. The International Commission for Radiological Protection (ICRP) is the international authority that has made recommendations on exposure limits (2). The U.S. Nuclear Regulatory Commission (NRC) is a federal agency that regulates the use and production of reactor by-product radioactive materials. NRC regulations often incorporate recommendations by the ICRP and/or the NCRP. The NRC publishes its radiation protection regulations in Title 10, Code of Federal Regulations as "Standards for Protection Against Radiation" (3). The Food and Drug Administration (FDA) regulates manufacturing of all medical X-ray equipment. Each state regulates the users of medical X-ray equipment. In some states (agreement states), the NRC has transferred its regulatory and licensing function to a state regulatory organization (see Appendix II).

IV. Personal Health Risks

Recognition of biological effects and risks from radiation exposure has ultimately resulted in the development of recommendations for limits of exposure and dose. The biological effects of radiation depend on the amount of energy absorbed by the cells and where in the cell the energy is absorbed. Biological effects are divided into deterministic and stochastic effects. *Deterministic effects* include the following: erythema, desquamation, cataracts, decreased white blood count, organ atrophy, fibrosis and sterility. The onset of any of these somatic effects depends on the absorbed dose, dose rate and the extent of the body area exposed. These effects have a dose threshold, and the intensity of the effect increases with increasing dose. *Stochastic effects* include cancer and genetic risk. With stochastic effects, the probability of biological effect increases with increasing dose, but the intensity of the effect is not a function of the absorbed dose. For example, a cancer produced by 100 rads is no worse than the same cancer induced by 10 rads (4).

Much of the information available on the effects of radiation exposure in humans is based on observations of the survivors of the Hiroshima and Nagasaki bombings at the end of World War II. For medical personnel who work in cardiac laboratories, the major concerns about radiation exposure are the potential risk of cancer, cataracts, genetic birth defects in offspring and damage to the fetus of a pregnant physician or staff member if the appropriate protective measures are not practiced.

A. Cancer

The most important somatic risk of low dose ionizing radiation is cancer induction (4). Recent extrapolations based on observations from Hiroshima and Nagasaki indicate that the risk of fatal cancer due to whole-body X-ray exposure is approximately 0.04% per rem (4% per Sv) for levels encountered in medical settings (5). Whether there is a lower threshold dose for the induction of cancer remains uncertain, but the BEIR V report recommended that safety guidelines should assume that a linear dose response occurs down to minute

Table 2. Ranges of Staff Radiation Effective Dose Equivalent in Cardiac Catheterization Laboratories*

Group	mSv/yr (range)	mrem/yr (range)
Physicians	2-60	200-6,000
Nurses	8-16	800-1,600
Technologists	2	200
Assistant technicians	0-2	0-200

*Data from reference 6. Group averages (in mSv/year) based on direct measurements with thermoluminescent dosimeters (TLDs) worn on the collar outside and above protective aprons. Traditional units (mrem/year) provided for consistency.

exposures (5). The Dose Equivalent to physicians and medical personnel averages less than 5 rem (50 mSv) per year as measured from a collar badge worn outside a lead apron (Table 2) (6). Since much of the body is shielded by the lead apron, a monitoring dosimeter worn outside lead shielding may overestimate the risk to the whole body by a factor of about 6. A Dose Equivalent of 5 rem (50 mSv) per year should be associated with a low incremental increase in risk (0.2% per year) compared to the lifetime risk of spontaneously occurring fatal cancer (estimated at 1 in 5 or 20% for the United States population) (7).

While the risk to medical personnel associated with the acute radiation exposure per case in catheterization laboratories is not of sufficient magnitude to be a major concern, the cumulative risk associated with a lifetime of exposure could become significant, especially if appropriate precautions are not taken. Table 3 summarizes the risk of developing fatal cancer with increasing lifetime radiation exposure (8). Assuming that the annual Dose Equivalent, measured by film badge, of a busy interventional cardiologist using a thyroid shield is 3 rem (30 mSv) per year, the cumulative occupational Dose Equivalent, measured outside a lead apron, would be in the range of 90 rem (900 mSv) over 30 years, which would be associated with a projected additional lifetime risk of developing cancer of about 3.6% [$90 \times 0.04\%$] in addition to the 20% estimated current risk of developing cancer in a lifetime. The estimated annual exposure for those who focus primarily on electrophysiologic procedures is lower, estimated to be less

Table 3. Estimated Probabilities for Developing Fatal Cancer From Lifetime Dose Equivalent*

Lifetime Dose Equivalent (rem)†	Fatal Cancer
0.1	0.004%
1.0	0.04%
10.0	0.4%
100.0	4.0%

*Data from Moore (8). †As measured outside lead shielding, without use of thyroid shielding; Note that the true dose equivalent may be overestimated by a factor of nearly 6. Values represent the risk expressed as percent; 1 rem = 10 mSv.

than 1 rem (10 mSv) per year, because of the reduced need for cineangiography and high intensity fluoroscopic imaging.

Cardiologists' hands receive the highest X-ray exposure during catheterization and electrophysiologic procedures because the hands are closest to the X-ray beam. Yet, hand exposures are frequently not monitored. Long-term "low" level radiation (i.e., of the order received in cardiology procedures) can pose a serious health risk, as has been demonstrated in the history of early radiation workers before radiation safety practices such as shielding and collimation were in use (9). The first cancers due to X-irradiation were skin cancer of the hand reported in physicians, dentists, physicists and X-ray technologists in the late 1890s and early 1900s. Most cases occurred after years of radiation dermatitis and a long latent period. Dentists who routinely held X-ray films in place in their patients' mouths were found to develop skin changes and cancers, many leading to amputation of the involved digits (4).

Physicians performing fluoroscopy and cine angiography should take precautions to protect their hands. Leaded latex gloves provide only limited shielding capability, attenuating only 20% to 30% of the X-ray beam. Use of leaded gloves may be counterproductive if the gloved hands are directly imaged, since the automatic dose rate control on most equipment will increase the intensity to compensate for the radiopaque image in the field, thereby increasing the dose. Therefore, training is the key to reducing and maintaining low exposures to the hands. If an operator's hands are visible on the TV monitor or the cine film, then practices should be altered.

B. Cataracts

Cataract formation is considered a deterministic effect of radiation exposure, i.e., its onset depends on the absorbed dose and rate of dose accumulation. If given in a single dose, the minimum amount associated with the development of a progressive cataract is about 200 rads (2 Gy) (4). Higher total doses can be tolerated when administered over longer time. Radiotherapy patients receiving 250 to 650 rads (2.5 to 6.5 Gy) in divided fractions have been reported to develop cataracts after an average latent period of eight years (4). On the other hand, cumulative exposures up to 750 rads (7.5 Gy) have resulted in no evidence of cataracts. A cardiologist adhering to the recommended Dose Equivalent to the lens of less than 15 rem/year (150 mSv/year) (10) may accumulate up to 450 rem (4.5 Sv) to the lens after working 30 years. Although there are limited data defining the actual risk of cataracts for cardiologists and workers in cardiology laboratories, the risk for radiation-induced cataract formation is likely to be small. Nonetheless, appropriate eye protection is warranted, including coverage to protect from splash exposure. Leaded eyeglasses may reduce the risk of future cataract development.

C. Radiation-Related Risks Before Conception—Genetic Risks

The natural incidence of spontaneous genetic mutation is estimated to be 6% in humans (11), but there is still uncer-

tainty about the quantitative additional effects of radiation. The only detected genetic impact on the offspring of survivors of the bombings of Hiroshima and Nagasaki was a slight change in the ratio of males to females (5). Because of the lack of definitive human data, estimates of potential genetic effects from radiation exposure on humans are extrapolated largely from experiments in mice. The analysis of experimental data in animals has led to the conclusion that while spontaneous mutations exist in nature, exposure to 100 rad (1 Gy) doubles the frequency of genetic mutations in humans (doubling dose) (5). This contrasts with data from survivors of the atomic bombs, which suggest that a value of 100 rad (1 Gy), equivalent to 100 rem of X-ray exposure, represents the lower 95% confidence limit for the human doubling dose (5). Assuming that appropriate shielding from lead aprons is employed, available data suggest that the annual gonadal Dose Equivalent of an invasive cardiologist is in the range of 70 to 160 mrem (0.7 to 1.6 mSv) per year (12). The risk of serious birth defects in the future offspring of irradiated parents is estimated to be 2×10^{-5} to 3×10^{-5} per rem (or per 10 mSv) (5,13). If one assumes a Dose Equivalent of 200 mrem (2 mSv) per year, the cumulative gonadal exposure over a period of 20 years would be 4 rem (40 mSv). It can be projected that the risk of serious birth defects would be 8×10^{-5} to 1.2×10^{-4} for 4 rem and 4×10^{-6} to 6×10^{-6} for 200 mrem (0.2 rem).

D. Radiation Risks During Pregnancy

Medical personnel may be concerned about their exposure to radiation if they are not appropriately protected during pregnancy because of the risks of fetal death, malformations, growth retardation, congenital defects, mental retardation and cancer induction. The estimated radiation dose to an adult that could potentially cause temporary or permanent sterility in that adult is approximately 500 rads (5 Gy). Embryonic death may occur at a dose of 10 to 50 rad (100 to 500 mGy) (14). These doses are far in excess of the gonadal radiation exposure normally received by properly shielded radiation workers (6) (Table 2). The maximum permitted dose for the fetus of a pregnant worker is 50 mrem (0.5 mSv) per month, or a total gestational Dose Equivalent of 500 mrem (5 mSv) (15). In practice, if one assumes a fetal exposure equivalent to waist level radiation Dose Equivalent of 3 mrem (0.030 mSv) per week measured under a 0.5-mm lead apron, the total gestational exposure would be about 120 mrem (1.2 mSv) for 40 weeks of gestation. According to the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), the risk of a congenital malformation, or of developing a malignancy after irradiation in utero, with doses of the order of 1 rem over the course of gestation is estimated at 1 in 500 (0.2%) (16). The corresponding risk for in utero exposure to 120 mrem (1.2 mSv) of X-radiation would be 1 in 4,166 (0.024%). Although case-control studies suggested an increase in childhood malignancies in children exposed to prenatal radiation (17), none of the cohort studies confirm these findings (6).

