

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, NRCPC = National Council on Radiation Protection and Measurements

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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

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

(ALARA) and unlikely to exceed 1 mSv during at least the remainder of the pregnancy (25).

A *hazard* is the potential for harm. In practical terms, a hazard often is associated with a condition or activity that, if left uncontrolled, can result in an injury or illness.

Kerma is kinetic energy released in matter is the energy from an x-ray beam that is transferred to a unit mass of a specified material in a small irradiated volume of that material (eg, air, soft tissue, bone). Kerma is measured in grays. For the x-ray energies covered in this guideline, the kerma produced in a small volume of material delivers its dose to the same volume (this is not true for high-energy radiation therapy).

Occupational exposure is radiation exposures to individuals incurred in the workplace as a result of situations that can reasonably be regarded as being the responsibility of management (radiation exposures received by patients associated with their medical diagnosis or treatment are excluded).

Personal equivalent dose is an operational quantity, $H_p(d)$, representing the dose equivalent in soft tissue at an appropriate depth (eg, 10 mm) below a specified point on the human body.

Protraction (of dose) is the delivery of dose over an extended period of time rather than over a brief period of time. Examples include the doses received from some occupational work environments, from continuous exposure to a radionuclide with a long half-life, and from ubiquitous background radiation.

Qualified medical physicist/medical physics expert: in the United States, a “qualified medical physicist” is an individual who is competent to practice independently one or more of the subfields of medical physics. The American College of Radiology recommends that the individual be certified in the appropriate subfield(s) by the American Board of Radiology in Diagnostic Radiological Physics or Radiological Physics (8). Certification by the American Board of Health Physics, or, in Canada, by the Canadian College of Physicists in Medicine, may also be relevant for evaluation of conceptus dose and risk determinations and evaluations. The qualified medical physicist must also be familiar with the relevant clinical procedures.

In Europe, the recognized term is “medical physics expert.” It is defined in European Directive 2013/59/Euratom (25) as “an individual or, if provided for in national legislation, a group of individuals, having the knowledge, training, and experience to act or give advice on matters relating to radiation physics applied to medical exposure, whose competence in this respect is recognized by the competent authority.”

Stochastic effects are radiation effects that demonstrate an increasing likelihood of occurrence with increasing dose, and whose severity of occurrence is independent of dose (ie, there is no threshold dose). Radiation induced cancers are examples of stochastic effects. The cancer most closely associated with intrauterine exposure to ionizing radiation is childhood leukemia (22).

Tissue reactions, also termed deterministic effects, are those for which the severity of the resultant detrimental health effect is dependent upon the dose of radiation, and for which a threshold usually exists, below which detrimental health effects are not observed (see *Threshold Dose*). The effect is not observed unless the threshold is exceeded, although the threshold dose is subject to biologic variation. Tissue reactions to the conceptus and individuals vary. In cases in which the threshold dose for a tissue reaction is exceeded in an organ or tissue, the severity of possible injury increases with increasing dose. Examples of tissue reactions in children and adults include skin injury, hair loss, and cataracts. Examples of tissue reactions in the conceptus may include malformations, growth retardation, mental disability, and microcephaly.

A *threshold dose* is the lowest radiation dose at which a specified tissue reaction is likely to occur. The International Commission on Radiological Protection (ICRP) defines the threshold dose as the dose estimated to result in only a 1% incidence of the specified tissue reaction (26). Threshold doses differ among individuals as a result of biologic variation. The threshold dose for skin injury also differs for

different anatomic sites of the same individual. With respect to intrauterine exposure, threshold dose has been most closely estimated for subsequent mental disability and microcephaly.

RISKS OF IONIZING RADIATION ON THE CONCEPTUS

Despite the large amount of epidemiologic, clinical, and experimental data, the risk associated with prenatal exposure to radiation remains uncertain. The risk to the embryo or fetus for tissue reactions (ie, deterministic effects, eg, birth defects, growth retardation, pregnancy loss, mental retardation) from prenatal exposure to the common sources of ionizing radiation in the United States (ie, environmental, occupational, and medical) is generally very low (5). At doses to the embryo or fetus lower than 100 mGy, the risk is small or possibly nonexistent (5,18). This statement is based on extensive mammalian animal studies and the few human epidemiologic studies conducted at these low doses (5). It should be noted that ionizing radiation from ubiquitous background sources or occupational exposure within regulatory limits typically result in doses to the embryo and fetus lower than 100 mSv (5). The risk of low doses of ionizing radiation on the conceptus is often overestimated by practicing professionals (5).

