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EXPERT CONSENSUS DOCUMENT

# 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness

A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways

*Developed in Collaboration With Mended Hearts*

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This document was approved by the American College of Cardiology Clinical Policy Approval Committee in November 2017 and by the approval bodies of the Heart Rhythm Society (HRS), North American Society for Cardiovascular Imaging (NASCI), Society for Cardiovascular Angiography and Interventions (SCAI), and Society of Cardiovascular Computed Tomography (SCCT) in January 2018.

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**Formerly named ACC Task Force on Clinical Expert Consensus Documents.

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## PREAMBLE

This document has been developed as an Expert Consensus Document by the American College of Cardiology (ACC) in collaboration with the American Society of Nuclear Cardiology, Heart Rhythm Society, Mended Hearts, North American Society for Cardiovascular Imaging, Society for Cardiovascular Angiography and Interventions, Society for Cardiovascular Computed Tomography, and Society of Nuclear Medicine and Molecular Imaging. Expert Consensus Documents are intended to inform practitioners, payers, and other interested parties of the opinion of ACC and document cosponsors concerning evolving areas of clinical practice and/or technologies that are widely available or new to the practice community. Expert Consensus Documents are intended to provide guidance for clinicians in areas where evidence may be limited or new and evolving, or insufficient data exist to fully inform clinical decision making. These documents therefore serve to complement clinical practice guidelines, providing practical guidance for transforming guideline recommendations into clinically actionable information.

The stimulus to create this document was the recognition that ionizing radiation-based cardiovascular procedures are being performed with increasing frequency.

This leads to greater patient radiation exposure and, potentially, to greater exposure for clinical personnel. Although the clinical benefit of these procedures is substantial, there is concern about the implications of medical radiation exposure both to patients and to medical personnel. The ACC leadership concluded that it is important to provide practitioners with an educational resource that assembles and interprets the current radiation knowledge base relevant to cardiovascular imaging procedures that employ ionizing radiation. By applying this knowledge base, cardiovascular practitioners will be able to select and perform procedures optimally, and, accordingly, minimize radiation exposure to patients and to personnel.

This online published document is a more comprehensive treatment of the knowledge base covered in 2 print published documents published under this document's title with subtitles "Part 1: Radiation Physics and Radiation Biology" and "Part 2: Radiological Equipment Operation, Dose-Sparing Methodologies, Patient and Medical Personnel Protection." In addition, this online document contains 3 sections that are not included in the print-published documents: Modality-Specific Operator Education and Certification, Quality Assurance, and Patient and Medical Personnel Radiation Dose Monitoring and Tracking: Programmatic and Individual Considerations.

To avoid actual, potential, or perceived conflicts of interest that may arise as a result of industry relationships or personal interests among the writing committee, all members of the writing committee, as well as peer reviewers of the document, are asked to disclose all current healthcare-related relationships, including those existing 12 months before initiation of the writing effort. The ACC Task Force on Expert Consensus Decision Pathways (formerly the ACC Task Force on Clinical Expert Consensus Documents) reviews these disclosures to determine which companies make products (on the market or in development) that pertain to the document under development. Based on this information, a writing committee is formed to include a majority of members with no *relevant* relationships with industry (RWI), led by a chair with no *relevant* RWI. Authors with *relevant* RWI are not permitted to draft or vote on text or recommendations pertaining to their RWI. RWI is reviewed on all conference calls and updated as changes occur. Author and peer reviewer RWI pertinent to this document are disclosed in Appendixes 1 and 2, respectively. Additionally, to ensure complete transparency, authors' *comprehensive disclosure information*—including RWI not pertinent to this document—is available online (see Online Appendix). Disclosure information for the ACC Task Force on Expert Consensus Decision Pathways is also available online, as well as the ACC disclosure policy for document development.

The work of the writing committee was supported exclusively by the ACC without commercial support. Writing committee members volunteered their time to this effort. Conference calls of the writing committee were confidential and were attended only by committee members and ACC staff.

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## 1. INTRODUCTION

### 1.1. Document Development Process and Methodology

#### 1.1.1. Writing Committee Organization

The writing committee consisted of a broad range of members representing 9 societies and the following areas of expertise: interventional cardiology, general cardiology, pediatric cardiology, nuclear cardiology, nuclear medicine, clinical electrophysiology, cardiovascular computed tomography (CT), cardiovascular imaging, and the consumer patient perspective. Both a radiation safety biologist and a physicist were included on the writing committee. This writing committee met the College's disclosure requirements for relationships with industry (RWI) as described in the Preamble.

#### 1.1.2. Document Development and Approval

The writing committee convened by conference call and e-mail to finalize the document outline, develop the initial draft, revise the draft per committee feedback, and ultimately approved the document for external peer review. All participating organizations participated in peer review, resulting in 21 reviewers representing 299 comments. Comments were reviewed and addressed by the writing committee. A member of the ACC Task Force on Expert Consensus Decision Pathways served as lead reviewer to ensure that all comments were addressed adequately. Both the writing committee and the task force approved the final document to be sent for ACC Clinical Policy Approval Committee. This Committee reviewed the document, including all peer review comments and writing committee responses, and approved the document in November 2017. The Heart Rhythm Society (HRS), North American Society for Cardiovascular Imaging (NASCI), Society for Cardiovascular Angiography and Interventions (SCAI), and Society of Cardiovascular Computed Tomography (SCCT) endorsed the document in January 2018. This document is considered current until

the Task Force on Expert Consensus Decision Pathways revises or withdraws it from publication.

## 2. PURPOSE

### 2.1. Document Purpose

This document's purpose is to assist cardiovascular practitioners to provide optimal cardiovascular care when employing ionizing radiation in diagnostic and therapeutic procedures. It is written to serve as an accessible resource that compiles the current radiation biology and safety knowledge base applicable to cardiovascular imaging. The document covers both patient and medical personnel safety issues for the 3 cardiovascular procedure classes that employ ionizing radiation: x-ray fluoroscopy, x-ray CT, and radionuclide scintigraphy. It includes discussions of radiation dosimetry and its determinants, radiation harm, basics of equipment operation, strategies to minimize dose, and issues of radiation monitoring and tracking. The document's goal is to enable cardiovascular practitioners to select the optimal imaging technique for a given clinical circumstance while balancing a technique's risk and benefits, and to apply that technique optimally to generate high-quality diagnostic images that deliver the greatest clinical value with minimal radiation exposure.

### 2.2. The Radiation Safety Issue

Cardiovascular procedures that employ ionizing radiation have transformed the practice of cardiovascular medicine. These procedures have great value for diagnosis and treatment of appropriately selected patients with known or suspected cardiovascular disease. In addition, they enable more refined recognition and characterization of cardiovascular disease. These procedures are also integral to either planning or executing numerous treatment modalities, which can have profound impacts on the outcomes of cardiovascular disorders.

However, ionizing radiation has molecular-level detrimental effects on exposed human tissue, with potential for injury both to patients and to exposed medical personnel. Consequently, it is desirable to minimize radiation exposure both to patients and to medical personnel in a manner consistent with achieving optimal health benefits. This principle requires that clinicians employ judicious selection of and conduct of radiation-employing procedures to achieve an optimal balance of a procedure's therapeutic benefit against the incremental risk conferred by the radiation exposure.

Currently, cardiovascular diagnostic and therapeutic procedures are a major source of patient exposure to medical ionizing radiation, accounting for approximately 40% of total medical radiation exposure (exclusive of radiation oncology) (1,2). Among occupationally exposed healthcare workers, interventional cardiologists and clinical electrophysiologists are among the most highly exposed, and there is potential for exposure to support personnel as well (in particular, nonphysician staff who work in x-ray fluoroscopy and nuclear cardiology environments) (3,4).

### 2.3. The Need for Physician Radiation Safety Education

Cardiovascular specialists have a responsibility to understand the radiation safety knowledge base, in particular, to:

1. Apply knowledge of the radiation safety knowledge base to make appropriate case selection choices.
2. Conduct radiation-assisted procedures optimally, minimizing exposure to patients and personnel.

There is evidence that many cardiovascular specialists who order and conduct radiation-employing procedures are not fully informed about the radiation doses that accompany the procedure or the associated health implications for their patients and for themselves (5,6). Consequently, there is a need to augment and standardize the level of knowledge and competence that cardiovascular specialists should hold in radiation safety and management. This knowledge base should be incorporated into training curricula and in physician board certification procedures.

Cardiovascular specialists fall into 2 categories requiring different levels of knowledge: those who order cardiac imaging procedures and those who perform them. Training curricula should furnish the level of knowledge appropriate for a particular physician's practice activity. Achieving this goal requires collaboration between various stakeholders in graduate and postgraduate education. The blueprints of certification and recertification examinations should include specifications of radiation safety subject matter. Training programs should configure their teaching curricula to prepare their trainees appropriately.

### 2.4. Appropriateness of Medical Radiation

The balance between a procedure's risk and benefit determines its appropriateness. Although the technical hazards that accompany a procedure are well known, the hazard associated with attendant exposure to ionizing radiation should also be considered a potentially important determinant of a procedure's risk-benefit relationship.

**TABLE 1 Typical Effective Doses for Cardiac Procedures**

| Modality | Protocol | Typical Effective Does (mSv) |
|---|---|---|
| MDCT | Coronary CT angiography: helical, no tube current modulation | 8-30 |
| MDCT | Coronary CT angiography: helical, tube current modulation | 6-20 |
| MDCT | Coronary CT angiography: prospectively triggered axial | 0.5-7 |
| MDCT | Coronary CT angiography: high-pitch helical | <0.5-3 |
| MDCT | CT angiography, pre-TAVR: coronary (multiphase) and chest/abdomen/pelvis | 5-50 |
| MDCT | Calcium score | 1-5 |
| MDCT | Attenuation correction | <0.5-2.0 |
| EBCT | Calcium Score | 1 |
| SPECT | 10 mCi $^{99m}$Tc sestamibi rest/ 30 mCi $^{99m}$Tc sestamibi stress | 11 |
| SPECT | 15 mCi $^{99m}$Tc sestamibi rest/ 45 mCi $^{99m}$Tc sestamibi stress | 17 |
| SPECT | 30 mCi $^{99m}$Tc sestamibi rest/ 30 mCi $^{99m}$Tc sestamibi stress | 18 |
| SPECT | 10 mCi $^{99m}$Tc sestamibi stress only | 2.7 |
| SPECT | 30 mCi $^{99m}$Tc sestamibi stress only | 8 |
| SPECT | 10 mCi $^{99m}$Tc tetrofosmin rest/ 30 mCi $^{99m}$Tc tetrofosmin stress | 9 |
| SPECT | 15 mCi $^{99m}$Tc tetrofosmin rest/ 45 mCi $^{99m}$Tc tetrofosmin stress | 14 |
| SPECT | 30 mCi $^{99m}$Tc tetrofosmin rest/ 30 mCi $^{99m}$Tc tetrofosmin stress | 14 |
| SPECT | 10 mCi $^{99m}$Tc tetrofosmin stress only | 2.3 |
| SPECT | 30 mCi $^{99m}$Tc tetrofosmin stress only | 7 |
| SPECT | 3.5mCi $^{201}$Tl | 15 |
| SPECT | Dual isotope: 3.5 mCi $^{201}$Tl rest/ 30 mCi $^{99m}$Tc sestamibi stress | 23 |
| SPECT | Dual isotope: 3.5 mCi $^{201}$Tl rest/ 30 mCi $^{99m}$Tc tetrofosmin stress | 22 |
| PET | 50 mCi $^{82}$Rb rest/ 50 mCi $^{82}$Rb stress | 4 |
| PET | 15 mCi $^{13}$N ammonia rest/ 15 mCi $^{13}$N ammonia stress | 2 |
| PET | 10 mCi $^{18}$F FDG | 7 |
| Planar | 30 mCi $^{99m}$Tc-labeled erythrocytes | 8 |
| Fluoroscopy | Diagnostic invasive coronary angiography | 2-20 |
| Fluoroscopy | Percutaneous coronary intervention | 5-57 |
| Fluoroscopy | TAVR, transapical approach | 12-23 |
| Fluoroscopy | TAVR, transfemoral approach | 33-100 |
| Fluoroscopy | Diagnostic electrophysiological study | 0.1-3.2 |
| Fluoroscopy | Radiofrequency ablation of arrhythmia | 1-25 |
| Fluoroscopy | Permanent pacemaker implantation | 0.2-8 |

Note: Current and ongoing engineering physical design and image processing software refinements enable dose reductions for all 3 modalities since the data in Table 1 were compiled. These lower doses can be achieved only if radiological equipment is current generation and if operators consciously take advantage of their improved capabilities. As the majority of the currently installed base of equipment is earlier generation, the data in Table 1 reflect most current exposure levels. Reproduced with permission from Einstein et al. (7).

CT = computed tomography; EBCT = electron-beam computed tomography; FDG = fluorodeoxyglucose; MDCT = multidetector-row computed tomography; PET = positron emission tomography; Rb = rubidium; SPECT = single-photon emission computed tomography; TAVR = transcatheter aortic valve replacement; Tc = technetium; Tl = thallium.

*Continued in the next column*

Physicians who either order or conduct such procedures need to:

1. Know the magnitude of a patient's risk associated with a procedure's radiation exposure.
2. Apply that understanding to determining the appropriate procedure and selecting the approach that provides the best balance of benefit and risk.

To assess the risk-benefit relationship for a given patient, the cardiovascular specialist who orders or performs the procedure should understand, in the context of that patient's clinical characteristics, how the radiation dose that accompanies the procedure may be detrimental to that patient's health and how the outcome of the procedure may be beneficial.

## 3. CURRENT TRENDS IN PATIENT AND MEDICAL PERSONNEL RADIATION EXPOSURE FROM CARDIOVASCULAR PROCEDURES

### 3.1. Trends in Patient and Medical Personnel Radiation Exposure

The past 2 decades have seen substantial development and refinement of the 3 cardiovascular imaging techniques that employ ionizing radiation: x-ray fluoroscopy, x-ray CT, and radionuclide scintigraphy. Engineering advances have improved image quality while in many cases reducing the radiation doses employed for image acquisition. These advances have greatly enhanced cardiovascular diagnostic and therapeutic capabilities, thereby improving both diagnosis and therapy.

Despite these engineering refinements, the patient radiation doses that accompany these procedures remain substantial and, for the most part, are at the upper range of radiation-based diagnostic studies. Medical professionals should be aware of the radiation dose that these studies deliver to patients. In addition, within a particular type of study, the radiation dose can vary substantially depending on image acquisition protocol and patient characteristics. For reference, the commonly performed cardiovascular diagnostic studies and their radiation dose ranges are listed in Table 1. Note that the doses delivered by x-ray CT and nuclear cardiology can vary substantially depending on particulars of image acquisition protocols.

Patient radiation dose ranges (in millisieverts) for the 3 principal radiation-based cardiovascular imaging studies: x-ray fluoroscopy, x-ray CT, and nuclear cardiology. Individual procedure categories are further subdivided according to types of image acquisition protocols. Note that for a particular procedure category, the dose can vary considerably depending on image acquisition protocol and, within a given image acquisition protocol, procedure conduct and patient characteristics.

However, augmented capabilities have led to increased utilization levels, resulting in greater radiation exposure both at the individual and at the population levels. In addition, refinement of x-ray fluoroscopic systems, yielding greatly improved image quality, has facilitated the development of increasingly complex cardiovascular interventional procedures. These procedures often require longer fluoroscopic times, resulting in larger radiation exposures than more basic procedures.

Increasing radiation exposure has the potential to increase the risk of adverse effects such as radiation-induced cancer. It is uncertain, however, whether medical radiation is in actuality increasing cancer incidence in the population, because a small increase would be difficult to detect against the large background incidence of cancer.

During the 2014 calendar year, the U.S. healthcare system performed, on Medicare beneficiaries, an estimated 925,848 diagnostic cardiac catheterization procedures, 342,675 percutaneous coronary interventions, 248,234 clinical electrophysiologic procedures, 61,207 cardiovascular x-ray CT scans, and 2,111,558 nuclear cardiology examinations, for a total of 3,689,522 cardiovascular procedures that use ionizing radiation in Medicare beneficiaries (8). Medicare beneficiaries are estimated to consume 30% to 40% of all cardiovascular procedures.

Natural background radiation averages 3.0 millisieverts (mSv) (see Section 4 for a discussion of the Sievert unit of radiation exposure) per person/year in the United States—equivalent to 150 posteroanterior chest radiographs (a posteroanterior chest-x-ray dose is 0.02 mSv; combined posteroanterior and lateral is 0.06 mSv) (9). At the population level, between 1987 and 2006, estimated per person total medical radiation exposure grew from 0.6 mSv/year (0.2 × background) to 3.2 mSv/year (1.07 × background) (10). Consequently, patients are currently receiving, on average, more radiation from medical sources than from natural background sources. 2006 is the latest year for which compiled data are available. (The National Council on Radiation Protection is currently compiling contemporary data—expected availability 2019—and it is likely that current average medical exposure will be found to have increased further). The 2006 medical exposure is equivalent to 160 posteroanterior chest x-rays per person/year. Risks associated with this exposure must be weighed in relation to the health status benefits achieved by these procedures.

Physicians who are invasive cardiovascular procedure operators are among the most highly exposed of the occupationally exposed healthcare workers. Measurements of interventional cardiologist operator exposure using current equipment and protection practices demonstrate an exposure range of 0.2 to >100 microsieverts (μSv) per procedure with a per-procedure average of 8 to 10 μSv (11). Thus, an active interventional cardiologist performing 500 procedures/year employing current technology may be expected to receive, in addition to background exposure, a dose of as much as 10 mSv/year or, in a most extreme scenario, 300 mSv over a 30-year active professional career.

Nonphysician clinical personnel working in an x-ray environment should receive substantially smaller doses than tableside operators, although nuclear cardiology technologists who handle radioactive materials tend to be more highly exposed. Determinants of nonphysician exposure include time spent in an active procedure room, location in the procedure room during active procedures, and exposure handling radioactive materials. There are no data that characterize the total number of exposed workers or their exposure values.

### 3.2. Potential Consequences of Patient and Medical Personnel Radiation Exposure

There are 3 important potential consequences of the growing use of ionizing radiation in cardiovascular medicine (see Table 2).

1. At the individual patient level, although many individuals receive little or no medical radiation exposure, some receive lifetime doses in excess of 100 mSv. At the population level, such doses are associated with a detectably increased cancer risk (12). Consequently, such exposures may place individuals at increased personal risk of developing cancer or tissue reactions, including skin injury and cataracts. The actual magnitude of this risk varies substantially with patient characteristics (see Section 5.4).

**TABLE 2 Potential Consequences of Patient and Medical Personnel Radiation Exposure**

| | |
|---|---|
| Individual Patient | Although many individual patients receive little or no medical radiation exposure, some receive lifetime doses in excess of 100 mSv. Doses in excess of 100 mSv are associated with a detectable increased cancer risk |
| Population | Increased total exposure incurred by total population of patients has the potential to increase the population incidence of cancer and other radiation-related disorders |
| Occupationally Exposed Workers | Occupationally exposed physicians and support staff may receive doses as large as 10 mSv per year over a career that may span 30–40 years. The implications of this level of exposure at the level of the individual practitioner are uncertain. |

2. At the population level, the increased total exposure incurred by patients has the potential to increase the population incidence of cancer.
3. With respect to medical personnel, occupationally exposed physicians and support staff may receive doses as large as 10 mSv/year over a career that may span 30 to 40 years. The implications of this level of exposure at the level of the individual practitioner are uncertain.

The ongoing magnitude of exposure to the general population and to occupationally exposed healthcare workers has health implications at the population level and for individual patients and healthcare workers. It is important that physicians and healthcare workers understand the ionizing radiation knowledge base and apply it to protect patients, themselves, and their colleagues through judicious case selection and appropriate conduct of radiation-assisted procedures.

## 4. THE MANY MEASURES OF RADIATION

### 4.1. Radiation Exposure and Dose Metrics

Ionizing radiation exposure and dosimetry are not easily characterized by simple metrics. Radiation exposure and dose may be considered from the perspective of 5 distinct but inter-related frames of reference. For this document's purpose, these metrics have specific meanings as defined in the following text:

- **Exposure:** the quantity of radiation that impinges on a tissue.
- **Absorbed Dose:** the concentration of energy deposited by radiation in a specific exposed tissue.
- **Equivalent Dose:** the absorbed dose adjusted by a radiation weighting factor to reflect the different degrees of biological damage caused by various types of radiation.
- **Effective Dose:** a metric that reflects the overall biological effect from radiation on an average subject from a particular radiation exposure scenario.
- **Injected Dose:** A metric that describes the quantity of radioactivity of a radioactive substance injected into a patient for a nuclear scintigraphy study (expressed in millicuries [mCi]). Injected dose is a determinant of the 4 dose parameters listed previously. However, the exact relationships between injected dose and absorbed dose and equivalent dose are complex, and are discussed in depth in Section 6.4.

A comprehensive assessment of radiation effects requires consideration of all 5 parameters. The relationships between these metrics are complex and are determined by the properties of both the radiation and the exposed tissue. For clarity in this document, the interaction of radiation with tissue will be characterized from the perspective of 4 of the previously mentioned inter-related frames of reference: exposure, absorbed dose, equivalent dose, and effective dose. It should be noted that in the literature, the terms "exposure" and "dose" are often used with less specific meanings than those used in this document. For this document's purpose, these metrics have specific meanings as defined in the following text.

**Exposure**

Radiation exposure refers to the presence of ionizing radiation at the location of the exposed tissue. This is quantified by standardized measures of a physical quantity that represent the amount of radiation present at that location. The typically used measure of radiation quantity is air kerma (Section 4.4.1), which is the amount of energy released by the interaction of the radiation with a unit mass of air. Its unit of measure is the gray (Gy). Its units are joules (J)/kg. One Gy is the quantity of radiation that when interacting with 1 kg of air releases 1 joule of energy. It should be noted that this is a measure of cumulative energy *intensity* as the energy deposition is normalized to a quantity of the absorbing material.

**Absorbed Dose**

Absorbed radiation dose is a measure of the energy that radiation deposits in an exposed tissue through interactions with its molecular constituents. It differs from exposure in that the radiation present at a given location does not deposit all of its energy there. The fraction of its energy that a given radiation exposure will deposit in the exposed tissue varies with the type and energy of the radiation and the tissue composition.

Absorbed dose is also a measure of the *intensity* of cumulative energy deposition (energy deposited per unit mass of tissue) and is expressed in Gy—joules of energy deposited per kilogram of tissue. In exposure by external radiation beams, dose is not uniform throughout the exposed volume, but varies, typically as a function of depth from the beam entrance port.

**Equivalent Dose**

Different types of ionizing radiation cause varying degrees of tissue injury for a given absorbed dose. Equivalent dose is a construct used to account for differences in tissue injury caused by different radiation types. X-rays and gamma rays are the benchmarks against which particle radiation types such as protons, neutrons, and beta particles are compared. Some particles, in particular, protons, neutrons and alpha particles, cause greater tissue injury at a given dose than do x-rays, gamma rays, and electron particles. To adjust for this variability, each radiation type is assigned a radiation weighting factor by which the absorbed dose (in Gy) is multiplied to yield a measure of the expected tissue injury caused by that dose. The unit of measure is the sievert (Sv) which is the absorbed dose in Gy multiplied by the radiation weighting

factor. Of the different radiation types, x-rays, gamma rays, and electron particles (electrons and positrons) are assigned a radiation weighting factor of 1. Other particle radiation types have weighting factors ranging between 2 and 20. For medical imaging, which employs x-rays and gamma rays, absorbed dose and equivalent dose take the same value, that is, an exposure with an absorbed dose of 20 mGy has an equivalent dose of 20 mSv.

**Effective Dose**

Effective dose is a measure of the estimated potential for a biological effect on the complete organism caused by a particular absorbed radiation dose. The effective dose construct has been developed as a measure of the estimated potential for a stochastic effect (such as cancer induction) that would be caused by a particular (nonuniform) absorbed radiation dose. It is the sum of the equivalent doses received by each organ with each organ equivalent dose multiplied by a coefficient that reflects that organ's sensitivity to a stochastic effect. The unit of effective dose is also the Sv, as discussed in greater depth in Section 4.5. The Sv, like the Gy of the absorbed dose's unit, is specific to its particular context and is equal to 1 joule/kg. The connection between effective dose and absorbed dose is that an effective dose of 1 Sv is associated with the same estimated stochastic risk that accompanies a uniform total body exposure with an absorbed dose of 1 Gy of radiation that has a radiation weighting factor of 1.

In medical radiation exposures, absorbed dose is typically not uniform throughout all tissues. For x-ray imaging, dose is concentrated in the body region being examined and varies with depth from the beam entrance port. For nuclear imaging, dose is concentrated in the tissues that most avidly take up the tracer or are involved in its elimination.

Different tissues have different sensitivities to radiation-induced effects. In the effective dose construct, each tissue is assigned a tissue-weighting factor that specifies its sensitivity to radiation effects. To calculate the effective dose in Sv, each exposed tissue's equivalent dose is multiplied by its tissue-weighting factor yielding that tissue's contribution to the overall risk. The contributions to risk from all exposed tissues are summed, yielding total risk, expressed as the effective dose in Sv. (How the effective dose is calculated is discussed in greater depth in Section 4.5).

It is important to note with regard to childhood and teenage radiation exposure that tissue weighting factors do not take into account the increased sensitivity of the tissue of the pediatric population. Thus, for children and adolescents, a given radiation exposure confers a greater risk than the same exposure would confer to an adult population. In addition, children who do not have life threatening disorders have a long life expectancy, which provides a longer period for radiation-induced illness to present (13).

### 4.2. Challenges in Relating Radiation Exposure and Dose to Risk of Detrimental Effects

Detrimental effects of radiation exposure typically present weeks to years following exposure. In addition, many detrimental effects, principally cancer, have a large background frequency that complicates the attribution of an effect in a particular subject to prior radiation exposure.

### 4.3. Types of Ionizing Radiation Used in Medical Imaging

Radiation in cardiovascular imaging consists of photons with energy >10 kiloelectron volts (keV) (x-rays and gamma rays) and positrons. The physical effect of such radiation is to eject electrons from atoms that comprise tissue molecules forming ions and free radicals. This causes molecular damage, potentially destroying a molecule or altering its function. This is the basis for the term "ionizing radiation" (discussed in detail in Section 5).

#### 4.3.1. X-Rays and Gamma Rays

X-rays and gamma rays are in a class of ionizing radiations, which is transmitted by photons. Photons travel at the speed of light, and have no mass and no charge. Their electromagnetic energy ranges from a few electron volts (eV) to millions of electron volts (MeV). The energies commonly employed in cardiovascular imaging are tens to hundreds of keV.

X-ray or gamma photons cause ionization by colliding with and ejecting electrons from atoms of constituent tissue molecules. Energy is exchanged in the process, with the ejected electron gaining energy of motion and the photon losing energy. The incident photon may or may not be extinguished by the interaction. After an initial interaction with an atom, photons that were not extinguished continue to travel through the exposed medium at a degraded energy. The weakened (scattered) photon can collide with additional atoms (further exposing the subject), potentially ionizing them as well, until either all of its energy is dissipated and the photon ceases to exist, or it escapes from the subject (exposing the environment).

X-rays used in x-ray fluoroscopy and x-ray CT have a of photon energy spectrum between 30 and 140 keV (the energy spectrum of x-rays generated in typical diagnostic x-ray tubes includes photon energies <30 keV, but the majority of these lower-energy photons are filtered out in the x-ray tube and do not expose the subject). Thallium-201 and Technetium-99m (Tc-99m) are the principal radionuclides used in cardiovascular nuclear scintigraphy studies. Thallium-201 releases photons primarily in the

68 to 80 keV range, similar to diagnostic x-rays. Tc-99m releases photons primarily in the 140 keV range.

#### 4.3.2. Positrons

Positrons are positively charged electrons. They have mass and charge. When positrons travel through a medium, their electrostatic charge causes them to interact readily with electrons in the medium, leaving a trail of ionization. Consequently, they have a very short mean free path in tissue of 6 to 7 mm with a maximum of 15.2 mm. Positrons continue to cause ionization until their energy decreases to a critical level, at which point they are annihilated by colliding with an electron of a constituent atom. This annihilation process releases 2 511-keV gamma ray photons that travel in opposite directions. Because the emitted photons have such high energy, they are minimally attenuated in tissue, and the majority reach the imaging detector. Rubidium-82 is the most commonly used positron emitter for myocardial perfusion imaging; nitrogen-13 ammonia is used less frequently for this purpose. Fluorine-18 deoxyglucose is used in cardiology for metabolic imaging and to detect myocardial sarcoid and other inflammatory conditions.

### 4.4. Relationships Between Exposure and Absorbed Dose

Medical radiation exposures occur in 2 ways:

1. Exposure from an external radiation beam (x-ray fluoroscopy and x-ray CT)
2. Exposure from radioactive decay within the subject (nuclear scintigraphy).

#### 4.4.1. Exposure From External Beams

For external radiation beams, the absorbed dose is determined by the total incident exposure, the properties of the incident radiation, and the volume of tissue exposed. Exposure from an external beam is measured with the parameter *air kerma*.

Air kerma is the standard unit of measure for x-ray beam exposure. Kerma is an acronym for "*k*inetic *e*nergy *r*eleased in *ma*terial." Kerma is an energy intensity measured in units of joules of energy released per kilogram of absorbing material (J/kg). The kerma unit of measure is the gray (Gy), which represents 1 joule of energy released per kilogram of absorbing material. The metric "air kerma" is used in medical x-ray fluoroscopic applications because the measurement is made using air as the absorbing material that is ionized by the incident radiation beam.

##### 4.4.1.1. Absorbed Dose in Tissue From an External Beam

As described in Section 4.1, radiation absorbed dose, as distinguished from exposure, is an energy *intensity,* the concentration of radiation energy actually deposited in the exposed tissue. Not all radiation energy that impinges on a tissue is absorbed. Some radiation (a variable quantity depending on both radiation and tissue characteristics) passes through the tissue without interacting with it, depositing no energy. (This fraction of the radiation is what generates the radiological image). Absorbed dose is also an intensity measured in gray (Gy), which represents deposition of 1 joule of energy per kilogram of irradiated tissue.

External beam energy deposition in tissue is not uniform. X-ray radiation is attenuated as it passes through tissue. For diagnostic x-rays, in most tissues, x-ray intensity decreases by approximately a factor of 2 for each 5 cm of tissue that it traverses. Thus, tissue exposed to an external x-ray beam, as occurs in x-ray fluoroscopy and x-ray CT, is not exposed uniformly—the dose decreases exponentially with depth from the beam entrance port. The incident beam air kerma is a good measure of dose at the body surface, but structures deeper than the body surface receive smaller doses. Thus, to estimate the dose to a particular body structure within the path of an x-ray beam but remote from the beam entrance site, adjustments have to be made to account for beam absorbance.