Fetal exposure to high doses of radiation can also potentially cause mental retardation. In Japanese survivors of the atomic bomb, the prevalence of marked mental retardation was highest in those irradiated between weeks 8 and 15 gestational age (5), corresponding to the time the fetal central nervous system is developing. The magnitude of this risk is approximately 1 chance in 25 (4%) per 10 rem (100 mSv) (5), but it remains unclear whether there is a threshold dose. The risk for mental retardation at the 0.05-rem/month limit for pregnant workers would be assumed to be much lower and could be reduced further if radiation exposure were severely limited between weeks 8 and 15 gestational age. A reduction in IQ seems a more robust measure of detriment. The Japanese survivor information would suggest a loss of approximately 20 to 30 IQ points per rem. The important time for inducing such effects would again be weeks 8 to 15 gestational age (18,19).

V. Concepts of Protection

A. Principle of "as Low as Reasonably Achievable" (ALARA)

The need for and potential benefit from obtaining a cardiac test or intervention involving exposure to radiation must always outweigh the risks involved in performing the procedure. Nonetheless, the risks should be minimized by utilizing techniques and procedures that keep exposure to a level *as low as reasonably achievable* (ALARA) (20). The principle of ALARA is the overriding axiom for all radiation workers. Its successful implementation requires applying the three cardinal principles of *increasing distance, decreasing time and use of shielding* in diverse settings and procedures. Practicing the ALARA principle involves understanding the factors responsible for levels of radiation exposure, as well as the best judgment of the responsible practitioner who must continually balance the specific techniques utilized with the quality of the images obtained.

1. X-ray intensity and energy. Intensity and energy of any X-ray exposure are two major factors to consider in radiation safety. *Intensity* refers to the number of X-ray photons in the X-ray beam, or the number of X-ray photons entering or exiting the patient. It should not be confused with penetration ability. Factors controlling the X-ray beam intensity are the mA (milliamp), kV (kilovoltage) and pulse width (time). The greater the number of electrons accelerated through the X-ray tube, or the greater the mA, the higher the X-ray intensity. There is a linear relationship between mA and intensity: When mA is doubled, the number of X-ray photons produced are doubled, assuming that kV and time are kept constant. To increase film density while maintaining contrast, mA is increased but kV remains unchanged.

The *penetrating ability* of the beam is determined by the energy of the beam, which is controlled by voltage applied across the X-ray tube. The higher the voltage the more energy the electrons acquire and the more they can lose as they travel toward the anode. When an electron is accelerated through a

potential difference of 1 volt it acquires the energy of 1 electron volt (1 eV). When it is accelerated through a potential difference of 100,000 volts (100 kV), it acquires 100 keV of energy, which it can lose as it slows down and release as a 100-keV X-ray.

Since the relationship between kV and intensity is exponential, a 15% increase in kV is equivalent to doubling the mAs. This "15% rule" is used to adjust techniques to maintain desired film density (21). While the number of photons increase, the primary effects of increasing kV are the increased penetration of the beam with concurrent reduction in energy absorbed and increased scatter. This reduction in the energy absorbed by bone and tissue reduces the contrast between them and results in lower image contrast.

2. Distance and intensity. Primary beam X-rays travel in straight but divergent directions as they exit the X-ray tube port and collimator. Because this divergence increases with distance, the number of X-ray photons per unit area decreases exponentially as the distance increases from the primary X-ray source, which may be considered a point source. Conversely, there is an exponential increase in the number of photons/area at closer distances to the source. The inverse square law can be used to calculate changes in primary beam exposure at different distances from the X-ray tube target. The law states that the intensity of X-rays is inversely proportional to the distance squared:

$$X \propto 1/d^2,$$

where X = exposure, and d = distance. If the distance from the source is doubled, then the exposure is reduced to 1/4. Conversely, if this distance were decreased by a factor of 3, then the exposure would be increased by a factor of 9.

The intensity of the X-ray beam is measured with an ionization chamber, because it is measuring the number of ionizations produced by X-rays in air. Since the number of photons in air also refers to exposure in air, the roentgen or milliroentgen is the unit of measurement for intensity. Often, exposure is used to indicate intensity.

The inverse square law also applies to radioisotope sources in nuclear cardiology, as illustrated in Table 4. Clearly, direct contact with radiation sources should be minimized: For instance, vials containing radioisotopes should be shielded and handled with tongs. Radioactive materials should be transported in a shielded container, preferably on a cart to avoid hand carrying. Imaging rooms should be large enough to permit the technologist to operate the console/computer at a reasonable distance from the patient. A separate waiting area should be considered for patients injected with radioactive material. Depending on its location, the waiting area may need to be shielded in order to comply with the 100-mrem/year limit for nonradiation workers who may have workstations near the nuclear cardiology waiting area.

3. Scatter X-rays. When X-rays enter the patient, some are absorbed totally by certain tissues, some are partially absorbed and change direction, and others penetrate the patient and enter the image intensifier. The X-rays that change direction

Table 4. Effect of Distance From Patient on Exposure From Common Radioisotopes*

Distance From Patient (cm)	Exposure Rate (mR/h per mCi)	Exposure for Typical Procedures (mR)†	
		Thallium (3.5 mCi)	^{99m} Tc (30 mCi)
1	698	1,629	13,960
5	28	65	558
15	3	7	60
30	0.8	1.8	16
100	0.07	0.2	1.4

*Data from reference 59. †The exposures are calculated for standard dose of 3.5 mCi of thallium or 30 mCi of ^{99m}Tc, assuming the imaging time is 40 minutes. 1 mCi = 3.7 × 10⁷ Bq. The energy of the photonic emission (70 keV for ²⁰¹Tl, 140 keV for ^{99m}Tc and 511 keV for ¹⁸F) plays a minor role in the actual absorption of radiation emitted from the patient, but it may make a major difference if body shielding (lead aprons) is employed. For example, approximate exposure rates from a patient injected with 20 mCi of ^{99m}Tc are:

Distance From Patient (ft)	Exposure Rate (mR/h)
1	5-8
3	1-2
6	0.1-0.3
3 (with 0.5-mm lead apron)	0.5

and exit all sides of the patient, including back toward the X-ray tube, are scattered X-rays. For this reason, forward, side and backscatter are terms frequently used. Side scatter is of concern during clinical procedures. The larger the beam size entering the patient, the higher the amount of scatter. The percent scatter at a 90-degree angle and at one meter from the patient is 0.1% of the intensity of the beam entering the patient. With a 5-R/min exposure rate entering the patient, the scatter at 1 meter from the patient would be 5 mR/min. However, exposure from scatter is highly angular dependent. Thus, the classic inverse square law may not necessarily apply to scatter radiation.

Some factors affecting scatter levels are high kV and mA, wide open collimators and large distances between X-ray tube and image intensifier. Since patient size and density are not controllable, collimation and keeping the image intensifier as close to the patient as possible are two operational methods that can be used to reduce scatter levels.

Even though scatter radiation is not emanating from a point source, the inverse square law can be used to estimate the level of scatter at distances other than 1 meter. For example, if the physician is standing at 12 inches instead of 39 inches from the patient, then the exposure rate is increased 11-fold.

The information in Table 2 reveals that physicians have the greatest radiation exposure in the cardiac catheterization laboratory and that nurses also receive considerable yearly exposure. Technologists and assistants receive considerably lower radiation exposure (6).

B. Personnel Shielding Options

It should be noted that personnel shielding is designed to effectively attenuate scatter X-ray levels, not primary beam exposures. As the X-rays are scattered they undergo loss of energy and penetration ability. A 0.5-mm lead apron is approximately equivalent to two half-value layers for the scatter radiation associated with a 100-kV beam. The half-value layer is the thickness of a given material that reduces the intensity of the radiation to 50%. The effectiveness of attenuation decreases with increasing kV.

Wraparound two-piece aprons, thyroid shields and eye protection are important personnel shields. Even though the primary operator may not often turn away from the radiation source, changes in beam angle to obtain angulated views and functioning as an assistant will expose more of the body, making the use of wraparound lead shielding desirable. Many are custom made for the individual because of the long hours of wear. The lead content of the aprons should be verified. Some manufacturers use 0.25-mm of lead to achieve 0.5-mm lead when the apron overlaps in the front. However, there is only 0.25 to 0.3 mm of lead in the back of the apron. Also, the neck and armholes should be small enough to prevent irradiation of mammary tissues. Pregnancy aprons and skirts are designed with additional lead and growing room. As a result, these shields are heavier than standard ones. Care needs to be taken to avoid back injuries when handling and wearing these aprons.

Lead aprons should be tested for defects before being used. The Joint Commission on Accreditation of Health Organizations (JCAHO) requires annual testing for defects and records of test results.

Additional shielding available includes ceiling-mounted lead acrylic face shields, table side drapes and mobile "door-type" shields, which are all effective options to reduce exposures to staff during long procedures.

C. Monitoring Personnel Exposures

According to NRC regulations, occupational exposure needs to be monitored for individuals working in laboratories producing exposures in excess of 10% of the applicable limits (3).