It has long been known that the developing conceptus is highly radiation sensitive (27). Exposure of the conceptus to higher doses of ionizing radiation can potentially lead to two types of adverse health effects, tissue reactions and stochastic effects. Tissue reactions result from damage to multiple cells and may be severe enough to cause cell sterilization or death. Stochastic effects originate from damage to single cells that is sufficient to cause a mutation but that does not impair cell division. Stochastic effects (principally cancer) increase in likelihood as dose increases. Two factors must be addressed: the likelihood of an adverse outcome and the severity of such an outcome (28,29).

The developing conceptus is radiation sensitive throughout the prenatal period (30). The effects of radiation exposure on the conceptus depend on multiple variables, including the gestational age, fetal cellular repair mechanisms, and absorbed radiation dose level. Higher doses of ionizing radiation can cause embryonic death, congenital malformations, growth retardation, and neurologic detriment (31). However, there is little support in the epidemiologic literature for the hypothesis that very low doses of radiation adversely affect pregnancy outcome (5). Much of the current knowledge of the harmful effects of ionizing radiation is from the follow-up of atomic bomb survivors, from patients who received radiation therapy for nonmalignant conditions, and from animal studies. Considerable uncertainty exists about the risks associated with radiation exposure from medical imaging and image-guided interventional procedures. Some of the current scientific basis for these effects on the conceptus is discussed later in this document. A more extensive treatment of the topic was published by the National Council on Radiation Protection and Measurements (NCRP) as report no. 174 (5).

Radiation-related risks are present throughout gestation. The magnitude of these risks is highly dependent on the gestational age during which exposure takes place and the conceptus' absorbed dose. Biologic systems with a high fraction of proliferating cells show high radiation responsiveness (27). Radiation risks are most significant during preimplantation and organogenesis and the first trimester, somewhat less in the second trimester, and least in the third trimester (22,30).

Although there are limited epidemiologic studies of ionizing radiation exposures in human pregnancies from which to determine directly the no-adverse-effect level for developmental and reproductive effects, there are extensive mammalian animal studies. These studies support the conclusion that the no-adverse-effect level from acute exposure for birth defects, growth retardation, pregnancy loss, and other tissue reactions is a dose to the conceptus of approximately 200 mGy at the most vulnerable stage of pregnancy. Experimental data indicate that the developmental effects of protracted and fractionated

irradiation are less than the effects of acute irradiation (5). There is no evidence that a radiation dose lower than 100 mGy during pregnancy is associated with an increased incidence of congenital malformation, stillbirth, miscarriage, growth, or mental disability (5,18).

Risks to offspring of medical radiation workers have been investigated (32,33). These investigations have shown no statistically significant or convincing evidence of an increased risk of cancer in offspring of female medical radiation workers.

REGULATORY REQUIREMENTS AND OTHER GUIDANCE

There are two overarching purposes of occupational radiation protection (26,34). The first is to prevent the occurrence of clinically significant radiation-induced tissue reactions by adhering to dose limits that are below apparent threshold levels. The second is to limit the risk of stochastic effects, including cancer, to a reasonable level in relation to societal needs, values, benefits gained, and economic factors. The ICRP and NCRP further espouse three principles of radiation protection (justification, optimization of protection, and dose limits) as essential elements of a framework for meeting these objectives (26,34). In this schema, justification is based on the expectation that the potential benefits to society exceed the overall societal cost. Optimization of protection is a process to ensure that the total societal detriment from justifiable activities (such as the practice of medicine) is kept ALARA, economic and social factors being taken into account. The principle of dose limits applies exposure limits to individual workers to ensure that procedures that are justified and optimized do not result in individuals or groups exceeding levels of acceptable risk.