##### 4.4.1.2. Kerma-Area Product: Incorporating the Volume of Exposed Tissue in X-Ray Fluoroscopy

Kerma (measured in Gy) is a measure of dose intensity (joules of energy deposited per kg of tissue). The risk of radiation harm is related both to the intensity of the radiation dose and to the quantity of tissue that receives the dose. (The greater the quantity of tissue that receives a given dose, the greater the risk.) Kerma-area product (KAP) is the product of the beam's kerma and its cross-sectional area. Thus, this parameter also incorporates the volume of tissue irradiated. This concept is particularly important in x-ray fluoroscopy, as imaging field sizes can vary considerably leading to very different KAPs from one examination to another.

##### 4.4.1.3. Kerma-Length Product: Incorporating the Volume of Exposed Tissue in X-Ray CT

CT delivers radiation to a patient in a manner quite different from that of projectional imaging or fluoroscopy. Typically, a narrow x-ray beam with a rectangular cross section is used to collect images from multiple angles as it rotates around the patient. This distributes the dose much more uniformly around the patient compared with projectional imaging. Instead of measuring an entrance air kerma to the patient, "dose" is measured by convention as an air kerma inside of an acrylic cylinder used to simulate a patient. Two sizes of cylinders are used: 32- and 16-cm diameters, often referred to as body and head phantoms, respectively. Air kerma is measured inside the phantom using an ionization chamber in the shape of a

pencil that is placed inside a hole that is appropriately drilled in the plastic phantom. This yields the dose "intensity" analogous to the air kerma measurement for x-ray fluoroscopy.

The phantom air kerma is multiplied by the axial scan length to incorporate the volume of tissue irradiated. This method generates a variety of dose metrics for x-ray CT; these are discussed in detail in Section 6. For example, the computed tomography dose index$_{100}$ (CTDI$_{100}$) is a measure of the dose delivered along a 100-mm scan length. Computed tomography dose index$_{w}$ (CTDI$_{W}$ weighted) accounts for the fact that more peripherally located structures, which are closer to the beam entrance, receive larger doses than deeper structures.

#### 4.4.2. Exposure From Radionuclides

Unlike external beam exposures, radionuclide exposures come from radioactive decay within the subject. In nuclear cardiology applications, a radiopharmaceutical is administered systemically and distributes throughout the body. Distribution may be preferential to particular tissues depending on the pharmacological properties of the radiopharmaceutical. The dose delivered by a radiopharmaceutical is determined by the activity administered, the tracer distribution, the tracer elimination rate, and the tracer's time-activity relationships. These data in combination with the tracer radionuclide's radiation characteristics permit estimation of radiation dose delivered to each organ or tissue. This model is discussed in greater detail in Section 6.

### 4.5. Estimating Effective Dose

The concept of effective dose was formulated to create a metric that estimates a given radiation dose's contribution to stochastic health risk—namely the risk of cancer induction and of genetic changes (see Section 5.2.2) (14). The effective dose concept is derived from 2 facts of radiation dosimetry:

1. Medical and occupational radiation exposures are generally not uniform, with some organs and tissues receiving greater exposures than others.
2. Sensitivity to radiation-induced detrimental effects varies among different organs and tissues.

The effective dose is expressed in units termed Sv (Section 4.1). The units are a special term for J/kg (the same as for the Gray). The Sv represents the hypothetical uniform whole-body dose that confers the same stochastic risk as the nonuniform dose actually delivered. A uniform total body absorbed dose of 1 J/kg of radiation that has a radiation weighting factor of 1 would yield an effective dose of 1 Sv.

The effective dose construct assigns each organ/tissue a weighting factor that reflects the tissue's sensitivity to radiation-induced stochastic risk. The calculation of effective dose involves estimating each organ's actual equivalent dose (in Gy). That dose is adjusted by multiplying it by the organ's tissue-weighting factor. The organ sensitivity-adjusted individual organ doses are summed to yield a total effective dose (in Sv).

For a chest exposure, absorbed dose is concentrated in the skin, mediastinal structures, lungs, breast, and thoracic bone marrow. Doses to these organs would contribute the largest components to the effective dose calculation. Smaller quantities of scattered radiation would expose the abdominal viscera and upper neck. As these organs would receive smaller exposures, their contribution to the effective dose calculation would be smaller. Other types of radiological examinations, such as x-ray CT and cardiac scintigraphy, would have different organ exposure distributions yielding different effective dose calculations.

Deriving a quantitative measure of a subject's estimated increased cancer risk due to a specified effective dose is complex because the risk magnitude is determined by numerous other variables, including subject age (children and young adults are more susceptible), gender (women are more susceptible), and natural life expectancy (longer natural life expectancy confers a longer time available for cancer to present [13]). Statistical models that attempt to quantify the dose-risk relationship have been developed based on large population exposures. These models are discussed in Section 5.4.

The individual tissue weighting factors have been revised over time as accumulating epidemiological evidence permits more precise estimates of organ sensitivity. The International Commission on Radiation Protection published the most recent organ sensitivity estimates in 2007 in ICRP Publication 103 (15). The estimates are listed in **Table 3**.

The tissue weighting factors are measures of the individual tissue's intrinsic sensitivities to radiation-induced cancer. Three applications of the effective dose concept have relevance for medical exposure to patients undergoing cardiovascular procedures and occupationally exposed medical personnel. They are:

1. For cardiac x-ray fluoroscopy and cardiac x-ray CT, the radiation is concentrated in the subject's chest. Thus, the exposures that contribute the most to stochastic risk are the thoracic red bone marrow; the lung; and, in females, the breast.
2. Measurements of exposure in phantoms provide models that enable the rough estimation of equivalent dose delivered to particular internal structures by the exposure as measured by the subject exposure parameters, including KAP product for x-ray fluoroscopy, kerma-length product for x-ray CT, and radionuclide

**TABLE 3** Tissue Weighting Factors Used to Calculate Effective Dose in Sieverts

| Organs | Tissue Weighting factors (ICRP103-2007) |
|---|---|
| Red bone marrow | 0.12 |
| Colon | 0.12 |
| Lung | 0.12 |
| Stomach | 0.12 |
| Breasts | 0.12 |
| Gonads | 0.08 |
| Bladder | 0.04 |
| Liver | 0.04 |
| Esophagus | 0.04 |
| Thyroid | 0.04 |
| Skin | 0.01 |
| Bone surface | 0.01 |
| Salivary glands | 0.01 |
| Brain | 0.01 |
| Remainder of body | 0.12 |
| **Total** | **1.00** |

Adapted from the International Commission on Radiological Protection (ICRP) (15).

doses for cardiovascular nuclear cardiology. These individual organ equivalent doses may then be converted to effective doses and summed to calculate an estimate of the subject's effective dose. As noted in the previous text, the absolute effective dose-risk relationship is modulated by subject characteristics.

3. Measurements of occupational exposure for healthcare workers may be used to estimate the worker's stochastic risk.

### 4.6. Synopsis of Measures of Radiation Exposure and Dose

The existence of the many different measures of radiation exposure and dose has the potential to cause confusion leading to misapplication of units of measure. Table 4 contains a synopsis of the principal metrics described in this section. In reporting radiation from an individual procedure to a specific patient, modality-specific parameters should be used. For x-ray fluoroscopic procedures, air kerma at the interventional reference point and KAP should both be reported. For CT procedures, the $CTDI_{vol}$ and dose-length product (DLP) (discussed in detail in Section 6.3.3) should be reported, along with the size of the CTDI phantom (32- or 16-cm). Effective dose has limitations for calculating individual patient dosimetry because, for example, the tissue weighting factors are gender and age averaged (not accounting for the fact that children and females are more sensitive). However, it may be useful to make general comparisons between modalities, protocols, and imaging strategies. Given that effective dose is an estimate that involves a number of assumptions, the calculated and reported values should be accompanied by the actual exposure measurements and a description of the methodology used for estimation, that is, a conversion factor.

## 5. HOW RADIATION CAN HARM PEOPLE

### 5.1. Mechanism of Radiation-Induced Biological Effects

Radiation-induced tissue injury is due to molecular alterations caused by particles or photons that have sufficient energy to induce ionization. Atoms ionized by radiation are frequently chemically unstable and transform themselves or their constituent molecules into free radicals. A common example is ionization of water, which upon interacting with an x-ray photon, decomposes into a free electron, a proton, and a hydroxyl radical. The hydroxyl radical, because of its unpaired electron, is highly reactive and interacts avidly with biomolecules (proteins or nucleic acids). Similarly, an x-ray photon can ionize an atom that is a constituent of a biomolecule. Thus, a biomolecule can be altered by either reacting with a radiation-generated free radical or by being directly ionized by radiation. The resulting structural change can alter a molecule's function.

Radiation-induced tissue damage from ionizing radiation takes many forms that have variable intervals between exposure and clinical presentation. Some harmful radiation effects appear within days to months following the exposure. Other harmful radiation-induced effects have long latent periods, becoming evident only many years following the inciting exposure, or may not present in the individual's remaining lifetime.

Damage to a molecule that is an important tissue constituent, such as a protein, can alter the cell's function. If a cell incurs sufficient damage to its constituent molecules it may not be able to maintain basic cellular operations and undergo necrosis. If a cell incurs strategic damage to its deoxyribonucleic acid (DNA), a previously normal gene may be transformed into an oncogene or the ionization process may lead to other changes in cellular environment that promote carcinogenesis.

### 5.2. Types of Radiation-Induced Health Effects

Radiation-induced health effects are divided into 2 broad groups that differ in their mechanism, the nature of their effects, their relationship to absorbed dose, and the temporal relationships between exposure and manifestation.

#### 5.2.1. Tissue Reactions (Formerly Called Deterministic Effects)

Tissue reactions are caused by radiation-induced injury to structural and functional molecules in cells. Cell necrosis will occur if the amount of molecular alteration incurred

**TABLE 4 Synopsis of Radiation Exposure and Dose Metrics**

| Metric | Unit | Utility |
|---|---|---|
| | | **Absorbed Dose-Related Parameters: Characterize Dose to Organ/Tissue or Whole Body** |
| Absorbed dose | Gy | Amount of ionizing radiation energy deposited per unit mass of tissue. 1 Gy = 1 Joule of energy deposited per kg of tissue. This metric is a concentration of energy deposition—not the total quantity of energy deposited. |
| Equivalent dose | Sv | Absorbed dose adjusted by a radiation weighting factor that adjusts for the specific tissue-injuring potential of the particular radiation type. Photons (x-rays and gamma rays) have a weighting factor of 1. Electrons also have a weighting factor of 1. Neutrons have larger weighting factors that vary with their energy level. For medical imaging, because only photons and positrons are used, absorbed dose and equivalent dose take the same value. |
| Effective dose | mSv | Calculated whole-body quantity used to roughly compare potential stochastic risks from different partial-body exposures. It is expressed as the uniform whole-body dose that would confer the stochastic risk equivalent to that caused by a regional exposure. |
| | | **Modality-Specific Parameters** |
| X-ray fluoroscopic air kerma (free-in-air) | Gy | Used to assess level of radiation present at a location. In x-ray fluoroscopy, cumulative air kerma at the interventional reference point can be used to approximate beam entrance port skin dose. (For isocentric C-arms, the reference point is located 15 cm from isocenter in the direction toward the x-ray source. This point in space approximates the location of beam entry into the patient, but due to variation in table height and tube angulation, is only an estimate of beam entrance port skin dose). |
| X-ray fluoroscopic Air-KAP, also referred to as dose-area product (DAP) | $Gy \cdot cm^2$ | Used to assess the total quantity of radiation delivered by an external beam. It is the product of the cumulated amount of air kerma and the area of a radiographic or fluoroscopic field. KAP is often used as the basis for estimating effective dose from a fluoroscopic procedure. |
| Computed tomographic dose index ($CTDI_{FDA}$, $CTDI_{100}$, $CTDI_w$, and $CTDI_{vol}$) | mGy | Used to assess relative level of radiation applied during a CT imaging sequence. This metric is a concentration of energy deposition in the exposed volume. It is not a total deposited energy quantity, as it does not incorporate the actual exposed volume (*See DLP below*). Different versions are used for varied purposes. |
| Computed tomographic dose-length product (DLP) | mGy·cm | Used to assess integrated amount of radiation applied along an axial length of a patient during a CT examination. Can be used to estimate effective dose from the procedure. |
| Radionuclide injected dose | mCi | A measure of the quantity of radioactivity injected for a nuclear scintigraphy study. The relationship of injected dose to other dose parameters is complex and includes the nature of the nuclide's radiation, the nuclide's half-life, the distribution in the body, and the elimination kinetics. |

CT = computed tomography; CTDI = computed tomographic dose index; KAP = Kerma-Area Product.

exceeds the cell's ability to repair itself and maintain function. If a sufficient fraction of an exposed tissue's cells malfunction, fail to heal properly, or necrose, macroscopically evident tissue injury will occur. Consequently, tissue reactions typically exhibit dose-related severity. Above the threshold dose, a greater dose will cause more extensive cellular injury to a greater number of cells, increasing the severity of the macroscopic effect in a dose-related fashion.

Skin injury is the most common tissue reaction observed in cardiovascular imaging. It occurs almost exclusively from x-ray fluoroscopic exposures and can be sufficiently severe to cause tissue necrosis. Other tissue reactions include cataract formation; bone necrosis; and, in the heart, damage to myocardium, cardiac valves, and coronary arteries. In addition, if a fetus incurs sufficient cellular injury at critical stages of organogenesis, development will be impaired (16).

Tissue reactions only become macroscopically evident if a threshold radiation dose is exceeded. A dose below the threshold dose, although it may cause unapparent cellular injury, will not cause a detectable reaction. This is because at subthreshold doses, even though some cells incur radiation-induced molecular change, the tissue is able to maintain function and viability because the damage does not kill a sufficient fraction of the cells or affect cellular function sufficiently to cause macroscopically evident tissue injury or functional alteration (below the threshold dose, a small number of cells in a tissue may undergo necrosis but not in sufficient numbers to produce a macroscopically detectable effect) (17).

Tissue reactions occur with a time delay between exposure and the appearance of tissue injury. This is due to the time required for molecular damage to evolve and to cause sufficient cellular dysfunction to lead to macroscopically evident injury.

Thus, a subject exposed to a dose that is subthreshold for a tissue reaction will appear normal initially with no macroscopic evidence of an effect on the exposed tissue. A subject who receives a greater than threshold dose will initially appear to be unaffected but the exposed tissue will, at a later time, show signs of injury. At doses above the threshold, the severity of visible tissue injury increases as absorbed dose increases.

#### 5.2.2. Stochastic Effects: Cancer

Stochastic effects are caused by radiation-induced damage to a cell's genetic material that causes the damaged

cell's DNA to be reprogramed into dysfunctional operation. The principal stochastic event of clinical importance is radiation-induced cancer.

Stochastic effects differ from tissue reactions in their dose relationship. Whereas tissue reactions have a definite dose threshold below which they do not occur and exhibit dose-related severity, stochastic events, in contrast, are not known to have a dose threshold and do not have a quantitative dose-related severity. Rather, their relationship to dose is probabilistic, and the severity of a stochastic event, should it occur, is not related to the dose that triggered it. The probability of a stochastic event is thought to increase approximately linearly with dose (18).

The difference between radiation-induced damage to constitutive structural cell proteins, which causes tissue reactions, and damage to DNA, which causes stochastic events, is that a single critically located DNA damage event can create an oncogene. Radiation-induced cancer either does or does not occur (or may not present within the subject's lifetime). The probability that it may occur is related to dose. The likelihood that a stochastic event will occur does not reach 100% even at very large doses.

Damage to a DNA molecule can have variable consequences depending on how the particular chemical change to a DNA molecule affects gene function. Damage to a noncoding region would most likely be inconsequential, whereas damage to a coding region could affect its gene product, and damage to a regulatory region could affect its regulation. Either of the latter 2 phenomena has the potential to transform a normally functioning gene into an oncogene.

This phenomenon explains how, although radiation exposure likely causes many DNA damage events, most of such events are inconsequential and may be repaired successfully. A clinically evident radiation-induced cancer event will occur only if radiation-induced injury affects a strategic segment of DNA and there is sufficient time following the radiation event for the cancer to develop, evolve, and present. Many other biological factors including age, gender, and genetics modulate the likelihood of inducing a stochastic event.

There is uncertainty about the quantitative relationship between dose and risk for stochastic events. At small doses, stochastic risk is small and difficult to distinguish statistically from zero. Theoretically, a single x-ray photon ionizing a strategic atom within a portion of DNA that encodes a critical gene could create an oncogene. This is the theoretical basis for the concept that there is no threshold dose below which stochastic risk is zero (see Section 5.4) (12).

#### 5.2.3. Stochastic Effects: Heritable Effects in Offspring

Theoretically, radiation injury to DNA in germ cells could cause a clinically important mutation that would not affect the exposed individual, but would be transmitted to that individual's offspring. Such effects have only been demonstrated in animal models but have not been observed in humans with statistical significance (19). The absence of any significant finding following exposures in humans indicates they have a very low probability that could be detected only in exposures to very large populations (20).

### 5.3. Tissue Reactions: Dose-Effect Relationships

#### 5.3.1. Skin Injury

The most common radiation-induced tissue reaction is skin injury at the beam entrance port following an x-ray fluoroscopically guided invasive procedure (17). Skin injuries from medical diagnostic radiation virtually only occur following fluoroscopic exposures because fluoroscopy is the only modality that has the potential to deliver a skin dose that exceeds the injury threshold. Although rare cases of skin depilation and erythema have occurred following x-ray CT examinations, these were caused by excessive radiation output due to improper programming of the x-ray parameters or a large number of scans being repeated over the same scan area.

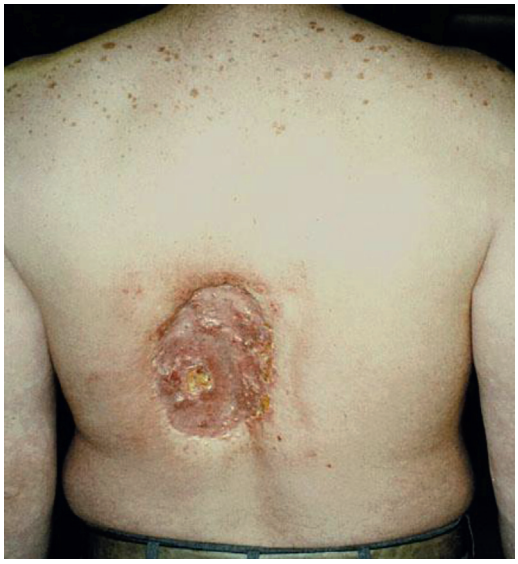
Skin entrance port injuries have shapes that reflect the shape of the x-ray beam, which is typically rectangular. These injuries vary in severity from erythema, to desquamation, to ulceration and necrosis. They are always located at the site of beam entrance, which is typically on the subject's back.

In some cases, transient skin erythema may occur within hours to a few days following the exposure and then resolve. A more significant erythema occurs after a delay of a week to a few weeks. More severe skin injury typically appears 4 to 8 weeks following the exposure. In extreme cases, the ulceration can become confluent and full thickness necrosis of skin may develop exposing underlying fat, muscle, and even bone (**Figure 1**).

The threshold dose that will cause a skin injury is variable, as is the relationship between dose injury severity. The skin dose for a particular procedure may be approximated by the cumulative air kerma (Section 4.4.1) at the interventional reference point. The x-ray system calculates this value. Thus, it is known during and at the conclusion of a procedure and can be used to estimate a patient's skin injury risk.

General guideline values for the ranges of threshold values for absorbed doses associated with degrees of skin injury severity are tabulated in **Table 5**. These values are approximations that will vary among patients. It is noteworthy that these values are for a single first-time exposure. The thresholds for injury due to a subsequent exposure are lower and are related to the magnitude of prior exposure(s) and the length of the interval between exposures.

**FIGURE 1 Full Thickness Skin Necrosis Caused By a Large-Dose X-Ray Fluoroscopic Procedure**



An example of full thickness skin necrosis (underlying muscle and fat are exposed) caused by a large-dose x-ray fluoroscopic procedure (90 minutes of fluoroscopy time). Note the rectangular area of skin discoloration surrounding the area of skin necrosis. The injury is on the left side of the subject's back indicating that the exposure was conducted in the right anterior oblique projection (17). (This image is available on the U.S. Food and Drug Administration Web site and is in the public domain.)

Fluoroscopic entrance skin doses vary greatly because of variations in procedure complexity, duration, and variations in patient radiological characteristics (see Section 6.2). Skin dose accumulates proportionally to procedure total fluoroscopic and cine acquisition time (the dose rate per frame during cine is typically 6 to 10 times greater than during fluoroscopy). In addition, and likely more importantly, skin dose is strongly affected by the patient's characteristics and the procedural techniques. Body habitus is the most important patient characteristic. Larger patients require a greater skin entrance port dose to achieve adequate x-ray penetration to the image detector. X-ray input dose is also affected by the radiological projection. Extreme degrees of rotational obliquity and cranial or caudal skew require a greater skin dose. Dose is also determined by equipment calibration and imaging protocol settings (see Section 7).

Thus, the prototypical patient at risk for a skin injury is an obese patient with diabetes who has undergone 1 or more long-duration procedures within the past several months and is under consideration for another procedure to be performed predominantly in a similar radiological projection.

### 5.3.2. Bone Injury

In addition to skin injury, on occasion, incident radiation can cause necrosis of superficial bones such as ribs. Although the dose to bone needed to cause osteonecrosis is greater than the dose to cause skin necrosis, the high calcium content of bone imparts a greater capacity to absorb x-ray photons. Consequently, the absorbed dose to superficial bone underlying the x-ray beam entrance port can exceed the absorbed dose to the overlying skin, yielding the potential for radiation-induced bone injury when doses are sufficiently high to cause skin necrosis.

### 5.3.3. Eye Injury: Cataracts

The single dose threshold that will cause vision-impairing cataracts in humans is not well characterized but is believed to be on the order of 500 mGy with a minimum latency of approximately 1 year (21). Cataract progression continues for more than a decade after exposure. It is noteworthy that early cataract lenticular changes are also increasingly being observed in physician operators who have a long career performing fluoroscopically-guided procedures (22). In this circumstance, the relationship of cataract development to years of continual accumulation of small doses to the eye is currently not well characterized. This area is currently a subject of ongoing study.

**TABLE 5 Radiation-Induced Skin Injuries—Relationship of Severity to Dose**

| Single Exposure Dose Range (Gy) | Skin Reaction | | | |
|---|---|---|---|---|
| | 0–2 Weeks | 2–8 Weeks | 8–40 Weeks | Long-Term (>40 weeks) |
| 0–2 | | | No observable effects | |
| 2–5 | Transient erythema | Possible epilation | Recovery of hair loss | Complete healing |
| 5–10 | Transient erythema | Erythema epilation | Recovery or permanent hair loss | At higher doses dermal atrophy or induration |
| 10–15 | Transient erythema | Epilation, possible desquamation | Prolonged erythema, permanent hair loss | Dermal atrophy or induration |
| >15 | Transient erythema, after very high doses ulceration | Epilation, moist desquamation | Dermal atrophy, secondary ulceration, necrosis | Dermal atrophy, possible late skin breakdown, ulceration, and necrosis of subcutaneous tissues |

Adapted from Balter et al. (17).

Whether or not prolonged low-level radiation exposure (such as occurs in occupational exposures) has the potential to affect the retina is currently not known.

#### 5.3.4. Tissue Reactions: Managing Skin Injuries

Less severe degrees of skin injury have the potential to heal. This constitutes the basis of management strategy. X-ray–induced skin injuries caused by absorbed doses less than that necessary to induce complete tissue necrosis can be managed successfully with good supportive dermatological care.

X-ray injured skin is fragile. Although a subnecrotic injury has the potential to heal if properly protected, mechanical trauma to the skin can aggravate the injury, causing skin to slough. Thus, the cornerstone of optimizing the outcome of a skin injury is mechanical protection while the skin attempts to repair the damage. Dressings and other treatment strategies that help the patient avoid applying pressure or friction to the affected area are important during this period. Skin biopsy should not be conducted in this circumstance, as the healing process is impaired.

Early recognition of a radiation-induced skin injury is essential to activate early treatment, which, in turn, prevents further injury to the damaged skin. The time delay between exposure and manifest injury can impede early recognition. Due to the inherent delay of weeks between exposure and the initial signs of skin injury, the patient and his/her physicians may initially fail to recognize the causal relationship. This recognition delay may cause inappropriate treatments to be applied initially.

The best strategy to facilitate prompt recognition is to warn the patient, family, and primary care physician of the potential for skin injury. The ACC/AHA/SCAI 2011 PCI guidelines state that it is a Class I recommendation that all patients who receive an air kerma at the interventional reference point >5 Gy should be counseled about the possibility of a skin injury and instructed how to respond to the earliest signs, should they occur (23).

### 5.4. Stochastic Effects: Radiation-Induced Cancer

Radiation-induced cancer is potentially the most important consequence of medical radiation exposure. The potential that a patient or a healthcare worker might develop a serious or fatal illness as a consequence of diagnostic medical radiation requires that medical personnel understand that risk, and the variables that determine its magnitude and strategies to mitigate it. Knowledge of the stochastic risk posed by the patient's radiation exposure is a variably important component of a procedure's risk-benefit relationship. Knowledge of the occupational hazard posed to healthcare workers who work in a radiation environment is an important factor that determines occupational radiation protective practices.

#### 5.4.1. Stochastic Effects: Attribution Challenges

One of the complex challenges in this field is to develop a quantitative measure of the incremental cancer risk conferred by medical radiation exposures. Attempts to construct evidence-based assessments are complicated by cancer's large background prevalence in unexposed populations and the latent period between exposure and the clinical presentation of a malignancy. These phenomena complicate efforts to attribute a particular cancer to a particular medical radiation exposure or group of exposures. Current concepts are derived from a combination of laboratory animal exposures and observational studies of large populations who received exposures substantially above background rates. Naturally, there is considerable uncertainty in these estimates.

Cancer is a prevalent family of disorders that commonly occurs spontaneously in the absence of radiation exposure greater than background. A subject's lifetime risk of developing cancer is roughly 46% (12), and lifetime risk of developing fatal cancer is about 23% (24). Because a radiation-induced cancer cannot be uniquely distinguished from a cancer due to other causes, the high background frequency renders it difficult to attribute a particular case to radiation exposure.

The latent period between exposure and clinical presentation also adds uncertainty to attribution of a particular cancer to a particular exposure. The latent period between exposure and emergence of most cancers may be as brief as 2 years or as long as decades. For leukemia, the minimum latent period is 2 years. Population-based studies have demonstrated a statistical association between leukemia and other childhood cancers in children exposed to large medical radiation doses (25,26). Pearce et al. (26) found a 3.18-fold increase in incidence of leukemia in a large cohort of children exposed to a mean dose of 51 mGy from CT scanning. Modan et al. (25), in a cohort of 674 children who underwent cardiac catheterization with a mean follow-up of 28.6 years (12,978 patient-years), found a 4.75 times increased risk of malignancies with a 6.3 times increase in lymphomas and a 4.9 times increased risk of melanoma (25).

#### 5.4.2. Stochastic Effects: Risk Metrics

At the population level, stochastic risk can be quantified as an increased cancer incidence in an exposed population compared with the background incidence in a comparable unexposed population. The magnitude of this risk is measured using 2 related but different metrics:

1. Excess relative risk. The rate of disease in an exposed population divided by the rate of disease in an unexposed population minus 1.0.

Excess relative risk is a ratio derived from the disease incidence in exposed and unexposed populations. For

example, if the lifetime rate of developing leukemia in an unexposed population is 500 cases per 100,000 (0.5%) and the rate in an exposed population is 1,250 cases per 100,000 (1.25%), the excess relative risk for the exposed population is (1,250/500) − 1.0 = 1.5.

2. Excess absolute risk. The rate of disease in an exposed population minus the rate of disease in an unexposed population.

Excess absolute risk is an incidence. Using the leukemia data cited in the first point, the excess absolute risk for the exposed population is 0.75%. This can also be expressed as the number of exposures needed to harm one individual, in this case, 1/0.0075 = 133.

Excess relative risk and excess absolute risk are complementary measures of the quantitative relationship of exposure to risk that collectively convey the overall importance of a risk factor. For example, if a disease has a small background incidence rate but has a large excess relative risk for exposure, the overall contribution of exposure to absolute risk (the number of cases caused by the exposure) is small because of the small background incidence. On the other hand, if a disease has a large background incidence rate and a small excess relative risk for exposure, the absolute risk impact of exposure may be large in terms of the number of cases attributable to the exposure because of the large background incidence.

#### 5.4.3. Stochastic Risk: Dose-Risk Relationships

The stochastic dose-risk relationship is an important determinant of medical radiation exposure's contribution to the future cancer risk of both patients and occupationally exposed healthcare workers. The majority of our understanding of this relationship in humans is derived from epidemiological studies of exposed human populations. The LSS (Life Span Study), conducted by the Radiation Effects Research Foundation in residents of Hiroshima and Nagasaki over a 50-year follow-up period, relates exposure data to cancer incidence, and provides some of the best quantitative data relating dose to future cancer risk (27).

This experience has limitations when applied to medical and occupational radiation exposure. The exposures incurred by the Hiroshima and Nagasaki populations consisted largely of whole body radiation delivered in a large, brief exposure that included substantial neutron exposure accompanied by residual exposure from environmental radioactivity and internalized radionuclides.

##### 5.4.3.1. Stochastic Risk: Qualitative Dose-Risk Relationships

Epidemiological studies such as the LSS have clearly identified a dose-related risk for cancers, including both leukemias and solid tumors. For example, in a large population, an increased risk of leukemia is statistically detectable at a total bone marrow dose of 1 Gy, and risk increases proportionately with larger doses (28). It is noteworthy that this dose is 50 to 100 times greater than the estimated total bone marrow dose for a Tc-99 nuclear scintigraphy stress test study. However, x-ray fluoroscopy and x-ray CT can deliver doses of that magnitude to portions of a subject's bone marrow (29).

Most statistical models derived from epidemiological data find a linear relationship between dose and increased future cancer risk, with no dose threshold below which radiation exposure makes no contribution to risk. This direct relationship has led to formulation of the *"linear-no threshold"* theory (15). Given the low incidence rates associated with small doses, the no threshold concept could be validated epidemiologically only by studies that would employ much larger population sample sizes than studies to date have achieved. The linear-no threshold model is the basis for the concept that radiation exposure should always be minimized (12). This is the foundation of the *ALARA* principle that radiation exposure should always be maintained *"As Low As Reasonably Achievable."*

Children and young adults are more sensitive to radiation and, accordingly, for a given exposure, have a greater risk of a radiation-induced stochastic event compared with the elderly. The young are more sensitive to a given radiation exposure because they, particularly growing children, have greater overall mitotic activity. In addition, because radiation-induced cancer has a latent period for induction with risk potentially persisting throughout a subject's lifetime, young people, who have a long natural life expectancy, are more likely to live long enough for a stochastic event to present. Children born with congenital heart disease are at greater risk than other children to increased radiation exposure given their ongoing need for cardiac catheterization and other radiation-based procedures. On the other hand, the elderly, because of a shorter natural life expectancy, may not survive long enough for an induced stochastic event to emerge.