1. Dose Equivalent, Effective Dose Equivalent and Effective Dose. The absorbed dose is the energy per unit mass deposited in the tissue and organs of the body. The Dose Equivalent is the result of modification of the absorbed doses to reflect the fact that some types of radiation are more effective in producing biological effects than are others. The Effective Dose Equivalent was introduced to allow for a consistent approach to estimating risks when different organs receive different levels of Dose Equivalent. This could occur either with partial body exposures or by exposure to internally deposited radioactive materials or simply because the X-ray energy is not sufficient to penetrate evenly throughout the body.

The Effective Dose Equivalent is used to assess the total risk of two specific radiation effects: risk of death from cancer

Table 5. Maximum Allowable Radiation Limits for Medical Radiation Workers From All Sources*

Whole body	5 rem/yr (50 mSv/yr)
Skin	30†–50‡ rem/yr (300–500 mSv/yr)
Hands, feet	50‡–75† rem/yr (500–750 mSv/yr)
Lens of the eye	5†–15‡ rem/yr (50–150 mSv/yr)
Fetus (pregnant worker)	0.5 rem/yr (5 mSv/yr); 0.05 rem/mo (0.5 mSv/mo)
Other, including thyroid	15 rem/yr (150 mSv/yr)
Cumulative exposure§	1 rem × age (10 mSv × age)

*Data from references 10, 49 and 50. †Limits established by some states that apply to X-ray and radioisotope workers that may differ from the NRC limits. Some states use 75 rem as the annual limit for extremities. ‡Federal limits for radioisotopes. §NCRP recommendation.

and risk of severe hereditary effects for two generations. In ICRP Publication 60 (2) and NCRP Report 116 (22), Effective Dose has been modified to include a nonfatal cancer component and severe genetic effects over all generations. Committed Effective Dose Equivalent is a simple summation of all the Effective Dose that will be delivered over the next 50 years from the intake of a given quantity of radioactive material.

Film badge readings used to be reported as one Dose Equivalent value per badge. Film badge processors modified their reports when the NRC mandated that whole-body occupational dose limits be specified as either Effective Dose Equivalent or the sum of Deep Dose Equivalent and committed Dose Equivalent, as skin/extremity Shallow Dose Equivalent and as Eye Dose Equivalent.

The NRC defines Effective Dose Equivalent (H_E) as the sum of the product of the Dose Equivalent to the organ or tissue (H_T) and the weighting factors (W_T) applicable to each of the body organs or tissues that are irradiated. The NRC uses a W_T of 1 for external exposures. The recorded Deep Dose Equivalent, or the Dose Equivalent at a tissue depth of 1 cm, is acceptable as the Effective Dose Equivalent by the NRC.

The maximal allowable exposures for medical radiation workers from all sources are listed in Table 5. Until, or unless, the federal and state regulatory agencies adopt the NCRP recommendation of expressing dose limits in terms of Effective Dose, records of radiation doses must be maintained as specified in the respective regulations.

2. Film badges. Personnel dosimetry monitors include those using X-ray film (film badges) or thermoluminescent dosimeters (TLDs), which use lithium fluoride crystals. Both detectors are placed in holders containing different filters. This allows the dosimetry laboratory to identify the type and energy of the radiation. Monitors are typically worn for one month before being submitted for processing. The laboratory processing the film badges compares the density of the film in the badge worn by an individual exposed to an unknown amount of radiation to film densities from known exposures. The solid lithium fluoride crystal atoms in a TLD absorb X-rays and their electrons are raised to a higher energy state after exposure to ionizing radiation. When the crystals are later heated, the excited electrons return to their normal energy levels and emit light in the process. The amount of light emitted is propor-

tional to the amount of radiation the crystal received. TLDs can be calibrated to provide tissue equivalent doses. A particular advantage of the TLD is that the response is largely independent of the X-ray energy. However, they are more costly than film badges. Film badges can be rechecked at a future date if a reading is ever questioned, whereas TLDs can be read only once. Pocket ionization chambers are other devices that can be read directly, thereby permitting case-by-case exposure readings. This may be of particular use to the pregnant worker who may wish to evaluate exposure on a frequent basis. Some pocket dosimeters have an audible warning device to warn the operator of intense radiation field exposure. The pocket dosimeters should be considered as additional rather than replacement monitoring tools to film badges or TLDs.

Film badge wearers should be certain that the front of the film badge is placed in line with the scattered X-rays for maximum accuracy. If the film badge is clipped with the back of the holder toward the beam, or if it is attached with only the edge toward the beam, the recorded results may not accurately reflect the actual exposures. Film badge results will be affected by extreme heat (left in a car on a hot summer day) and moisture. The damage from being placed in a washer or dryer is not repairable.

In practice, if a single badge is worn it is usually placed outside the apron at collar level. This monitors exposure to head, lens of the eye and neck and is important to ensure that lens and thyroid dose equivalents are within recommended limits. In the nuclear cardiology laboratory, the badge is to be worn at the level of highest exposure—at the chest or waist. When two badges are worn (as recommended), one is worn outside the apron at the neck and one is worn under the apron at the waist. The second badge monitors the effectiveness of the lead apron. During pregnancy the under-apron waist badge will monitor fetal exposures. A third useful badge is the ring badge, which is particularly important in the nuclear laboratory when working with radiopharmaceutical injections. Cardiac angiographers may not be able to wear ring badges and maintain a sterile environment; however, some badges are available that can be sterilized or can be worn during scrubbing. Since the hands are often the closest part of the body to the beam and subject to the highest exposure, particularly during angiography involving the pelvic and femoral vessels, individual angiographers should consider the feasibility of wearing a ring badge. When wearing a ring badge, the label (which indicates the TLD position) should be placed palm side down to accurately assess hand exposure.

For wearers of a single film badge, the radiation risk can be estimated from the film badge's recorded Deep Dose Equivalent for individuals wearing lead aprons and one film badge worn at the neck outside the apron, by dividing the film badge Deep Dose Equivalent value by 5.6 (6).

For wearers of two film badges, the radiation risk can be estimated from the Deep Dose Equivalent recorded by the film badge worn at the waist under the lead apron and the film

badge at the neck outside the apron by the following equations (6).

For *Effective Dose Equivalent: risk of death from cancer/heredity defects*:

$$H_{E(\text{estimate})} = 1.5H_W + 0.04H_N,$$

where W = waist, and N = neck.

For *Effective Dose: risk of death from cancer/heredity defects, a component of the risk of nonfatal cancer, hereditary effects over all generations*:

$$E_{(\text{estimate})} = 0.5H_W + 0.025H_N.$$

The NCRP recommends that an occupational worker's cumulative Effective Dose Equivalent should not exceed that person's age multiplied by 10 (Table 5) (6). The NCRP recommends that regulatory agencies should express dose limits in terms of Effective Dose.

3. Monitoring in the nuclear cardiology laboratory. The annual Effective Dose Equivalent in the nuclear laboratory must be measured and recorded. The individual's exposure history should be obtained whenever possible. The film badge worn is the most widely used personal dosimeter used in the nuclear cardiology laboratory. It should be worn at chest or waist level. Ring badges (frequently using TLDs) should be worn by nuclear cardiology personnel handling radioisotopes. Routine monitoring of hands, clothes, work and decay areas must be performed. Radiation survey meters must be used to evaluate external radiation from various sources, such as radiopharmaceutical packaging or disposal materials, and in the event of a spill to evaluate contamination. Liquid scintillation counters or well counters should be used to measure wipe tests for routine weekly contamination assessment. Wipe tests are performed to assess removable contamination not detected by portable survey meters. Internal exposures are monitored with bioassays. In most instances, however, internal exposure usually does not need to be measured in personnel performing only nuclear cardiology testing, unless volatile radioisotopes (i.e., iodine) are used in the area or if staff become internally contaminated. Bioassays should be done if any pregnant staff members are internally or externally contaminated.

4. Response to overexposure. When properly applied, the combination of limiting radiation exposure and following optimal practices, which include appropriate equipment selection and use, maintaining distance from X-ray sources and using shielding, should prevent excessive exposure in every operator, regardless of caseload and complexity. Thus, when radiation badges or review of personal exposure history indicates that exposure exceeds recommended (or personally acceptable) limits, it is vital that critical reviews of equipment performance and laboratory and individual practices be conducted, in addition to a possible temporary reduction in number of cases. The measures outlined in Section VII to reduce risks of radiation exposure are strongly recommended. To merely remove a worker from the laboratory without determining causes of the increased exposure is punitive,

encourages poor compliance with monitoring requirements and ultimately endangers all laboratory personnel and possibly patients. The responsibility for such a review is shared by the hospital, laboratory director, radiation safety officer/medical physicist and the individual operator. All parties should participate in the problem solving required to prevent future excessive exposures. Techniques and technologies should be carefully examined and updated or revised on a regular basis so that no operator is endangered or prohibited from practice. Documenting fluoroscopy time and cine time per case and per type of procedure can be valuable in assessing patterns that may be contributing to increases in radiation exposure.

VI. Radiation Exposure in Cardiovascular Practice

A. Radiation Exposure During Diagnostic and Interventional Cardiac Catheterization

Any attempt to compare published studies of radiation exposure levels during diagnostic or interventional cardiac catheterization procedures must be performed with circumspection due to the lack of standardization of data acquisition and the uncontrolled variables of patient size, equipment differences, radiographic technique and advances in technology. In one recent study, the hospital radiation badges that most commonly exceeded established limits were worn by personnel in the cardiology division (23). A prospective study of radiation practices suggested that cardiologists were probably inconsistent in their use of badges and appropriate shielding (23). The implications are that cardiologists are exposed to significant levels of radiation that could pose a health hazard if they do not abide by standard safety precautions.