The upper limits for justified and optimized occupational exposures are provided by a system of dose limits for radiation workers and members of the public. Doses from ubiquitous background radiation are not included in these dose limits. Occupational exposure is controlled by a limit on the annual effective dose and on annual equivalent doses to specific organs or structures (eg, lens of the eye, hands) of individual workers as recommended by NCRP (34) and ICRP (26,35) and promulgated by various regulatory agencies. For example, in Europe, limits for occupational exposures are included in the European Directive 2013/59/Euratom (25). In the United States, the dose limit for occupational exposure to ionizing radiation from licensed radioactive material is established by the Nuclear Regulatory Commission (NRC) (36). Although these dose limits were established for exposures to NRC-regulated radioactive material, individual states have often adopted the dose limits for exposures from other sources of ionizing radiation (37). However, the implementation methodologies associated with limits and guidance varies from state to state in the United States (15,38), so it is important for facilities to know and follow local requirements.

Specific restrictions apply to the occupational exposure of pregnant women (10). The ICRP recommends that the standard of protection for the embryo and fetus should be broadly comparable to that provided for members of the general public (26). The ICRP and the European Commission recommend that, after a worker has declared her pregnancy, her working conditions should ensure that the equivalent dose to the unborn child is ALARA and unlikely to exceed 1 mSv during at least the remainder of the pregnancy (25,26). This is further mandated in the International Basic Safety Standards (39).

In the United States, for occupational situations, the NCRP recommends a monthly equivalent dose limit of 0.5 mSv to the embryo/fetus (excluding medical and natural background radiation) once the pregnancy is known (34). This is based on the expectation that a monthly limit will control exposure during potentially sensitive periods of gestation. The U.S. Environmental Protection Agency (40) guidance is 5 mSv during the entire gestation period. The NRC (41) has a regulatory limit of 5 mSv during the entire pregnancy of a declared pregnant woman, with further guidance how to apply the limit. The U.S. Department of Energy has also promulgated similar guidance (42).

The NCRP does not currently believe that specific controls are required for occupationally exposed women who are not known to be pregnant (34).

Regulatory requirements with respect to the declaration of pregnancy must be followed. These differ among countries. Some countries require a pregnancy to be declared (43). In the United States, workers who do not wish to declare their pregnancy are not required to do so (44–46). This is related to the right to privacy for the individual expectant female: she is not required to make known that she is pregnant to her employer, even if it is obvious that she is (37). Of course, formal declaration of a pregnancy by a pregnant worker permits supervisors, if necessary, to take steps to control occupational exposure to radiation to less than that permitted for a nonpregnant worker (5). Although special rules apply for pregnant workers, key aspects of these rules include privacy and fairness. Facility policies need to be established for an institution (47), recognizing that declaration of pregnancy is a personal issue that needs to be decided by the affected individual (37).

In addition to establishing dose limits for workers and the requirement that licensees use engineering controls and procedures (ie, administrative controls) to the extent practicable to comply with the ALARA principle, NRC (41) has also established the equivalent dose limit for the embryo and fetus of an occupationally exposed woman. If worker activities are such that an individual could receive more than 1 mSv (annual effective dose) from external sources or occupational intake of radioactive material, the occupational radiation protection program is required to have a fetal assessment program (43).

MONITORING PREGNANT OR POTENTIALLY PREGNANT WORKERS

It is important to realize that the assessment of dose conducted as part of the radiation safety program is meant to demonstrate regulatory compliance with the established limits, not to calculate the true equivalent dose received by the embryo or fetus (5). Conformance to the dose limit is most commonly demonstrated through the use of a single personal dosimeter worn under any protective apron by the pregnant worker at waist level from the date the pregnancy is declared until delivery (48). Sometimes an additional dosimeter is placed on the mother's abdomen, again under any radiation protective clothing (49). At those centers where two-dosimeter worker monitoring systems are used, workers who may become pregnant should wear the "inside" dosimeter at waist level.

Occupationally exposed radiation workers who have declared their pregnancy should be monitored monthly and provided with their monthly dose record (5). This dosimeter overestimates actual dose to the embryo and fetus because radiation attenuation by the mother's tissues is not considered (10,48). The dose to the embryo and fetus can generally be approximated as one half of the personal equivalent dose at 1 cm, $H_p(10)$, for the dosimeter under the protective apron at the abdomen/waist (50,51). External dosimeters are typically calibrated to provide the dose at a depth of 1 cm.