The Committee to Assess Health Risks from Exposure to Low Levels of Ionizing Radiation of the National Research Council has examined a number of statistical models that relate *incremental cancer risk to absorbed radiation dose* for individual solid organ cancers and leukemia. These models also incorporate important patient characteristics including age and gender. The models were published in the 2006 report: Biological Effects of Ionizing Radiation (BEIR) VII (12).

Although there are a variety of models with variable goodness of fit to available datasets, they all have several common features that are of pragmatic significance.

1. Risk has a graded relationship to total dose. Models differ with respect to the exact mathematical relationship, but clearly show that risk increases with accumulated dose.
2. Excess cancer incidence is statistically detectable in population studies at a dose of 100 mSv in adults and in smaller doses in children (30-32). These observations support the concept that there is no threshold dose below which there is no stochastic risk.
3. Dose-response risk for solid organ cancer correlates loosely with the organ's intrinsic mitotic activity. Thus, the solid organs that are most radiation-sensitive are: lung, female breast, colon, bladder, and thyroid.
4. Hematopoietic tissues have high dose sensitivity and a shorter latent period for leukemia induction than solid organs have for primary cancer induction.
5. Females have greater risk and a steeper dose-risk relationship than males. Some, but not all of this difference is attributable to breast sensitivity.
6. Risk and dose-risk relationships have a strong relationship to age, with subjects <30 years of age having greater dose sensitivity. Children have a particularly enhanced susceptibility to leukemia and melanoma (25). Beyond age 30, dose sensitivity is less strongly age-related (13). However, for older subjects, among whom background incidence rates are greater, excess absolute risk may still be important, even though excess relative risk may be smaller
7. The length of the latent period for clinical presentation of an induced cancer may decrease the importance of considering radiation-related risk for elderly patients who have limited natural life expectancies.

#### 5.4.3.2. Stochastic Risk: Quantitative Dose-Risk Relationships

The quantitative relationship between radiation exposure and increased cancer risk has implications both for a patient undergoing a medical procedure and for an occupationally exposed healthcare worker. The quantitative stochastic dose-risk relationship is a component of a particular procedure's risk-benefit relationship. Risk models attempt to quantify the risk that accompanies exposure to provide a context for understanding a given exposed subject's risk and the implications for occupationally exposed healthcare workers.

The LSS population study has provided the largest and most rigorously studied dataset on which to build statistical models that quantify risk. The BEIR VII Committee evaluated multiple mathematical models for both cancer incidence and cancer-related mortality to achieve the best goodness of fit to the LSS data. The models, developed for total solid organ cancer, individual solid organ cancers, and leukemia, incorporate gender, age at exposure, and total dose to predict the future cancer risk for a particular exposed subject. The models provide our best current assessment of the quantitative relationship of radiation dose to future cancer risk.

**TABLE 6 Baseline Lifetime Risk Estimates of Cancer Incidence and Mortality**

| | Incidence | | Mortality | |
|---|---|---|---|---|
| **Cancer site** | **Males** | **Females** | **Males** | **Females** |
| Solid cancer* | 45,500 | 36,900 | 22,100 (11) | 17,500 (11) |
| Stomach | 1,200 | 720 | 670 (11) | 430 (12) |
| Colon | 4,200 | 4,200 | 2,200 (11) | 2,100 (11) |
| Liver | 640 | 280 | 490 (13) | 260 (12) |
| Lung | 7,700 | 5,400 | 7,700 (12) | 4,600 (14) |
| Breast | – | 12,000 | – | 3,000 (15) |
| Prostate | 15,900 | – | 3,500 (8) | – |
| Uterus | – | 3,000 | – | 750 (15) |
| Ovary | – | 1,500 | – | 980 (14) |
| Bladder | 3,400 | 1,100 | 770 (9) | 330 (10) |
| Other solid cancer | 12,500 | 8,800 | 6,800 (13) | 5,100 (13) |
| Thyroid | 230 | 550 | 40 (12) | 60 (12) |
| Leukemia | 830 | 590 | 710 (12) | 530 (13) |

Note: Number of estimated cancer cases or deaths in population of 100,000 (No. of years of life lost per death). The numbers are the estimated number of cases or deaths per 100,000 people. The numbers in parentheses are the estimated number of years of life lost per cancer death. *Solid cancer incidence estimates exclude thyroid and non-melanoma skin cancers. Reproduced with permission from BEIR VII (12).

The BEIR VII models' general structure includes a coefficient that relates dose linearly to risk and modulating coefficients that account for subject gender and age at exposure. These models can be applied to calculate expected excess relative and absolute risks for a variety of common scenarios. These ratios and rates provide a context with which to judge the contribution of an exposure to a subject's overall risk.

**Background Cancer Risk in the Overall Population**

Table 6 displays lifetime incidence and mortality risk data for all cancers. This provides a measure of background incidence and mortality rates in unexposed populations upon which the excess risks that accompany radiation exposure are superimposed.

Thus, an unexposed subject's lifetime risk of developing solid cancer or leukemia is approximately 46% and lifetime risk of cancer mortality is approximately 23%.

**Incremental Cancer Risk Attributable to Patient Medical Radiation Exposure**

The BEIR VII models calculate coefficients that estimate the excess relative risk and excess absolute risk per Sv of exposure. Because subject age is an important risk

**TABLE 7** Estimated Age-Related Gender-Averaged Incremental Risk for Solid Cancer Incidence and Mortality per Sievert of Radiation Exposure (BEIR VII Model)

| Age at Exposure, yrs | <15 | 15-30 | 30-45 | 45-60 | >60* |
|---|---|---|---|---|---|
| | | | Incidence Risk | | |
| Excess Relative Risk/Sv | 0.78 (0.58, 1.06) | 0.63 (0.49, 0.81) | 0.42 (0.28, 0.62) | 0.43 (0.23, 0.79) | 1.7 (0.76, 3.8) |
| Excess Absolute Risk (cases/10,000 yrs·Sv) | 57 (43, 76) | 40 (30, 48) | 23 (16, 33) | 20 (11, 36) | 67 (35, 131) |
| | | | Mortality Risk | | |
| Excess Relative Risk/Sv | 1.12 (0.80, 1.58) | 0.63 (0.46, 0.84) | 0.35 (0.22, 0.55) | 0.25 (0.10, 0.55) | 0.55 (0.19, 1.7) |
| Excess Absolute Risk (cases/10,000 yrs·Sv) | 29 (21, 39) | 18 (14, 25) | 12 (8, 19) | 8 (4, 19) | 17 (6, 45) |

*Note: Large confidence intervals for age >60 years reflect smaller study cohort size. Adapted from BEIR VII (12).

determinant, different age ranges have different coefficients (the coefficients being larger for younger subjects). Using these coefficients, a given subject's excess relative and absolute risks for a given exposure can be calculated by extrapolation applying the linear-no threshold concept.

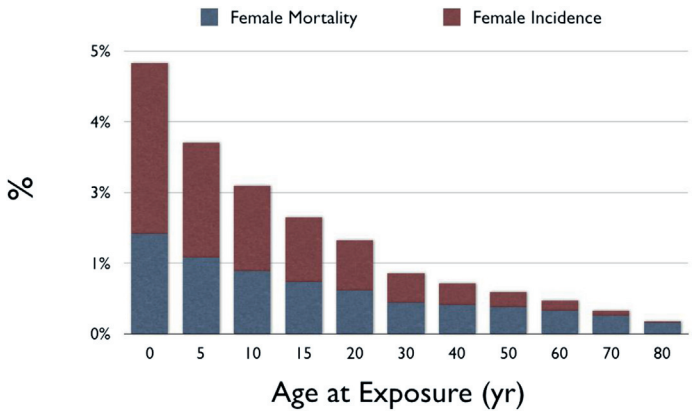
Table 7 tabulates the gender-averaged excess relative risk ratios and the excess absolute risk rates derived from the BEIR VII model for incidence and mortality for all solid cancers (excluding thyroid and nonmelanoma skin) associated with a dose of 1 Sv calculated as described in Section 5.4.1.1. Calculations are displayed for multiple age cohorts. For example, for the population age 15 to 30 years, the cancer incidence in an exposed population would be 63% greater than in an unexposed population. An effective dose of 1 Sv is substantially greater than typical for even extreme patient doses that would occur in medical practice; typical accumulated doses in clinical medicine would be 100 mSv or less. The calculated probabilities displayed here are substantially greater than would be expected in clinical medicine. The 1 Sv dose was selected to illustrate the age and gender sensitivity relationships.

Excess absolute risk is expressed as the estimated number of cases or deaths that would occur over a follow-up of 10,000 patient years in a patient cohort exposed to an effective dose of 1 Sv. For example, using this metric, an excess absolute risk of 40 cases per 10,000 person-years means that a population of 1,000 exposed patients would be expected to develop 40 additional cancer cases (4% of the population) over a 10-year follow-up period. These cases, which would be in addition to the background cancer incidence rate, would be attributable to the exposure. It is noteworthy that the precision of the risk estimates for subjects with ages >60 years is limited by small sample sizes in the studied population. The data in Table 7 demonstrate the age relationship to sensitivity to induced cancer. It is also noteworthy that, although sensitivity is substantially greater in children, the excess relative risk of exposure is relatively constant for ages >30 years. The data are gender averaged, and thus, do not reflect differences between males and females.

An alternative strategy to express the impact of radiation exposure on future cancer risk that is more clinically meaningful is to calculate the lifetime attributable risk for cancer incidence and mortality. This calculation yields the percent of exposed patients who in the future are projected to develop a cancer attributable to the exposure. Calculations can be made for both cancer incidence and cancer mortality. Figures 2 and 3 display the results of estimate calculations for the effect of a whole-body 100-mGy exposure (a moderately large, but more plausible medical exposure dose than 1 Sv) on model-predicted incidence and mortality for both genders stratified by age at exposure. The impact of the model's gender and age at exposure variables is highly evident. Children age 15 years and under are projected to have incremental incidence rates in the range of 2% for males and 4% for females (it should be noted that exposures of this magnitude should occur less frequently in children than in adults because their smaller body size requires a smaller dose for a given examination; however, this does not generally occur in practice). Children who require surgery for congenital heart disease will undergo higher doses than those who do not because of their ongoing needs for evaluation (33). Model-projected incremental mortality rates are approximately one-half of the incidence risks. In older patient groups, the predicted incremental rates are substantially smaller, but are certainly not negligible—on the order of 0.3% to 0.5% for incidence, with smaller gender differences than in the pediatric age range.

These data are displayed graphically in Figures 2 and 3.

**FIGURE 2** Estimated Cancer Incidence and Mortality for Females Attributable to a 100-mGy Radiation Exposure as a Function of Age




Stacked bar graph depicts the lifetime attributable risk for cancer incidence and mortality for women attributable to a 100-mGy total body (100 mSv) exposure as a function of age at exposure. Note the strong relationship between age at exposure and risk. Adapted from BEIR VII (12).

**FIGURE 3** Estimated Cancer Incidence and Mortality for Males Attributable to a 100-mGy Radiation Exposure as a Function of Age


Stacked bar graph depicts the lifetime attributable risk for cancer incidence and mortality for males attributable to a total body 100-mGy (100 mSv) exposure as a function of age at exposure. Note the strong relationship between age at exposure and risk. Note also the smaller incidence and mortality rates in men compared with women at each age range. Adapted from BEIR VII (12).

### 5.4.4. Incremental Cancer Risk Attributable to Radiation Exposure for Occupationally Exposed Healthcare Workers

Occupationally exposed healthcare workers typically incur very small doses on a daily basis that can accumulate over time to a significant exposure. Occupational exposures are typically smaller and differently distributed than patients' medical exposures. Healthcare workers in x-ray environments employ protective garments. Consequently, their exposures are heterogeneous in terms of the exposure magnitude received by different body parts. Healthcare workers in nuclear cardiology incur exposure when handling radioactive materials and are at risk of exposure from radiopharmaceutical spills or accidents.

The BEIR VII models may overstate the stochastic risk to occupationally exposed workers. Most human stochastic risk data (such as the BEIR VII models) are derived from comparatively large exposures delivered over relatively short time periods. There are few observational human data that assess cancer risk from long-term daily

**TABLE 8** Lifetime Attributable Risk for All Cancers for Two Radiation Exposure Scenarios Relevant to Occupationally Exposed Healthcare Workers (BEIR VII Model)

| | Incidence (%) | | Mortality (%) | |
|---|---|---|---|---|
| Exposure scenario | 1 mGy/yr throughout life (80 mGy) | 10 mGy/yr ages 18-65 (640 mGy) | 1 mGy/yr throughout life (80 mGy) | 10 mGy/yr ages 18-65 (640 mGy) |
| Males | 0.62 | 3.06 | 0.33 | 1.70 |
| Females | 1.02 | 4.29 | 0.50 | 2.39 |

Adapted from BEIR VII (12).

small exposures. Most of the available data come from studies of nuclear plant operators (34). These observational data have not identified an increased cancer incidence in this cohort of occupationally exposed workers chronically exposed at low-dose rates.

Applying the BEIR VII models to dose levels and occupational exposure durations that are typical for healthcare workers working in a medical radiation environment finds a small but measurable increase in future cancer risk for occupationally exposed workers. The results of these calculations are displayed in Table 8, which displays estimated lifetime attributable risk for cancer induction and cancer mortality for 2 scenarios:

1. Medical worker receives a very low dose (1 mGy/year) throughout life such as one might experience living at high altitude. This would result in a lifetime incremental exposure of 80 mGy that would confer an additional cancer mortality of 0.33% in men and 0.50% in women.
2. Medical worker receives the largest anticipatable occupational dose of a person working in an x-ray fluoroscopic environment for his/her entire adult working life receiving an upper range of exposure. This would confer an additional cancer mortality of 1.70% in men and 2.39% in women.

#### 5.4.4.1. Implications of Occupational Exposure in Healthcare Workers

Although a healthcare worker's incremental risk of an occupational exposure-related cancer is small compared to the background risk, the risk is dose-related and likely not negligible at higher doses. This phenomenon underscores the importance of applying the ALARA principle both to patients undergoing radiation-employing procedures and healthcare workers who conduct them.

Based on the risk estimates cited in the previous text, the current exposure limits for occupationally exposed workers recommended by the International Commission on Radiation Protection (ICRP) are in Table 9 (15).

It should be noted that the ICRP standards (Europe) are more stringent than the National Council on Radiation Protection (NCRP) standards (United States). Historically, standards have become more stringent over time. Consequently, the most stringent standards are presented.

As demonstrated in the calculations based on the BEIR VI models, a full career-length exposure at the upper range of the ICRP limits would be associated with a detectable increased cancer risk. These calculations and estimates emphasize the importance of rigorously following the ALARA principle.

#### 5.4.4.2. Implications of Fetal Radiation Exposure

The human embryo and fetus undergo multiple complex processes (cell division, differentiation, and migration) that are sensitive to radiation effects. Consequently, the human embryo and fetus are more sensitive to radiation effects than adults. This phenomenon has implications for the impact of radiation exposure to both patients and to occupationally exposed workers who are known to be or who may be pregnant.

Knowledge of the effects of ionizing radiation on the human embryo and developing fetus is derived from multiple sources including the Hiroshima, Nagasaki, and Chernobyl experiences, as well as radiation of pregnant experimental animals (35). Detrimental radiation effects include embryonic death, fetal malformations, impaired fetal development (particularly neurological), and increased risk of future cancer (12,36,37). The type of event and its dose-risk relationship is variable throughout the stages of pregnancy and is summarized in Tables 10 and 11 (38-40).

The principal risk of radiation exposure to the early embryo during the blastogenesis phase of development is intrauterine death, which would be experienced as failure to establish a pregnancy, as at this stage, critical injury to

**TABLE 9** Recommended Exposure Limits for Occupationally Exposed Workers

| | |
|---|---|
| Total body | 20 mSv/yr averaged over defined periods of 5 yrs with no individual annual exposure to exceed 50 mSv. |
| Lens of the eye | 100 mSv/5 yrs (20 mSv/yr) |
| Skin | 500 mSv/yr |
| Hands and feet | 500 mSv/yr |

Adapted from the International Commission on Radiological Protection (15).

**TABLE 10** Estimates of Adverse Embryonic and Fetal Events as a Function of Fetal Radiation Dose

| Acute Radiation Dose* to the Embryo/Fetus | Time Post Conception | | | | |
|---|---|---|---|---|---|
| | Blastogenesis (up to 2 wks) | Organogenesis (2–7 wks) | Fetogenesis (8–15 wks) | Fetogenesis (16–25 wks) | Fetogenesis (26–38 wks) |
| **< 0.05 Gy (5 rads)†** | **Noncancer health effects NOT detectable** | | | | |
| **0.05-0.50 Gy (5-50 rads)** | Incidence of failure to implant may increase slightly, but surviving embryos will probably have no significant (noncancer) health effects | ■ Incidence of major malformations may increase slightly<br>■ Growth retardation possible | ■ Growth retardation possible<br>■ Reduction in IQ possible (up to 15 points, depending on dose)<br>■ Incidence of severe mental retardation up to 20%. depending on dose | **Noncancer health effects unlikely** | |
| **> 0.50 Gy (50 rads)**<br>*The expectant mother may be experiencing acute radiation syndrome in this range, depending on her whole-body dose.* | Incidence of failure to implant will likely be large.‡ depending on dose, but surviving embryos will probably have no significant (noncancer) health effects | ■ Incidence of miscarriage may increase, depending on dose<br>■ Substantial risk of major malformations such as neurological and motor deficiencies<br>■ Growth retardation likely | ■ Incidence of miscarriage probably will increase, depending on dose<br>■ Growth retardation likely<br>■ Reduction in IQ possible (>15 points, depending on dose)<br>■ Incidence of severe mental retardation >20%, depending on dose<br>■ Incidence of major malformations will probably increase | ■ Incidence of miscarriage may increase, depending on dose<br>■ Growth retardation possible, depending on dose<br>■ Reduction in IQ possible, depending on dose<br>■ Severe mental retardation possible, depending on dose<br>■ Incidence of major malformations may increase | ■ Incidence of miscarriage and neonatal death will probably increase depending on dose§ |

***Note: This table is intended only as a guide. The indicated doses and times post conception are approximations***. *Acute dose: dose delivered in a short time (usually minutes). Fractionated or chronic doses: doses delivered over time. For fractionated or chronic doses the health effects to the fetus may differ from what is depicted here. †Both the gray (Gy) and the rad are units of absorbed dose and reflect the amount of energy deposited into a mass of tissue (1 Gy = 100 rads). In this document, the absorbed dose is that dose received by the entire fetus (whole-body fetal dose). The referenced absorbed dose levels in this document are assumed to be from beta, gamma, or x-radiation. Neutron or proton radiation produces many of the health effects described herein at lower absorbed dose levels. ‡A fetal dose of 1 Gy (100 rads) will likely kill 50% of the embryos. The dose necessary to kill 100% of human embryos or fetuses before 18 weeks' gestation is about 5 Gy (500 rads). §For adults, the LD50/60 (the dose necessary to kill 50% of the exposed population in 60 days) is about 3-5 Gy (300-500 rads) and the LD100 (the dose necessary to kill 100% of the exposed population) is around 10 Gy (1000 rads). Reproduced with permission from the Centers for Disease Control and Prevention (41).

a small number of cells is likely to be lethal. Exposure during the organogenesis phase has the potential to cause fetal malformations. Later exposure during the fetogenesis phase can cause growth retardation and impaired neurological development, and can potentially increase the fetus' future cancer risk.

**TABLE 11** Estimated Risk for Cancer from Prenatal Radiation Exposure

| Radiation Dose | Estimated Childhood Cancer Incidence*† | |
|---|---|---|
| **No radiation exposure above background** | 0.3% | 38% |
| **0.00–0.05 Gy (0–5 rads)** | 0.3%–1% | 38%–40% |
| **0.05–0.50 Gy (5–50 rads)** | l%–6% | 40%–55% |
| **> 0.50 Gy (50 rads)** | >6% | >55% |

Estimated lifetime‡ cancer incidence§ (exposure at age 10 years). The right column tabulates the estimated lifetime incidence of cancer for the same exposure incurred at age 10 for comparison to the estimated childhood incidence from fetal exposure. *Data published by the International Commission on Radiation Protection. †Childhood cancer mortality is roughly half of childhood cancer incidence. ‡The **lifetime cancer** risks from prenatal radiation exposure are not yet known. The lifetime risk estimates given are for Japanese males exposed at age 10 years from models published by the United Nations Scientific Committee on the Effects of Atomic Radiation. §Lifetime cancer mortality is roughly one third of lifetime cancer incidence. Reproduced with permission from the Centers for Disease Control (41).

In considering these risks, it is important to link the risk to threshold radiation doses. This knowledge base has been summarized by the Centers for Disease Control and Prevention in **Table 10** (41). In this table, dose ranges are expressed in Gy rather than in Sv, as the Sv construct is not applicable to embryos and fetuses.

The increased childhood cancer risk caused by fetal radiation exposure is less well characterized, and whether or not fetal radiation exposure might confer a lifelong increased cancer risk is not known. Estimates of childhood cancer risk are summarized in **Table 11**. The available data indicate minimal detectable childhood risk at fetal doses <50 mGy but increased risk at doses >50 mGy.

A general synthesis of the fetal radiation dose data indicates that fetal doses <50 mGy (as distinguished from maternal exposures to other body regions) are not associated with a detectable increase in frequency of any adverse fetal outcomes. For external beam maternal exposures (x-ray fluoroscopy and x-ray CT), fetal exposures are substantially less than the exposure to the imaged or unshielded body region unless the uterus is directly in the

imaged field or, in the case of healthcare worker occupational exposure, if the mother's abdomen is not shielded (discussed in Section 6). Fetal doses between 50 and 500 mGy are associated with detectable increased frequencies of all of the adverse fetal effects. Fetal doses >500 mGy are likely catastrophic (and may well be catastrophic to the mother as well) and are unlikely to occur in medical radiation circumstances.

The American College of Radiology (ACR) provides guidance about the need to screen for pregnancy prior to performing a diagnostic test involving ionizing radiation. Prior to an examination, all patients of menstrual age (typically ages 12 through 50 years) should be questioned about pregnancy status using a standardized questionnaire and/or direct questioning by the technologist with documentation added to the medical record. Most diagnostic studies deliver far less than 20 mGy to the uterus, including single-phase CT studies of the abdomen (42). However, a fluoroscopic interventional procedure may deliver doses above 100 mGy and demands planning and caution. For such studies, the ACR recommends a pregnancy test be obtained within 72 hours of the procedure, unless medical urgency prevents it. Chest radiography during the first and second trimesters, and extremity or head and neck radiography, may not be altered by pregnancy status and would not require pregnancy testing (42).

The most effective way to limit radiation exposure to the pregnant patient is to consider the indications and necessity for a particular examination, carefully weighing the risks and benefits. Cardiovascular imaging teams should follow the screening and counseling recommendations established for other ionizing radiation imaging. Diagnostic x-rays pose no risk to lactation (43). In addition, lactating women do not need to discontinue breastfeeding after receipt of intravascular iodinated contrast because <1% will be excreted into breast milk and <1% of that will be absorbed by the infant (43).

For nuclear imaging, there are concerns about the administration of radioactive iodine as it readily crosses the placenta, preferentially accumulates in the thyroid gland, and has a half-life of 8 days, and thus may injure the fetal thyroid gland. Tc-99m, however, which has a shorter half-life, will cause less fetal exposure. For nuclear cardiology perfusion imaging, Rb82 positron emission tomography (PET) would cause the least fetal exposure.

## 6. MODALITY-SPECIFIC RADIATION EXPOSURE DELIVERY

### 6.1. General Principles

#### 6.1.1. Characteristics of Medical Diagnostic Radiation

The radiation employed in all cardiovascular diagnostic modalities (x-ray fluoroscopy, x-ray, CT, and nuclear cardiology imaging techniques) is *low linear energy transfer* radiation. Ninety-five to ninety-nine percent of x-ray energy that enters the subject is either absorbed or scattered within the subject. The remaining 1% to 5% of the incident x-ray penetrates the subject, reaching the image detector to form the image. Absorption is required to form diagnostic x-ray images, but degrades nuclear scintigraphy images. For both diagnostic x-ray and nuclear scintigraphy, the majority of radiation energy released by the x-ray tube or radioactivity administered to the subject either exposes the subject or is scattered out of the subject with the potential to expose nearby medical personnel.

#### 6.1.2. Tools Used to Estimate Absorbed Dose

Estimates of absorbed dose for x-ray fluoroscopy and x-ray CT are based on models developed by exposing instrumented phantoms to incident x-ray beams that replicate the beams used in diagnostic imaging, and measuring absorbed dose at different points within the phantom. These models are applied to calculate an estimated absorbed dose based on the incident beam intensity, photon energy characteristics, exposure time, and the size of the exposed body region. Model-derived estimates are just that—estimates. Since models do not include all of the important dose-determining variables, actual absorbed doses may vary considerably from estimates.

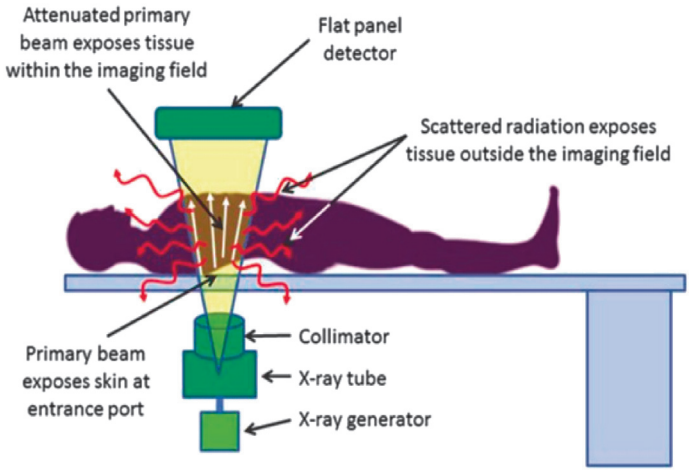
Estimating absorbed dose from radionuclides is an entirely different discipline that is discussed in Section 6.4.

### 6.2. X-Ray Fluoroscopy

#### 6.2.1. X-Ray Fluoroscopy Subject and Operator Dose Issues

X-ray fluoroscopy differs from other ionizing radiation imaging techniques in that the beam entrance port is relatively small. Consequently, the skin at the beam entrance port is the most intensely exposed tissue. Subject skin doses can reach levels that cause skin tissue reactions (see Section 5). Typically, x-ray fluoroscopy is the only imaging technique with the potential to cause such a reaction. X-ray fluoroscopy also has the potential to deliver a dose to internal structures in the imaging field remote from the beam entrance port that is large enough to cause stochastic effects. X-ray photons are also scattered within the subject and deliver dose to subject tissues that are outside the imaging field. Consequently, assessment of the implications of subject exposure from x-ray fluoroscopy must consider entrance port skin dose, which is the dose received by internal structures within the imaging field and by other internal structures outside the imaging field. Other scattered photons exit the subject and can expose nearby medical personnel.

**FIGURE 4** Diagrammatic Representation of an X-Ray Fluoroscopy System to Illustrate X-Ray Exposure Modality




The primary beam, collimated to a rectangular cross section, enters the patient, typically through the patient's back. It is attenuated and scattered within the imaging field. The primary beam exposes the subject within the imaging field. The scattered primary beam radiation can expose structures within the subject that are remote from the imaging field.

### 6.2.2. Basics of Operation of an X-Ray Cinefluorographic Unit

An x-ray cinefluorographic unit generates controlled x-rays in an x-ray tube that are collimated to regulate the size and shape of the x-ray beam. The beam passes through the subject forming images that are detected by a flat panel detector (Figure 4). The x-ray tube output (and accordingly the exposure to the subject) is modulated by feedback circuitry from the unit's imaging chain to achieve an optimally exposed image.

There are 2 different x-ray fluoroscopic system parameters that are used to characterize x-ray exposure and dose:

1. Cumulative dose at the interventional reference point. This parameter is a measure of the radiation dose (expressed as air kerma) that enters the subject. It is measured and displayed in real time by current state-of-the-art x-ray fluoroscopic systems.
2. Dose at the image detector. This is a measure of the attenuated radiation dose that penetrates the subject and reaches the detector to form the image. It is typically <5% of the dose at the interventional reference point.

#### 6.2.2.1. X-Ray Cinefluorographic Unit Operating Parameters

There are multiple imaging parameters that influence the x-ray exposure associated with an x-ray cinefluorographic examination. These are:

1. **X-ray image detector dose per pulse.** This is the dose for each x-ray pulse (typically measured in nanogray (nGy) that reaches the x-ray system detector. This parameter is set by the x-ray unit calibration and is a determinant of image clarity and detail (discussed in greater depth in Section 7.2). It is important to point out that the detector dose is considerably smaller than the subject dose, as generally ≤5% of the incident radiation penetrates through the subject and reaches the detector.
2. **X-ray unit framing (pulsing) rate.** This is the number of pulses that the x-ray system generates per unit of time. This is an operator-selectable parameter that generally ranges between 4 and 30 pulses/second and is a determinant of image temporal resolution.
3. **Imaging field size.** This is the cross-sectional area of the x-ray beam that impinges on the subject. This is discussed in greater depth in the section "Kerma-Area Product."
4. **X-ray beam filtration.** An x-ray tube produces a spectrum of x-ray photon energies. The lower-energy photons (photon energies <30 keV) do not have sufficient penetrating power to reach the detector, and thus expose the subject without contributing to image formation. These "undesirable" photons are typically "filtered" out of the x-ray beam by interposing layers of aluminum and copper in the x-ray tube exit port.

The x-ray dose delivered to a subject during a fluoroscopic examination is determined by the combination of the previously mentioned parameters and also by

subject characteristics. Larger doses per pulse, larger field sizes, and faster framing rates all increase subject exposure.

Because x-ray systems are calibrated to image with a particular detector dose, the intrinsic radiographic density of the subject influences the dose that must be delivered to the subject to achieve a particular dose that reaches the detector. Thus, all other parameters being the same, a larger, heavier subject will receive a larger dose than will a smaller, lighter subject.