Most catheterization laboratories monitor collar-level radiation exposure (outside the lead apron), and many also monitor waist-level exposure under the apron. The mean collar-level exposure per case for physicians who perform coronary angiography and percutaneous transluminal coronary angioplasty (PTCA) has been reported to be 4 to 16 mrem (0.04 to 0.16 mSv) (24-27). The use of suspended leaded acrylic shields was variable in these studies. The significant impact of operator technique on the level of exposure can be seen in the reduction of waist-level exposures (under the lead apron) from 3.3 mrem (0.033 mSv) to 1.4 mrem (0.014 mSv)/operator per week when operators restricted use of the left anterior oblique view (which results in much higher scatter at the cardiologist's position than the right anterior oblique view) (12). In this study, left anterior oblique views resulted in 2.6 to 6.1 times the operator dose of equivalently angled right anterior oblique views. Moreover, although cine generates far more radiation per second than fluoroscopy, the authors found that fluoroscopy was a greater source of total radiation by a ratio of 6.3 to 1 because of its protracted use (12). Other studies have found that waist-level exposure beneath a 0.5-mm lead apron was 1 to 2 mrem (0.01 to 0.02 mSv) per case for

Table 6. Air Scatter Levels (mrem/h)* Measured During Fluoroscopy for Radiofrequency Ablation†‡

Subject	X-Ray Projection		
	PA	RAO	LAO
Cardiologist			
Femoral position			
Beam open: no shield	47	21	80
Subclavian position			
Beam open: no shield	70	30	210
Beam collimated: no shield	36	11	100
Beam open: shield used	2	7	5
Monitoring personnel			
Beam open: no shield	15	9	30
Nurse			
Beam open: no shield	8	5	4

*Assumes QF = 1 was used for measurements reported. †Measurements do not assume use of pulse mode fluoroscopy. ‡Data from Lindsay et al. (29). LAO = left anterior oblique; PA = posteroanterior; RAO = right anterior oblique; shield = leaded-acrylic shield positioned between beam and operator.

diagnostic coronary angiography and PTCA, representing approximately a 95% reduction in exposure from measurements outside the apron (28). In addition, use of lead eyeglasses decreases radiation exposure to the lens to about 2.6 mrem (0.026 mSv) per case, representing a 35% reduction compared with measurements outside the glasses (28). These data underscore the dramatic attenuating effects of protective lead aprons and the effects of radiographic projection, proper collimation and entry exposure rates from the primary beam. Other procedural modifications, including use of last image hold capability and pulsed fluoroscopy, should further reduce exposure.

Studies of radiation exposure in cardiac catheterization laboratories have usually focused on the primary operator because the exposure of other medical personnel is lower. There are limited data pertaining to the exposure of physicians who assist during cardiac catheterizations and for technologists and nurses. The mean radiation doses of waist-level (under apron) and collar-level (outside apron) exposures during PTCA were 0.5 mrem (0.005 mSv) and 3 mrem (0.03 mSv) per case, respectively, for an assisting physician in one study (28). These values represent 10% to 30% of the primary operator's exposure. This is consistent with the observation that attending physicians generally have lower exposure levels than physicians-in-training (25) who often spend more time in the position of the primary operator and work more slowly. It should be recalled that the inverse square law is a potent factor influencing nonprimary operator and support staff exposure. As shown in Table 6, the exposure of a nurse stationed a few feet from the primary beam was 2% to 11% of the exposure for the primary operator, depending on the angulation of the beam relative to the nurse's position (29). Appropriate use of portable shielding and positioning of the nurses and technologists can reduce their exposure to very low levels.

The advent of complex and prolonged coronary interventional procedures has further increased levels of radiation

exposure. This also pertains to the area of digital imaging, which places unique constraints on input dosing, fluoroscopy and personnel exposure. From a radiologic standpoint, the main differences between cardiac diagnostic and interventional procedures are the increased duration of the procedure and the altered ratio of fluoroscopic to cine time during cardiac intervention (30). The requirement for high contrast video systems has, on the one hand, resulted in the development of high detection quantum efficiency (DQE) image intensifiers and reduced input exposure to the image intensifier. On the other hand, the requirement for enhanced resolution in the coronary tree has led manufacturers to provide stations for fluoroscopic exposures approaching those of cine technique ("high contrast" fluoroscopy). These inherently conflicting elements must be balanced in order to optimize procedural outcome and minimize personnel exposures. Additional approaches include pulse-mode fluoroscopy, progressive television scanning (31) and fiber optic coupling of the output phosphor of the image intensifier to the television pickup tube, allowing for lower image intensifier input radiation requirements. The current enthusiasm for "filmless" cardiac catheterization facilities represents another potential means of reducing overall radiation exposure. However, at the present time, the caveats noted above with respect to extended fluoroscopic procedures become even more important to reduce personnel exposure in these environments.

B. Radiation Exposure During Pediatric Cardiovascular Procedures

Although pediatric cardiologists have been performing cardiac catheterizations in infants and children for over 30 years, data regarding their occupational exposure are sparse (32-34). Examination of radiation safety issues has focused primarily on the exposure of the pediatric patient (35-38). Radiation exposure during arrhythmia ablation procedures in children, as measured by fluoroscopy duration, has been shown to be comparable to adults (39,40). However, results of studies pertaining to diagnostic and therapeutic catheterization in adults may not be uniformly applicable to pediatrics because of differences in the types of procedures that are performed and the size of the patient, which affect both the intensity of the beam required to obtain a satisfactory image and the degree of scatter radiation. Radiation scatter is greater for larger patients than for smaller ones for a given angiographic projection, and it can be difficult to make optimal use of shielding when variably angulated or biplane views are required for analysis or treatment of congenital abnormalities. These technical limitations may adversely affect radiation exposure to physicians and the medical personnel who assist them.

The actual measurements and estimated radiation exposure to medical personnel reported in the literature vary widely, reflecting differences in the duration of fluoroscopy, exposure rate and the area of the body at which exposure was measured. Li et al. (32) measured radiation doses to all staff involved with pediatric cardiac catheterization procedures (0 to 14 years

old). Measurements were made at the hand, neck and the chest under the lead apron. As the one closest to the patient throughout the procedures, physician exposure was higher than that for the assistant, technologist or nurse. The exposures reported per case for the physician were 1.4 to 34.8 mrem (0.014 to 0.348 mSv) (mean 8.8 mrem [0.088 mSv]) at the lens and 1.5 to 66.3 mrem (0.015 to 0.663 mSv) (mean 18.2 mrem [0.182 mSv]) at the thyroid. Wu et al. (33) also reported levels of physician exposure to be greatest at the left knee (3.4 ± 1.9 mrem [0.034 mSv]), with the thyroid, umbilicus and left third finger each receiving an average dose <1 mrem (<0.01 mSv). Attenuation of scattered X-rays by lead aprons was 60 to 90%.

Henderson et al. (34) studied the radiation exposure of anesthesiologists participating in pediatric cardiac catheterizations. Average use of fluoroscopy was 225 minutes per month. Dosimeter readings placed at forehead level averaged 103 mrem (1.03 mSv) (range 30 to 180 mrem [0.30 to 1.8 mSv]) for the first month and dropped to 38 mrem (0.38 mSv) (range 20 to 70 mrem [0.2 to 0.7 mSv]) during the second month. Heightened awareness on the part of the anesthesiologists led to self-initiated improvements in radiation safety practice and is the most likely explanation for the significant decrease in exposure from the first to the second month (34).

There are several considerations affecting radiation exposure to medical personnel that are unique to pediatric procedures. These include the need for greater magnification for optimal visualization of structures in small patients, the use of higher frame rates during cineangiography, interference from patient motion and changes in the indicators for performance of pediatric cardiac catheterizations. The use of two-dimensional echocardiography has replaced diagnostic cardiac catheterization in diagnosing many congenital heart lesions. Cardiac catheterization in pediatric patients is presently restricted to answering complex diagnostic questions or performing interventional techniques, including balloon angioplasty, placement of stents or occlusion devices, coil embolization and ablation of arrhythmias. Thus, the increased complexity of interventional procedures has increased imaging requirements and could adversely affect radiation exposure unless there are compensatory reductions in the radiation dose by technical advances or improved safety practices.

C. Radiation Exposure During Electrophysiology Studies and Pacemaker Implantations

The radiation exposure to medical personnel from scattered radiation during electrophysiology studies has been estimated using TLDs or by recordings from an electrometer/ion chamber (29,41,42). Radiation levels due to scattered radiation for left anterior oblique right anterior oblique, and anterior views have been recorded at the position occupied by a physician performing the procedure and for monitoring personnel positioned approximately 8 feet from the chest. Table 6 lists the secondary beam measurements obtained from these positions (29). Appropriate collimation of the X-ray field reduced the exposure to the patient and to medical personnel by 40%. As

expected, the exposure is greatest for the physician who manipulates the catheter. These recordings were obtained at waist level with the assumption that the physician would be positioned at the patient's right side to maneuver the catheters inserted through the femoral or subclavian veins. Exposure rates for the physician are considerably higher during manipulation of a catheter inserted through the subclavian vein because of closer proximity to the primary beam.

The calculated Effective Dose Equivalent to the physician who manipulates catheters from the femoral area during an ablation procedure is 1.8 mrem (0.018 mSv) per case with an exposure of 55 minutes of fluoroscopy, which was the mean fluoroscopy time reported in one study (29). This calculation assumes 1) the field of image is appropriately collimated; 2) the physician maintains a distance of 30 inches from the patient's chest; and 3) standard leaded aprons and thyroid collars are worn. The calculated Effective Dose Equivalent is 2.8 mrem (0.028 mSv) per case if a thyroid collar is not used. A physician who performs 250 ablation procedures per year will incur a predicted Dose Equivalent of 450 mrem (4.5 mSv) per year, which is 9% of the recommended annual limit for radiation workers. Effective Dose Equivalent to the eye is about 8 mrem (0.080 mSv) unless an effort is made to reduce exposure by means of a leaded acrylic shield or leaded glasses. The calculated Dose Equivalent for personnel at the monitoring station was 0.2 to 0.6 mrem (0.002 to 0.006 mSv) per case or 54-162 mrem (0.054 to 0.16 mSv) per 250 cases depending on the position of the individual relative to the image intensifier. Estimates for radiation exposure rates for medical personnel assisting in a busy electrophysiology laboratory are provided in Table 6 (29).