The dosimeter should be evaluated monthly. When the dosimeter shows an average value for personal dose equivalent, $H_p(10)$, of less than 0.1 mSv per month, the equivalent dose to the embryo and fetus is in conformity with applicable ICRP and NCRP recommendations (48). Electronic dosimeters could be used to provide rapid access to data (52,53), along with the use of a dose-of-record accredited dosimeter (54).

The employee has the option to request and wear an abdominal/waist badge regardless of whether a pregnancy declaration has been made. The fetus is most sensitive to radiation effects between 8 and 15 weeks of pregnancy (5,55). This period is often before the pregnant worker announces her pregnancy to coworkers or supervisors, and therefore she may wish to request a fetal badge before actually declaring pregnancy. A worker who is contemplating pregnancy may also request an abdominal/waist badge. Readings from this badge can

help to establish the likely conceptus dose that would be received with a normal work schedule.

Workers need to know their occupational dose to ensure that they are working safely and within regulatory limits. Dose data will not be accurate unless staff members always wear their dosimeters, wear them correctly, and turn them in to be read at each monitoring frequency (typically monthly). Proper placement of radiation badges and careful monitoring of these badges, especially during pregnancy, should be emphasized. Badges should not be left on protective garments (unless the protective garment is specifically assigned to an individual), as other workers may use the protective garment. This would result in erroneous dose level attributed to the pregnant worker (15).

ESTIMATING RADIATION DOSE TO THE CONCEPTUS FOR PREGNANT OR POTENTIALLY PREGNANT WORKERS

Qualified medical physicists/medical physics experts should assist in estimating radiation dose to the conceptus for pregnant or potentially pregnant workers. Information about typical patient doses, C-arm positions, and the worker's position relative to the patient during FGI procedures can be used to perform retrospective estimation of the radiation dose to the surface of the woman's abdomen or the uterus during the first postconception weeks (53). The conceptus dose before the declaration of pregnancy may be estimated by using data published by Faulkner and Marshall (50), including ratios of dose to the uterus to personal dosimeter readings for various x-ray tube potentials and personal dosimeter positions. Similarly, Osei et al (56,57) used computational methods to estimate the conceptus dose in a number of typical fluoroscopic environments (varying tube position, beam energies, and lead apron equivalent thicknesses). Their data demonstrate that, in all situations, the ratio of the conceptus dose to the personal dosimeter reading at waist level under an apron is always less than 0.5 mSv, agreeing with earlier assumptions made by the ICRP (22). Historical personal dose data can therefore provide a useful estimate of the potential for conceptus doses. When necessary, more detailed and accurate dose estimates can be made. For example, Damilakis et al (53) have developed dose data for converting air kerma values from occupational exposures to conceptus dose by using Monte Carlo simulation and give a useful methodology for estimating conceptus dose to electrophysiology cardiologists. An estimation of maximum workload allowed for each month of gestation period following pregnancy declaration can help to ensure compliance with the conceptus dose limits and application of the ALARA principle (53).

Kim et al (11) reviewed occupational doses to operators performing certain FGI procedures. Occupational dose per procedure varied widely. Overall, mean operator radiation dose per case measured over personal protective garments at the trunk ranged from 2 to 1,600 μ Sv (median, 302 μ Sv). Under-apron measurements at the trunk yielded the lowest doses per case, ranging from 0 to 240 μ Sv (median, 9 μ Sv). For cardiac catheterization procedures (9), the mean dose per procedure measured over personal protective devices ranged from 3.5 to 750 μ Sv at the trunk. Under-apron measurements at the trunk yielded much lower doses per case, ranging from 0 to 16 μ Sv. For a given procedure, there was variation in individual measurements, even within the same institution. Not uncommonly, this variation was as much as 10-fold. Factors that affect only operator dose are the principal causes for the wide variation in operator dose normalized by patient dose. Kim and Miller (58) determined that operator dose could change several fold depending on the operator's position with respect to the patient and as much as an order of magnitude depending on the use of radiation shielding. Current data show that under-apron personal dose equivalent $H_p(10)$ measurements are typically less than 250 μ Sv (with a median of approximately 10 μ Sv) per case. Therefore, in most cases, the conceptus dose for these operators is likely less than 125 μ Sv, and generally less than approximately 5 μ Sv per case. With proper use of radiation safety measures, current data do not justify

precluding pregnant physicians from performing FGI procedures. Of course, any assessment of anticipated conceptus doses should be performed based on current practice in the interventional radiology suite or laboratory.