### 6.2.3. Measures and Determinants of Subject and Operator Exposure

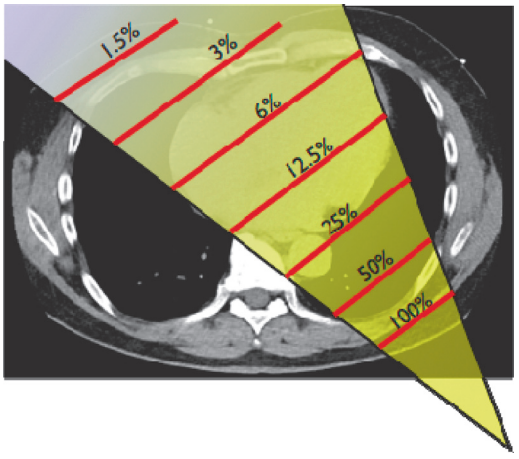
#### 6.2.3.1. Cumulative Air Kerma at the Interventional Reference Point

The cumulative air kerma of the incident x-ray beam at the interventional reference point (described in Section 4), is the basic measurement used to calculate estimates of subject entrance port skin dose and is the metric that most accurately estimates tissue reaction risk. It is a measure of the energy density (measured in Gy) of the radiation that enters the subject. X-ray fluoroscopic systems sold in the United States since 2006 are required to measure or calculate and display an estimate of this parameter both instantaneously and cumulatively for a complete examination. Operators can potentially apply this information to make procedure conduct decisions, enabling them to weigh the risk of a skin injury against the importance of continuing a procedure. This information can also be used to inform a patient of his/her potential skin injury risk.

Cumulative air kerma at the interventional reference point is a much more meaningful subject exposure parameter than the total fluoroscopic time, which does not account for subject density, cine acquisition time, or changes in frame rate or angulation. The x-ray system's automatic exposure controller determines the x-ray exposure intensity. Exposure intensity is determined by the system's set detector dose and the subject's intrinsic radiological density. Subject density is determined by body habitus (larger patients are more dense) and projection angle (extremes of obliquity and skew require greater dose). Consequently, the exposure rate delivered during an x-ray fluoroscopic examination can vary over a large range.

Subject skin exposure within the beam entrance port is somewhat greater than the air kerma at that location. This is because some of the radiation that enters the subject is scattered in the opposite direction (backscatter). The backscattered radiation sums with the incident radiation from the primary beam, increasing entrance port skin exposure. Depending on x-ray field size, entrance skin exposure is typically around 10% to 40% greater than incident air kerma.

**FIGURE 5** Diagram Showing the Estimated Decreasing Intensity of X-Ray Exposure With Depth Within the Subject

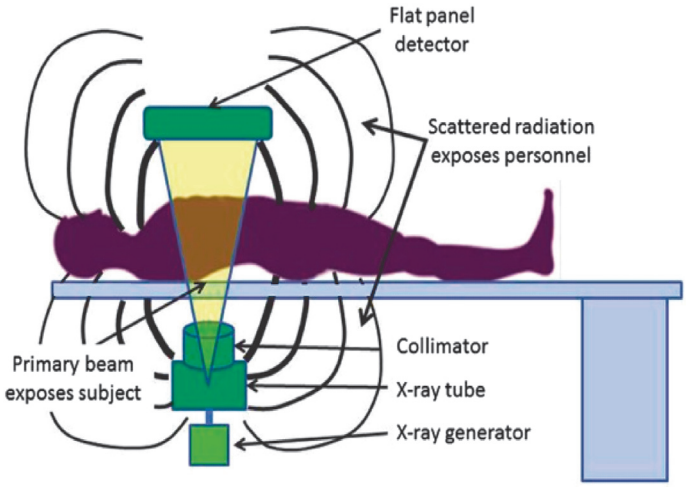



In this example, (right anterior oblique projection), the beam enters the left side of the subject's back. Beam intensity decreases with depth within the subject due to a combination of beam divergence with distance (inverse square law) and absorption within the subject. The overall effect of these processes is to attenuate the beam intensity that exits the subject to 5% or less of the incident intensity.

X-ray exposure to the subject is not uniform. As an x-ray beam passes through a subject, tissue absorption attenuates its intensity (see **Figure 5**). Consequently, tissue closer to the beam entrance port receives a larger dose than deeper-lying tissue and tissue at the beam exit port (closest to the imaging detector) receives the smallest dose. The dose delivered to a location deeper within the subject's body is determined by the beam intensity and the specific x-ray absorbance of the tissue at that location. For soft tissue, the dose is about 6% greater than the air kerma at that location. Bone absorbs x-ray more avidly than soft tissue. Consequently, dose to bone is 3 to 4 times greater than air kerma at that location. Model-based estimates of the relationship between incident air kerma exposure and absorbed dose at deeper subject structures can be applied to calculate an estimate of the dose delivered at more deeply located structures within the subject.

Because of scattering within the subject, some scattered x-ray is also directed to locations outside the area of the x-ray beam and exposes tissue outside the imaging area (see **Figure 4**). The magnitude of this exposure is

**FIGURE 6** Diagrammatic Representation of the Pattern of X-Ray Scatter From a Subject Undergoing X-Ray Fluoroscopy




Note that scattered x-ray emanates from the subject in all directions.

considerably less than that of tissue within the imaging area. Scattered radiation that leaves the subject's body is the principal source of exposure to nearby medical personnel (Figure 6).

#### 6.2.3.2. Kerma-Area Product

KAP, sometimes referred to as dose-area product (described in Section 4), is commonly used as a metric to estimate a subject's total absorbed dose. It incorporates both dose and exposed tissue volume into a single measurement. Air kerma is a measure of dose *intensity* (measured in J/kg) reflecting the number of ionization events per unit mass of exposed tissue. However, it does not measure the quantity of tissue that receives that density of radiation energy, and thus, does not measure the *total quantity* of ionizing radiation that impinges on a subject. For a given incident radiation exposure, the larger the quantity of tissue that receives that exposure, the more tissue ionization events will occur conferring a greater potential for a stochastic event.

KAP is expressed in units of Gy · $cm^2$. It is calculated by multiplying the beam air kerma by its cross-sectional area. It should be noted that some x-ray system manufacturers report KAP in units of $\mu Gy \cdot m^2$ (1 $Gy \cdot cm^2$ = 100 $\mu Gy \cdot m^2$). It should also be noted that air kerma and KAP represent cumulative doses from an exposure, not exposure rates.

An important characteristic of KAP is that its value in a diverging x-ray beam is independent of the distance from the source. This is because the beam intensity (air kerma) decreases proportionally to the square of the distance while the beam area increases with square of the distance.

KAP is affected both by air kerma output and by collimation or field size. Thus, if exposure intensity is constant, reduction in exposure field size decreases KAP. At a constant exposure field size, increasing radiation output increases KAP. This phenomenon underscores the importance of minimizing the exposed field size in x-ray fluoroscopic examinations.

#### 6.2.3.3. Application of KAP in Cardiovascular X-Ray Fluoroscopy to Estimates of Effective Dose to Patients

The total cumulative KAP is the best readily available measurement of the total radiation dose delivered to a subject by an x-ray fluoroscopic procedure. A number of assumptions are involved in estimating an effective dose value from a KAP measurement. General estimates of the relationship between KAP exposure to the thorax in $Gy \cdot cm^2$ and effective dose in Sv made using measurements in phantoms derive a coefficient of 0.20 $mSv/Gy \cdot cm^2$ (44). By this estimate, a combination coronary arteriography and percutaneous coronary intervention that delivers a KAP exposure of 50 $Gy \cdot cm^2$ would impart an effective dose to the subject of 10 mSv. The implications of that dose magnitude are discussed in Section 5.4.

### 6.2.4. Measures and Determinants of Physician Operator and Healthcare Worker Occupational Exposure

#### 6.2.4.1. Application of KAP in Cardiovascular X-Ray Fluoroscopy to Estimates of Effective Dose to Medical Personnel

Medical personnel who conduct x-ray fluoroscopic procedures are rarely exposed directly to the primary x-ray beam. They are exposed by scattered radiation that emanates from the patient (**Figure 6**). The scattered radiation intensity is directly related to the KAP rate, and the total scattered radiation for a procedure is related to the procedure's cumulative KAP. The amount of scattered radiation that reaches and delivers absorbed dose to medical personnel is determined by:

1. The distance of the exposed medical personnel from the x-ray source—scattered x-ray intensity decreases proportionately to the square of the distance from the source.
2. The effectiveness of shielding employed by the exposed medical personnel.

#### 6.2.4.2. Physician and Medical Personnel Exposure Monitoring

For exposed medical personnel, estimates of actual doses delivered to different structures and organs cannot be measured directly and must be calculated from models derived from instrumented phantoms. Most estimates are based on measurements made by personal radiation monitors (formerly known as "film badges"), which can be worn both outside protective garments (at the collar level on the left side) and under protective garments (at waist level). The outside badge measures the dose that reaches unshielded structures of the head while the badge underneath the apron measures the radiation level that penetrates the protective apron reaching the subject. Effective dose can be roughly estimated from the reading of a single badge worn outside the apron at the collar (neck) or it can be more accurately estimated by combining measurements from the 2 badges. Typically, the under-apron badge reading, represented as $H_{(u)}$ and measured in units of mSv, should be <5% of the collar badge reading for an 0.5-mm lead-equivalent protective apron. The collar badge reading is represented by $H_{(col)}$, also measured in units of mSv.

Several different, but similar, models for both single- and dual-badge applications have been developed. The NCRP (Reports 122 and 168) recommends the following formula for estimating effective dose—E(estimate)—from single- or dual-badge readings (38,45):

For a single-badged worker, E in units of mSv may be estimated as:

$$E(\text{estimate}) = H_{(col)} \Big/ 21$$

The divisor of "21" in this formula is consistent with the fact that the protective garments intercept approximately 95% of the incident radiation. This formula assumes that a thyroid collar is worn shielding cervical bone marrow and the thyroid. Other models developed for no thyroid collar shielding have divisors of 14 (46,47). The difference between these 2 divisors emphasizes the importance of the thyroid collar.

When 2 badges are worn, one under the apron and the other over the apron around neck level, E in units of mSv is estimated as:

$$E(\text{estimate}) = 0.5\, H_{(u)} + 0.025\, H_{(col)}$$

These calculations assume the presence of a thyroid shield.

Caution is advised regarding regulatory requirements in the assessment of E from personal radiation monitors. Regulatory agencies may adopt rules for calculation of effective dose (or the closely related, older quantity called effective dose equivalent) that differ greatly from those described here. This text reflects the NCRP's recommendations for effective dose (as opposed to the somewhat different effective dose equivalent). Regulatory agencies do not have to adopt the recommendations of the NCRP in their rules and may choose more restrictive methods of estimating regulated personnel exposures.

#### 6.2.4.3. Exposure Levels for Operating Physicians

Multiple studies have endeavored to identify a quantitative relationship between a procedure's cumulative KAP and the effective dose to operating personnel. There is necessarily considerable variation among estimates. Sources of variation include operators' distance from the x-ray source and the degree and effectiveness with which operators employ shielding to protect themselves. The dose to operators per $Gy \cdot cm^2$ to the patient has decreased moderately over time with equipment improvement, increased operator awareness, and better utilization of shielding. The most current studies find a range of 0.02 to 0.12, with typical values clustering about 0.1 $uSv/Gy \cdot cm^2$ cumulative dose (48). (Note that the estimated patient exposure is 200 $uSv/Gy \cdot cm^2$ suggesting that patient exposure is roughly 2000 times operator exposure.) Applying these values, a "typical" combined coronary arteriogram and straightforward coronary interventional procedure utilizing a cumulative KAP of 50 $Gy \cdot cm^2$ would deliver a 5 uSv effective dose to the physician operator standing roughly 1 meter from the center of the primary beam while delivering 10 mSv to the patient.

Observational data indicate a per-procedure operator dose range from 0.2 to 38 uSv with typical median values being 5 uSv (11,48). An operator performing 500 procedures/year at a typical effective dose of 5 uSv per procedure, would be expected to receive a total effective dose of

2.5 mSv/year—well below the ICRP recommended dose limit of 20 mSv/year. It is important to point out that these estimates are based on effective use of all protective measures.

These estimates of operating physician exposure are representative for physician operators who are in the closest proximity to the radiation source. The exposure to other medical personnel who are in the procedure room but not in immediate proximity to the radiation source would be expected to be less—decreasing as the square of the distance from the source. Thus, a scrubbed assistant, who would be approximately twice as far from the source, would be expected to receive roughly one-fourth the exposure of the primary operator. Personnel who are circulating in the room at a distance at least 4 times the distance from the source as the primary operator would be expected to receive roughly 1/16 or less of the dose received by the primary operator.

#### 6.2.4.4. Radiation Protection Considerations for Pregnant or Potentially Pregnant Occupationally Exposed Workers

As discussed in Section 5.4.4, although radiation exposure to the human embryo and fetus should always be minimized (as is the case with all human exposure), no measurable increase in adverse fetal outcomes has been detected at fetal or embryonic exposures <50 mGy. For occupationally exposed workers in an x-ray fluoroscopy environment, proper shielding and practices should keep uterine exposures well below this level for the duration of a pregnancy. Because the uterus is a deep structure and is inside protective garments, the dose to the uterus delivered by scattered x-ray is greatly attenuated compared with the dose to unshielded areas. Measurements made in phantoms indicate that the uterine dose in a subject wearing a 0.25-mm lead equivalent apron is <2% of the collar dose (outside protective garments). Thus, for an occupationally exposed worker to receive a uterine dose of 50 mGy would require an accumulated collar badge dose of 2.5 Gy.

A pregnant female occupationally exposed worker should wear, in addition to the customary collar film badge, an abdominal badge worn under the apron to estimate the uterine dose. This will verify that the uterine dose is within the range that is considered to be safe for the fetus. Detailed recommendations for protection of the pregnant or potentially pregnant worker in interventional radiology have been published, and these are directly relevant to cardiology operators and staff (49). Unfortunately, a recent survey indicates low adherence to such recommendations. Only 20% of women reported the use of fetal radiation badges while participating in radiographic imaging procedures while pregnant, and 24% reported using additional lead protection. Over 60% reported either having no workplace policy on pregnancy or being unaware if their department had a policy regarding radiation exposure during pregnancy (50). Thus, although it is clear that with adequate precautions and protection a pregnant healthcare worker can work in an x-ray fluoroscopy environment without detectably jeopardizing her fetus (51,52), all workplaces should develop and enforce training and policies regarding monitoring and radiation reduction procedures for pregnant operators and staff (50). Thus, it is clear that with adequate precautions and protection a pregnant healthcare worker can work in an x-ray fluoroscopy environment without detectably jeopardizing her fetus (51,52).

### 6.3. X-Ray CT

#### 6.3.1. X-Ray CT Subject and Operator Dose Issues

Although x-ray CT, like x-ray fluoroscopy, is an external beam exposure technique, unlike x-ray fluoroscopy, the incident beam is distributed circumferentially around the subject. Consequently, x-ray CT subject skin doses should never approach levels that could cause skin injury. (The potential for skin injury exists if scanners are improperly calibrated or if multiple scans of the same body region are performed close together in time.) Thus, for the x-ray CT subject, harm issues should be confined to stochastic risk. Similarly, x-ray CT clinical operating personnel are not routinely in the room with the subject during exposure so personnel exposure should be negligible.

#### 6.3.2. Basics of Operation of an X-Ray CT Unit

The dose delivered by an x-ray CT examination can vary substantially depending on patient characteristics and the settings of multiple scanner operating parameters. Configurable CT technique parameters that can affect dose include x-ray tube potential (measured in kV); x-ray tube current (measured in milliamperes [mA]); and scan protocol, for example, axial or helical, pitch, gating protocol, scan rotation time, beam width, scan length, and beam filtration.

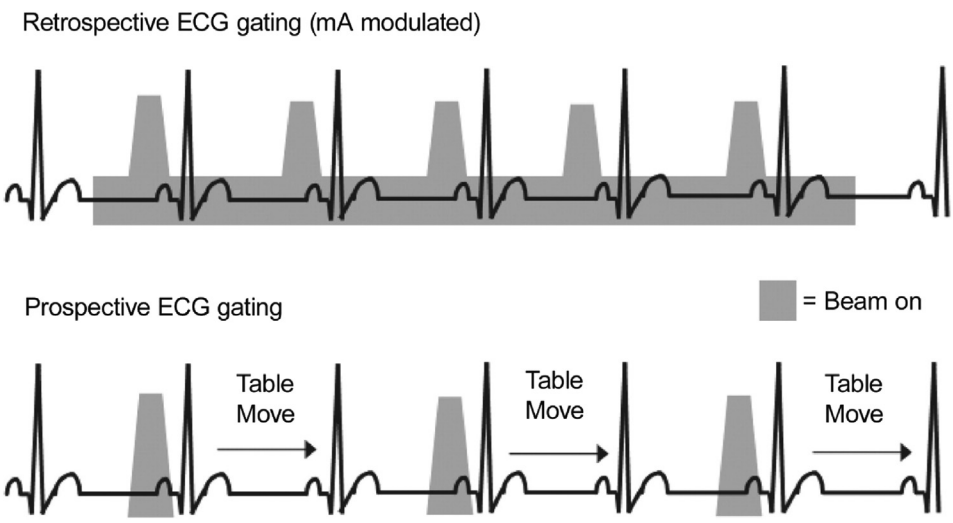
Image quality is affected by imaging parameter selection. This selection involves a conscious tradeoff between image quality and dose. Other parameter selections, such as gating protocol, do not necessarily affect image quality but do affect the amount of radiation used to acquire an image set.

Electrocardiographic (ECG) gating is important in cardiovascular imaging to minimize motion artifact. Gating protocol selection can have a major influence on subject dose in cardiovascular imaging.

There are 2 types of gating (**Figure 7**):

**Retrospective gating** involves x-ray exposure continually over the cardiac cycle. Because exposure occurs continuously, retrospective gating delivers greater exposure than prospective triggering.

**FIGURE 7 Comparison of Retrospective ECG Gating With Prospective ECG Gating**




With retrospective gating, the intensity-modulated x-ray beam is on for the entirety of the R-R intervals during imaging. With prospective gating, the x-ray beam is on for about 26% of every other R-R interval. Reproduced with permission from Shuman et al. (53).

Retrospective gating can be valuable when continuous 4-dimensional data are needed for functional assessments, analyses of intracardiac shunts, and studies directed toward cardiac valves or valve prostheses. When retrospective gating is used for coronary CT angiography, images with the smallest amount of motion-related artifacts are used to analyze coronary anatomy; however, all image sets can be available to assess myocardial motion, if desired.

**Prospective triggering** involves synchronizing exposure to a selected portion of the cardiac cycle. The goal of prospective triggering is for exposure to occur only when cardiac motion is minimal. For studies that are not intended to assess motion-related functionality, prospective triggering, if successful, can avoid unnecessary exposure.

As with x-ray fluoroscopy, x-ray CT images can be acquired at different dose levels with concomitant impact on image noise. Operators can select among dose levels depending upon the study's purpose. Coronary computed tomography angiography (CTA) requires greater spatial resolution than do examinations for basic cardiovascular structure. Imaging protocols and their impact on patient dose are discussed in greater detail in Section 7.

### 6.3.3. X-Ray CT Measures of Subject Exposure

As x-ray CT imaging technology has evolved, it has become apparent that multiple dose parameters are needed to precisely specify the dose delivered by an examination. The dose delivered by an x-ray CT examination should be considered from 2 perspectives:

- **Dose intensity:** Dose per unit mass of tissue. This is a measure of the intensity of the dose used to generate the images and is determined by the combination of scanner parameter settings and subject characteristics.
- **Volume of Tissue Exposed During the Examination.** This incorporates, in addition to the dose intensity, the subject volume scanned. The total dose delivered to a subject is the product of the dose intensity and the volume of tissue exposed.

There are a number of different metrics in use as measures of subject dose in x-ray CT. It is noteworthy that many of these metrics are derived from the measurement of x-ray tube air kerma. However, in the CT lexicon, the term "dose" is very widely used. Accordingly, this discussion will use the term "dose" rather than "kerma."

#### 6.3.3.1. CTDI: A Measure of Dose Intensity

Several related CT dose index terms have been formulated. CTDI was first defined in 21 CFR 1020.33(c) as the average dose detected over a 100-mm length in a phantom from an imaging acquisition of 14 slices (not necessarily a 100-mm imaging length). Thus, CTDI is an index of dose imparted by a unit scan length. All CTDI terms are measures of dose intensity, not measures of the total dose delivered to a subject. Given that scan lengths vary depending on the purpose of the

examination, the actual subject dose will also be proportional to the scan length.

#### 6.3.3.2. $CTDI_{100}$

$CTDI_{100}$ is a refinement of CTDI that standardizes all dose index measurements to a standardized scan length of 100 mm. However, this definition also has some utility problems. The dose delivered by an x-ray CT examination is not uniform across the exposed subject volume. Doses at the more superficial locations within the exposed volume are substantially greater than doses at deeper locations closer to the exposed volume center.

#### 6.3.3.3. $CTDI_w$

The $CTDI_w$, or weighted $CTDI_{100}$, is an index developed to approximate the average radiation dose delivered to a cross section of a subject's body. It allows for nonuniformity of dose with depth. $CTDI_w$ is a modification to $CTDI_{100}$ in which the peripheral dose and center dose are added together in a weighted fashion (2/3 peripheral dose + 1/3 central dose).

#### 6.3.3.4. Volume CTDI

Pitch is a fundamental characteristic of helical scanning and is defined as the ratio of the scanning beam width (in mm) to the length of table movement during 1 gantry rotation. If the table movement length is equal to the width of the scanning beam, there is no beam overlap between slices and the pitch is 1.0. If the beam width is greater than the table movement, there will be beam overlap between rotations and the pitch will be <1.0. If the beam width is less than the table movement, the pitch will be >1.0.

Pitch determines how the scanning mode distributes radiation along the scan length. A value of pitch <1.0 delivers a higher overall dose and a value >1.0 delivers lower overall dose.

To account for the impact of pitch on dose, a new refinement to $CTDI_w$, $CDTI_{vol}$, was introduced. It is simply calculated as $CTDI_w$/pitch. This is the dose index most currently used.

$CTDI_{vol}$ is the weighted absorbed dose to air of a 1-cm axial length of the examined subject located in the middle section of a 100-mm length scan of an acrylic cylinder for a specific CT technique. Its unit of measure is the mGy. It accounts for both the exposure directly delivered to the 1-cm thick slice and also for exposure delivered to that slice by scatter from adjacent imaged tissue. The cylinder must be specified as either 32- or 16-cm diameter and must be positioned in the center of scanning bore of the CT unit during measurement.

#### $CTDI_{vol}$ Special Considerations for Exposure in Children

It is noteworthy that for identical techniques, smaller subjects receive a higher dose than larger subjects. Estimates of $CTDI_{vol}$ for body imaging made utilizing a 32-cm thick phantom substantially under-represent the dose received by small individuals, especially children. Although using a 16-cm phantom might provide a more accurate assessment of the actual amount of radiation delivered to small subjects, the 32-cm phantom is currently specified by the International Electrotechnical Commission and is most commonly used. As an approximation for small subjects, the dose index measured using the 16-cm phantom will be about a factor of 2 greater than the dose index measured using a 32-cm diameter phantom. For similar reasons, the use of a 32-cm phantom may result in overestimation of dose for subjects with thoracic dimensions >32 cm.

#### 6.3.3.5. Size-Specific Dose Estimate

Initial efforts to develop a dose index that better reflects differences in subject habitus have led to the introduction of a quantity called the size-specific dose estimate. The size-specific dose estimate is a normalization of $CTDI_{vol}$ that takes into account subject size. This may become a more important measure for radiation management in the future. However, current scanners do not yet automatically determine or report the size-specific dose estimate. Its incorporation into practice is still to be determined.

#### 6.3.3.6. DLP: A Measure of the Total Dose Absorbed by the Subject

$CTDI_{vol}$ is a measure of dose intensity that, when multiplied by the longitudinal length of the scan, provides a measure of dose received, the dose-length-product (DLP). Thus, if the scan length for a procedure is 30 cm and $CTDI_{vol}$ is 20 mGy, then the DLP is 600 mGy·cm. If the scan length were only 15 cm, using the same protocol the DLP would be 300 mGy·cm. DLP is a better predictor of stochastic risk when compared with CTDI.

### 6.3.4. X-Ray CT Measures of Effective Dose

The benefits and shortcomings of effective dose (expressed in units of mSv) as an indicator of stochastic risk are addressed in Section 4.5. For CT imaging, European Commission-sponsored guidelines from 2000 (54) and 2004 (55) have suggested a simple approximation of the effective dose that can be obtained by multiplying the DLP by a conversion factor k (unit: $mSv \cdot mGy^{-1} \cdot cm^{-1}$) that varies dependent on the radiation sensitivity of different body regions and patient ages. The European guideline documents offer conversion factors for CT of the head, neck, chest, abdomen, pelvis, and legs, all based on Monte Carlo simulations of single-slice CT scanners and the then-current definition of effective dose, which was subsequently updated with the introduction of the new tissue weighting factors (**Table 3**) in ICRP Publication 103 (15). Conversion factors for chest CT in these documents

ranged from 0.014 to 0.019 mSv · $mGy^{-1}$ · $cm^{-1}$ in adults, and 0.013 to 0.039 mSv · $mGy^{-1}$ · $cm^{-1}$ in children. The 0.014 mSv · $mGy^{-1}$ · $cm^{-1}$ factor, which was subsequently included in American Association of Physicists in Medicine guidelines (56), is most commonly used for chest CT in adults. However for CT examinations confined to the cardiac region, such as most coronary CT angiography and calcium scoring scans, since the cardiac region is more radiosensitive than the rest of the chest, several studies (57-61) have demonstrated that estimates of cardiac conversion factors are considerably greater, ranging from 0.017 to 0.043 mSv · $mGy^{-1}$ · $cm^{-1}$ in adults, depending on the scanner, protocol, and methodology used, with an average figure of 0.026 mSv · $mGy^{-1}$ · $cm^{-1}$ (62).

#### 6.3.4.1. X-Ray CT Measures of Effective Dose in Children

Pediatric CT dosimetry is complicated by the fact that scanners and studies have variably used 32- or 16-cm phantoms for the determination of DLP (see Section 6.3.3.4). For that reason, when reporting CTDI or DLP in children, the phantom size used should always be specified. In children, European guidelines for chest CT conversion factors (63), based on the 32-cm phantom, range from 0.013 mSv · $mGy^{-1}$ · $cm^{-1}$ (10 years) to 0.039 mSv · $mGy^{-1}$ · $cm^{-1}$ (0 years), depending on age. Only a few studies, and only 2 using contemporary cardiac scanners, have determined cardiac CT-specific conversion factors for children. Normalized to the 32-cm phantom, the conversion factors by Podberesky et al. (64) averaged 0.092 mSv · $mGy^{-1}$ · $cm^{-1}$ for age 1 year and 0.082 mSv · $mGy^{-1}$ · $cm^{-1}$ for age 5 years, whereas the conversion factors by Trattner et al. (63) were 0.099 mSv · $mGy^{-1}$ · $cm^{-1}$ for age 1 year and 0.049 mSv · $mGy^{-1}$ · $cm^{-1}$ for age 10 years. Thus, when estimating effective radiation dose from $CTDI_{vol}$ and DLP in cardiac CT, it is important to understand that the conversion factor used is specific to either a 32- or 16-cm phantom, may be cardiac- or chest-specific, and may or may not be scanner-, protocol-, and age-specific. For that reason, when reporting effective dose, both the phantom size and the specific conversion ($k$) factor used should be specified. Dose calculations that are adjusted for age and size should not be used interchangeably with background radiation estimates that are not similarly adjusted, or to compare between modalities without similar adjustments in calculated dose (65).

### 6.3.5. X-Ray CT Dose Alert Monitoring

The ‘‘Protecting Access to Medicare Act of 2014’’ requires that imaging providers comply with the National Electrical Manufacturers Association XR-29 Standard Attributes on CT Equipment Related to Dose Optimization and Management, also known as Medical Imaging & Technology Alliance Smart Dose (http://www.medicalimaging.org/policy-and-positions/mita-smart-dose/). To be compliant with the Medical Imaging & Technology Alliance Smart Dose, a CT scanner must possess 4 attributes:

1. DICOM-compliant radiation dose structured reporting (https://www.nema.org/Standards/Pages/Standard-Attributes-on-CT-Equipment-Related-to-Dose-Optimization-and-Management.aspx).
2. Dose check features (https://www.nema.org/Standards/Pages/Computed-Tomography-Dose-Check.aspx).
3. Automatic exposure control.
4. Reference adult and pediatric protocols (https://www.nema.org/Standards/Pages/Supplemental-Requirements-for-User-Information-and-System-Function-Related-to-Dose-in-CT.aspx).

Since January 1, 2016, Medicare has reduced by 5% the reimbursement for the technical component of imaging procedures performed in imaging centers, physician offices, and hospital outpatient settings on CT equipment that is not in compliance with all 4 attributes of the Medical Imaging & Technology Alliance Smart Dose.

## 6.4. Patient and Personnel Exposure in Nuclear Cardiology

### 6.4.1. Patient Exposure in Nuclear Cardiology

In contrast to projectional or tomographic transmission imaging with x-rays, radiation dose to the subject from scintigraphy comes from within; from ionizing radiation emitted by a radiopharmaceutical that has been administered to the subject. Most often, the radiopharmaceutical is administered intravenously and distributes throughout the body. Consequently, unlike x-ray imaging, which principally exposes the imaged structures, the radioactive tracer exposes the entire body, not just the heart and adjacent structures. Organs receiving the highest radiation dose may not be the imaged structures. Furthermore, the patient’s behavior after study completion can alter the rate of radiopharmaceutical excretion, which can affect the overall radiation dose from the procedure.

The following information is employed to estimate the effective dose from a radiopharmaceutical exposure (which is meant to approximate the equivalent uniform whole-body dose):

1. Quantity of radioactivity administered.
2. Radiopharmaceutical distribution within the subject.
3. Kinetics of distribution to and elimination from each organ.
4. Radiosensitivity of each exposed organ.
5. Physical half-life of the radionuclide and its emitted photon or particle energy.

Much of the methodology for performing these calculations as well as relevant regulations is governed by the International Commission on Radiological Protection (ICRP), whose publications specify methodology and best

practices for estimating radiation dose from radiopharmaceuticals.

In addition, there is a second framework for estimating the radiation dose from radiopharmaceuticals, called the MIRD formalism (Medical Internal Radiation Dose). Many of the MIRD methods have been developed by the Society of Nuclear Medicine and Molecular Imaging's Committee on Medical Internal Radiation Dose, which has resulted in several publications that review this topic in greater detail (66,67).

The MIRD approach measures the concentration of the radiopharmaceutical in several organs/body compartments/whole body at multiple time points after administration. These concentrations at different times are used to estimate a residence time curve for each organ and the area under that curve allows the calculation of the cumulative activity from a given radiopharmaceutical administration.