The concern about radiation exposure in the electrophysiology laboratory has generally focused on ablation procedures because they can be protracted. It can be anticipated that as experience is gained by a physician the duration of fluoroscopy required to perform a procedure, and consequently the radiation exposure, will decrease. A recent study compared the radiation exposure during ablation procedures performed in 500 patients between 1990 and 1995 (43). Despite the ongoing training of new fellows in clinical electrophysiology, there was a significant decrease in the amount of fluoroscopy used during ablation procedures. The fluoroscopy time per case for ablation of patients who underwent ablation of atrioventricular node reentry or an accessory pathway decreased from 49 minutes in the period from 1990 to 1993 to 37 minutes in 1994 to 1995 as the experience and technique of the trainers improved. While diagnostic electrophysiology studies and pacemaker implantations also require fluoroscopic guidance, these procedures generally employ only 5 to 10 minutes of fluoroscopy or less.

D. Radiation Exposure in Nuclear Cardiology

The radiation exposure for patients and staff in the nuclear cardiology laboratory is relatively low. Each laboratory is under the supervision of a Radiation Safety Officer who is

Table 7. Commonly Used Isotopes in Nuclear Cardiology

Isotope	Half-Life	Energy (keV)
Thallium-201 (^{201}Tl)	73 h	68-83, 162
Technetium-99m ($^{99\text{m}}\text{Tc}$)	6 h	140
Indium-111 (^{111}In)	67.2 h	171, 246
Fluorine-18 (^{18}F)	110 min	511
Rubidium-82 (^{82}Rb)	76 s	511
Nitrogen-13 (^{13}N)	10 min	511

responsible for enforcing federal and state regulations. Nuclear physicians and technologists are trained in radiation safety and are required to promote radiation safety in the laboratory.

The most commonly used isotopes in nuclear cardiology are listed in Table 7 and protocols describing their use are detailed in Table 8. *Thallium-201* (^{201}Tl) is used to assess myocardial perfusion and viability, but its long half-life significantly limits the dose administered. The shorter half-life of *technetium-99m* ($^{99\text{m}}\text{Tc}$) allows a higher injectable dose. The higher dose combined with higher energy of $^{99\text{m}}\text{Tc}$ offers a significant advantage over ^{201}Tl with regard to image quality. Two $^{99\text{m}}\text{Tc}$ -labeled myocardial perfusion agents are commonly in use today: $^{99\text{m}}\text{Tc}$ -sestamibi (Cardiolite) and $^{99\text{m}}\text{Tc}$ -tetrofosmin (Myoview). These two compounds can be employed for first-pass ventriculography as well. $^{99\text{m}}\text{Tc}$ -pertechnetate is used in gated equilibrium blood pool "MUGA" studies and first-pass ventriculography. Technetium-99m pyrophosphate has been used for infarct avid imaging with pyrophosphate accumulation in necrotic myocardium, enabling the identification of patients with acute myocardial infarction. *Indium-111* (^{111}In)-labeled antibodies (Myoscint) are currently available for detecting the presence and location of myocardial injury in patients with myocardial infarction, myocarditis, allograft rejection or trauma.

Several positron-emitting (PET) radionuclides are in fairly wide clinical use. *Rubidium-82* (^{82}Rb) and *N-13 ammonia* (^{13}N) are both perfusion tracers, and deoxyglucose when labeled with *fluorine-18* (^{18}F) has been used in the assessment of myocardial viability. Fluorodeoxyglucose (^{18}F FDG) is cyclotron-produced, but its relatively long half-life allows delivery to off-site facilities. ^{82}Rb is generator-produced; ^{13}N is cyclotron-produced. Other tracers have been demonstrated to have utility in the assessment of myocardial perfusion and metabolism but are not widely used clinically and are beyond the scope of this report.

Imaging with a positron-emitting radionuclide is based on the fact that a positron interacts with an electron to yield photons emitted in opposite directions with 511 keV energy. Hence these photons have significantly higher energy than more conventional nuclear cardiology isotopes. Traditionally, tomographic systems utilized with PET tracers have consisted of a ring of detectors around the body that allows coincidence detection (i.e., the detection of two photons by opposing detectors within a given time window). More recently, new generations of dual-head single-photon emission computed

Table 8. Common Nuclear Cardiology Protocols*

	Isotope	Injected Dose (mCi)	Acquisition Duration (min)
First-pass radionuclide angiography	^{99m} Tc	25	1-2
Planar/SPECT equilibrium gated blood pool	^{99m} Tc	20-30	2-30
Planar/SPECT perfusion	²⁰¹ Tl	2.5-3.5	10-40
Planar/SPECT perfusion (with reinjection)	²⁰¹ Tl	3+	10-40+
		1.5@2-4 h	10-40@2-4 h
Planar/SPECT perfusion	^{99m} Tc-MPA	20-25	10-30
Planar/SPECT perfusion (2-day stress-rest)	^{99m} Tc-MPA	20-30+	10-30+
		20-30 next day	10-30 next day
Planar/SPECT perfusion (1-day stress-rest with reinjection)	^{99m} Tc-MPA	10-15+	10-30+
		25-30@2-4 h	10-30@2-4 h
Planar/SPECT perfusion (1-day rest-stress with reinjection)	^{99m} Tc-MPA	8-12+	10-30+
		22-25@2-4 h	10-30@2-4 h
Dual-isotope SPECT perfusion (rest-stress)	²⁰¹ Tl	2.5-3+	15-30+
	^{99m} Tc-MPA	22-25@< 1 h	20-40@< 1 h
Technetium-99m pyrophosphate	^{99m} Tc	15	10-40
Metabolic FDG imaging (SPECT or PET)	¹⁸ FDG	10	15-45
Indium-111 antimyosin antibodies	¹¹¹ In	2.0	10-40

*Study duration depends on the use of single or multidetector cameras, as well as on the number of views acquired (planar studies). FDG = fluorodeoxyglucose; MPA = myocardial perfusion agent (^{99m}Tc-sestamibi, ^{99m}Tc-tetrofosmin); PET = positron emission tomography; SPECT = single-photon emission computed tomography (tomographic).

tomographic (SPECT) cameras allow for imaging of PET tracers such as ¹⁸FDG. This is done using either an ultra high energy collimator or coincidence detection. Hence, PET myocardial agents may become routinely used in the nuclear cardiology laboratory.

The reported average occupational exposure in a nuclear medicine or nuclear cardiology department is significantly less than maximal permissible doses. The mean annual Dose Equivalent for nuclear medicine personnel is 100 to 140 mrem (1 to 1.4 mSv) (10). The occupational exposure varies with the type of activity performed, with maximal exposure occurring for radiopharmacists and individuals injecting radioisotopes (44) (Table 9). Exposure is lower for technologists working in a nuclear medicine department as compared to a positron emission tomography imaging (PET) facility (45).

Circumstances of radiation exposure in the nuclear cardiology laboratory can be divided into four categories: 1) tracer preparation (for information on specific radioisotope emissions, see Table 7); 2) administration of tracer and patient monitoring; 3) imaging; and 4) quality control. The most important source of exposure in nuclear cardiology is the handling of radioactive material, which includes drawing a dose from a radioactive vial, eluting the generator, preparing a radioactive kit, labeling red blood cells for radionuclide angiography (RNA) or injecting a radioactive material. The use of unit-doses, as opposed to the in-house use of ^{99m}Tc generators, decreases radiation exposure to the radiopharmacist or person eluting the generator. Patients injected with radioisotopes should be considered unshielded sources during the time there is radioactivity in the body. Thus, exposure to staff by a patient is dependent upon the dose injected and the half-life of the isotope used. Physicians, nurses and technologists are exposed at the time of physical examination or patient prepa-

ration for stress testing if the radioisotope has already been injected. After tracer injection, staff exposure occurs when taking blood pressure, examining the patient or removing the electrodes or intravenous tubing which is radioactive. Positioning a patient and acquiring or processing studies on a computer console located close to the imaging table represent increased opportunities for exposure for the nuclear personnel. Positioning may be more difficult with sicker patients and with planar as compared to SPECT imaging. As computer technology and camera-gantry design improve, patient positioning is made easier, thereby reducing exposure time for the technologist.

Table 9. Average Yearly Effective Dose Equivalent for Nuclear Medicine Personnel*

	Total Effective Dose Equivalent (whole body) (mrem)	Hand (mrem)
Maximum annual Effective Dose Equivalent (regulatory limit)	5,000	50,000
Reported clinical exposures		
Bloe and Williams (45)		
Nuclear medicine (n = 846)	178	988
PET laboratory (n = 6)	412	1,745
Radiopharmacist (n = 103)	181	14,490
Owens et al. (44)		
Nuclear cardiology*	144	72
Nuclear medicine*	72	60
Nuclear pharmacist*	288	21,200
Injection operator*	300	996

*Extrapolated from average monthly doses. In the nuclear cardiology laboratory (44), the monthly average was 60 radionuclide ventriculographic and 380 myocardial perfusion studies with either ²⁰¹Tl or ^{99m}Tc agents. n = sample size.

Other sources of exposure include performance of camera quality control assessment, manipulation of flood sources or phantoms and decontamination of a spill. Personnel exposure will also occur when handling waste or contaminated supplies.