Although not addressed in this document, internally deposited radionuclides may pose special problems for protection of the conceptus because some radionuclides remain in the body for long periods of time. Their transfer, and the doses delivered to fetal organs, are not well known (34). It is important to limit the intakes of radionuclides by pregnant women so the equivalent dose to the conceptus does not exceed the recommended limit. For the present, the NCRP (34) has recommended that the intake of radionuclides, once pregnancy is known, be limited to approximately one twentieth of the values of the annual limit on intake for workers. Detailed descriptions of assessment methodologies for equivalent dose from radionuclides to the embryo and fetus have been published (59).

MINIMIZING CONCEPTUS DOSE

Reduce Patient Dose to Reduce Operator Dose (and Conceptus Dose)

Any practice involving radiation exposure should be justified. The practice should result in a net positive benefit to the exposed individual or society. When a procedure that uses radiation is justified, the resulting doses to patients, occupational workers, and members of the public should be optimized with regard to radiation protection. Doses should be maintained within the ALARA principle, economic and social factors taken into account (5,26). The pregnant worker and her conceptus are best protected in a facility that uses best practices for radiation safety (48,60).

Although risks from occupation exposure are considered minimal as long as the regulatory dose limits are met, some of the more complex, high-dose FGI procedures could result in annual effective doses exceeding 20 mSv for a workload of 1,000 cases per year (10). As efforts to effectively manage the dose that the patient receives from such procedures continue (10), the dose to the performing physician should also decrease as a result of the strong relationship between patient and operator dose (61–64). Decreasing patient dose will typically result in a proportional decrease in scatter dose to the operator and other personnel in the room (48,65,66). Therefore, techniques that reduce patient dose will generally also reduce dose to the conceptus of pregnant occupational workers. **Table 1** (10,24,38,43,48,60,66–71) provides a list of key considerations for dose reduction.

Use Personal Protective Garments/Shielding

In the medical environment, it is common practice for physicians, nurses, and radiologic technologists to wear lead or lead-equivalent aprons to keep their dose to a minimum (5,10,72). In addition, the practice of maintaining as great a distance as possible from the source of radiation consistent with providing good medical care should be employed when possible (5,10,73,74). Protective wraparound aprons with thyroid shields are the principal radiation protection tool for workers in interventional radiology and cardiology (48,65,66). They should be used at all times. Properly fitted aprons are of particular importance for female operators and staff to provide adequate shielding for the conceptus during pregnancy.

Most states in the United States have criteria requiring 0.50-mm lead-equivalent coverage, although some states may allow 0.25 mm (38). The vest/skirt configuration is preferred by many operators to reduce the risk of musculoskeletal/back injury (75–77). This wrap-around style is typically 0.25-mm lead-equivalent, overlapping anteriorly, so that, when worn, the double thickness anteriorly provides 0.5-mm lead equivalence. Transmission of x-rays through a protective apron depends on its elemental composition, its lead equivalency, and the energy of the x-rays. Christodoulou et al (78) found that transmission of 70–100-kVp x-rays through a selection of nominally 0.25-mm lead-equivalent composite or lead-free aprons was

Table 1. Practical Actions to Control Dose to the Pregnant Patient and Conceptus When Performing Image-Guided Fluoroscopic Interventions (10,24,38,43,48,60,66–71)