Different radiopharmaceuticals have different elimination kinetics. For example, a typical small molecule used for cardiac imaging like Tc-99m sestamibi has quite rapid initial uptake in tissues followed by a slower washout that generally follows first-order (exponential) kinetics. On the other hand, a radiolabeled immunoglobulin G antibody can remain in the circulation for days or weeks with much slower uptake into other tissues.

Most radiopharmaceuticals used for diagnostic imaging emit gamma rays. A high-energy photon emitted from the heart will have the potential to deposit ionizing energy in the heart, but can also deposit energy in any tissue though which it passes. Therefore, the MIRD method uses organ residence times as input into anthropomorphic phantoms that model the radiation dose delivered to a given organ, both from radionuclides within the organ and also from activity in other organs, to estimate the total dose (in Gy) received by each organ. These values are multiplied by the individual organ radiation sensitivities to yield the individual organ doses, which are then summed to calculate the whole body effective dose for the subject in mSv.

Although the MIRD applies to dose from gamma rays, PET radiopharmaceuticals emit positrons, which are essentially positively charged electrons that are emitted from the nucleus and travel only a few millimeters prior to incurring an annihilation event that emits a pair of 511 keV photons. These photons have very high penetrating power and do not significantly expose the subject as they exit from their site of origin. PET nuclides, thus, deliver all of their energy close to the site where the decay occurs and exposure is essentially limited to exposure from activity within that organ.

Radioactivity within the subject decreases over time due to a combination of physical decay of the radionuclide and elimination of the nuclide from the subject. The combination of these 2 processes is expressed as the radiopharmaceutical's "effective" half-life. The effective half-life is shorter than the shortest of the physical or biological half-life, although in cases when 1 of the 2 components is very long, the effective half-life can be almost the same as the shorter of physical or biological half-life. For example, Tl-201 chloride has very slow elimination from the body and so the effective half-life is close to the 73-hour physical half-life.

A commercially available U.S. Food and Drug Administration (FDA)-approved software package (OLINDA/EXM, VU e-Innovations, Nashville, Tennessee) implements the MIRD method for calculating effective dose from a radiopharmaceutical administration. This software permits calculation of an estimated whole body effective dose (in mSv) per megabecquerel administered. (One megabecquerel is the quantity of a radioactive material that produces 1 million radioactive decay events per second.)

It is important to emphasize that these models simulate an "average" person. The exact radiation dose to a given subject may vary substantially from the expected values. For example, a subject with poor renal function will eliminate a renally-excreted radiopharmaceutical more slowly than will the "average" normal volunteer used to model dosimetry estimates, and consequently, will receive a larger actual dose than the model estimate. It is critical to understand this limitation and not to consider the radiation doses estimated for a given subject to be highly precise calculations for a specific individual, although they are quite accurate on a population level.

Consensus guidelines do not exist regarding the need to screen patients for pregnancy prior to diagnostic nuclear medicine testing. However, such guidelines are particularly needed because nuclear cardiology using photon-emitting nuclides has the potential to cause substantial uterine exposure. Two groups have advocated universal screening by questioning women of childbearing potential with postponement or pregnancy testing for those whose last menstrual period was over 10 days (68), or for an expected radiation dose over 1 mSv (69). Laboratories should develop their own policies to direct their approach to screening, testing, and counseling pregnant or potentially pregnant patients. The administration of radionuclides to pregnant women should be undertaken only after careful deliberation about the clinical benefit to the mother and potential harm to the fetus. Physicists should be consulted to provide an accurate assessment of exposure. Most agents result in low overall exposure, but some have advocated avoiding the use of 18F-fluorodeoxyglucose in pregnant women (70,71). Adjustments to protocols should be considered to reduce exposure if image quality is not affected. A patient should be encouraged to void her bladder frequently after injection to reduce prolonged

fetal exposure (72). For some nuclides, including Tc-99m pertechnetate and Tl-201, interruption in breastfeeding is recommended, for hours to days (73).

Finally, there are 2 additional issues to consider:

1. Because most radiopharmaceuticals are excreted, the frequency of elimination can greatly alter the dose to specific organs in contact with the excreta. For example, for a renally excreted radiopharmaceutical, radiation dose to the bladder wall is increased by excreted activity in the urine. Thus, the less often that a subject voids, the higher the dose. Dosimetry studies usually specify a minimum rate of urination (e.g., asking the subject to void at least every 2 hours). If clinical subjects are not given adequate instructions on hydration and voiding, their bladder dose (and the bladder contribution to overall effective dose) could be significantly higher than published values.
2. Radiopharmaceutical imaging studies, both PET and single-photon emission computed tomography (SPECT), which employ attenuation correction (an important adjunctive technique that improves accuracy of reconstructed images), utilize a hybrid radiation-based technique to estimate attenuation. These techniques employ either a rod radiation or an x-ray radiation source. This is now commonly done with CT (termed PET/CT or SPECT/CT). Thus, the total radiation dose that the subject receives is the sum of the radiopharmaceutical effective dose and the CT or rod source dose to the area exposed. In most cases, rod source dose is very low and negligible, or nearly negligible. However, depending on the CT imaging protocol used, the CT dose may be greater and, in some cases, can equal or exceed the radiopharmaceutical dose. Therefore, dose reduction strategies need to consider all sources of exposure from the study as well as to tailor the technique to get the necessary information with the minimum radiation dose to the subject.

#### 6.4.2. Personnel Exposure in Nuclear Cardiology

In contrast to the dosimetric calculations needed to estimate effective dose to a subject from radiopharmaceutical administration, the dose to personnel is generally more straightforward and closely mirrors the exposures discussed in Section 4 with 2 important caveats:

1. The photons emitted from the subject from radiopharmaceuticals are generally of higher energy than the x-rays emitted from fluoroscopy or CT devices. Only the most energetic x-rays used in CT have an energy of 140 keV; the vast majority of Tc-99m gamma rays have an energy of around 140 keV (some photons that exit the subject will have decreased energy as a result of scatter interactions), and the photons emitted from positron annihilation have an energy of 511 keV. Photons in this energy range readily penetrate the 0.5-mm lead equivalent of conventional diagnostic x-ray protective materials. Therefore, personal shielding devices, such as lead aprons or leaded glasses, are less effective and consequently are rarely used. Instead, nuclear cardiology personnel rely on the principles of time and distance. Because the total photon flux from nuclear studies is far lower than from x-ray tubes, limiting the duration spent near a radioactive subject is generally sufficient limitation of exposure. Therefore, personnel should limit the duration they spend in close proximity to either the dose syringe or the injected subject as much as reasonably possible.
2. Whereas the X-ray tube used in CT or fluoroscopy is either generating x-rays or not, the radiopharmaceutical is a continuous source of activity that can be excreted via body fluids or spread during administration. Thus, subject blood and excreted body fluids are radioactive and are a potential source of radiation exposure to personnel, particularly if an accident or an error causes a healthcare worker to become contaminated. Therefore, careful and routine monitoring for contamination is required. If contamination occurs, a medical physicist often needs to be involved to estimate the dose received by the worker. The reason for involving a medical physicist in cases of contamination is that monitoring devices (body dosimeters or ring badges) assume a relatively uniform dose to the person that can be accurately represented by the dose to the small dosimeter. However, a spill of radiopharmaceutical on a technologist's shoe could result in a meaningful dose to the foot but barely register on a dosimeter worn on a coat lapel.

## 7. MODALITY-SPECIFIC DOSE REDUCTION STRATEGIES

### 7.1. General Principles

Table 12 indicates core principles to follow for the use of medical ionizing radiation for diagnostic and therapeutic procedures.

**TABLE 12 Core Principles for the Use of Medical Ionizing Radiation for Diagnostic and Therapeutic Procedures**

| |
|---|
| 1. The examination should be conducted such that the dose received by the patient and attendant medical personnel is the smallest necessary to yield satisfactory diagnostic efficacy. |
| 2. Diagnostic and therapeutic efficacy should not be compromised in the interest of sparing radiation dose. |
| 3. If the study's purpose can be achieved employing a modality that does not employ ionizing radiation, serious consideration should be given to the alternative modality. |

#### 7.1.1. Case Selection

The most effective way to reduce patient radiation exposure is not to perform the radiation-based procedure altogether; a radiation-based procedure should be used only when it is the preferred choice among alternative modalities that do not involve radiation exposure (e.g., stress echo or stress cardiovascular magnetic resonance). If equivalent diagnostic information can be obtained by the alternative imaging modality, that study should be selected in preference to a radiation-based procedure, all other considerations being equal. This is particularly important in children and adolescents.

It is critical to utilize appropriate use criteria in selecting patients to undergo diagnostic and therapeutic procedures. One factor among many incorporated in the determination of appropriateness in these documents is procedural risk, including risk from radiation. In choosing between a radiation-based modality and one that does not use ionizing radiation, one must weigh both the clinical efficacy, including sensitivity and specificity of each alternative modality, and importance of the risk to the particular patient conferred by the radiation exposure. Although it is important to always seek to minimize patient radiation exposure (this is a particular consideration in younger patients who have long natural life expectancies), it is equally important to not withhold appropriate studies due to undue concern of the radiation-related risk.

#### 7.1.2. Dose-Determining Variables

The radiation dose delivered to patients and medical personnel (regardless of modality) is affected by several variables that are under the operator's control. These are:

1. Equipment quality and calibration
2. Equipment operating protocols
3. Operator conduct

Radiological equipment image quality is strongly influenced by the quantity of radiation that reaches the image detector and is used to form the image. This *"detector dose"* is different from the dose that the patient receives, as it is a small fraction of the total incident radiation and refers only to the radiation that penetrated the patient to reach the detector.

As each of these variables influences the dose delivered to the patient (and also, potentially to operating medical personnel), each provides an opportunity to reduce dose.

#### 7.1.3. Image Quality Issues

Image quality is a major determinant of an examination's diagnostic accuracy. Inadequate image quality may either cause incorrect diagnoses or a need to repeat an examination—requiring additional patient exposure. Consequently, it is imperative that radiological equipment meets current image quality standards, be maintained in prime working order, and is used properly to produce high-quality diagnostic images.

In addition, there are choices that balance image quality and dose. In the earlier days of x-ray and nuclear imaging, image quality was sufficiently poor to be diagnosis-limiting, and only the best image quality achievable could be accepted. This led to equipment calibration that employed detector doses that were large by today's standards.

Current imaging equipment produces much higher-quality images with the potential to employ smaller detector doses. There are circumstances in which the "best" or lowest-noise image that the system can deliver is better than needed for diagnosis. Consequently, there are circumstances in which operators can choose to accept a lower image quality, which is still sufficiently diagnostic, to reduce patient (and operator) radiation dose.

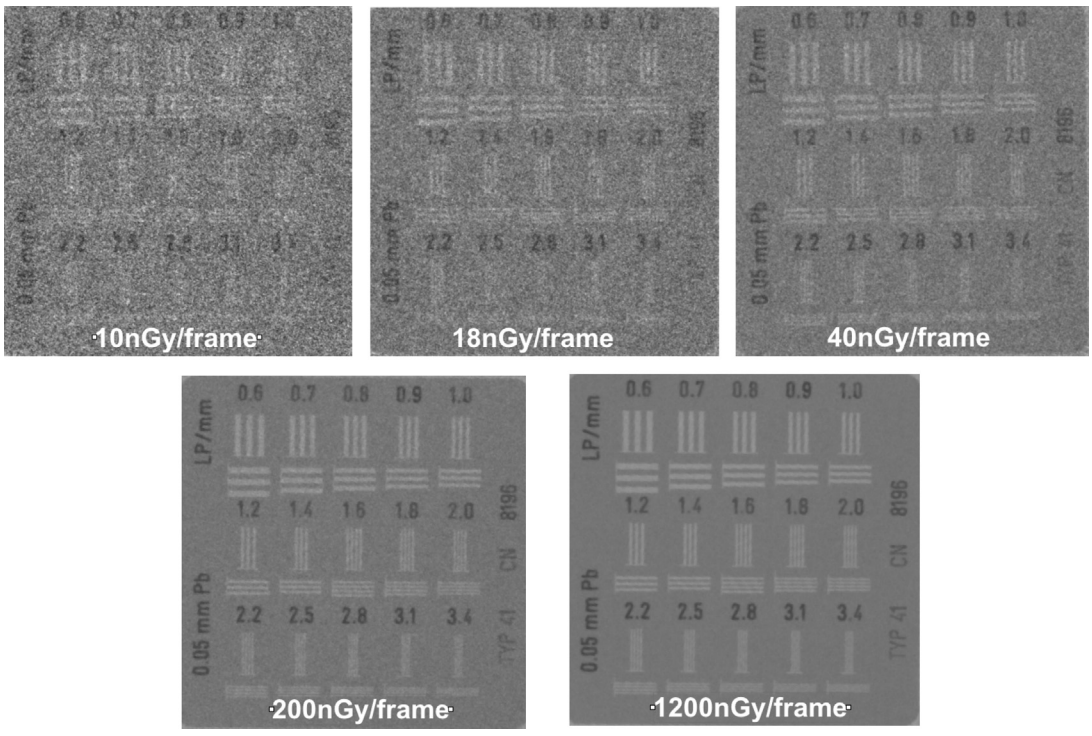
Image quality is determined by both spatial and temporal resolution, the signal-to-noise ratio, the contrast-to-noise ratio, and the presence of imaging artifacts. Most tactics that increase either spatial resolution (by improving signal-to-noise ratio and contrast-to-noise ratio) or temporal resolution (by increasing framing rate) do so at the cost of increased dose. The challenge is to optimize these properties by balancing the tradeoffs between dose and image quality.

##### 7.1.3.1. Spatial Resolution: Detector Input Dose, Pulse Width, and Nuclear Scan Acquisition

In general, image detector signal-to noise ratio is inversely proportional to the square root of the detector dose. Low signal-to-noise ratio images have a "grainy" appearance because a small number of x-ray photons reach the detector to form an image. This grainy quality, termed "quantum mottle," becomes smoother as dose increases, improving the ability to perceive image detail. This principle applies to all ionizing radiation-based imaging techniques.

Examples of the impact of detector dose on image noise for x-ray fluoroscopic imaging are presented in Figure 8. These are images of a line pair phantom that are acquired at different detector doses ranging from 10 to 1,200 nGy/frame. As the number of photons reaching the detector increases, image noise decreases and the image becomes smoother. Over a defined range, as image noise decreases, perceptible image spatial resolution increases. For each imaging modality there is an upper limit of dose beyond which further dose increase, although it may produce a smoother appearing image, does not yield greater image detail of diagnostic importance. Thus, dose is an important determinant of noise, and noise affects the ability to perceive detail. Consequently, for each

**FIGURE 8** **Images of a Line Pair Phantom Acquired in an X-Ray Fluoroscopic System at Different Detector Doses (as Labeled on the Individual Images)**




Note the progressive decrease in image noise and the ability to perceive image detail as the dose increases: 10 nGy/frame, an unacceptably low dose; 18 nGy/frame, representative dose for low-dose fluoroscopy; 40 nGy/frame, representative dose for standard-dose fluoroscopy; 200 nGy/frame, representative dose for cine acquisition; 1,200 nGy/frame, representative dose for digital subtraction imaging.

imaging purpose, there is a dose level that delivers sufficient image quality for diagnosis while minimizing dose.

Similarly, the image noise in x-ray CT images is determined in part by the number of x-ray photons that reaches the scanner detectors. Larger doses will yield images with less noise and, within limits, greater spatial resolution. For x-ray CT, the spatial resolution required to assess myocardial contours, and, accordingly, the dose needed to achieve it, is less than that required to characterize coronary artery lesions. For nuclear scan images, the number of gamma ray counts that are acquired to construct the image determines the image noise and, accordingly, its spatial resolution, which improves as the number of counts acquired increases. The number of counts acquired is determined by both the amount of radioactivity administered for the examination, which determines the number of counts per unit time, and the image acquisition time, with longer acquisition times acquiring a larger number of counts.

#### 7.1.3.2. Temporal Resolution: Pulse Duration and Frequency

The cardiovascular system moves. This imposes additional requirements on cardiovascular imaging systems, and raises 2 issues:

1. If image acquisition time is too long, object motion will cause the image to be blurred (motion unsharpness) just as a photograph of a moving object will be blurred if camera shutter speed is too slow. X-ray fluoroscopy systems deliver x-ray in a brief (2 to 10 milliseconds [ms]) pulse for each fluoroscopic or cine acquisition frame. The pulse duration is analogous to a camera shutter speed (5 ms pulse duration is equivalent to 1/200 s camera shutter speed).
2. If an image series (such as an x-ray fluoroscopy cine acquisition) is acquired at too slow of a frame rate, events that occur during time periods shorter than the framing rate will not be resolved. In addition, at slower frame rates, object motion will cause the resulting image to have a jerky quality.

The cumulative dose from an examination is proportional to the total number of frames exposed. Thus, for the same total duration of exposure, a faster frame rate will deliver a proportionately greater total exposure.

These issues pose different challenges for the different cardiovascular imaging modalities.

### 7.2. X-Ray Fluoroscopy

Of the 3 imaging modalities, x-ray fluoroscopy has the greatest variation in dose per procedure and has the potential to deliver the largest dose to patients and also to operators and nearby medical personnel. In addition, operator choices and behavior and equipment quality and calibration have substantial influences on dose. Consequently, it is important for physicians who perform x-ray fluoroscopically guided procedures to be well-versed in equipment operation and the parameters that affect dose.

#### 7.2.1. General Principles

As discussed in Section 4, there are 2 patient dose parameters that are reported by current fluoroscopy systems. These parameters are determined in part by x-ray equipment calibration and in part by operational conduct decisions that are under the operator's control. The 2 parameters are:

1. Cumulative air kerma, which is a measure of exposure intensity and correlates with the risk of tissue reactions.
2. Cumulative air KAP, which is a measure of the total energy delivered to a subject and correlates with stochastic risk.

The total dose delivered during an x-ray fluoroscopic imaging examination is the product of the dose per frame and the total number of frames in the examination (determined, in turn, by the framing rate [in frames/s] and the imaging duration). Each of these parameters is a determinant of the total dose, and each presents an opportunity to control dose. Each also presents potential tradeoffs in diagnostic utility. Optimal imaging requires operator attention to each of the parameters to achieve an optimal balance between image quality and dose.

#### 7.2.2. Digital X-Ray System Operating Modes

Digital x-ray imaging systems operate in 3 modes that employ different detector doses to achieve different image spatial resolution (see **Figure 8** for examples).

1. **Fluoroscopy:** the lowest dose per frame imaging protocol that yields images with the lowest spatial resolution. Fluoroscopy is intended to provide visual guidance for catheter manipulation but not to generate images suitable for anatomic diagnosis. Typical fluoroscopic dose rates range between 20 and 40 nGy/frame.
2. **Cine Acquisition:** an intermediate dose per frame imaging protocol intended to provide diagnostic quality images for archiving and diagnostic interpretation. Cine acquisition images have reduced image noise compared with fluoroscopic images but should still have visible noise. Typical cine acquisition dose rates are in the range of 200 nGy/frame. Interpretation of these somewhat noisy images is frequently aided by visual integration of a moving display of sequential images. Current x-ray units are generally configured for a single dose per frame for cine acquisition that has been selected to provide an optimal balance between dose and image noise.
3. **Digital Subtraction Algorithms:** the highest dose per frame imaging protocol for digital subtraction algorithms. Digital subtraction enhances the visualization of low concentration of x-ray contrast, enabling smaller contrast doses. However, because digital subtraction algorithms are highly sensitive to image noise, high doses per frame are needed to enable the subtraction algorithms to function effectively. Consequently, digital subtraction algorithm per frame dose rates are much higher (typically 1,200 nGy/frame) than for cine acquisition.

#### 7.2.3. X-Ray System Calibration, Operation, and Dose

X-ray fluoroscopy systems are typically designed to adjust the dose to the detector automatically to achieve a programmed image brightness. The dose to the detector is set by the system calibration. Current radiological equipment has selectable operating protocols that can vary the radiation dose per frame employed for fluoroscopy and the framing rate for both fluoroscopy and cine acquisition. Equipment operators should be familiar with the uses and capabilities of the different operating protocols and should select the protocol that is most appropriate for a particular patient's clinical circumstances (38,74).

At a typical framing rate of 15 frames/s with a typical 5-ms pulse duration, the x-ray beam is only on for 5 ms of the 66.7 ms occupied by each video frame. Current digital video systems employ image gap-fill to eliminate the image flickering that historically accompanied slow frame rates. However, although gap-fill avoids the flicker in the video image presentation, it does not improve temporal resolution. Slow frame rate fluoroscopic and cine acquisitions, although gap-filled, have an obligatory jerky quality because of the longer interval between frames.

The goals and purposes of a particular examination determine the optimal balance between radiation exposure and the image's spatial and temporal resolution. For example, for x-ray fluoroscopy, the spatial and temporal resolution required for general catheter

placement and manipulation is less than that required to perform coronary or structural cardiac interventional procedures. Consequently, in this application, slower frame rates and lower doses per frame can be used to reduce exposure without compromising clinical effectiveness.

In addition to selecting the optimal dose-determining imaging protocol, operator conduct can also affect patient dose. Dose is also affected by equipment positioning, radiation field size, and exposure time. This is discussed in detail in subsequent sections.

#### 7.2.3.1. Temporal Resolution Issues and Dose Tradeoffs

Because the cardiovascular system moves, x-ray fluorographic imaging requires short (typically between 3 and 8 ms for adults, as short as 2 ms for children) pulse durations to limit image motion unsharpness.

In addition, to capture the details of a moving object, an x-ray fluorographic system must have a framing rate commensurate with the degree of motion. Temporal resolution requirements vary depending on the nature of the procedure. Faster framing rates deliver a greater dose. The optimal compromise balances the smoothness of image presentation against the dose required by the framing rate.

Fluoroscopic temporal resolution requirements vary substantially depending on the examination's purpose. General catheter placement can be accomplished with fluoroscopic frame rates as slow as 3 to 4 frames/s. More complex procedures such as coronary and structural interventions require greater temporal resolution and employ frame rates between 10 to 15 frames/s.

Cine acquisition frame rates also vary with the purpose of the examination. For coronary arteriography, a frame rate of 10 to 15 frames/s is generally adequate. For adult ventriculography, 30 frames/s is preferred to achieve more precise identification of end diastole and end systole. In pediatric applications, framing rates as frequent as 60 frames/s are occasionally needed.

### 7.2.4. Determinants of Total Dose for an Exposure

#### 7.2.4.1. Dose Per Frame and Framing Rate

The total dose for a particular exposure is the product of the dose per pulse and the total number of pulses in the exposure. Thus, 3 parameters—dose per pulse (in nGy per pulse), the pulse rate (in pulses per second), and the exposure duration (in seconds)—combine to determine the total dose for an exposure.

For fluoroscopy mode, current x-ray units typically provide 3 tableside-selectable fluoroscopy detector doses per frame levels—these doses produce different degrees of image noise and tableside fluoroscopy pulse rates ranging from 4 to 30 pulses/s.

For cine acquisition mode, the detector dose per pulse is set by the service engineer. The operator can select among multiple pulse rates.

The optimal parameter settings for a fluoroscopic examination or a cine acquisition run are determined by the patient's particular circumstances, which affect diagnostic requirements for spatial and temporal resolution. The operator is responsible for determining the operating parameters (dose per pulse and pulse rate) that balance the diagnostic requirements of image spatial and temporal resolution and the dose associated with the examination.

#### 7.2.4.2. X-Ray Imaging Field Size and System Positioning

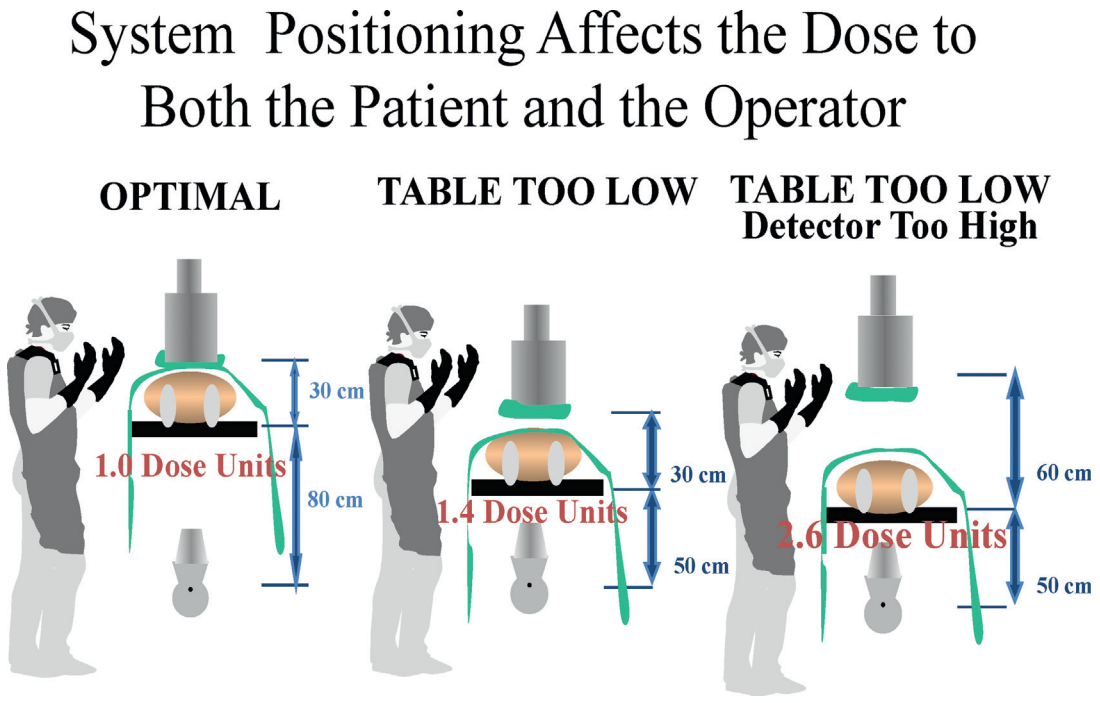
While the dose per pulse and the number of pulses determine the total dose intensity (in Gy) delivered to the patient, the product of the total dose and the imaging field size determines the total amount of radiation energy (expressed as the KAP in $Gy \cdot cm^2$, discussed in Sections 4 and 5) that the patient receives. The total KAP determines the patient's stochastic risk associated with the exposure. In addition to the examination's total number of pulses and the detector dose per pulse, the KAP is affected by 2 additional parameters that are under the operator's control: the imaging field size selected and system positioning.

While reducing KAP is beneficial to the patient, it is also beneficial to the operator and nearby medical personnel, because scattered x-ray dose (to the operator and nearby personnel) is directly related to KAP. Consequently, the operator has a personal interest to minimize KAP.

**X-Ray Imaging Field Size**

Current x-ray systems link brightness stabilization detection to a collimator position that samples only the detector area receiving the collimated x-ray beam. Consequently, the dose per pulse to the detector is not affected by collimator position. However, the KAP is directly related to the size of the imaged area. The consequence of this phenomenon is that, at a given detector zoom (magnification or input phosphor size) mode, smaller image area sizes deliver proportionately smaller KAPs. Thus, at a given detector zoom mode, reducing exposed field size by collimation to the smallest size necessary minimizes the KAP that the patient receives. This is not true for changing detector zoom modes. Detector dose per pulse increases as the zoom magnification increases. Thus, for the same actual image size, the KAP delivered by an uncollimated image at a greater zoom

**FIGURE 9** Diagrammatic Representation of the Effect of System Positioning on Patient and Operator Radiation Exposure During X-Ray Fluoroscopy




Note that in the "table too low" circumstance, the entrance port dose delivered to the patient is increased compared with optimal positioning. In the "table too low, detector too high" circumstance, the entrance port dose to the patient is further increased. In addition, in the "table too low" circumstance, the scattered dose to the operator increases because less of the scattered dose is intercepted by the detector (17).

mode is greater than an image of the same size acquired collimated at a lesser zoom mode.

**X-Ray System Positioning**

There is an optimal distance between the patient's skin surface and the x-ray source (typically approximately 70 cm). If the patient is positioned too close to the x-ray source, the full x-ray output is concentrated on a smaller area of the patient's skin, increasing the patient's beam entrance port exposure rate. This can increase the patient's skin injury risk. If the patient is positioned too far from the x-ray source, the image receptor necessarily must also be positioned further away from the source and the inverse square law requires a greater x-ray output to achieve the requisite dose to the detector. Although this latter positioning does not increase patient entrance port skin exposure rate, increased kVp required to achieve adequate detector dose causes decreased image contrast, potentially degrading image quality.

X-ray detector positioning is also an important determinant of dose to the patient as well as the exposure to medical personnel from scattering. If the detector is positioned substantially above the thorax, the image magnification caused by beam divergence will decrease the size of the beam entrance port, causing the patient to receive a larger skin dose. In addition, the x-ray image detector, when positioned close to the patient's chest, intercepts a substantial portion of the radiation scattered within the patient that would otherwise reach medical personnel; accordingly, x-ray detector positioning contributes to medical personnel protection (Figure 9).

#### 7.2.5. Procedures and Practices to Minimize Patient and Personnel Exposure

Because so many variables affect patient and medical personnel exposure, there are abundant opportunities to minimize exposure to both constituencies.

##### 7.2.5.1. X-Ray Equipment Quality, Calibration, and Maintenance

Invasive cardiovascular x-ray imaging facilities have a responsibility to maintain and update x-ray equipment to produce quality images at the minimum detector input dose needed to generate such images. Equipment should be well maintained and its calibration should be surveyed periodically to verify that it is operating within appropriate specifications. Facility clinical leadership should collaborate with the x-ray system vendor and the

institution's radiological physicist to verify that detector doses are minimized consistent with optimal image quality.

The x-ray system should provide beam spectral filtering that is consistent with current standards. These standards have become more stringent over time. Current systems provide both aluminum and copper filtration that is selected automatically by algorithms that use overall subject characteristics to achieve optimal image quality and beam filtration.

The x-ray system should provide reduced-dose operating protocols for low-dose and low frame rate imaging programs that can be employed to reduce exposure in circumstances where this will not compromise procedure conduct or diagnostic image quality. Ideally, the low-dose fluoroscopic calibration should be very low (on the order of 2 0 nGy per pulse). This will provide an image of sufficient quality for general catheter placement but not for more advanced coronary interventional procedures. A typical standard (or intermediate)-dose fluoroscopic dose rate is on the order of 40 nGy/pulse and is typically suitable for all but the most demanding coronary interventional procedures.

Typical cine acquisition detector input doses range from 140 to 240 nGy/pulse. The facility's physician director collaborates with the service engineer to determine the detector dose that provides satisfactory diagnostic quality images with an appropriate level of image noise. It is important that the physician director understand the variables that determine image quality and the tradeoffs between image noise and dose to arrive at the optimal compromise dose rate.