Additionally, if the nuclear cardiology laboratory is located inside a nuclear medicine department, workers may be exposed to contamination from airborne radioactivity from isotopes used for aerosol and ventilation studies if proper protective mechanisms are not in place. These isotopes include ^{99m}Tc DTPA, ^{133}Xe and ^{81m}Kr rypton. Sodium iodide, used for thyroid scans, is very volatile.

Some nuclear cardiology laboratories store waste materials for decay, since ^{99m}Tc and ^{201}Tl have relatively short half-lives. Regulations require that the material be stored for 10 half-lives, after which less than 0.1% of the activity remains. Additionally, the waste material should be surveyed before disposal or shipping. To avoid exposure, the radioactive waste holding area should be appropriately shielded, secured and surveyed weekly.

E. Anticipated Exposure From Techniques in Development

Brachytherapy, the local application of radioactive sources at the coronary endoluminal surface, is a novel and potentially efficacious modality of transcatheter therapy in patients with coronary disease. Preliminary results in humans using both beta and gamma sources indicate a striking effect on angiographic restenosis rates compared to conventional PTCA (46-48). Should such therapies prove to be effective in large scale clinical trials, considerable effort must be devoted to the training and credentialing in the use of these isotopes. Furthermore, since patient and operator exposure will vary widely depending on the type of energy used, considerable data still need to be reported on the absorbed dose for the patient, operator and support personnel for each isotope used.

VII. Recommendations for Limiting Radiation Exposure

A. Fluoroscopy and Angiography in Adult and Pediatric Cardiac Laboratories

Recommendations for the maximum allowable radiation exposure for physicians and other medical personnel who perform and assist with invasive cardiovascular procedures have been published by the Society for Cardiac Angiography and Interventions (49,50) (summarized in Table 5). These recommendations correspond with NRC and state regulatory exposure limits. It is incumbent on physicians who perform these procedures to ensure that all personnel adhere to standard safety precautions to avoid excessive radiation exposure. Personnel who assist in the procedure should be stationed as far as practical from the patient and should be appropriately shielded. Precautions that substantially limit radiation exposure are summarized in Table 10.

1. Equipment factors. Technical design changes available to reduce patient and operator dose during fluoroscopy include pulsed digital imaging, fluoroscopy, high efficiency image intensifiers, solid state coupling, thin copper filters, frame averaging and last image hold.

2. Operator-dependent practices. Fluoroscopy should be used as sparingly as possible to position catheters, and pulsed digital fluoroscopy should be used when available. Pulsed digital fluoroscopy maintains image quality while reducing exposures approximately 50% when compared to continuous fluoroscopy (51,52). Since cine is a high dose imaging mode, it should be used efficiently for image recording. Redundant views should be avoided. Magnification should be used only when necessary as the increase in entrance dose to the patient is approximately equal to the ratio of the area of the input phosphor in the magnified mode to the area of the input phosphor used for the nonmagnified mode (i.e., 7 inch² divided by 9 inch²) (21). In other words, the dose is 1.7 times higher in the 7-inch mode compared to the 9-inch mode. This increased dose to the patient results in increased scatter levels. Proper use of shutters to collimate the beam will reduce scatter exposure levels because the amount of scatter originating from the patient is directly related to the area of the beam. By reducing scatter, collimation also improves image quality.

It is especially important that operators take advantage of the inverse square law. The benefit of increasing the distance between the operator and the primary beam should not be underestimated. If the operator increases his or her distance from the beam from 2 feet to 4 feet, there is a reduction in waist level exposure to one-fourth the original level. This effect is particularly dramatic for other medical personnel whose radiation exposure is low if they are properly positioned at distances greater than 8 feet from the patient.

3. Shielding. Physicians should also make full use of personal shielding in using lead aprons, thyroid collars and leaded eye protection. Lead aprons and thyroid shields should be fluoroscoped at least annually to check for cracks and holes. Table side drapes and ceiling suspended leaded acrylic shields are important components of radiation protection. A leaded acrylic shield that is properly positioned can reduce exposure to the operator's thorax and head by about 90% (29). C-arm position changes necessitate repositioning the ceiling mounted shield to maintain its effectiveness. Designs vary for the table side drapes. Some are available with a hinge to allow moving a section of the drape to maintain shielding effectiveness when the X-ray tube position is changed. The cumulative effects of these precautions markedly reduce exposure to radiosensitive tissues and should limit annual radiation doses to levels well below published safety guidelines.

B. Recommendations for Radiation Protection in the Nuclear Laboratory

The three cardinal principles of radiation protection (increase distance, decrease time, use shielding) should be routinely applied to the nuclear cardiology laboratory. The specific

Table 10. Recommendations for Reducing Radiation Exposure in the Catheterization and Electrophysiologic Laboratories

Equipment factors—incorporate as many as possible
1. Pulsed progressive fluoroscopy
2. Additional copper filters
3. Digital-only cine acquisition
4. Last image hold feature
5. Image looping
6. High frequency generator
Operator-dependent functions
1. Minimize patient exposure
2. Limit number and length of cine runs
3. Use least amount of fluoroscopy time possible
4. Minimize use of magnification
5. Use proper collimation of primary beam
6. Utilize appropriate shielding above and below table: —side table drapes —ceiling mounted shield —mobile “door” shields
7. Maintain distance from primary beam
8. Keep image intensifier as close to patient as possible
9. Maintain source to entrance distance as long as practical (recommended distance > 50 cm)
10. Select highest kilovoltage that provides the needed contrast
11. Avoid use of “boost” or high dose modes that can increase radiation exposure tenfold
Laboratory maintenance
1. Conduct periodic inspections and testing of X-ray unit(s)
2. Inspect X-ray lead shields and lead aprons/thyroid shields at least annually or more frequently to detect cracks
Operator shielding
1. Wear two-piece lead apron that wraps around body, covering back to protect from scattered X-rays
2. Select proper-fitting lead aprons: —minimize armhole openings —cover entire torso —extend to mid thigh —wear properly designed and weighted maternity aprons when pregnant or planning pregnancy
3. Wear thyroid shield
4. Wear eye protection: leaded eyeglasses with temple shields protect against splash exposure and reduce lens exposure to radiation
5. Adhere to universal precautions for blood-borne pathogens
Monitoring
1. Wear two badges: —one under lead apron at waist level —one outside lead shields at collar level
2. Consider use of a sterilizable ring on arm closest to X-ray tube to approximate hand exposure, especially if performing peripheral angiography
3. Regularly review personal exposure
4. Adjust techniques and practices if exposure exceeds recommended levels
5. Record fluoroscopic and cine times for each case to allow correlation with film badge readings
Training
1. Participate in annual didactic safety training sessions
2. Ensure that all new personnel and trainees acquire radiation safety training before working in laboratories
3. Establish laboratory equipment and practice standards to reduce interindividual variations in adherence to recommendations

steps to utilize these principles in reducing radiation exposure in the nuclear cardiology laboratory are listed in Table 11.

In general, all personnel should participate in annual didactic training sessions. New personnel must be adequately trained prior to working in the laboratory. Finally, laboratory practice standards should be established to increase adherence to recommended guidelines and regulatory requirements.

To increase distance, direct contact with radioactive sources should be avoided by wearing gloves, handling vials with tongs, transporting materials on a cart and keeping vials and syringes in a leaded storage container. During the stress test, workers should maintain adequate distance (at least 1 meter) from patients. If increasing distance is not possible, consideration should be given to observing from behind a transparent leaded shield of 0.5 mm lead-equivalent. A separate waiting room may have to be provided for patients who have been injected. The room may have to be shielded in order to comply with the 100 rem per year limits for nonradiation workers who may be located in the vicinity.

To reduce time of exposure, whenever possible patients should be questioned and examined before injecting radioactive materials into them. Work in the vicinity of radioactive sources should be accomplished as rapidly as possible, especially in the hot lab.

Workers do not need to wear lead aprons during routine clinical studies. Some tasks, such as preparing a ^{99m}Tc generator, warrant the use of a table lead “L” shield and may warrant the use of a lead apron.

The basic rules for avoiding contamination resemble the “universal precautions” used to protect personnel from blood-borne pathogens and are listed in Table 11.

C. Radiation Safety Training

All personnel who enter areas of radiation exposure must be instructed on the health risks associated with ionizing radiation and the means of minimizing exposure. Any individual who regularly enters a cardiology laboratory should receive annual radiation safety training. Personnel who occasionally enter the laboratories or who are not directly working in a restricted area, but who may be in contact with patients injected or treated with radiopharmaceuticals, including nurses, aides, house officers and transport personnel, should also receive training. In addition, information on risk of exposure and minimizing exposure should be easily accessible by all personnel.