- Use all available information to plan the interventional procedure.
- Use available patient dose-reduction technologies.
- Position yourself in a low-scatter area whenever possible.
- Use protective shielding. Use aprons or standing portable shields to reduce conceptus dose when applicable depending on exposure situation.
- Use appropriate imaging equipment whose performance is controlled through a quality-assurance program.
- Obtain appropriate training on radiation dose, ALARA techniques, conceptus risks, and overall radiation safety practices.
- Wear your dosimeters and know your dose.
- Strictly adhere to dosimetry and monitoring using a monitoring badge worn at the abdominal/waist under personal protective lead.
- Keep beam-on time to an absolute minimum.
- Remember that dose rates and scatter dose rates will be greater and dose will accumulate faster in larger patients.
- Keep the x-ray tube at maximal distance from the patient.
- Keep the image receptor (image intensifier or flat-panel detector) as close to the patient as possible.
- Do not overuse geometric magnification.
- Remove the grid during procedures on small patients or when the image receptor cannot be placed close to the patient.
- Always collimate as tightly as possible to the area of interest.
- When the procedure is unexpectedly prolonged, consider options for positioning the patient or altering the x-ray field or other means to alter beam angulation so that the same area of skin is not continuously in the direct x-ray field.
- Keep the x-ray tube below the table whenever possible.
- Use low dose rate pulsed fluoroscopy.
- Use last-image-hold instead of spot fluorographic images to record the study and to plan technique.
- Minimize exposure from DSA by using as low a frame rate as possible and by limiting the number of images to the smallest number necessary to achieve the diagnostic/therapeutic goal. Store fluoroscopic loops instead of performing DSA if the higher image quality provided by DSA is not needed clinically.
- When performing DSA, step out of the room or behind a full-length standing portable shield.

ALARA = as low as reasonably achievable, DSA = digital subtraction angiography.

approximately in the range of 4%–20%, whereas, for nominally 0.5-mm lead-equivalent aprons, it was approximately in the range of 0.6%–7%. These values can be compared with transmission of 70–100-kVp xrays through 0.25 mm and 0.5 mm of pure lead of 5%–15% and 0.5%–5%, respectively (78). Typically, standard anterior 0.5-mm lead-equivalent apron decreases dose by a factor of 10–20 (79).

Very few individuals working in the interventional environment accumulate as much as 1 mSv in a year as measured by a personal dosimeter under the apron (10). The shielding provided by a standard protective lead apron is usually sufficient to protect the embryo and fetus for typical exposure to workers involved in interventional procedures (80). Pregnant women can use standard aprons and change to a larger size as needed, or use aprons specifically designed for pregnant workers that can accommodate the enlarging abdomen (43). Pregnant workers who desire additional radiation protection for their conceptus can wear an additional lead apron or a maternity apron (37) with double-lead inserts over the pelvis (1.0-mm lead equivalent). This could decrease conceptus dose by an additional factor of approximately 10 compared with a standard lead apron (79,81), although its additional weight may cause the worker significant fatigue and strain during the course of lengthy procedures (20,82). The additional weight may also increase the potential for musculoskeletal and back pain, or exacerbate these symptoms, which are commonly encountered during a normal pregnancy, even when aprons are not worn (43).

Operator Actions and Work Modifications

Additional restrictions may be imposed when an occupationally exposed woman declares a pregnancy, depending on her job functions and her historical prepregnancy dosimeter values (5). A recommended approach for supervisors is to evaluate historical badge data, estimate conceptus dose accumulated before declaration, and anticipate the conceptus dose and the maximum workload allowed for each

month following declaration of pregnancy (53) (see *Estimating Radiation Dose to the Conceptus for Pregnant or Potentially Pregnant Workers*). With appropriate precautions, conceptus doses will typically remain within recommended limits without changes in occupational tasks (37).

The pregnant operator should make appropriate efforts to reduce her exposure, consistent with the principle of optimization of protection. This includes minimizing fluoroscopy time (eg, possibly by prohibiting less experienced individuals from operating the fluoroscopy pedal or controls). Careful planning may reduce unnecessary fluoroscopy. Substituting ultrasound for fluoroscopy guidance may be helpful as long as it does not affect patient care or procedure outcomes. Whenever possible, the pregnant worker should step into the control room during imaging runs (38), and, at minimum, should stand behind a full-length lead shield in the procedure room. Doubling the distance between the operator and the radiation source will typically reduce the exposure by a factor of four (10). If the pregnant operator cannot step away from the table, movable lead shields could be used and placed between the x-ray beam and the operator. The radiation beam should be collimated as tightly as possible for the clinical task to reduce scatter. Table 1 provides a list of key considerations for dose reduction.