#### 7.2.5.2. Physician Operator Conduct

**Dose Awareness and Monitoring**

Appropriate physician operator conduct begins with awareness of dose and a commitment to minimize radiation exposure to patients and to healthcare personnel. Operators should be cognizant of the variables that determine image quality and dose to achieve the best balance of image quality (as clinically necessary to conduct a procedure effectively) and radiation exposure (75,76).

Current x-ray units display real-time values for air kerma dose rates and cumulative air kerma and KAP. The physician operator should be aware of these values and their interpretation throughout a procedure. Where clinically appropriate, the physician operator should consider total accumulated dose in making procedure conduct decisions.

**X-Ray System Operational Issues**

Imaging modality, imaging time, and image field size are 3 important dose-affecting parameters that are under the operator's direct control. Operators should select the lowest-dose imaging modality that is appropriate for a particular application. This includes using an image field size that confines exposure to the structures of interest, using the lowest-dose fluoroscopy program, and using the slowest fluoroscopy pulse rates that yield appropriate quality images (77).

Operators should use the x-ray system collimator to minimize the exposed field size. Operators should optimize system positioning with the procedure table at the optimal distance from the x-ray tube and the image detector as close to the patient as possible.

The operator should pay particular attention to minimizing exposure time. This includes limiting fluoroscopy to actual catheter manipulations that require fluoroscopic visualization and minimizing cine run durations. Maneuvers that do not require fluoroscopic visualizations such as pullbacks can be conducted without fluoroscopy.

Current x-ray systems also provide a number of capabilities that enable some common tasks to be performed without additional fluoroscopy. "Last image hold" maintains the last acquired frame on the monitor available for more detailed study, avoiding a need for additional x-ray exposure. Current systems provide virtual collimator position indicators that allow the operator to position the collimator without an x-ray exposure—enabling optimal field size adjustment while avoiding unnecessary exposure due to adjusting collimator position. In addition, current x-ray systems provide a virtual image of the effect of repositioning a patient, reducing the need to use additional fluoroscopy for the sole purpose of setting up a particular position for an examination.

#### 7.2.5.3. Physician and Medical Personnel Shielding and Protection

Protective shielding of operators and personnel provides substantial protection. Standard shielding for diagnostic x-ray ranges between 0.25 and 0.5 mm of lead or another material, such as titanium, in a thickness that has an x-ray absorbance equivalent to 0.5 mm of lead. A 0.5 mm lead equivalent apron absorbs 95% of 70 kVp x-ray and 85% of 100 kVp (78,79). The 70 kVp value is a closer representation of the spectral distribution of scattered x-ray photons that can expose medical personnel.

Medical personnel working in an x-ray procedure room should wear 0.25- or 0.5-mm equivalent lead aprons augmented with neck thyroid shields and humeral shields. The protection provided by thyroid collars is particularly important. The thyroid collar shields the thyroid and the cervical bone marrow, 2 highly radiosensitive structures that are located in an area of high radiation scatter. By attenuating the dose to these structures, the thyroid collar decreases the effective dose to

the operator by approximately one-half. In addition to lead aprons, medical personnel who work close to the x-ray source should wear leaded eye protection with side shields. Lead or lead-equivalent hats may reduce cranial dose, but potential benefits are to date theoretical based upon anecdotal reports of increased left sided brain tumors in interventional cardiologists (80).

The protection afforded by lead garments should be augmented by portable shielding. Typical in-room shielding includes a ceiling-mounted lead-impregnated poly(methyl methacrylate) shield that can be placed between the patient's thorax and the operator's upper body. This can intercept scattered radiation that would otherwise strike tableside personnel. The importance of ceiling-mounted shields cannot be overstated. Proper use of these shields reduces operator eye exposure by a factor of 19 (81). Under-table mounted 0.5-mm lead-equivalent shielding intercepts backscatter off of the patient and the x-ray table that would otherwise strike the operator's lower body.

In addition to lead-equivalent shielding, the inverse square law is one of the best sources of protection. X-ray intensity decreases as the square of the distance from the source. This relationship has implications for physician operators, because operator position in relation to the x-ray source can make a large difference in exposure magnitude. It also has important implications for circulating medical personnel.

Circulating personnel should be positioned remotely from the x-ray source and, as a result of that distance, should receive negligible exposure. When circulating personnel need to approach close to the patient, the physician operator has a responsibility to not operate the x-ray system until the circulating person has finished and is no longer in close proximity to the x-ray source (74,82).

#### 7.2.6. Pregnant Occupationally Exposed Workers

##### 7.2.6.1. Uterine Exposure Considerations for Pregnant or Potentially Pregnant Occupationally Exposed Workers

As discussed in Section 5.4.4, no measurable increase in adverse fetal outcomes has been detected at fetal or embryonic exposures below 50 mGy. For occupationally exposed workers in an x-ray fluoroscopy environment, proper shielding and practices should keep uterine exposures well below this level for the duration of a pregnancy. Because the uterus is a deep structure and is inside protective garments, the dose to the uterus delivered by scattered x-ray is greatly attenuated compared with the dose to unshielded areas. Measurements made in phantoms indicate that the uterine dose in a subject wearing a 0.25-mm lead apron is <2% of the collar dose (outside protective garments). Thus, for an occupationally exposed worker to receive a uterine dose of 50 mGy would require an accumulated collar badge dose of 2.5 Gy. The shielding provided by a standard well-fitted lead apron is sufficient to protect the fetus for typical exposures during procedures. Aprons specifically designed for pregnant workers provide additional lead inserts over the pelvis, although the additional weight of such aprons may limit their use (49).

##### 7.2.6.2. Radiation Protection and Monitoring Practices for Pregnant or Potentially Pregnant Occupationally Exposed Workers

A pregnant female occupationally exposed worker should wear, in addition to the customary collar film badge, an abdominal badge worn under the apron to estimate the uterine dose. This will verify that the uterine dose is within the range that is considered to be safe for the fetus. Thus, it is clear that with adequate precautions and protection, a pregnant healthcare worker can work in an x-ray fluoroscopy environment without detectably jeopardizing her fetus (51,52). As for patients, breast-feeding need not be interrupted for occupational ionizing radiation exposures.

#### 7.2.7. Alternative Imaging Techniques

There are a number of alternative imaging techniques that provide structural and guidance information that can supplement or replace x-ray fluoroscopic imaging. These include intravascular and intracardiac ultrasound, other forms of ultrasound, cardiac magnetic resonance, and electromagnetic mapping. In some circumstances, these imaging techniques are superior to x-ray fluoroscopy and have the additional advantage that they do not require ionizing radiation. They are being increasingly widely adopted in clinical electrophysiological procedures and in structural heart interventional procedures as adjuncts to and partial replacements for conventional x-ray fluoroscopic imaging.

#### 7.2.8. Summary Checklist for Dose Sparing in X-Ray Fluoroscopy

| Checklist of Dose-Sparing Practices for X-Ray Fluoroscopy | |
|---|---|
| Case selection | ☐ Consider patient age, comorbidities, natural life expectancy |
| | ☐ Consider appropriateness and utility of nonradiation-based imaging techniques |
| Equipment calibration | ☐ Fluoroscopic and cine doses as low as compatible with diagnostic image quality |
| Procedure conduct | ☐ Minimize beam-on time |
| | ☐ Use lowest-dose fluoroscopy setting suitable for a particular task |
| | ☐ Collimate imaging field size to the area of interest |
| | ☐ Use the slowest framing rates suitable for a particular task |
| | ☐ Minimize cine acquisition run durations |
| | ☐ Minimize patient-detector distance |
| | ☐ Maximize employment of operator shielding |

### 7.3. X-Ray CT

#### 7.3.1. X-Ray CT General Principles

The past 2 decades have seen an explosive growth in the sophistication and capabilities of x-ray CT scanners. Current-design scanners provide enhanced-quality noninvasive images of the cardiovascular system. The easy availability of high-quality images provides both important adjuncts to cardiovascular diagnosis and a strong incentive for utilization.

Achieving optimal images at minimal dose requires an expert team to coordinate patient management and protocol selection including image acquisition, reconstruction, and interpretation. The team needs to select the imaging protocol most likely to acquire diagnostic-quality images that achieve the examination's goals while exposing the patient to the smallest necessary radiation dose (83-85).

The keys to minimizing radiation exposure in cardiac CT are:

1. Appropriate case selection.
2. Scanner capability and protocol selection.
3. Proper patient preparation.
4. Appropriate examination conduct.

##### 7.3.1.1. Case Selection Appropriateness

The first principle to reduce patient radiation exposure due to CT examinations is to avoid performing examinations that will prove to be nondiagnostic. Appropriate case selection should consider whether a CT examination will answer the clinical question(s) posed. This choice includes weighing relative contraindications due to conditions (such as marked obesity, atrial fibrillation, extensive coronary calcification, or a patient's inability to cooperate) that degrade image quality. Case selection should incorporate the appropriate use criteria formulated collaboratively by the ACC and other organizations (86-88).

##### 7.3.1.2. Procedure Planning and Patient Preparation

In planning the examination, it is important to select the acquisition protocol that is optimal for the patient's condition and physical characteristics, and the examination's goals. Newer x-ray CT scanners provide improved acquisition modes that have the potential to decrease patient dose substantially.

Depending upon the clinical indication for the examination, patient preparation for cardiac CT may be vitally important both to achieve an optimal quality study and to minimize radiation dose. It is important to minimize motion artifacts caused by rapid heart rates and patient motion. This requires effective patient education to optimize cooperation to eliminate body motion and breathing during the examination. When targeting the coronary arteries, heart rate control with appropriate use of beta blocker premedication is particularly important because the lowest-dose scan protocols require a low and consistent heart rate to maximize the effectiveness of ECG gating and image quality. Target heart rates will depend on scanner hardware, but in general a regular rhythm with rates in the range of 50 to 70 beats/min is preferred.

The dose delivered by the examination can also be influenced substantially by examination conduct decisions. The most obvious choice is to take care to confine the examination to the part of the body that is relevant to the examination's goal and to take care not to expose irrelevant anatomical regions. Equally important is to tailor the acquisition protocol to the spatial and temporal resolution needed for the particular examination's purpose. For example, imaging of structure for congenital heart disease requires less spatial resolution (and accordingly, lower doses) than coronary imaging.

#### 7.3.2. Equipment Quality and Calibration

Equipment calibration and preventive maintenance as part of quality assurance and control programs play an important role in reducing radiation dose by facilitating dose optimization. This is discussed in greater detail in Section 9. CT scanner design has improved substantially in recent years with improved detectors and more refined acquisition protocols enabling current scanners to produce higher-quality images at lower patient doses.

#### 7.3.3. Variables That Affect Patient Dose for X-Ray CT

The radiation dose to a patient is determined by a combination of the patient's physical characteristics and scanner protocol selection. Patient exposure will necessarily increase with patient size and body mass index. Depending upon the specific acquisition parameters, the increased exposure need not increase dose to radiosensitive tissues. Patient size is not a variable that determines exam appropriateness as long as the patient's size does not preclude obtaining diagnostic quality images.

X-ray CT systems may either use a constant x-ray tube output or, in some acquisition protocols, use ECG-gated variable output. The operator selects the acquisition protocol based on patient characteristics and the study purpose with the intent to deliver a sufficient exposure to permit an acceptable degree of noise in the reconstructed images.

The x-ray CT system operator is responsible to select the scanning protocol that optimizes the examination's

diagnostic yield while minimizing dose. The following are essential considerations in this process:

1. Scan length. Scan length, defined as the distance imaged along the cranio-caudal axis, should be kept to a minimum to encompass only the anatomy of interest and not expose structures that are not relevant to the examination's purpose. Care needs to be taken to ensure that the diaphragm position seen on the topogram is the same as during the scanning. This requires similar breath hold instructions.
2. X-ray beam intensity. X-ray beam intensity is determined by both the x-ray tube potential (in units of kV) and the x-ray tube current (in units of mA). Modern CT scanners modulate the tube current dynamically throughout the CT acquisition to minimize radiation exposure.

   **Tube potential:** Studies of radiation dose reduction have demonstrated that the most important single factor in controlling radiation dose is adjustment of x-ray tube voltage (89-91). Increasing tube voltage increases the x-ray beam's mean photon energy level, and increases radiation dose roughly proportionally to the square of the voltage. Thus, at a constant tube current, a decrease of tube voltage from 120 to 100 kV reduces the radiation dose by almost 40%. In most scanners, the x-ray tube voltage may be adjusted between 70 to 140 kilovolts (kV). The voltage is selected by the operator based on subject weight or body mass index. A commonly used adjustment scale that provides diagnostic quality in most scanners is: 120 kV for patients with body mass index $\geq$30 kg/m$^2$, 100 kV for body mass index 21 to 29 kg/m$^2$, and 80 kV for body mass index $<$21 kg/m$^2$ (83). Image noise decreases as potential increases, so that in extreme cases (body mass index $\geq$40 kg/m$^2$) the maximum tube potential of 150 kV may be necessary to produce diagnostic quality images. Consequently, selecting the tube potential involves a trade-off between image noise and dose.

   **Tube current:** The x-ray tube current (in mA) is defined as the number of electrons accelerated across the tube per unit of time and is proportional to the number of x-ray photons produced per unit time. The radiation dose is linearly proportional to the tube current. Image noise is inversely proportional to the square root of the tube current. Thus, decreasing tube current at a given tube potential decreases the radiation dose at the expense of increased image noise. The tube current may be modified based upon patient size assessed by visual inspection, measurement of body weight or body mass index, thoracic circumference or diameter, or noise measurement from a cross-sectional prescan or topogram. Most modern scanners offer tube current modulation based upon the thickness of the body estimated from the topogram. Modulation may be applied longitudinally as well as circumferentially. This approach can reduce radiation exposure of thoracic CT examinations by 20% without increasing image noise (92). A specific form of tube current modulation that is applicable to retrospective ECG gating (see the following text) modulates the tube current during each heart beat relative to position within the R-R interval. This method is discussed in specific detail within the subsequent section on retrospective ECG.
3. Rotation time. The time required for the gantry to perform 1 rotation is a selectable parameter. Exposure increases linearly with rotation time.
4. X-ray beam filtration. Filters placed beneath the x-ray tube are used to selectively attenuate low-energy x-rays that do not significantly contribute to the image but do contribute to radiation dose (85). The net effect is to increase the mean energy of the x-rays while not altering the maximum energy. Filters may be small, medium, or large and either flat or bowtie. The choice of filter depends on the size of the patient and the acquisition field of view.
5. Scan acquisition mode. This is a major determinant of radiation dose. Different acquisition modes can deliver substantially different doses while producing similar images. There are 3 principal CT scan modes: axial or "conventional" scanning, helical scanning, and fixed table or single-station scanning.

   **Axial scanning** may or may not be ECG triggered. It images a portion of the anatomy during a single gantry rotation while the table is stationary. The table advances to the next contiguous position, which is based upon the width of the detector array, and another scan ensues. The process is repeated until the full anatomy of interest has been imaged.

   **Helical scanning** combines continuous gantry rotation with continuous table advancement to trace a contiguous helical or "spiral" path from the origin to the terminus of the scan. The ratio of the width of the detector array to the distance that the table advances per complete gantry rotation is the scan pitch. Radiation exposure for helical scanning at a pitch of 1 is comparable to axial scanning. When the pitch is $<$1, the radiation exposure is greater; when the pitch is $>$1, then radiation exposure is decreased. A specialized form of helical scanning, called "*high pitch*" scanning, has been developed for use in dual-source CT scanners. Dual-source scanners with 2 x-ray tube/detector systems can interleave 2 sets of projection data acquired simultaneously; however, the 2 beams are separated in-plane by approximately 90%, allowing the pitch to increase to $>$3. When applied to imaging the heart, the reduced overlap between gantry rotations in this scanning mode reduces radiation dose more than any of the other scan modes, to values of $<$1 mSv (93,94). However, high-pitch scanning at its current stage of development is vulnerable to image artifacts, and suitable

for coronary artery imaging only in patients with slow, very regular heart rates. It does have value in circumstances where minor imaging artifacts can be accepted (such as pulmonary vein mapping).

**Fixed table scanning** is a specialized form of axial scanning performed when using a CT scanner with a detector array with a width that equals or exceeds the length of the anatomy of interest. In this instance, the table remains stationary during a single or multiple gantry rotations. Radiation exposure approximates axial scanning when a single gantry rotation is applied and increases linearly with increased gantry rotation time.

6. Cardiac motion compensation. Compensation for cardiac motion is rarely applied outside of direct cardiac and aortic root imaging. Thus, the majority of cardiovascular medical imaging does not employ ECG gating or triggering. In contrast, when imaging the heart or aortic root, cardiac motion compensation is critical to avoiding motion-related artifacts that substantially degrade image quality. Depending upon the scan mode, 1 of 2 cardiac compensation methods is used.

**Prospective ECG triggering:** Prior to the scan, the operator "prospectively" selects an imaging window within the cardiac cycle, which may be defined as a percentage from one R-wave to the next or an absolute time delay after each R-wave (6). Scans are then triggered to coincide with the selected scan window. Prospective triggering may be applied to each of the 3 scan modes. In the case of axial scanning, ECG triggering is used to trigger the acquisition at each table position. Scanning occurs during every other heartbeat, and the table is incremented during intervening heart beats. The principle is the same with fixed table scanning; however, here a single scan is acquired, initiated based upon the ECG trigger. Finally, in the case of high-pitch scanning, a single sub-second helical acquisition may be triggered based upon a prospectively acquired ECG. For the specific application of coronary CTA, prospective triggering has been associated with the lowest-dose scans; however, effective prospective triggering requires a regular, slow heart rate (typically 50 to 65 beats/min in most scanners). The data acquisition window may be widened (padding) to allow for retrospective adjustments of the acquisition window at the expense of increased radiation. A disadvantage of prospective gating is the potential that, if the image quality proves to be unsatisfactory, the entire scan must be repeated because no projection data are available from other portions of the cardiac cycle.

**Retrospective gating**: Applicable to both helical and fixed table scan modes. With helical scanning, acquisition is performed using a low pitch of approximately 0.2. The slow acquisition images the entire cardiac anatomy across the entirety of a cardiac cycle, providing a 4-dimensional dataset that allows each spatial location within the heart to be reconstructed at any time-point across the cardiac period. Data are continuously acquired along with the ECG signal while covering the anatomy of interest. The data are subsequently rebinned at each slice location for image reconstruction, according to the time of the cardiac cycle from the ECG signal. The selection of a specific time-point for reconstruction is determined after the scan is completed or "retrospectively." The principle is the same for fixed-table scanning; however, here, there is no table movement. Multiple gantry rotations with a wide detector provide the 4-dimensional, temporally resolved data.

Retrospective gating is the only method that allows the assessment of dynamic cardiac structures such as native and prosthetic valves, myocardium, and chamber dimensions. It can also reveal intracardiac shunts and dehiscent graft anastomoses, owing to variations in iodine enhancement across the cardiac cycle. When compared with prospective triggering, coronary CTA performed with retrospective gating offers diagnostic image quality of the coronary arteries in patients with higher basal heart rates and a greater degree of beat-to-beat variability and allows assessment of regional myocardial function; however, it is associated with a higher radiation dose. Typically, image reconstruction for "static" coronary CTA uses only the time period during the cardiac cycle when cardiac motion is minimal (diastole), and the helically arranged projection data from other periods of the cardiac cycle are ignored. This scanning mode, while radiation-inefficient, has a number of advantages. In particular, the entire image dataset is available for image reconstruction, enabling post-processing selection of the best quality images. In addition, because image data are available from the entire cardiac cycle, images from different portions of the cardiac cycle can be combined to construct cine loops that can be used to examine global and regional left ventricular function.

**ECG-triggered tube current modulation:** As discussed in the preceding section, "Tube Current," ECG-triggered tube current modulation is used to reduce radiation dose during systole when there is the greatest cardiac motion and can reduce the radiation exposure significantly. In this circumstance, tube current is at nominal value only during the portion of the cardiac cycle likely to be used for reconstruction (typically end diastole). During the remainder of the cardiac cycle, the tube current is reduced to reduce radiation output. Recent refinements of this technique have allowed reduction of the length of time ("window") during which tube current is nominal and reduction of tube current during the undesired portions of the cardiac cycle by 20% and to as little as 3% to 5% of the nominal value (95-97). A potential disadvantage of this technique is that images reconstructed from

projection data acquired with low tube current may be too noisy to be diagnostic for coronary anatomy. Retrospectively ECG-triggered tube current modulation works best in patients with stable sinus rhythm and low heart rates (specific thresholds depend on scanner characteristics).

7. Image reconstruction. Filtered back-projection has historically been used to reconstruct CT images from projection data. The advent of greater computing power has made an alternative statistical method—iterative reconstruction—practical for CT. This method predicts projection data based upon an initial assumption about the attenuation in each voxel and compares that data to measured projection data. The voxel attenuation values are modified iteratively until an acceptable level of error between the predicted and measured data is obtained. The resulting reconstructed images have lower noise values compared with those obtained with filtered back projection. This permits reducing tube voltage and/or current to obtain images with comparable noise and lower radiation dose (98,99). One important characteristic of iterative reconstruction is that excessively low-dose images do not appear grainy, as is the case with filtered back projection. Instead, structures become blurred and can develop a blotchy appearance, undermining their diagnostic effectiveness.
8. Image postprocessing filters. These may also be applied to acquired images to reduce image noise while preserving image contrast and edges. The feasibility of using these filters for radiation dose reduction has been recently demonstrated (100).

#### 7.3.4. Summary Checklist of Dose-Sparing Practices for X-Ray CT

| Checklist of Dose-Sparing Practices for X-Ray Computed Tomography | |
|---|---|
| Case selection | ☐ Consider patient age, comorbidities, natural life expectancy<br>☐ Consider appropriateness and utility of nonradiation-based imaging techniques |
| Equipment calibration | ☐ Acquisition detector doses as low as compatible with diagnostic image quality |
| Procedure planning | ☐ Select lowest-dose acquisition protocol compatible with study goals. Retrospective gating should be selected when feasible<br>☐ Use ECG-gated variable tube output if retrospective gating is used |
| | ☐ Use the lowest x-ray tube voltage compatible with adequate diagnostic quality image acquisition |
| | ☐ Use the lowest x-ray tube current compatible with diagnostic quality image acquisition. Use topogram-based tube current modulation |
| | ☐ Use the largest scan pitch compatible with adequate diagnostic quality image acquisition |
| Study conduct | ☐ Minimize patient heart rate<br>☐ Confine scanned body area to the area relevant to the study's diagnostic purpose |

### 7.4. Nuclear Cardiology Techniques

#### 7.4.1. Nuclear Cardiology General Principles

There are 2 categories of nuclear cardiac imaging:

1. Single photon imaging, which is intrinsically a planar format technique in which images can be acquired in either planar or tomographic (SPECT) formats.
2. Positron imaging, which is an obligatory tomographic format (PET).

PET generally administers a smaller radiation dose to the patient and is less affected by patient attenuation. It is currently more expensive to perform than SPECT because the scanners, being more complex, are more expensive to acquire, and because some of the radiopharmaceuticals used in PET are currently more expensive than those used in SPECT.

Achieving optimal image quality in nuclear cardiology involves considering more than just spatial resolution. Nuclear cardiology images compare tracer activity at different locations in moving structures. Consequently, image noise, contrast, and temporal resolution are often more important imaging attributes as long as image spatial resolution meets a necessary minimum value.

Like x-ray imaging, nuclear image quality is in part determined by the quantity of radiation that reaches the detector to form the image. This presents dose-image quality tradeoffs that are similar to the tradeoffs in x-ray imaging. Quality is also influenced by the quality of the equipment, with more recent scanners being more sensitive and able to generate a quality image from a smaller number of counts.

#### 7.4.2. Nuclear Cardiology Equipment Quality, Calibration, and Maintenance

In nuclear cardiology imaging, achieving an optimal balance of image quality and patient dose requires that the imaging equipment be in good operating order. Nuclear cardiology imaging equipment has benefited from substantial engineering progress. These improvements include new detector designs and better electronics, both for PET and SPECT, ultimately resulting in greater sensitivity. For example, current state-of-the-art solid state (cadmium zinc telluride) detectors achieve a direct electrical signal output from an incident photon, eliminating the need for photomultiplier tube scintillation detection and improving energy resolution. Novel cardiac-specific designs allow for a much higher effective detector size focused on the heart.

All of these improvements enable acquisition of a satisfactory image from a smaller radiopharmaceutical dose, reducing patient exposure. Nuclear cardiology facilities should endeavor to have recent-generation equipment and an organized program of equipment performance surveillance. This is discussed in greater detail in Section 9.

#### 7.4.3. Nuclear Cardiology Spatial Resolution and Image Detector Dose

Overall, achieving an optimal balance of patient exposure and image quality requires a judicious balancing of image acquisition parameters, hardware, imaging time, and radiopharmaceutical dose.

To have a diagnostic image, the "good" signal must outweigh the noise (the signal to noise ratio). Typically, noise is approximately the square root of number of counts (101). Thus, signal to noise ratio is exponentially proportional to the overall number of counts that form the image. For example, if 100 counts are collected, noise would account for about 10 counts (square root of 100 is 10), and signal to noise ratio would be 10. On the other hand, if 10,000 counts are collected, the signal to noise ratio would be 100.

The impact of signal to noise and system sensitivity affects choices of subject radiopharmaceutical dose, comfort, and convenience. An image, to be of diagnostic quality, should be properly collimated and be formed from a requisite number of counts.

Three variables affect the number of registered counts:

1. The imaging system's sensitivity.
2. The amount of radioactivity administered to the subject. This affects the dose the subject will receive from the procedure.
3. The length of time that counts are acquired to form the image. This affects the scan acquisition time, with implications for the subject's experience, and the amount of scanning time needed to complete the study with implications for facility throughput.

Typically, a given scan acquisition is conducted until a requisite number of counts has been collected. If the radiopharmaceutical dose administered is small, although the radiation dose to the subject will be smaller, a longer scan acquisition time will be required. Patients cannot lie still indefinitely. Consequently, there are limitations to practical acquisition duration without introducing motion artifacts.

#### 7.4.4. Procedures and Practices to Minimize Patient Exposure

The variables that affect patient dose that can be adjusted in nuclear myocardial perfusion imaging include: radiopharmaceutical selection and dose, image acquisition time, whether to routinely acquire rest images, and mode of stress.

##### 7.4.4.1. Radiopharmaceutical Choice

**SPECT Imaging Agents: Tc-99m and Tl-201**

The most commonly used SPECT radiopharmaceuticals use Tc-99m bound either to sestamibi or tetrofosmin. These radiopharmaceuticals have largely supplanted Tl-201 chloride because of Tc-99m's superior imaging characteristics and lower radiation dose to the subject. A typical effective dose range for a 1-day Tc-99m rest-stress imaging protocol is 9.8 to 16.3 mSv (102). However, Tl-201 has a pharmacological advantage in that it redistributes over time, providing a viability assessment with no additional radiation exposure. Thus, Tl-201 has a role that may be considered in cases when viability data is needed.

**PET Imaging Agents: Rb-82 Chloride, N-13 Ammonia, F-18 Fluorodeoxyglucose**

PET myocardial perfusion imaging can be done with a number of radiopharmaceuticals. All positron emitters yield photons with energies of 511 keV, which is ideal for imaging.

The most commonly used agent is Rb-82 chloride. Rb-82 has a very short physical half-life, which confers an advantage, an operational challenge, and a disadvantage. The advantage is that the rapid physical decay can achieve high count rates with a substantial decrease in subject dose. The operational challenge is that the radionuclide dose must be administered promptly after it is generated, and the patient must be imaged immediately after nuclide administration. The disadvantage is that the short half-life requires that only pharmacological stress can be used. This means that the independent prognostic information available from exercise stress is lost unless a separate nonimaging exercise stress is performed.

PET's radiation dose advantage is slightly offset by the fact that PET imaging requires attenuation correction, which requires an additional x-ray CT exposure. The amount of additional radiation from the x-ray CT component is variable depending on the technique used, but should be very small compared with the radionuclide dose. Many centers currently perform CT attenuation correction for SPECT as well, so if a high-dose CT protocol is used, the total amount of radiation employed may not be that different between SPECT and PET.

N-13 ammonia is an excellent imaging agent for quantification of myocardial blood flow. It is cyclotron-generated and has a 10-minute half-life. The latter results in a subject radiation dose for a rest-stress study of only 2.2 mSv, which is even lower than Rb-82 rest-stress myocardial perfusion imaging. Because of its very short half-life, N-13 imaging can only be conducted in a facility with an on-site (or very nearby) cyclotron, and production must be very tightly paired to administration. This presents logistical and financial challenges that limit the availability of N-13 imaging.

Rb-82 chloride, which has a 75-second half-life, is generator-produced. This makes it more readily available than N-13. It provides a viable alternative to Tc-99 SPECT imaging in centers that have the infrastructure of PET scanners and sufficient clinical volume to amortize the generator cost. Rb-82's short half-life results in a subject

radiation dose for a rest-stress study of 3.3 to 3.8 mSv that is a fraction of the dose from a Tc-99m sestamibi 1-day rest-stress imaging study (103,104).

F-18 is cyclotron-generated and has a 110-minute half-life. The 18-fluoride anion is then incorporated into glucose to make 18-fluorodeoxyglucose. Because of the relatively short half-life, it must be administered promptly. It is widely used to image tumors and inflammation. In cardiovascular medicine, it is of value to detect viable and hibernating myocardium and to image myocardial sarcoid and inflammation.

#### 7.4.4.2. Imaging Protocol Choice

**Imaging Agent**

There are a variety of imaging protocol strategies that provide different opportunities to reduce subject dose. Each involves compromises and tradeoffs.

As Tc-99m imaging agents and Rb-82 do not redistribute, separate radiopharmaceutical injections are needed for the stress and the resting scans. Because of Rb-82's short physical half-life, both injections can utilize the same dose, as the first dose's will have decayed by the time the second dose is administered (typically 20 to 30 mCi). However, for a Tc-99m same-day stress-rest protocol, the first administration is with a lower dose (typically 10 mCi) and the second employs a higher dose (typically 30 mCi). The basis of this strategy is that the higher dose of the second administration overwhelms the residual counts from the first administration. This necessarily means that the lower-dose administration may be count-poor and may be nondiagnostic, particularly in larger patients. In such cases, a 2-day protocol using the maximal dose each day is preferred.

**Stress-Rest Versus Rest-Stress Protocol**

Stress-first and rest-first acquisition protocols have different merits, and choosing between them involves balancing a number of considerations. The choice balances the important goal of reducing patient dose against the requirement to ensure acquisition of a fully diagnostic study. A low-dose stress-first protocol offers the potential to acquire a diagnostic study at reduced total patient dose if the stress images are of good quality and are normal. If the stress image is normal, there is no need to do a rest image, and the study can be completed with a single low-dose injection. Use of stress-first imaging in some patients has been recommended as a best practice protocol by the International Atomic Energy Agency (101) and is widely practiced effectively in Europe. However, although stress-first imaging offers the potential of saving dose when the stress images are normal, it also means that the stress image, arguably the more important of the 2, is acquired with a lower radiopharmaceutical activity; in some patients—particularly in those with significant obesity—this may compromise image quality and thereby the study's overall diagnostic accuracy. In addition, if the stress image is abnormal, the rest image must be obtained anyway for a complete study.