It is strongly recommended that formal didactic sessions be incorporated into the training of physicians and other medical personnel who work in catheterization, electrophysiology and nuclear laboratories. The content should include basic principles of radiation physics, radiation biology, radiation safety practices, monitoring procedures and potential health risks. Training sessions should be completed before beginning any participation in cardiology laboratories and annually thereafter. Training sessions also should routinely address concerns that may exist about exposure to radiation prior to conception

Table 11. Recommendations for Reducing Radiation Exposure in the Nuclear Cardiology Laboratory

Laboratory design features

1. Observe patients from behind a transparent, leaded shield of 5-mm lead-equivalent material
2. Provide a separate waiting room for patients who have received an injection; determine the need for room shielding; have a large enough room to permit adequate distance between patients and personnel

Operator-dependent functions

1. Avoid direct contact with radiation sources:
 - wear gloves, remove gloves before leaving the area
 - handle shielded vials of radioactive substances with tongs
 - keep vials and syringes in leaded storage holders
 - transport shielded radioactive materials on a cart
2. Maintain adequate distance from the patient (who is a radiation source once injected)—recommended minimum = 1 meter
3. Limit duration and frequency of visits to the hot laboratory
4. Work as rapidly and carefully as possible with radioisotopes
5. Assess and examine patients before injection of radioactive materials
6. Do not eat, drink, smoke, apply cosmetics or linger in an area where radioactive materials are used or stored
7. Do not place personal belongings (books, purses, clothing) on laboratory work surfaces
8. Never pipette by mouth; use a syringe, propipettor or other remote control device

Laboratory procedures

1. Always line trays, benches and hoods with absorbent paper before using radioactive materials to confine spills and facilitate decontamination
2. Contain and clean all spills immediately; report all spills and other incidents to the Radiation Safety Officer immediately
3. Handle all used materials with similar precautions to those for radioisotopes and shield storage areas for radioactive waste
4. Use and store radioactive materials such that unauthorized persons are prevented from using or removing such material
5. Alternate personnel handling of flood sources and phantoms
6. No food, drink or personal effects should be stored in laboratory refrigerators
7. Limit storage of radioactive solutions to clearly labeled shielded containers; these containers shall be labeled, "CAUTION—RADIOACTIVE MATERIAL" and must show the isotope, dose and date
8. Use unit doses of radiopharmaceuticals, if possible

Operator shielding

1. Wearing of lead aprons is not warranted during clinical studies but can be considered for use during elution of generators, during cleaning up spills and when manipulating a phantom
2. A table leaded "L" shield should be used for elution of a ^{99m}Tc generator
3. Wear goggles when necessary
4. Wear laboratory coat when handling radioactive materials
5. Wash hands and monitor hands with a survey meter after working with radioactive materials
6. Adhere to universal precautions for blood-borne pathogens

Monitoring

1. Wear a film badge or TLD on the chest at all times in the laboratory
2. Wear a ring badge if handling radioisotopes
3. Monitor all injuries occurring while handling radioactive materials for contamination
4. Conduct weekly wipe tests to assess contamination of laboratory surfaces

Training

1. Ensure that all new personnel and trainees acquire radiation safety training before working in laboratories
2. Provide sufficient training opportunities with "dummy" materials before permitting a new worker to handle radioisotopes
3. All workers should participate in annual didactic safety training sessions
4. Establish laboratory practice standards to reduce interindividual variations in adherence to recommended guidelines

and during pregnancy. Women who are familiar with the risks, precautions and monitoring capabilities can feel comfortable and supported when deciding how to integrate family planning and work duties.

D. Recommendations for Radiation Protection of Women Staff Members Who Are or Desire to Become Pregnant

As discussed in Section IVB, the risk of genetic alteration of reproductive cells by radiation exposure is low. Women and men who adhere to recommended radiation safety precautions (Tables 10, 11 and 12) should feel reassured their exposure will not endanger their future children. The risks of radiation exposure to the fetus can be minimized by additional shielding and monitoring measures outlined in Table 12. It should be made clear that physicians may safely perform or assist studies during pregnancy, but ultimately, each woman has the prerogative to determine whether or not she will do so. With planning, the cardiologist-in-training can meet procedural requirements even if she limits her radiation exposure during pregnancy.

The NCRP recommendations state that the dose to the fetus from occupational exposure of a declared pregnant worker should not exceed 0.5 rem (5 mSv) over the entire pregnancy and 0.05 rem (0.5 mSv) during any single month of the pregnancy (15). In addition, the NRC regulations state that any substantial variation above a uniform monthly exposure rate to a pregnant woman should be avoided (3). This estimated exposure should include all occupational exposures if the individual holds several jobs. The pregnant worker should declare her pregnancy although this declaration is voluntary, and provide an estimated date of conception so the accumulated dose to the fetus can be subtracted from 0.5 rem (5 mSv) to determine the dose the fetus will be allowed to receive during the remainder of the pregnancy. If the dose is determined to be 0.45 rem (4.5 mSv) or greater, it is the Radiation Safety Officer's responsibility to ensure that the fetus receives only 0.05 rem (0.5 mSv) during the remainder of the pregnancy. Personal monitoring with film badge or dosimeter after declaration of pregnancy is indicated if the individual may receive 10% of the 0.05 rem (0.5 mSv) fetal dose. The dose to the fetus is considered equivalent to the sum of the Deep Dose Equivalent recorded on the mother's film badge and the dose to the fetus from any radionuclides found in the mother and fetus. The Deep Dose Equivalent will be monitored by a film badge located at waist level under any protective garment. In addition, the internal dose to the fetus should be determined by bioassay if the declared pregnant woman's internal exposure is likely to exceed in one year the committed Effective Dose Equivalent of 0.05 rem (0.5 mSv) (53). This may occur if the mother is exposed to an internal uptake of radioactive material, as may happen in the nuclear medicine department when performing aerosol studies or manipulating iodides or if she has undergone treatment or testing with radioactive pharmaceuticals before or during pregnancy. A description of the

Table 12. Recommendations for Radiation Protection of Women Who Are or Desire to Become Pregnant

Exposure

1. Pregnant women should be able to safely perform all duties provided that strict attention is paid to exposure limits
2. Exposure should not exceed 0.5 rem (5 mSv) over entire pregnancy or 0.05 rem (0.5 mSv) in any single month
3. Consider reducing exposure during gestational weeks 8-15 to reduce risk of fetal mental retardation

Shielding

1. Use same precautions as all operators (see Table 10)
2. Use maternity aprons
3. Other shielding options are not recommended, such as:
 - lead underwear
 - double aprons, which may cause imbalance and injury
4. Inspect lead aprons fluoroscopically on a monthly basis

Monitoring

1. Two film badges should be worn in the catheterization or electrophysiology laboratory:
 - one at neck outside of lead
 - one at waist inside of lead
2. In the nuclear laboratory, two film badges should be worn:
 - one at chest level
 - one at waist level (if lead is worn, only the waist badge is worn under lead)
3. Badges should be monitored monthly, although weekly is ideal
4. Women in the catheterization and electrophysiology laboratories, particularly with a personal exposure history for the current year > 0.1 rem, should monitor exposure on a case-by-case basis using a pocket ionization chamber and maintain a record of readings; this does not substitute for a badge that monitors cumulative exposure

Counseling

1. Every woman has the prerogative to choose between continuing her professional activities within exposure recommendations listed above or restricting them during all or part of her pregnancy
2. Such decisions should be based on knowledge of risks, monitoring options and shielding techniques and, most important, personal history of radiation exposures
3. Every woman should have the opportunity to discuss these issues privately and confidentially with an unbiased knowledgeable individual (e.g., a radiation safety officer). At the time the pregnancy is declared, the woman and radiation safety officer will review previous exposure records, evaluate monthly exposure history and plan activities and monitoring during the pregnancy
4. Cardiology laboratory directors should recognize that pregnancy by itself should not limit activities in the laboratory but should support female personnel who choose to reduce their exposure by limiting their radiation-related activities

calculation of internal doses is beyond the scope of this document.

1. Minimizing radiation exposure to the pregnant worker. Since the maximal permissible dose for the fetus is 0.5 rem (5 mSv), the maximal occupational dose per pregnancy of a pregnant worker can be considered to be 0.5 rem (5 mSv). At the time of declaration of pregnancy, several measures should be taken. The pregnant worker should meet with the radiation safety officer. The risk to the fetus from radiation should be explained and the necessity of abiding by the radiation protection rules reinforced. Previous records should be examined in order to evaluate if the fetus has received any exposure. In all

laboratories, a second badge should be worn at the waist level under the lead apron to monitor fetal exposure. This “fetal” badge is worn in addition to the badge worn at the collar or chest level. Film badges should be monitored monthly. At present, some monitoring companies provide weekly reading for waist (fetal) badges so maternal exposure can be rapidly adjusted, if necessary. The consideration of modifying duties, especially during gestational weeks 8 to 15, should be discussed (4,14). If the average exposure measured by the underapron waist badge is below the monthly limit for the fetus, then the daily routine need not be changed.

There are no written policies regarding modification of duties in pregnant workers in nuclear cardiology laboratories (54,55). Any change in duty is certainly easier to accomplish in a large clinic than a small clinic. Benedetto (55) recommends removing a pregnant technologist from any duty involving the handling of therapeutic doses, the elution of generators and preparation of radiopharmaceutical kits. However, handling doses below 15 mCi of ^{99m}Tc or ^{201}Tl does not impart a significant exposure to pregnant workers. One can switch temporarily to unit dose delivery from a radiopharmacy instead of in-house preparation of radiopharmaceuticals. Manipulation of phantoms and flood sources should be minimized. Performing intrinsic uniformity testing that requires the use of a point source of radioactivity instead of extrinsic uniformity testing requiring a flood source, should be considered. The advantages and drawbacks of wearing a lead apron in the nuclear laboratory should be discussed between the radiation safety officer and the pregnant worker. Lead aprons are not fully effective at shielding from the radiation from ^{99m}Tc and, if worn, these aprons should cover the back and side as well as the front. These “maternity” aprons are so heavy that they may cause back pain and injury. They may, however, be used for specific tasks involving significant radiation.

2. Recommended maximum dose. Debate has arisen regarding the NRC regulations limiting radiation exposure to the pregnant worker. The maximal permissible dose to the fetus of a pregnant worker is 0.5 rem (5 mSv), whereas the maximal dose to the general public, hence to the fetus of the general public, is 0.1 rem (1 mSv)! The ICRP has recommended that the maximal permissible dose to the fetus of a pregnant worker be equal to that of the public, that is, 0.1 rem (1 mSv). According to the ICRP, such a limit can be achieved by applying a limit of 0.2 rem (2 mSv) to the woman’s abdomen. Others recommend a maximal Dose Equivalent of 0.13 rem (1.3 mSv) to the abdomen (56). Overall, provided that the cardinal rules of radiation protection are respected, the risk from occupational exposure to the fetus should not exceed the risk to the fetus in the general population.