The employer of a declared pregnant worker must evaluate the work situation and ensure that conceptus dose is kept below the maximum permissible level during the remaining gestation period. Efforts should be made to keep conceptus doses within the ALARA principle. When sound radiation safety practices are maintained, pregnant individuals involved in most FGI procedures generally do not need to limit their time in the procedure room to remain below the dose limit for the conceptus (10). Indeed, the exclusion of pregnant workers from fluoroscopic procedures solely on the basis of radiation risks to the conceptus cannot be justified on scientific grounds, may alter the contribution that female employees

will make to the specialty (43,83,84), and may encourage job discrimination (53).

When a worker is pregnant a redelineation of roles has been suggested, with redistribution of responsibilities where possible (30,38). This approach is typically not required on the basis of radiation protection, and its implementation depends on the facility's being sufficiently large and flexible to be able to accommodate the change without adversely affecting patient care (85). An ethical consideration is also involved, as another worker would have to incur additional radiation exposure instead of the pregnant worker (22). Of course, a worker's right to a safe and supportive work environment stands (20). A pregnant worker may request a change to a job outside the FGI unit.

EDUCATION AND TRAINING

Every employer has an obligation to provide information on hazards to its employees, and to establish mechanisms to maintain a safe and healthful work environment. Many countries, including all European Union member states, mandate Occupational Health and Safety Management Systems (86). In the United States, these programs are called Workplace Injury Illness Prevention Programs, and are mandatory in 15 states (86). Employers are typically required to provide hazard awareness training to their employees upon initial hire and then periodically, usually annually, thereafter. Because ionizing radiation has long been identified as a workplace hazard, policies and procedures should be in place for anyone who routinely works around sources of ionizing radiation. Anyone who is occupationally exposed to ionizing radiation should be informed of this fact (5). In the United States, the NRC (87) requires that all individuals likely to receive an annual effective dose of 1 mSv or more from working around radioactive material in the course of their employment be instructed in the health protection issues associated with exposure to radiation. Many useful overall guidelines for training in radiation protection and management have been developed for interventional radiology and cardiology (10,24,48,60,73,74,88,89). As with other radiation workers, all persons potentially exposed to radiation in a fluoroscopy suite should use safe radiation safety practices (5,90,91).

Optimization of protection can be achieved through continuing education and training of physicians in radiation physics and radiation protection (11,92,93). It has been shown that increasing operator awareness can lead to marked decreases in occupational dose (94,95). Increasing physicians' awareness of radiation dose levels, determinants of dose, and protective measures to reduce dose can be improved by providing regular training in radiation protection. Indeed, an operator's awareness of radiation exposure could result in a marked decrease in his or her occupational dose (58).

Written maternity and declared pregnant worker policies are recommended because workers need to know what is expected of them and that they will receive unbiased consideration. Decisions about working in a radiation environment need to be made by the employer, in setting up facility policy, and by the employee, in making personal choices (37). All new workers should be provided the facility policy. A female employee has the right to know the potential radiation hazards to her unborn child before she is pregnant and also (in those countries in which a declaration of pregnancy is voluntary) before she decides to formally declare her pregnancy (53). Female radiation workers should be informed about radiation doses during pregnancy and should be provided with accurate information on risks in order to be able to make prudent decisions regarding family planning and their career.

COUNSELING PREGNANT OR POTENTIALLY PREGNANT WORKERS

Counseling on the risks to the conceptus from exposure to ionizing radiation is an important part of a radiation protection program for

Table 2. Spontaneous Pregnancy Risks in General Population (17,59)

Type of Risk	Spontaneous Risk*
Risk of very early pregnancy loss (before first missed period)	~1 in 3
Risk of spontaneous abortion in known-pregnant women	~1 in 7
Risk of major congenital malformations	~1 in 33
Risk of severe mental disability	~1 in 200
Risk of childhood leukemia per year	~1 in 25,000
Risk of early- or late-onset genetic diseases	~1 in 10
Prematurity	~1 in 25
Growth retardation	~1 in 33
Stillborn	~1 in 50–250
Infertility	~1 in 15 couples