The American Society of Nuclear Cardiology imaging guidelines balance these competing priorities in protocol selection (102,105). While noting that "in patients without a high pre-test probability of a stress perfusion defect or left ventricular dysfunction or dilatation, a low-dose stress/high-dose rest Tc-99m protocol is advantageous because a significant percentage of these patients will have normal stress imaging, thereby obviating the need for the rest imaging with its additional radiation exposure," the guideline allows that in "larger patients (e.g. >250 lbs or BMI >35) or in female patients where significant breast attenuation is anticipated, a low dose of Tc-99m radiotracer may result in suboptimal images and a 2-day imaging protocol with higher activities (18 to 30 mCi) for each injection may be preferable."

Thus, stress-first imaging is advisable in subjects who are good imaging subjects and who do not have a high pretest probability of an abnormal study. Of note, the use of attenuation correction and/or prone imaging may increase the proportion of patients who are appropriate subjects for stress-first imaging. For larger patients or females with significant breast attenuation, a 2-day protocol is advisable. Depending on the practice setting, rest-first imaging would be appropriate in subjects who are likely to have abnormal stress imaging, or who will be difficult to image but for whom a 2-day study is not feasible.

#### 7.4.4.3. Image Acquisition Practices

The patient dose for a nuclear cardiology study is determined by the radionuclide used and the dose injected. The dose required is determined by the capabilities of the imaging equipment, how it is used, and the practical time-period to acquire images. Increasing the efficiency of image acquisition lowers the amount of radioactivity needed, reducing the dose administered to the patient. Current scanners acquire counts more efficiently than earlier models and make it possible to use lower injected radioactivity doses.

The activity required to acquire a diagnostic study is also influenced by aspects of the acquisition technique. There are a number of practices that, if followed, will enable acquisition of quality diagnostic images at smaller radioactivity doses. It is important to emphasize that these are study conduct decisions that should be made individually, based on the particulars of the patient and the study goals by the physician responsible for the study.

1. Camera positioning. Radioactive emission intensity decreases with the square of distance from the source to the detector. Consequently, it is critical to position

the camera as close as possible to the patient throughout the acquisition. By doing this diligently, image quality at a specific dose will be maximized, enabling the use of a smaller radioactivity dose. Many modern systems automatically contour to the patient's body. Accordingly, it is important to position the patient such that no extraneous material will increase the patient-to-detector distance (e.g., excess blankets, patient's arms, and so on).

2. Iterative image reconstruction. Iterative reconstruction techniques can improve image quality from a given dataset. Iterative reconstruction capabilities are incorporated into current SPECT and PET systems. Thus, virtually all SPECT and PET acquisitions should be reconstructed with an iterative technique because, compared with filtered back projection, iterative technique improves image quality for a given radiation dose. The specific reconstruction parameters can significantly alter the image smoothing/noise characteristics, and so these parameters can be adjusted to the preferences of the reader, with input from the manufacturer and medical physicist.
3. Attenuation correction x-ray dose. The x-ray dose employed for attenuation correction adds to the exposure from the radionuclide tracer. While attenuation correction is important to improve diagnostic accuracy, it is important to minimize the magnitude of the additional radiation exposure. Attenuation correction-capable scanners utilize either rod-source or CT-source radiation. Rod-source is intrinsically low dose (typically <1 mSv and has been reported to be as low as 0.04 mSv—substantially less than the radionuclide tracer dose). CT-source, on the other hand, can be highly variable and substantially greater depending on the CT acquisition protocol employed. Consequently, if a scanner utilizes a CT scan for attenuation correction, operators should ensure that the acquisition protocol generally employs the lowest dose available (106,107).

#### 7.4.5. Procedures and Practices to Protect Occupationally Exposed Healthcare Workers in Nuclear Cardiology Facilities

Occupationally exposed healthcare workers are at exposure risk from 3 sources:

1. Exposure incurred when handling radiopharmaceuticals prior to administration.
2. The ambient radiation from the radioactive patient.
3. Residual radiation from an inadvertent or unrecognized contamination or spill.

Contained doses of radiopharmaceuticals should be properly shielded to minimize the escape of radiation into the environment to expose healthcare workers. Although some radiation emanating from a patient who has received a radiopharmaceutical dose inevitably escapes into the environment, the magnitude of exposure to healthcare workers can be managed by protocols that minimize the time that workers are in close proximity to radioactive subjects. There is also the potential for radiation exposure to members of the public, including the patient's family. However, at the doses administered clinically, exposure to the public is small and well within regulatory limits. Therefore, in this case, no specific instructions are warranted.

The consequences of contamination or a radiopharmaceutical spill can be much more severe. This is particularly problematic as human senses cannot detect radiation. Thus, there is a potential for a spill or contamination to occur without the workers realizing it. Because of this possibility, it is necessary to have in place rigorous spill-protective practices; rigorous safety protocols that govern personal conduct in "hot" areas; and rigorous surveillance of equipment, work surfaces, and personnel for radioactive contamination.

In particular, a substantial radiation exposure to personnel can occur if they ingest or otherwise take in radiopharmaceutical from contamination, volatilization, and so on. Therefore, it is critically important to avoid eating, drinking, applying cosmetics, and so on in areas where radioactivity may be present. Furthermore, alcohol-based hand sanitizers, although useful in preventing spread of infection, are not effective at removing radiopharmaceutical contamination. Consequently, rigorous hand washing is the principal protective strategy to remove/neutralize potential radiopharmaceutical contamination.

#### 7.4.6. Summary Checklist of Dose-Sparing Practices for Nuclear Cardiology

| Checklist of Dose-Sparing Practices for Nuclear Cardiology | |
|---|---|
| Case selection | ☐ Consider patient age, comorbidities, natural life expectancy<br>☐ Consider appropriateness and utility of nonradiation-based imaging techniques |
| Modality selection | ☐ Select the appropriate technique and radionuclide that provides diagnostic quality information at the least patient radiation dose.<br>Dose relationships:<br>N-13 $H_3$ PET < Rb-82 PET < Tc-99m SPECT < Tl-201 SPECT |
| Equipment calibration | ☐ Use scanners with cadmium zinc telluride [CZT] detectors |
| Procedure planning | ☐ Use stress-rest protocol in preference to rest-stress when the overall clinical situation (clinical scenario and patient imaging characteristics) is appropriate<br>☐ Use the smallest radionuclide dose compatible with adequate count acquisition rates |
| | ☐ Position camera head as close to the patient as possible |
| | ☐ Use iterative reconstruction |
| | ☐ Minimize radiation exposure for attenuation correction |

**TABLE 13 Dose Minimization Strategies**

| | | | | | |
|---|---|---|---|---|---|
| *X-Ray Fluoroscopy* | **Use alternative nonradiation-based imaging techniques** (ultrasound, magnetic resonance imaging, electromagnetic mapping) when appropriate. | **Radiological equipment**: Current state-of-the-art equipment calibrated for minimal dose exposures. | **Operator conduct**: Optimal system positioning, minimal imaging field size, minimal exposure time. | **X-ray system operating modes**: Slowest frame rate and the smallest dose per frame consistent with diagnostic quality imaging and appropriate procedure guidance. | **Medical personnel protection**: Optimal use of protective garments and shields, maximize distance from the x-ray source, and minimize patient exposure (which, in turn, minimizes medical personnel exposure). |
| *X-Ray CT* | **Study appropriateness**: Ensure that an x-ray CT examination is the optimal imaging technique to answer the clinical question. | **Radiological equipment**: Equipment should be current state of the art, in good working order, and calibrated for minimal dose exposures. | **Scan protocol**: Select the lowest-dose scan protocol that will provide images of diagnostic quality to answer the clinical question. | **Scan size**: Confine the imaged body region to the smallest area needed to answer the clinical question. | |
| *Nuclear Cardiology* | **Study appropriateness**: Ensure that nuclear cardiology study is the optimal imaging technique to answer the clinical question. Consider PET rather than SPECT imaging if feasible and appropriate. | **Imaging equipment**: Equipment should be current state of the art, in good working order, and calibrated for minimal dose exposures. | **Scan protocol**: Select a stress-rest protocol when appropriate (according to ASNC guidelines). | **Radiopharmaceutical choice**: Tc-99m is preferred for SPECT. Avoid Tl-201 except for studies focused particularly on myocardial viability issues. | **Radiopharmaceutical dose**: Use the smallest injected dose that will provide sufficient counts for imaging in a practical time period. |

ASNC = American Society of Nuclear Cardiology; CT = computed tomographic; PET = positron emission tomography; SPECT = single-photon emission computed tomography; Tc = technetium; Tl = thallium.

### 7.5. Summary of Dose Minimization Strategies in X-Ray Fluoroscopy, X-Ray CT, and Cardiovascular Nuclear Scintigraphy

Table 13 summarizes dose minimization strategies for the imaging modalities discussed in this document.

## 8. MODALITY-SPECIFIC OPERATOR EDUCATION AND CERTIFICATION

### 8.1. General Principles

Physicians who operate or supervise the operation of radiological equipment should be able to operate it in a manner that achieves optimal image quality while minimizing radiation exposure to patients and to attendant medical personnel (including themselves). To achieve this successfully requires the physician operator/supervisor to hold the following requisite core knowledge bases:

1. The basics of radiation physics, radiation biology, and radiation protection.
2. Equipment operation knowledge base specifically relevant to the imaging modality:
   - How the equipment operates.
   - How settings, configuration, and other operational choices affect image quality and radiation dose.

Although overall competency in radiological techniques requires understanding image interpretation in addition to equipment operation, this section focuses on the knowledge required to achieve optimal equipment operation to minimize radiation exposure without compromising image quality.

#### 8.1.1. Regulatory Authority

Organizations that have governance over training for users of ionizing radiation include the U.S. Nuclear Regulatory Commission (NRC), the U.S. Department of Labor Occupational Safety and Health Administration, The Joint Commission, and state governments. There is considerable state-to-state variation in the degree of regulatory oversight and establishment and enforcement of minimum mandatory training requirements. The healthcare institutions have credentialing responsibility and, accordingly, are responsible to ensure that all healthcare providers who operate radiological equipment hold a requisite understanding of the relevant modalities.

#### 8.1.2. Professional Society Guideline and Position Statements

The Conference of Radiation Control Program Directors is a consortium of radiation safety officers that has produced a series of resolutions including “That the CRCPD encourage healthcare facilities to require appropriate education and training of all personnel, to include physicians, before they are permitted to operate fluoroscopic machines, and that this training include radiation safety and the biological effects of radiation exposure.” This is

codified in a statement applicable principally to x-ray fluoroscopy and issued in 2004 (108). The Conference of Radiation Control Program Directors recommends to state regulatory agencies that all persons operating fluoroscopic x-ray systems complete training in the following before using fluoroscopy independently: 1) biological effects of x-ray; 2) principles of radiation protection; 3) factors affecting fluoroscopic outputs; 4) dose reduction techniques for fluoroscopic x-ray systems; 5) principles and operation of the specific fluoroscopic x-ray system(s) to be used; 6) fluoroscopic and fluorographic outputs of each mode of operation on the system(s) to be used clinically; and 7) applicable requirements of these regulations. Regulatory authority to implement these recommendations as regulations resides with individual states' departments of health.

The ACC has published expert consensus documents and training standards (COCATS [Core Cardiovascular Training Statement]) for all aspects of cardiovascular medicine and specifies training in radiation safety and protection in those documents (75,109–112). Similar documents have been published by the ACR and the American Council for Graduate Medical Education (16,113,114).

### 8.2. X-Ray Fluoroscopy

#### 8.2.1. Physician Responsibilities

Operator choices and conduct are of paramount importance in affecting patient and operator dose during x-ray fluoroscopically guided procedures (discussed in detail in Section 7). There are many equipment calibration and operational conduct choices under the physician operator's control that influence the radiation dose received by the patient and by the attendant healthcare personnel. It is important that physician operators understand the variables affecting patient and personnel radiation exposure and that they apply this understanding to minimize exposure to patients and to attendant personnel. This requires initial education for trainees and, for experienced operators, periodic refresher training and orientation to new equipment features and controls.

#### 8.2.2. Operator Training/Education Recommendations and Requirements

There are no regulatory requirements for specific training of physician operators of x-ray fluoroscopic units.

In 2000, the European Commission published recommendations that interventional cardiology specialists achieve a high level of knowledge regarding the general principles of radiation protection, operational radiation protection, and radiation protection of patients and staff. Achieving a medium level of knowledge is recommended for:

1. Radiological quantities and units.
2. Physical characteristics of the x-ray or therapy machines.
3. Fundamentals of radiobiology and biological effects of radiation.
4. Quality control and quality assurance.
5. Regulations and standards for ionizing radiation.

The European Commission suggests 20 hours of instruction to achieve this knowledge base (115).

In 2004, the ACC, in conjunction with the American Heart Association, Heart Rhythm Society, and Society for Cardiovascular Angiography and Interventions, crafted a clinical competence statement on physician knowledge to optimize patient safety and image quality in fluoroscopically guided invasive cardiovascular procedures (75).

The ACC, in its 2008 COCATS training statement, outlined a detailed blueprint for the knowledge base to be held by practicing interventional cardiologists. This included understanding x-ray imaging, including the design and operation of fluoroscopy and fluorographic units, digital imaging and storage, radiation physics, factors that influence image quality, radiation quality assurance, and the physiology using x-ray contrast media (116). This statement was updated in 2015. This comprehensive work outlined a detailed curriculum that conforms to The Joint Commission standards. Specific recommendations for the appropriate clock hours for training were not made, but a range between 2 and 20 hours of instruction time has been recommended by other experts in the field. The most recent ACC training statement on training in cardiac catheterization states that trainees should understand the principles of radiation safety (111).

The American Board of Internal Medicine includes the basic principles of x-ray imaging, radiation protection, and radiation safety in its interventional cardiology examination blueprint (117). The Society for Cardiovascular Angiography and Interventions published recommendations for establishing a radiation safety program for the cardiac catheterization laboratory in 2011 (74). The NCRP has recommended initial training for fluoroscopic credentialing and refresher training for recredentialing (39).

### 8.3. X-Ray CT

#### 8.3.1. Physician Responsibilities

Cardiovascular CT, and in particular coronary CT angiography, is a complicated procedure that is demanding to do well. Many protocol decisions are required to optimize dose and image quality. Currently available radiological equipment can employ many different image acquisition protocols, which can have major impacts on both image quality and patient dose (discussed in depth in Section 7.3). There is good evidence that special dose-reduction

training results in sustained lower median doses, and this is especially true in lower-volume centers (118). Consequently, physicians who conduct cardiovascular CT examinations are responsible to hold the requisite knowledge base to employ optimal image acquisition and to be able to make informed equipment selection choices. Physicians who supervise x-ray CT facilities are, in addition, responsible to understand equipment capabilities to make optimal choices in equipment selection.

#### 8.3.2. Society-Developed Operator Training/Education Requirements

The SCCT and the ACR have published guidelines on radiation dose and dose optimization strategies in cardiovascular CT (33,119).

Standardized training has been endorsed in the United States (110,120,121) with appropriate emphasis on radiation dose, radiation exposure factors, hazards of radiation exposure to both patients and CT personnel, and technical aspects of scan acquisition. The ACR has published certification criteria for radiologists who perform cardiovascular CT (114).

Many of the practices that impact radiation safety in cardiovascular x-ray CT are related to scanner quality and imaging protocol selection, which are determined principally by the facility clinical leadership. The cognitive and technical skills necessary for the competent performance of cardiovascular CT are addressed in an American College of Cardiology Foundation/American Heart Association clinical competence statement, endorsed by multiple professional societies dedicated to cardiac imaging, in 2005 (120) and updated in 2015 (110). This statement follows the standard 3 clinical competence-level model, with the 3 levels requiring different training durations and minimum numbers of mentored examinations performed or interpreted. Level 3 training is required to qualify individuals to serve as a director of a cardiac CT facility, and requires 6 months of training at a minimum of 35 h/week. "Knowledge of the physics of CT and radiation generation and exposure" is among the cognitive skills listed as required for competence in cardiovascular CT, but the amount of time or specifics of instruction in radiation biology, dosimetry, and safety are not specified.

Certification and recertification in cardiovascular CT can be achieved in various ways. The SCCT endorses the cardiovascular CT experience as required by the American College of Cardiology Foundation/American Heart Association clinical competence statement (122). The SCCT also offers designation as fellow to members who show "evidence of ongoing interest and contribution in cardiovascular diseases through cardiovascular CT" following completion of training.

The Certification Board of Cardiovascular Computed Tomography, part of the Alliance for Physician Certification and Advancement, administers a certification examination to document "mastery of a defined body of knowledge" (123). Certification is for a period of 10 years. Criteria for recertification have been published online (124).

### 8.4. Nuclear Cardiology Techniques

#### 8.4.1. Physician Responsibilities

Nuclear cardiology equipment used for cardiovascular imaging has a range of capabilities and complexity spanning from relatively simple single-headed gamma cameras for planar imaging to cardiac-specific solid-state detector multipinhole collimated devices and to highly sensitive time-of-flight capable PET devices with and without hybrid CT scanners. The practitioner must be familiar with the specific capabilities of the system being used as well as its calibration and quality control requirements (see Section 9.4.2). The facility director should oversee equipment selection, maintenance and calibration, and imaging protocol policies so that the facility will generate consistently high-quality images while minimizing patient dose. The physician director must also be familiar with the workings of the instrumentation being used to be able to recognize and identify signs of equipment malfunction. The physician director must be an authorized user, is responsible to oversee all aspects of the radiopharmaceutical use, and is responsible for the conduct of the technologists who are administering radiopharmaceuticals to patients and acquiring images.

#### 8.4.2. Summary of Current Regulatory Requirements

Nuclear cardiology is subject to considerably greater governmental regulation than the other radiation-based imaging modalities. There are multiple regulatory requirements that govern nuclear imaging procedures.

##### 8.4.2.1. Authorization to Prescribe Radiopharmaceuticals

Radiopharmaceuticals are under the purview of the FDA and, under Federal law, can only be administered to patients by a prescription of a physician who has satisfied federal (NRC) criteria for status as an Authorized User (AU). AU status is obtained by meeting the legal criteria of the NRC as legally outlined in 10.CFR.35.200 (125) and 10.CFR.35.290 (126) for "Imaging and Localization." Board certification by the American Board of Nuclear Medicine, American Board of Radiology in Diagnostic Radiology and/or Nuclear Radiology, or the Board of Nuclear Cardiology are pathways to AU status, because these certification examinations meet 10.CFR.35 criteria.

The education and training requirements to be an AU are issued by the NRC and specify didactic and practical training requirements. Education and training include 80 hours of classroom instruction and 700 hours of clinical experience. Although passing a certifying examination

developed by 1 of the previously mentioned organizations provides evidence of AU eligibility, status can also be approved on the basis of attestation of training by an AU.

NRC AU status is specific to particular categories of radiopharmaceutical use, such as dilution studies, imaging and localization studies, and various therapeutic uses. In general, those authorized on the basis of CBNC certification will be authorized only for imaging and localization studies.

The NRC rules are based on federal laws but many states have become "agreement states" wherein a significant portion of the oversight is transferred to the state (or local) regulatory agencies. These states or municipalities must adhere to the minimum regulations set forth by the NRC, but can impose stricter limitations in some aspects (some areas, like training requirements, cannot be modified). Therefore, the AU must understand the specific constraints imposed by the local regulatory agencies and not assume that federal guidelines are the only ones that must be followed.

#### 8.4.3. Operator Training/Education Requirements

As discussed in the previous section, much of the training required for handling radiopharmaceuticals and for conducting and interpreting nuclear cardiac imaging is specified by the NRC guidelines for AU status and is also addressed in the ACC COCATS-4 training statement (109).

For hybrid imaging techniques, the reader should have some knowledge and understanding of x-ray CT cardiovascular imaging. Although the CT images acquired with the minimum radiation dose are not of full diagnostic quality and are intended principally for attenuation correction and anatomic localization, there is the potential that important and recognizable anatomic data may be evident on the CT component. Thus, while the CT images should be reviewed with a primary focus on registration, there is also a responsibility to examine them for potentially important incidental findings that would warrant clinical follow up (e.g., pulmonary parenchymal nodules). These interpretations should be made with the caveat that the CT images are not of full diagnostic quality.

## 9. QUALITY ASSURANCE

### 9.1. Introduction and General Principles

A robust quality assurance process is central to the safe and efficient operation of any clinical service and is particularly important when the service's activities expose the patient and personnel to potential risk, as is the case with procedures that utilize ionizing radiation. Because radiation is undetectable by human senses, there is potential to undervalue its importance as a hazard and for inadvertent or unrecognized excessive exposure either to patients or to personnel. Consequently, quality assurance procedures must be in place to verify that patient and personnel exposures are minimized. Quality assurance, guided by the ALARA principle, involves both examining current practices and monitoring exposures of patients and personnel.

Quality assurance has 2 principal goals:

1. To survey a facility's current operations with respect to the exposures being delivered to patients and personnel and to compare them to benchmark values (where available).
2. To identify improvement opportunities to decrease exposures.

Action to limit patient ionizing radiation exposure was proposed in a 2010 FDA white paper (127). In this publication, FDA recommended 3 actions to optimize the safe use of radiation-based medical imaging:

1. Establish requirements for manufacturers of CT and fluoroscopic devices to incorporate additional safeguards into equipment design, labeling, and user training.
2. Partner with the Centers for Medicare and Medicaid Services to incorporate key quality assurance practices into accreditation and participation criteria for imaging facilities and hospitals.
3. Collaboration between the healthcare professional community and FDA to develop diagnostic reference levels for CT, fluoroscopy, and nuclear cardiology procedures locally and also through a national radiation dose registry.

The ACR has implemented a dose index registry that permits participating sites to compare their dose indexes to regional and national values (128). This registry currently is principally oriented toward diagnostic reference dose levels for x-ray CT abdominal and head examinations with little emphasis on x-ray CT of the chest and x-ray fluoroscopy.

Successful quality assurance involves monitoring and tabulating radiation exposure to patients and clinical staff. These data should be monitored over time for trends as well as to identify individual outlier cases. Clinical staff and operators should receive feedback characterizing their individual performances and exposure. There should be ongoing efforts to continue to reduce patient and personnel exposure as new developments or practices emerge.

Modifiable determinants of radiation exposure that form the basis of radiation safety quality assurance include:

1. Equipment quality and calibration.
2. Imaging protocol selection.

3. Equipment operator and personnel conduct.
4. Identification and follow-up of high exposure procedures.

The interactions of each of these variables in the aggregate determine the magnitude of exposure to both patients and personnel. Success of a quality assurance program, and consequently minimizing exposure, requires support and collaboration at the level of the institution, the facility administrative leadership, and the facility clinical personnel.

### 9.2. X-Ray Fluoroscopy

#### 9.2.1. X-Ray Fluoroscopy Regulatory Issues and Societal Policy Statements

Currently, dose calibration for x-ray fluoroscopic units is largely at the discretion of the equipment manufacturer. Statutory regulation of permissible dose ranges is sparse. The FDA governs the maximum permissible fluoroscopic dose at the interventional reference point at 88 mGy/min in standard fluoroscopy mode and permits a high-dose fluoroscopy mode of 176 mGy/min for limited use under special circumstances (129).

The ACC has previously published recommendations for quality assurance in cardiac catheterization laboratories. These recommendations address radiation safety in x-ray fluoroscopy (130).

#### 9.2.2. X-Ray Fluoroscopic Radiological Equipment Quality and Calibration

Quality assurance in x-ray fluoroscopy begins with assuring that x-ray equipment is in good operating order and is calibrated to achieve optimal image quality at minimal dose. Interventional catheterization and electrophysiology laboratories should have regular evaluation by the institution's qualified medical physicist. Equipment survey should include an assessment of image quality and radiation dose. The steps required include:

1. Acceptance testing: measurement of the baseline equipment performance when initially installed (to confirm that the unit is performing to baseline specifications).
2. Longitudinal surveillance testing: performance measurement should be conducted periodically to identify possible deterioration in equipment performance, and to verify correction of deterioration. If performance deteriorates, the equipment manufacturer should recalibrate the unit or renovate it if necessary.

Typical x-ray system calibrations are expressed as the dose reaching the detector in nGyper pulse. Current x-ray fluoroscopic systems display this dose value in the metadata accompanying recorded images. For current state-of-the-art equipment, the following are representative factory default image detector dose settings with the detector in a 22-cm zoom mode (typical zoom for coronary angiography):

- Low-dose fluoroscopy: 20 nGy/pulse
- Standard-dose fluoroscopy: 40 nGy/pulse
- Cine acquisition: 200 nGy/pulse

These should be considered benchmark values. X-ray fluoroscopic units that deliver doses substantially greater than these values should be recalibrated or renovated to achieve similar doses or, if not remediable, retired.

#### 9.2.3. X-Ray Fluoroscopic Imaging Protocol Selection Practices

A laboratory should develop a culture of selecting the imaging protocol that provides satisfactory image quality permitting accomplishment of the task at hand while employing minimum dose. Operators should be acculturated to use low-dose fluoroscopy and slow pulse rates when applicable, such as for general catheter placement, while reserving standard dose fluoroscopy and faster pulse rates for tasks that require greater spatial and temporal resolution. X-ray system default parameters should be set to low-dose protocols so that a conscious act is required to select a higher-dose protocol. Pyne et al. (131) evaluated the clinical and radiation dose impact of reducing fluoroscopy and cine framing rates from the commonly used 15 to 10 pulses/s. This demonstrated the expected 38% reduction in dose per procedure, and they found that operators rapidly adapted to the slower framing rates. Thus, they achieved a 38% dose reduction without compromising clinical efficacy (131).

#### 9.2.4. X-Ray Fluoroscopic Operator and Personnel Conduct

Physician operators are responsible to operate x-ray fluoroscopic equipment in a manner that optimizes the safety of patients, laboratory occupationally exposed personnel, and themselves. This requires a radiation safety awareness culture on the part of both the physician operators and the laboratory personnel. Physician operators should be acculturated to minimize beam on time, optimize system positioning, use collimators to minimize image field size, and use protective shielding. In particular, physician operators should be cognizant of protecting the laboratory personnel. This includes maximizing laboratory personnel distance from the radiation source, interrupting fluoroscopy when laboratory personnel need to approach a patient, providing portable shielding within the laboratory for circulating personnel, and providing an out of laboratory control room for the personnel who are monitoring but not directly attending to the patient.

Similarly, laboratory personnel need to be cognizant of the factors that affect their personal radiation exposure to optimize their personal protection. As the catheterization

laboratory's physician personnel and case mix expand to encompass new medical disciplines and procedures, it is essential that all operating physicians—cardiologists and cardiac and vascular surgeons—hold requisite radiation protection knowledge and adhere to appropriate radiation safety procedures and protocols. It is noteworthy that radial access for cardiovascular procedures has the potential to increase operator exposure unless the operator is careful to maximize his/her distance from the radiation source (132).

Initial training in radiation safety with annual updates should be the norm for all personnel who work in an x-ray fluoroscopic environment.

#### 9.2.5. X-Ray Fluoroscopic Patient Radiation Exposure Monitoring

There are 2 types of readily available patient exposure metrics that are calculated by the x-ray unit:

- Procedure fluoroscopy and cine acquisition time
- Patient exposure metrics: total air kerma at the interventional reference point and total procedure KAP

Patient dose and imaging time monitoring should be conducted with 2 purposes:

1. To identify trends for excessive dose and imaging times in group data from overall facility experience. This will enable identification of physician operators who employ excessive fluoroscopic and cine times.
2. To identify individual outlier procedures that receive excessive exposures. This will enable recognition and prompt treatment of patients who are at risk of radiation skin injury.

Appropriate quality assurance surveillance should include both of these parameters. In particular, patient interventional reference point doses that exceed the threshold for potential skin injury (5 Gy) should be reviewed and the affected patients should be counseled to be aware of the skin injury potential. A follow-up protocol should be in place for these patients. The Joint Commission has identified a skin entrance dose >15 Gy as a reviewable sentinel event (133).

#### 9.2.6. Effectiveness of Programs to Minimize Patient Radiation Exposure in X-Ray Fluoroscopy

Approaches to minimizing patient radiation exposure in the fluoroscopy suite include optimizing equipment performance and improving operator behavior. Changing operator behavior to reduce radiation dose can be accomplished with physician education and increasing operator awareness of radiation dosing (134).

A comprehensive program for radiation dose reduction was undertaken at the interventional cardiology laboratories of the Mayo Clinic, Rochester, Minnesota, in 2008. Along with technical optimization of the equipment and fellow education, radiation exposure was announced during the case in air-kerma increments of 3,000 mGy. Procedures exceeding 6,000 mGy were referred to the radiation safety committee, and immediate physician feedback was provided. Over the course of 3 years, a 40% reduction in radiation dose was achieved (76).

The Mayo Clinic experience also provides benchmark data for fluoroscopy time and patient dose at the interventional reference point. They report a median fluoroscopy time for left heart catheterization and coronary arteriography of 5.8 minutes and for percutaneous coronary intervention of 15.7 minutes. The corresponding skin doses for coronary arteriography were median 467 mGy with a 75th percentile of 936 mGy. For percutaneous coronary intervention, the median skin dose was 952 mGy with a 75th percentile of 1,491 mGy. These values reflect a combination of operator proficiency and x-ray equipment quality and calibration.

### 9.3. X-Ray CT

#### 9.3.1. X-Ray CT Regulatory Issues and Societal Position Statements

##### 9.3.1.1. Governmental Regulation

The FDA regulates CT imaging systems under 2 statutes (135):

1. As radiation-emitting electronic products under the Radiation Control for Health and Safety Act
2. As medical devices under the Medical Device Amendments to the Food, Drug, and Cosmetic Act.

The regulations implemented under these laws place controls or requirements on the manufacturers of CT scanners rather than on the users. Under the Radiation Control for Health and Safety Act, the FDA administers an equipment performance standard for diagnostic x-ray systems (136). This standard:

1. Establishes minimum radiation safety requirements for CT scanners.
2. Requires that manufacturers produce CT scanners that comply with the radiation safety requirements of the performance standard.
3. Requires manufacturers to certify that their products meet the standard.

As part of this certification, manufacturers set forth in their quality assurance manuals lists of standard tests to be performed, and specify the phantoms to use for the testing.

