Guidelines for Patient Radiation Dose Management

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Abbreviations: ACR = American College of Radiology, FDA = Food and Drug Administration

THE membership of the Society of Interventional Radiology (SIR) Safety and Health Committee represent experts in a broad spectrum of interventional procedures from both the private and academic sectors of medicine. Generally, these Committee members dedicate the vast majority of their professional time to performing interventional procedures; as such, they represent a valid broad expert constituency of the subject matter under consideration.

Technical documents specifying the exact consensus and literature review methodologies as well as the institutional affiliations and professional credentials of the authors of this document are available upon request from SIR, 3975 Fair Ridge Dr, Ste 400 North, Fairfax, VA 22033.

METHODOLOGY

The SIR produces its safety-related documents using the following process. Documents of relevance and timeliness are conceptualized by the Safety and Health Committee members. A recognized expert is identified to serve as the principal author for the document. Additional authors may be assigned dependent upon the magnitude of the project.

An in-depth literature search is performed by using electronic medical literature databases. Then, a critical review of peer-reviewed articles and regulatory documents is performed with regard to the study methodology, results, and conclusions. The qualitative weight of these articles is assembled into an evidence table, which is evaluated and used to write the document such that it contains evidence-based data, when available.

When the literature evidence is weak, conflicting, or contradictory, consensus is reached by a minimum of 12 Safety and Health Committee members. A Modified Delphi Consensus Method (Appendix A) is used when necessary to reach consensus. For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter.

The draft document is critically reviewed by the Safety and Health Committee members, either by means of telephone, conference calling, or face-to-face meeting. The finalized draft from the Committee is sent to the SIR membership for further input and criticism during a 30-day comment period. These comments are discussed by the Safety and Health Committee, and appropriate revisions are made to create the finished document. Before its publication, the

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INTRODUCTION

In the early 1990s, the U.S. Food and Drug Administration (FDA) received reports of significant radiation-induced skin injuries associated with interventional fluoroscopy (1), prompting the release in 1994 and 1995 of three guidance publications on documenting radiation use (2–4). A number of professional radiological societies, including the SIR, have been working since then to reduce the frequency of these events. In 2007, the American College of Radiology (ACR) published its recommendations on issues related to patient radiation exposure in medicine. This document focuses mostly on diagnostic imaging procedures, such as computed tomography (CT) and nuclear medicine, and not interventional procedures (5). The ACR's 2008 revision of the Technical Standard pertaining to the management of the use of radiation in fluoroscopically guided procedures (6) takes a different, but complementary, approach to the topic than that used in this SIR guideline. Fluoroscopically guided invasive procedures may require the use of significant quantities of radiation for their completion. This can put patients at risk for deterministic radiation injuries. In addition, all irradiated patients are at risk for an increased incidence of stochastic injuries.

These guidelines are written to be used for radiation dose management related to interventional radiologic procedures. The most important processes of care are (*a*) patient selection, (*b*) procedure performance, (*c*) patient monitoring, and (*d*) appropriate documentation and follow-up. The outcome measures or indicators for these processes are individualized patient radiation risk assessment, appropriate informed consent relating to radiation risk, and compliance with recording administered dose.

Concerns over patient radiation doses are valid. Nonetheless, it must be clearly understood that the goal of all interventional radiology procedures is to treat patients and thereby improve their well-being. This will almost always require administration of some radiation and may sometimes require the administration of clinically significant amounts of radiation. In general, the risk of radiation is low compared to other procedural risks, and the benefits of imaging guidance are great (7). Image-guided procedures typically cause less morbidity and mortality than the equivalent surgical procedure. An informed patient will virtually always agree that the potential harm due to radiation is less than the potential harm due to a procedure that is cancelled, incomplete, or clinically inadequate because of concerns over radiation.

DEFINITIONS

Absorbed Dose

The energy imparted per unit mass by ionizing radiation to matter at a specified point. The International System of Units (SI) unit of absorbed dose is the joule per kilogram. The special name for this unit is the gray (Gy). For purposes of radiation protection and assessing dose or risk to humans in general terms, the quantity normally calculated is the mean absorbed dose in an organ or tissue.

Air Kerma

The energy extracted from an x-ray beam per unit mass of air in a small irradiated air volume. Air kerma is measured in grays. For diagnostic x-rays, air kerma is the dose delivered to that volume of air.

Biologic Variation

With respect to radiation, the differences among individuals in the threshold dose required to produce a deterministic effect or the differences in degree of effect produced by a given dose. Biologic variation may be idiopathic, due to underlying disease, or due to patient age. The skin on different parts of the body and different skin types vary in radiosensitivity (8).

C-arm Fluoroscopic System

A fluoroscopic system consisting of a mechanically coupled x-ray tube and image receptor. Such systems typically have two rotational degrees of freedom (left-right and cranial-caudal). Most of these systems have an identifiable center of rotation called an isocenter. An object placed at the isocenter remains centered in the beam as the C-arm is rotated. C-arm fluoroscopes may have either fixed or variable source-to-image receptor distance. Radiation protection strategies differ for these different classes of systems.

Cumulative Dose (CD)

See Reference point air kerma.

Deterministic Effect

Detrimental health effect for which the severity varies with the dose of radiation, and for which a threshold usually exists (ie, causally determined by preceding events). The effect is not observed unless the threshold is exceeded, although the threshold dose is subject to biologic variation. Once the threshold dose is exceeded in an individual, the severity of injury increases with increasing dose. Examples of deterministic effects include skin injury, hair loss, and cataracts.

Dose

General term used to denote mean absorbed dose or effective dose. The particular meaning of the term should be clear from the context in which it is used. In this document "dose" means the absorbed dose to tissue unless otherwise specified.

Dose-Area-Product (DAP)

See Kerma-area-product.

Effective Dose (E)

The sum, over specified tissues, of the products of the dose in an organ and the tissue weighting factor for that tissue. Current techniques for estimating effective dose use computer simulation based on a "model" body and statistical simulations of radiation exposure. This yields only a gross approximation of effective dose. The stochastic risk to an average member of an irradiated population is expressed in terms of sieverts (Sv). Effective dose is often used in the literature to roughly estimate the radiogenic risk to an individual. Age and sex modifiers, appropriate to the irradiated individual, should be applied to such calculations.