3. Legal issues. The legal status of women who choose to work in an environment where they are exposed to radiation is unambiguous. Title VII of the Civil Rights Act of 1964, as amended by the Pregnancy Discrimination Act, forbids fetal protection policies and specifies that unless pregnant employees differ from others in their ability to work, they must be

treated the same as other employees for all employment-related purposes. Decisions about the welfare of future children are left to the prospective parents. The provisions of the Pregnancy Discrimination Act prohibit an employer from discriminating against a woman because of her capacity to become pregnant unless her reproductive potential prevents her from performing the duties of her job. These principles were reviewed and upheld by the United States Supreme Court in a decision delivered by Justice Blackmun in 1991 (57).

VIII. Summary

Given the large number of cardiac procedures involving radiation being performed in the United States by an increasing number of workers, the principles for reducing radiation and monitoring exposure should be known and followed by every practitioner, trainee and assistant in every laboratory. The rapid development of new technologies in the cardiology laboratories and increasing volumes and case complexity all suggest that radiation protection is of vital and increasing importance. This document has reviewed the health risks of radiation exposure and provided practice-specific recommendations for minimizing those risks. In particular, the concerns of women who are planning to become or who already are pregnant have been addressed. It is hoped that future research will further modify procedures to reduce risks to the lowest possible level.

Appendix I. X-Ray Production Overview

In order to understand why certain procedures or equipment designs reduce exposures, it is necessary to understand how X-rays are produced and the impact of production on image quality.

X-rays are produced electronically by accelerating electrons from a cathode to an anode mounted within an evacuated glass "bulb." Heating the cathode releases electrons. Applying kilovoltage ("kV") across the two electrodes accelerates the electrons toward the anode. These traveling electrons are called "tube current," or the mA (milliamp). Pulse width refers to the duration of each pulse of the beam.

X-ray production results in the formation of an isotropic source of X-rays. The glass X-ray tube is encased, or "housed," in lead and steel shielding that has a small opening called a window or port. X-rays penetrating the lead housing are termed *leakage radiation*. X-rays passing through the port constitute the primary beam. A box-like device attached at the port contains an adjustable shutter or collimating mechanism that shapes and changes the size of the primary beam. Aluminum and/or copper filters are placed in the port to absorb the low energy component of the X-ray beam. This use of filters reduces skin dose, since the low energy X-rays are primarily absorbed by the skin. Low energy X-rays are not used for imaging since their energy is too low to penetrate the patient.

Fluoroscopy uses either continuous or pulsed X-ray beam. Patient and staff exposures are reduced when pulsed progressive fluoroscopy is used in place of continuous fluoroscopy with interlaced TV cameras. In order to pulse the beam, some pulsed fluoroscopy systems use a grid in the X-ray tube to control the number of electron pulses traveling to the anode. Other systems pulse the generator. Rapidly pulsing the beam and maintaining image quality requires fast, accurate, and consistent X-ray output. Conventional 12-pulse three-phase generators utilize mechanical devices responding to computer controls. Additional beam on time is frequently needed while the mechanical arm of the conventional autotransformer moves into the position required to produce the kilovoltage designated by the computer. High frequency generators with fast closed loop circuits are electronic devices that respond very quickly, accurately, precisely and consistently to the computer's commands. As a result, high frequency generators are frequently used with pulsed progressive digital fluoroscopy.

Pulsed progressive fluoroscopy refers to the use of pulsed beams as described above and of progressively scanned TV cameras in place of interlaced TV cameras. Progressive scanning permits reducing the standard 60 pulses per second to 30 pulses per second. This reduction in pulses reduces the exposure to the patient, to the staff and to the image intensifier. The manufacturers have addressed this reduction in entrance exposure to the image intensifier (EEII) by improving the image intensifier designs, increasing mAs/frame, increasing frame averaging and other techniques.

Once the X-ray beam is produced, it passes through the patient and the fraction of the beam that is not absorbed exits the image intensifier, which is the first component of the imaging chain. The imaging chain consists of the image intensifier (II), the TV camera and TV monitor. With digital imaging, the computer becomes an integral component of the imaging chain. For film cine, a 35-mm cine camera is added to the chain. Absorption and conversion efficiency of the II, the characteristics of the TV camera, TV monitor, computer design and programs are major factors affecting analog and digital fluoroscopy image quality.

In general, the higher the EEII, the better the image quality. The EEII is the exit exposure from patient. Because the size and density of the patients vary, the relationship between the two is such that skin entrance exposures vary until the preset EEII is obtained. A common misconception is that the patient skin entrance exposure is the same as EEII. Caution is needed in assuming that any percent reduction in the EEII means that the patient exposure is reduced by that percentage. If the EEII is higher than the preset value, the automatic brightness control (ABC) system reduces the exposure until the preset value at the II entrance is reached. The patient's exposure will also be reduced, but the percentage reduction may not equal that of the II. Patient size and density as well as beam filtration will affect the percentage reduction at the patient's skin surface.

When X-rays enter the II, they are converted to light and then to electrons, which are accelerated through a potential difference of about 30,000 volts. They strike the II's anode and are converted back to light. The number of electrons accelerated and the brightness of the light output is directly related to the number of X-ray photons entering the input phosphor of the II. Optical lenses, light sensor, cine and TV cameras are located at the output end of the II.

Manufacturers set the EEII for each imaging mode to obtain the required light brightness at the output phosphor. To maintain the EEII, some manufacturers use a light sensing device, and others monitor the voltage variations across the TV camera. Both of these methods are part of a feedback system, the ABC, that signals the generator to adjust pulse width, mA, and/or kV to maintain the designated EEII. Many new fluoroscopy units have the option of selecting normal and magnified image modes, low or high dose modes in conventional and/or digital fluoroscopic systems.

The ABC system and the automatic dose control system (ADC) work together. The ABC's purpose is to maintain the required EEII. The ADC's purpose is to limit X-ray tube exposure output not to exceed a preset maximum to ensure compliance with federal and state regulations. To verify compliance with these regulations, measurement of maximum exposure rates depends on the type of fluoroscopy unit. For under the table X-ray tube fluoroscopic units, the maximum output is measured at 1 cm above the tabletop. For C-arm fluoroscopy units, the maximum output is measured at 30 cm from the entrance of the II, not the X-ray tube source. The first measurement technique corresponds with measuring skin entrance exposure rates, but the measurement point for C-arms does not. It is a measurement reference point only. The regulatory limits for maximum exposure rates are 10 R/min for routine fluoroscopy and 20 R/min for high dose rate fluoroscopy. There is no limit when in the record mode.

The ABC system will signal the generator to produce the designated pulse width, kV and mA needed to achieve the preset EEII. If the patient is very large and dense, or if the distance between the X-ray tube and the II is increased, the ABC may drive the generator to its maximum factors. The ADC will limit the achievable pulse width, mA, and/or kV so as not to exceed regulatory exposure limits. As a result, the maximum pulse width, mA, and kV may not be adequate for good image quality when the II is at its maximum distance from the X-ray tube. The distance between the tube and the II is increased whenever the angle needs to be changed (i.e., going from anteroposterior to left anterior oblique). Once angulation change has been completed, returning the II as close as possible to the patient will improve image quality and reduce both patient entrance exposures and scatter levels to the staff.

There are two methods of magnification: geometric and electronic. If the II is moved away from the patient (and therefore the X-ray tube source), the image is geometrically

magnified and the dose output goes up. This is called the air gap technique of magnification.

Selecting a magnified mode on the II results in a smaller section of the II being exposed, and the image is magnified by the II. The increase in the EEII is proportional to the inverse square ratio of the areas of the fields of view (FOVs) when the normal 9-inch FOV is changed to the magnified 6-inch FOV:

$$\frac{\text{Exposure rate at 6-inch FOV}}{\text{Exposure rate at 9-inch FOV}} = \frac{9^2 \text{ inch}}{6^2 \text{ inch}} = 2.25.$$

Since a smaller portion of the input phosphor is being exposed, less light is created at the output phosphor. In order to maintain enough light output for acceptable image quality, the ABC system will cause the X-ray tube mA to increase significantly. Increased mA produces increased patient exposures and increased scatter. The increased magnification produces better spatial resolution. This is another example of the conflict between image quality and dose reduction. It is common to have two or three magnified FOVs with new fluoroscopy units.

Appendix II

Table A1. Regulatory Agencies Governing Medical Radiation

Name (abbreviation)	Role
Nuclear Regulatory Commission (NRC)	Regulates special nuclear material (plutonium enriched in ²³³ U and ²³⁵ U, and by-product material of nuclear fission). Their regulations are found in Title 10 of the Code of Federal Regulations (10 CFR) (1). The most important parts for medicine are Parts 19, 20, 30 and 35
Individual states (agreement states)	Regulate the same radioisotopes as the NRC as well as naturally occurring and accelerator-produced radioisotopes and X-ray equipment used
Individual states (nonagreement states)	Regulate naturally occurring and accelerator-produced radioisotopes and X-ray equipment used. (Do not regulate same isotopes as the NRC.)
Food and Drug Administration (FDA)	Regulates radiopharmaceutical development and manufacturing and the performance and radiation safety requirements involved in the production of X-ray equipment. Their regulations are contained in Title 21 of the Code of Federal Regulations
Department of Transportation (DOT)	Regulates the transportation of radioactive materials
Environmental Protection Agency (EPA)	Regulates the release of radioactive material to the environment

Information about risks from ionizing radiation used in setting limits come from the following sources: United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) (16) and Committee on Biological Effects of Ionizing Radiations (BEIR V) (5).

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