##### 9.3.1.2. Societal Standards

The ACR, American Association of Physicists in Medicine, NCRP, International Electrotechnical Commission, and

the International Commission on Radiation Units and Measurement are prominent among the organizations that are involved in setting x-ray equipment standards, and provide guidance on how to comply with the regulations set forth by law, including the implementation of quality assurance and quality control programs.

The pertinent ACR/American Association of Physicists in Medicine technical standards require that all CT equipment undergo performance evaluation upon installation, and be monitored by a qualified medical physicist to ensure that it is functioning properly at least annually, or more often if required by state or local regulatory agencies. A qualified medical physicist is competent to practice independently in 1 or more subfields in medical physics, as evidenced by certification (e.g., from the American Board of Radiology, the Canadian College of Physics in Medicine, or the American Board of Medical Physics), continuing education, and experience. The qualified medical physicist must be familiar with:

1. Principles of imaging physics and of radiation protection.
2. The guidelines of the NCRP.
3. Laws and regulations pertaining to the performance of CT scanners.
4. The function, clinical uses, and performance specifications of the CT scanner.
5. Calibration processes and limitations of the instruments used for testing performance (137).

#### 9.3.2. X-Ray CT Equipment Quality and Calibration

Equipment calibration and preventive maintenance as part of quality assurance and control programs play an important role in reducing radiation dose by facilitating dose optimization. Regularly scheduled performance monitoring is important to verify that x-ray CT systems produce optimal-quality diagnostic images at a radiation dose appropriate for an examination's imaging purpose (83,137). Periodic surveys of equipment performance are important, as x-ray CT units can drift out of calibration without readily noticeable changes in imaging performance. Performance evaluation and quality control may reveal deviations in either radiation output or imaging performance (or both) (83).

Components of regular (at least annual) performance monitoring as part of a quality assurance program include the following radiation output characteristics immediately pertinent to radiation dose:

1. Radiation beam width (collimation).
2. Reconstructed image thickness.
3. Measurement of radiation output ($CTDI_{vol}$ or the equivalent) for representative examinations.
4. Estimates of patient radiation dose for representative examinations.

Measured scanner output and patient dose should be compared with the values reported by the scanner console and with the appropriate guidelines, recommendations, or reference levels (if available) (137).

Each facility, in accordance with national and state regulatory agencies, can decide to conduct additional, more frequently performed routine testing of additional imaging performance characteristics. A continuous quality assurance program should evaluate at least:

1. CT number accuracy (average and standard deviation of water).
2. Image noise and field uniformity.
3. Image artifacts.
4. The acquisition workstation (98).

Quality assurance testing may make use of a phantom such as that developed by the ACR (138), which is designed to measure CT number accuracy, slice thickness, low contrast resolution, CT number uniformity, and high contrast resolution.

If performance evaluation or quality assurance show that the measured values for any of these parameters fall outside the established tolerances, appropriate investigative or corrective actions should be undertaken. Such actions may include a service request by a field engineer, typically from the scanner manufacturer. The medical physicist should evaluate in a timely fashion the need for repeat performance testing after a major component of a CT scanner has been repaired or replaced (137).

#### 9.3.3. X-Ray CT Imaging Protocol Selection

Adoption of and adherence to standardized imaging protocols for standard imaging circumstances is important for consistency, particularly with CTA imaging. Guidance for imaging protocols has been proposed by expert consensus to derive the maximum diagnostic yield with the minimum radiation exposure (83). Although the specific imaging protocol should be tailored to the individual patient and the goals of the imaging study, patient exposure can be minimized by employing best practices and adhering to standardized protocols whenever possible. A research collaborative of 15 hospital imaging centers in Michigan undertook an initiative to reduce the radiation dose in cardiac CTA scanning. A best-practice model with physician and technologist education was employed to promote consistent application of dosage reduction techniques. As a result of this initiative, patients' median radiation dose decreased by 53% without change in image quality. It was concluded that to achieve and then maintain this positive change, ongoing radiation dose monitoring and review would be needed (118).

#### 9.3.4. X-Ray CT Patient Radiation Exposure Monitoring

Currently, at a national level, it is not routine practice to monitor and tabulate the radiation dose received during individual CT scans. However, trends are emerging at the level of individual states toward more rigorous assessment. Since 2012, California requires that either $CTDI_{vol}$ or DLP as displayed on the scanner console be included in every radiology report. Beginning in 2016, the Joint Commission's new diagnostic imaging standards also required documentation of CT dose in a retrievable format for every patient examination (139).

### 9.4. Nuclear Cardiology

#### 9.4.1. Nuclear Cardiology Regulatory Issues

##### 9.4.1.1. Governmental Regulation

Nuclear imaging facilities, because they handle radioactive material, are subject to statutory regulation by a variety of governmental bodies. These include the Nuclear Regulatory Commission, the FDA, the Department of Transportation, and the Department of Homeland Security. Additional regulation also is provided by state and municipal departments of health.

These regulations, which are extensive, govern the handling, storage, and administration of radioactive materials. Additionally, regulations govern the design of facilities to ensure appropriate radioactive material storage and handling as well as shielding appropriate for the radionuclides to be used in a facility. Regulations also govern radiation surveillance procedures including requirements for radiation detecting and measuring equipment.

##### 9.4.1.2. Societal and Industrial Standards and Guidelines

The National Electrical Manufacturer's Association provides guidance on acceptance testing including defined metrics of equipment performance both for SPECT and PET systems. The American Association of Physicists in Medicine adds additional recommended SPECT and PET acceptance testing procedures.

Laboratory accreditation agencies, such as the ACR and the Intersocietal Accreditation Commission, also provide guidance documents that detail the required specific tests for specific instrumentation and procedures and the records that must be kept and available for inspection. In additional, The Joint Commission may require review of any documents relating to patient care, including gamma camera and PET quality assurance records (140–145).

#### 9.4.2. Nuclear Scintigraphy Equipment Quality and Calibration

SPECT and PET scanners can drift out of calibration without clearly evident changes in clinical images. Thus, it is essential that these instruments' performance be surveyed regularly. Comprehensive quality assurance programs cover many different aspects of nuclear imaging. Specific measurements are recommended on a daily, weekly, and quarterly basis. In most facilities, calibration and quality control is conducted with assistance of a medical physicist and/or vendor service. Some accreditation criteria, for example ACR accreditation, require oversight by a certified medical physicist.

Although older systems required significant user involvement for quality control and calibration, most modern PET/CT systems and an increasing fraction of current SPECT and SPECT/CT systems have built-in automated daily quality control procedures. With these systems, all that is required of the user is to place a sealed source phantom in the appropriate location and launch the process (some systems even include a quality control source that automatically moves into the field of view). The acquisition and data analysis is automatic and yields either a passing or failing result. These processes have become so simplified that there is no valid excuse for not performing quality control and calibration checks as prescribed by the manufacturer.

Although uniformity is important for planar imaging, it is particularly important for SPECT as any nonuniformities will be propagated and magnified by SPECT image reconstruction algorithms. SPECT quality control must also include verification of the center of rotation.

##### 9.4.2.1. Conventional Gamma Cameras

Gamma cameras, including those used to acquire SPECT data should have daily performance assessments. This includes "peaking" detectors to verify accuracy of the photon energy window and obtaining uniform flood fields to verify uniform responsiveness over the imaging field. Ideally, a scanner should be re-peaked just prior to each data acquisition. Weekly tests include center of rotation, bar phantom imaging to verify spatial resolution, and high count flood acquisition. Quarterly quality assurance tests include evaluation of tomograms acquired and reconstructed using standardized multipurpose phantoms of Plexiglass and radioactive water, which typically include spheres and rod sections of various sizes, from which image contrast, spatial resolution, and field uniformity are quantified. Reconstruction of a point source is used quarterly to verify consistency of tomographic spatial resolution. For SPECT cameras that use translating radioactive rod sources for attenuation correction, daily low-count floods and weekly high-count floods are required.

##### 9.4.2.2. PET Systems

Daily quality control involves testing all of the detector modules by acquiring a blank scan or phantom scan. Sensitivity should be quantified weekly by cross

referencing to dose calibrator readings, and at least annual testing should be performed of accuracy, scatter fraction, and attenuation correction accuracy. Quarterly measurements typically are performed of standardized multipurpose phantoms of Plexiglass and radioactive water, which typically include refillable cylinder inserts and rod sections of various sizes, from which standard uptake value, spatial resolution, and field uniformity are quantified.

#### 9.4.2.3. CT Component of SPECT/CT and PET/CT Units

Additional considerations must be given to equipment quality assurance and radiation issues related to the CT component of SPECT/CT and PET/CT imaging. For the CT component, daily tube warm-up and air calibration checks are recommended, and weekly or monthly water phantom checks of slice thickness, accuracy, and positioning. Appropriate registration between SPECT and CT or PET and CT transaxial images are verified along with attenuation correction accuracy at least quarterly, if not more frequently.

At a minimum, a daily uniformity flood must be acquired to verify that count acquisition is uniform. Spatial resolution should be assessed weekly by imaging a bar phantom. It is particularly critical that the planned maintenance includes photopeak calibration for all isotopes employed by the facility.

### 9.4.3. Nuclear Scintigraphy Attenuation Correction Equipment Quality and Calibration

Attenuation correction greatly improves diagnostic accuracy and is an extremely valuable adjunct to conventional SPECT and PET imaging. It provides the potential to remove attenuation-related artifacts and/or permit quantification. However, attenuation correction adds a transmission scan imaging procedure to the nuclear acquisition with the potential to add importantly to the total patient radiation dose. Different transmission scanning protocols involve different incremental exposures. It is important to select the protocol that causes the smallest patient exposure.

### 9.4.4. Nuclear Cardiology Patient Radiation Exposure Monitoring

As discussed in the previous text, the patient dose from nuclear studies derives from the radiopharmaceutical dose combined with the dose from any coacquired transmission scan. For studies that include a rod source transmission scan, this is generally negligible. For studies including a CT, the CT dose ideally should be monitored in the same manner as doses for standalone diagnostic CT studies (albeit with different targets). For the radiopharmaceutical dose, individual patient monitoring and measurements are not performed. In lieu of this, each department should review, at least on an annual basis, their procedure manual and prescribed radiopharmaceutical doses. The review should include a comparison with published practice guidelines to ensure that the doses used are as low as reasonable to ensure diagnostic image quality and in line with those recommended by consensus statements/published guidelines. However, it is important to note that different instrumentation may have substantially different sensitivity and other parameters, and so one cannot simply choose the lowest dose suggested in guidelines as this may be insufficient for diagnostic image quality on some systems.

### 9.4.5. Nuclear Cardiology Clinical Personnel Exposure Protection and Monitoring

Because staff in nuclear cardiology are routinely in close proximity to radioactive materials, as well as to patients who have been administered radiopharmaceuticals, it is critical that all staff members be monitored with personal dosimeter badges. These must be worn in a reproducible fashion and stored in a location with typical background radiation. Most staff members require a whole-body dosimeter badge. Additionally, staff who handle dose syringes should also wear a ring dosimeter to enable separate calculation of whole body and extremity dose.

The frequency of badge exchange may be tailored to expected exposure, with those with very low expected exposure needing perhaps quarterly badges. For most staff in nuclear cardiology, monthly monitoring is appropriate. Dosimeter results should be available to all staff and should be reviewed by the radiation safety officer. It is good practice to set trigger levels (e.g., 10% of the annual dose limit, discussed in Section 5), and any staff members who exceed the trigger level in a given month or quarter should have their practice patterns reviewed to ensure that their doses adhere to the ALARA principle. Of note, because many nuclear cardiac imaging centers are multidisciplinary facilities with technologists, nurses, physicians, and so on, staff-monitoring protocols should be based on actual work duties and likelihood of radiation exposure rather than making assumptions based on a given staff member's training or job title. Monitoring should err on the side of over monitoring rather than under monitoring.

Occupational radiation exposure to radiopharmaceuticals is different from exposure to x-ray beams in that external shielding is less protective. Since the potential for uterine exposure is more prominent in nuclear cardiology, there are specific procedures and lowered exposure limits for pregnant staff members. Of note, these do not apply unless a staff member has declared in writing that she is pregnant. Upon declaration of pregnancy, additional monitoring is appropriate with a separate fetal badge that may need expedited processing and potentially more frequent exchange. The facility radiation

safety officer is responsible for determining the maximum permissible fetal dose for the pregnant staff member and for ensuring that she is properly monitored, with reporting occurring in a time frame that accurately assesses her fetal and overall exposure, thus ensuring that accumulated exposure is within guideline limits.

## 10. PATIENT AND MEDICAL PERSONNEL RADIATION DOSE MONITORING AND TRACKING: PROGRAMMATIC AND INDIVIDUAL CONSIDERATIONS

Currently, technology exists to measure and track cumulative radiation dose for both patients and occupationally exposed healthcare workers. The importance of tracking the accumulated radiation dose of occupationally exposed healthcare workers is indisputable as it is important for their protection and can indicate a need for corrective action when necessary. However, compared with occupational dose tracking, patient medical exposure dose tracking is more complex and nuanced. This is in part because of uncertainty surrounding the actual health impact of current medical radiation practices (146,147).

Now that current imaging equipment and electronic medical records make patient dose monitoring and tabulation feasible, the question has been raised as to whether tracking cumulative individual patient medical radiation exposure is a worthwhile undertaking that has practical clinical value. Patient-level tracking technologies have been proposed such as an electronic "smart card" that would be updated following each medical exposure (148). The FDA together with the ACR and other societies developed the "Image Gently" educational and social marketing program, which was followed by the "Image Wisely" campaign. This program offers a medical imaging history card that patients can use to track an estimate of their personal accumulated radiation exposure (149,150). The FDA has posted a white paper on its website titled "White Paper: Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging," in which the agency advocates for a national radiation exposure tracking system (127).

### 10.1. Requirements for Dose Monitoring and Tracking

For cumulative radiation dose data acquisition to be meaningful, it must be compiled rigorously and completely. To track a patient's radiation dose, it is critical that all exposures be monitored, reported, and recorded in a standardized manner. To do so, it would be necessary to:

1. Record radiation exposure from all medical tests and procedures involving radiation. This requires that radiation exposure metrics be included in all test and procedure reports in a standardized manner using discrete, uniform parameters that allow for the calculation of cumulative radiation exposure.
2. Compile standardized exposure data from all radiation-based modality procedures automatically in management systems and electronic medical records/electronic health records.
3. For occupationally exposed workers, compile occupational exposure data to include medical exposure data.

### 10.2. Program-Level Dose Monitoring and Tracking

Program-level patient dose tracking provides potentially valuable quality assessment data. It has value in monitoring both:

1. A program's overall radiation-based cardiovascular procedures utilization rates.
2. The range of administered per-procedure radiation doses for comparison to national norms and identification of outliers.

Consequently, for quality assessment and improvement purposes, a program should track, compile, and analyze its radiation exposure data.

### 10.3. Patient-Level Dose Monitoring and Tracking

Currently, a medical procedure's radiation exposure data are not systematically recorded. Consequently, data are not uniformly stored in electronic health records in a format that permits searching exposure values and tabulating accumulated exposures. In addition, patients frequently access care in multiple health systems. Consequently, at this time there is no infrastructure to enable compiling comprehensive patient-based radiation dose data that would permit rigorous assessment of total accumulated medical radiation exposure.

There is uncertainty about the value to a medically exposed patient of tracking his/her cumulative exposure (7). For cumulative exposure tracking to provide clinical management value, the patient's radiation exposure history and accumulated dose must be relevant to the decision to conduct a future radiation-based examination or procedure. Since a patient's tissue reaction risk is linked to prior, and, particularly, recent exposures, exposure history has a clear relevance for tissue reaction risk and might potentially influence the choice to conduct a subsequent procedure.

On the other hand, although compiling an estimate of total accumulated exposure provides a potential estimate of a patient's future stochastic risk, the linear-no threshold concept indicates that the *incremental* (above baseline) cancer risk that would be conferred by an individual radiation-based procedure would be independent of the patient's prior accumulated exposure. Thus, based on this concept, prior exposure history should not be a factor in

determining a proposed procedure's appropriateness. The decision to conduct the procedure should be based on overall appropriate use guidelines for the procedure in the context of the patient's current health circumstance.

There are complex considerations regarding the added value of a patient having knowledge of his/her accumulated medical radiation dose. Although one's accumulated radiation dose is an important element of health information to which any person is entitled, it is challenging to interpret such information. Interpretation of a given patient's accumulated radiation dose requires advanced understanding of the radiation safety knowledge base and must be interpreted in the context of the patient's age, overall state of health, and appropriateness of proposed medical procedures. Thus, physicians need to be sufficiently informed about radiation safety to be able to interpret a patient's own clinical circumstance, assist a patient in understanding the significance and context of his/her accumulated radiation dose, and make thoughtful evidence-based recommendations concerning the appropriateness of additional radiation-based procedures.

Overall, based on the current radiation safety knowledge base, the importance for quality assessment of facilities and institutions tracking and monitoring procedure and patients' total radiation exposure is clear. On the other hand, a program of rigorously tracking a patient's lifetime cumulative radiation exposure appears to provide little clinically important value for that patient's future clinical management.

## 11. SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

### 11.1. The Issue

During the past 2 decades, there has been an explosive growth in the capabilities of both diagnostic examinations and therapeutic procedures that employ ionizing radiation. This growth has been fueled by a combination of improved imaging capability resulting from refined radiological equipment engineering and of extended procedure capability and complexity. As a result, there has been both an increase in procedure utilization rates and an escalation of their complexity. These developments have increased medical radiation exposure both at the population and the individual level, creating the potential for greater radiation-induced harm both due to individual patient tissue reaction radiation injury risk and, potentially, to increased population-level cancer risk. Both patients and occupationally exposed healthcare workers are potentially at an increased cancer risk.

Radiation-related hazard presents an additional variable to weigh when considering whether to undertake a given procedure, when making choices among alternative procedure modalities, and when weighing procedure conduct decisions. The healthcare profession is responsible to be aware of this issue and to work to optimize the risk-benefit balance both for the individual and at the population level.

#### 11.1.1. Patient Participation in Clinical Imaging Decisions

Patients should participate with their physicians in the decision to undertake any medical procedure that involves risk, and radiation risk is no exception. Patients should understand the radiation component of a procedure's overall risk and interpret it in the context of the procedure's overall risk-benefit relationship. Thus, physicians are responsible to explain the radiation component of a procedure as well as the other aspects of a medical procedure. These explanations, which should be comprehensive and rigorous, can be challenging to conduct given that many patients have limited understanding of radiation metrics and effects (7). Current understanding is that the incremental stochastic risk associated with a particular procedure is almost always an extremely small component of the procedure's total risk and can generally be discounted.

### 11.2. Clinical Value of Radiation-Based Imaging Studies and Radiation-Guided Therapeutic Procedures

A procedure's risk-benefit relationship determines its overall clinical value (and, consequently, its appropriateness). The risk conferred by radiation exposure is a component of a procedure's overall risk complement. The established benefit to patient health outcomes of radiation-based cardiovascular diagnostic and therapeutic procedures is substantial. The radiation-associated hazard is generally very small in absolute terms and certainly in comparison to hazards from other components of a procedure. In appropriate circumstances, radiation-based cardiovascular procedures have substantial clinical value that justifies the attendant risk, including the small associated radiation-associated hazard. Nonetheless, the radiation component is real and should be assessed in considering a proposed procedure's appropriateness.

The risk of radiation-caused cancer is not uniform across the entire population. In addition to being linearly related to dose magnitude, patient characteristics—particularly age, gender, and comorbidities—modulate the risk associated with a particular radiation exposure. Because most radiation-induced cancer requires a minimum of 5 years to emerge (some as early as 2 years [12]), the potential for radiation-induced cancer is less relevant in patients with shorter life expectancies. The risk is the least important for elderly patients who have important comorbidities and most important for

children and young adults with a long life expectancy, particularly females, in addition to those with congenital heart disease who have an ongoing need for evaluation and risk an increased lifetime cumulative exposure.

### 11.3. Individual Patient Risk and Population Impact (Including Occupationally Exposed Workers)

Medical radiation cancer risk has 2 potential impacts: a categorical effect on the exposed individual, and an aggregate probabilistic effect on the exposed population.

Individual patient risk is linearly related to the total effective dose. The risk estimate that accompanies a particular total dose may be further refined by calculating the effective dose in mSv (taking into account the individual organ exposure magnitude) and also by considering patient characteristics including age, gender, and life expectancy.

The overall population risk is the potential for an increase in population cancer rates caused by the population's aggregate medical radiation exposure. This effect is difficult to detect because of cancer's large background frequency and the comparatively small magnitude of accumulated medical exposures. Nonetheless, now that the U.S. population's aggregate medical radiation exposure is greater than background, there is reason for concern that medical radiation may become a contributor to overall cancer incidence.

### 11.4. The ALARA Principle

The ALARA principle has long been the guiding principle governing medical radiation exposure. It is based on the linear-no threshold model of radiation cancer risk and states that medical radiation exposure should be employed judiciously and that healthcare professionals are responsible for minimizing radiation exposure both to patients and to healthcare personnel.

### 11.5. The Potential to Minimize Exposure to Patients and Personnel

Physicians have 2 options available to minimize patient medical radiation exposure:

1. Choice of procedure modality
2. Choice of procedure conduct

#### 11.5.1. Imaging Modality Choice

Procedure modality choice is based on the purpose and goals for the procedure. Often more than a single modality can be employed to address a clinical issue. If alternative modalities provide truly comparable diagnostic utility, a modality that does not employ radiation would be preferable to a radiation-based modality. For example, for some stress testing circumstances, both nuclear perfusion imaging and echocardiographic imaging can have equivalent utility. On the other hand, depending on patient characteristics affecting echocardiographic image quality, the ability of a patient to exercise, or on the clinical question to be addressed, nuclear perfusion imaging may be sufficiently superior to echocardiographic imaging to offset the small risk of attendant radiation exposure.

#### 11.5.2. Procedure Conduct Choice

Procedure conduct choices can also have a substantial impact on the attendant radiation dose. With current imaging technology, the best image achievable may actually be better than needed. In some circumstances employing a smaller radiation dose, although degrading image quality somewhat, can still yield images of sufficient quality for diagnosis. Examples include x-ray fluoroscopy at lower detector doses and/or slower framing rates, CT scanning at lower detector doses, and nuclear perfusion imaging employing smaller tracer doses.

#### 11.5.3. Protecting Occupationally Exposed Workers

It is important to be vigilant to minimize healthcare worker occupational exposure. Healthcare workers who work in radiation environments are typically young and therefore more susceptible. Someone working in a radiation environment for an extended period has the potential to accumulate a substantial exposure. Healthcare worker occupational exposure is greatest in an x-ray fluoroscopy environment. There is a synergistic incentive to minimize patient x-ray fluoroscopy exposure because the same practices that decrease patient exposure also decrease occupational exposure. X-ray fluoroscopic environments also have ample opportunity to control occupational exposure through standard protective practices.

### 11.6. Physician Responsibilities to Minimize Patient Exposure

All physicians, whether or not they work in a radiation environment, have a responsibility to minimize patient exposure. This responsibility falls into 3 domains: procedure selection, procedure conduct, and facility management.

#### 11.6.1. Case Selection

When selecting a diagnostic or therapeutic procedure, a physician is responsible to understand the procedure's complete risk-benefit relationship and, when there are alternative procedures to choose among, select the most appropriate procedure. Radiation exposure is an important consideration that must be weighed in this choice. It is important to consider the patient characteristics that

modulate that risk. In particular, the patient's risk factors, including patient age, comorbidities, and natural life expectancy, should be considered. For younger patients without comorbidities, radiation-based imaging is less preferred than for older patients with limited life expectancies. Physicians should employ the ACC appropriate use criteria as a point of departure in making these judgments. When feasible, particularly in younger patients, an alternative imaging procedure that does not use ionizing radiation may be preferable (e.g., cardiovascular magnetic resonance or echocardiography).

#### 11.6.2. Procedure Conduct

Physicians who perform radiation-based procedures are responsible for understanding the variables that determine patient dose and adjusting procedure conduct to achieve successful diagnosis or therapy while employing the minimal necessary dose. In x-ray fluoroscopy, this begins with attention to beam-on time, beam collimation, and system positioning to minimize dose to both the patient and to nearby clinical personnel. In addition, physicians should select the imaging protocol (detector dose, frame rate) that minimizes dose while providing diagnostic quality images. In x-ray CT, it is important to select the lowest dose imaging protocol that will yield diagnostic quality images. In addition, care should be taken to limit the examination to the body region of interest. Similarly, in radionuclide scintigraphy, which is one of the largest radiation exposure procedures in cardiovascular medicine, it is important to consider radiation dose and endeavor to minimize it when selecting a protocol. It is important to select the radionuclide species that delivers the least radiation exposure while best answering the clinical question(s) at hand, and to administer the smallest radiopharmaceutical activities likely to ensure diagnostic image quality. Stress-first imaging, which has the potential to deliver substantially less dose, is preferred for subjects who have a reasonable pre-test probability of a normal study and who are good imaging subjects (see Section 7). Rest-first imaging is appropriate for subjects who are more challenging to image and are likely to have abnormal studies. Thus, both physicians ordering and physicians conducting nuclear cardiology studies should individualize the protocol according to the patient's characteristics with a goal of minimizing patient dose without compromising diagnostic quality.

#### 11.6.3. Facility Management

Physicians who manage facilities that use ionizing radiation are responsible for ensuring that those facilities generate high-quality images at minimal radiation exposure to patients and personnel. These responsibilities include radiological equipment selection, calibration, and maintenance; establishing imaging protocols that optimally balance image quality and exposure; and fostering a culture of minimizing patient radiation exposure and maximizing personnel protection.

Radiological equipment should be capable of generating diagnostic quality images at minimal dose. A unit that is in good operating order but requires a greater than current state-of-the-art dose to generate quality images should be considered obsolete. Such a unit should be either renovated or replaced. The facility's managing director should collaborate with the radiological equipment company's service engineers and the institution's radiological physicist to verify that equipment is optimally calibrated. The equipment should provide user control of imaging dose parameters so that operators can select the imaging protocol that best balances image quality and dose.

The facility's physician director should monitor the facility's overall radiological performance by tabulating patient procedure doses and personnel doses to ascertain that these doses are within guideline levels. Individual large outlier exposures should be investigated and explained, and corrective action should be taken if indicated.

#### 11.6.4. Imaging Equipment Renovation and Replacement

The past decade has seen prodigious engineering efforts by equipment manufacturers to improve image quality while decreasing radiation dose. Current imaging units generate vastly better images with less radiation and incorporate features that permit operators to select lower-dose imaging techniques when appropriate. If an older imaging unit requires larger radiation doses than the current state of the art, it should be considered obsolete even if it is in good working order and should be either replaced or, if feasible, renovated to bring its performance up to current standards.

### 11.7. Patient Radiation Dose Tracking

Technology now exists that could be applied to create a comprehensive patient dose tracking system. There has been some advocacy to create such systems. However, current understanding of the biological basis of cancer induction by radiation does not support a clinical utility to the patient of longitudinal tracking. Based on the linear-no threshold concept, the incremental cancer risk associated with a particular medical exposure is independent of prior exposure magnitude. Knowing a patient's lifetime accumulated radiation exposure provides no additional information of clinical decision-making value with respect to the incremental stochastic risk that would be conferred by a contemplated radiation exposure (although knowledge of prior exposure can aid in predicting the tissue reaction risk). The radiation-based risk that should be weighed when deciding whether to

conduct a given procedure is the incremental risk that the procedure's exposure adds to the patient's background risk. Consequently, knowing the amount of prior exposure is not a factor in the decision to conduct a proposed procedure. Accordingly, tabulating a patient's aggregate radiation exposure adds little practical clinical value. The principal value of a radiation tracking program would be to provide data for future clinical research to more precisely define the dose-stochastic risk relationship for doses in the medical range.

### 11.8. Need for Quality Assurance and Training

Properly conducted quality assurance is essential for consistent facility operation, and for providing reliable high-quality imaging while minimizing radiation exposure.

Quality assurance requires verifying equipment performance and calibration and monitoring metrics of patient and personnel exposure. Proper training of all personnel is essential. Good training ensures that all clinical personnel have the requisite understanding of radiation physics, radiation biology, and radiation protection. In addition, training should create a culture of respect for radiation hazard and a commitment to minimize exposure and maximize protection.

## PRESIDENT AND STAFF LIST



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**KEY WORDS** ACC Expert Consensus Document, nuclear cardiology, positron emission tomography radiation, radiation risk, radiation safety, single-photon computed tomography, x-ray computed tomography, x-ray fluoroscopy

## APPENDIX A. AUTHOR RELATIONSHIPS WITH INDUSTRY AND OTHER ENTITIES (RELEVANT): 2018 ACC/HRS/NASCI/SCAI/SCCT EXPERT CONSENSUS DOCUMENT ON OPTIMAL USE OF IONIZING RADIATION IN CARDIOVASCULAR IMAGING–BEST PRACTICES FOR SAFETY AND EFFECTIVENESS

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*Continued on the next page*

## APPENDIX 1. CONTINUED

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*Significant relationship.

†No financial benefit.

CCOR = Colorado Cardiovascular Outcomes Research; VA = Veterans Affairs.

## APPENDIX B. PEER REVIEWER INFORMATION: 2018 ACC/HRS/NASCI/SCAI/SCCT EXPERT CONSENSUS DOCUMENT ON OPTIMAL USE OF IONIZING RADIATION IN CARDIOVASCULAR IMAGING: BEST PRACTICES FOR SAFETY AND EFFECTIVENESS

This table represents the individuals, organizations, and groups that peer reviewed this document. A list of corresponding comprehensive healthcare-related disclosures for each reviewer is available as an Online Appendix.

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ABIM = American Board of Internal Medicine; ACC = American College of Cardiology; ACPC = Adults With Congenital Heart Disease and Pediatric Cardiology; AHA = American Heart Association; ASNC = American Society of Nuclear Cardiology; HRS = Heart Rhythm Society; NASCI = North American Society for Cardiovascular Imaging; SCAI = Society for Cardiovascular Angiography and Interventions; SCCT = Society of Cardiovascular Computed Tomography; SNMMI = Society of Nuclear Medicine and Molecular Imagine; UT = University of Texas.

## APPENDIX C. ABBREVIATIONS

ALARA = as low as reasonably achievable

AU = Authorized User

CT = computed tomography

$CTDI_{100}$ = is a measure of the dose delivered along a 100-mm scan length

$CTDI_w$ = weighted or average CTDI given across the field of view

DLP = dose length product

eV = electron volts

Gy = gray

FDA = Food and Drug Administration

ICRP = International Commission on Radiation Protection

KAP = Kerma-area product

Kerma = kinetic energy released in material

keV = kiloelectron volts

ms = millisecond

mSv = millisieverts

MIRD = medical internal radiation dose

PET = positron emission tomography

RWI = relationship with industry

Sv = sievert

uSv = microsieverts (1/1,000 of a millisievert, 1/1,000,000 of a sievert)