Occupational Radiation Protection of Pregnant or Potentially Pregnant Workers in IR: A Joint Guideline of the Society of Interventional Radiology and the Cardiovascular and Interventional Radiological Society of Europe

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ABBREVIATIONS

ALARA = as low as reasonably achievable, FGI = fluoroscopically guided intervention, $H_p(10)$ = personal dose equivalent, ICRP = International Commission on Radiological Protection, NRC = Nuclear Regulatory Commission, NRCP = National Council on Radiation Protection and Measurements

PREAMBLE

The memberships of the Society of Interventional Radiology (SIR) Safety and Health Committee and the Cardiovascular and Radiological Society of Europe (CIRSE) Standards of Practice 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. In addition, the authors also include other experts in radiation safety.

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., Suite 400 N., Fairfax, VA 22033.

METHODOLOGY

SIR and CIRSE produce their safety-related documents using the following process. Documents of relevance and timeliness are conceptualized by SIR Safety and Health Committee members and the CIRSE Standards of Practice Committee. 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 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 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 (1,2) is

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used when necessary to reach consensus. For purposes of these documents, consensus is defined as 80% Delphi participant agreement on a value or parameter. Recommendations are derived from critical evaluation of the literature and evaluation of empirical data from the Safety and Health Committee and the Standards of Practice committee members' practices. Agreement was reached on all statements in this document without the need to use modified Delphi consensus techniques.

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

INTRODUCTION

All individuals are exposed to ubiquitous background radiation (3), which is always present in the environment and results from radiation emitted from naturally occurring radionuclides inside and outside of the body, and from cosmic radiation. In addition, individuals may be exposed to radiation from medical procedures, consumer products, industrial radiation sources, and air travel, as well as from some educational and research activities (4). Individuals working in occupations that use radiation sources or radioactive materials can also be exposed as a result of proximity to these sources or materials (5).

Some of the most common occupations with potential for radiation exposure are in medicine (staff involved in fluoroscopically guided procedures, radiologic technologists, nuclear medicine technologists, radiochemists who prepare radiopharmaceuticals, brachytherapists, and nurses) (6). Worldwide, the mean effective dose for medical workers with recordable dose during 2002 was 1.6 mSv, and for interventional radiology or cardiology was 3.0 mSv (6). In the United States, the mean annual effective dose for medical workers with recordable dose during 2006 was 0.75 mSv (4). At a high-volume hospital in the United States, the mean annual effective dose during 2011 for physicians involved in fluoroscopically guided interventions (FGIs) was 1.6 mSv, and for technicians and nurses involved in FGIs was 1.1 mSv (7).

FGI procedures are performed frequently throughout the world, with the number of these procedures performed annually having increased significantly during the past two decades (8). Effective doses from occupational exposures resulting from FGI procedures are consistently higher than in other medical applications. Occupational doses to physicians performing these procedures vary widely depending on the type of FGI procedure, the type of equipment used, the types of safety features employed, as well as the training the physicians have received (9–13).

For most radiation workers, the small risk of exposure to low-level ionizing radiation is an accepted part of the job. However, pregnant radiation workers may have heightened concerns about the risks to their unborn child (14,15). These workers, including those who are medical professionals (16), have many misconceptions about the risks of ionizing radiation on the developing fetus (17). Even minimal radiation exposure to the conceptus can provoke significant concerns on the part of the expectant mother or her physician (18). Often, workers receive misinformation concerning the reproductive and developmental risks of radiation exposures from colleagues, physicians, nurses, doctors in training, other health care professionals, friends, the news media, or the Internet. For residents, fellows, physicians, nurses, or technologists, pregnancy can exacerbate the stresses of an already challenging work experience (19), along with the additional worry of radiation exposure to the fetus (20). A lack of accurate knowledge of the risks associated with such exposures, or misinformation regarding these risks can cause great anxiety (21,22), work-related stress, and potentially even the unnecessary termination of pregnancy (22). A better understanding of these risks, and ways to reduce them can help address concerns that may lead women to avoid these professions. It should also help to counter potential discrimination or work constraints that result from a worker's pregnancy or potential pregnancy.

Consideration is already given to all patients, including pregnant women, who may need medical radiography. Guidelines to minimize risk to the patient and conceptus exist (23,24). This guideline is intended to assist interventionalists and their staff in managing and counseling staff on pregnancy-related issues. An understanding of radiation doses and associated risks is necessary to avoid potential discrimination and unnecessary constraints on pregnant or potentially pregnant women while protecting the conceptus. Interventionalists and their staff should apply procedures in a manner that ensures consistency with the recommendations in this guideline and the requirements of their national, state, or political jurisdictions. When there are discrepancies between these recommendations and legal requirements, the more rigorous requirements should take precedence.

The pregnant or potentially pregnant worker should be aware that careful planning, an understanding of the risks, and minimization of radiation dose by employing appropriate radiation safety measures can address many of her potential concerns and permit her, in most cases, to safely perform procedures without incurring significant risks to the conceptus.

DEFINITIONS

Absorbed dose is the energy imparted per unit mass by ionizing radiation to matter at a specified point. For the purposes of radiation protection and assessing dose to humans in general terms, the quantity normally calculated is the mean absorbed dose to an organ or tissue. When absorbed dose calculated in the context of pregnancy, the radiation dose of interest is the absorbed dose to the conceptus and not to the mother (22). The special name for the International System of Units unit of absorbed dose is the gray (Gy), and it is defined as the absorption of 1 J of ionizing radiation by 1 kg of organ or tissue. Absorbed radiation dose to the conceptus is expressed in grays or milligrays (1 Gy = 1,000 mGy). For comparison with earlier units 1 Gy is equal to 100 rad.

Administrative controls are controls that govern the way that work is done, including timing of work, policies and other rules, and work practices such as standards and operating procedures.

Air kerma is the energy from an x-ray beam that is transferred to a unit mass of air in a small irradiated air volume. Air kerma is measured in grays.

Conceptus describes the product of conception at any time between fertilization and birth.

Deterministic Effect: see *Tissue Reaction Dose* is a general term used to denote an amount of radiation. 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.

Effective dose is the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body. The effective dose is intended for use as a protection quantity (eg, the prospective dose assessment for planning and optimization in radiologic protection, and demonstration of compliance for regulatory purposes). Effective dose is measured in sieverts (Sv).

Engineering controls are methods built into the design or modifications of facilities, equipment, and procedures to minimize a hazard.

Equivalent dose is the mean absorbed dose from radiation in a tissue or organ multiplied by a radiation weighting factor for that radiation. Equivalent dose is measured in sieverts. This is the quantity used by most European regulations to establish the dose limit. According to the European Basic Safety Standards, the equivalent dose to the unborn child should be as low as reasonably achievable

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