*Spontaneous risks facing an embryo at conception (ie, 0 mGy radiation dose).

pregnant workers. A potentially pregnant or declared pregnant worker may be extremely concerned about the outcome of the pregnancy following exposure to occupational radiation, and a counseling session with her (and the father, if possible) is often useful. A calculation of conceptus exposure by a qualified medical physicist/medical physics expert can be informative and reassuring (17). In the United States, upon formal written declaration of pregnancy by a woman, the employer is required to provide counseling that includes the potential effects of radiation exposure to the embryo and fetus (5). Counseling by a qualified medical physicist/medical physics expert should be available at all institutions.

Counseling should include a discussion of the risks present during every pregnancy as well as the potential risks in a nonexposed population (Table 2) (17,59). Nonexposed women are those who do not work with radiation, and are exposed only to natural background radiation. Background radiation is ubiquitous and is typically approximately 0.75–1 mSv during gestation (96). It is important to note that, even in a nonexposed population, risks to the pregnancy are not minor (30). They include a 15% or higher spontaneous abortion rate, a 1%–6% incidence of a major malformation, a 4% intrauterine growth retardation rate, and a 4%–10% incidence of genetic diseases (17,22,97,98). It is also important to include in the discussion that, without additional radiation exposure, the lifetime risk for the conceptus of developing cancer is approximately one in three, the risk for fatal cancer is approximately one in five (22), and the natural risk of childhood cancer is less than one in 500 (98). When the potential spontaneous risks in a nonexposed population have been discussed, a qualified medical physicist/medical physics expert should provide information about the estimated probability of delivering a child free of radiation-related adverse outcomes based on estimated conceptus doses, and should compare these probabilities versus those for a zero conceptus dose (Table 3) and versus the occupational and declared pregnant worker limits. Counseling should include a discussion of the “all-or-none” principle of teratology to avoid needless interruption of pregnancy out of unfounded fear of an adverse pregnancy outcome (5,99). Framing the discussions in these ways can help to maximize information transfer while minimizing fear. The counseling team must listen carefully to the worker's questions and take as much time as is necessary to ensure that she understands the complex information being presented.

Women should be counseled that conceptus doses maintained below the regulatory guidance of 5 mSv (in the United States) or 1 mSv (in the European Union) over the course of pregnancy present no

Table 3. Probability of a Live Birth without Malformation or without Childhood Cancer as a Function of Radiation Dose (22,31)

Dose to Conceptus	No Malformations (%)	No Childhood Cancer (%)	Neither (%)
0 mSv	96.00	99.93	95.93
0.5 mSv	95.999	99.926	95.928
1.0 mSv	95.998	99.921	95.922
2.5 mSv	95.995	99.908	95.91
5.0 mSv	95.99	99.89	95.88
10.0 mSv	95.98	99.84	95.83
50.0 mSv	95.90	99.51	95.43
100.0 mSv*	95.80	99.07	94.91

*For conceptus doses > 100 mSv, consult a qualified medical physicist/medical physics expert for risk estimates.

measurably increased risk of prenatal death, malformation, or impairment of mental development compared with the background incidence of these entities (22), as exposure to less than 50 mSv has not been associated with an increased rate of fetal anomalies or pregnancy loss (18,97,100). Although termination of pregnancy is an individual decision, and is affected by many factors, it should be emphasized that conceptus doses less than 100 mSv should not be considered a reason for terminating a pregnancy (17,22,98,100,101). In an extremely rare case of conceptus doses greater than 100 mSv, the qualified medical physicist/medical physics expert should refer to available national and international guidance (5,22) when providing counseling.

RECOMMENDATIONS

The pregnant or potentially pregnant worker should be aware that careful planning, understanding of the risks, and minimization of occupational 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.

Each facility should have a written radiation safety policy/program for pregnant and potentially pregnant workers that addresses: declaration of pregnancy, occupational exposure, dosimeter use and readings, duties, and risk/benefit of additional shielding. Institutions have an obligation to publish or make their policies known regardless of the employee's pregnancy status at the time of the request. In the United States, policies need to recognize that declaration of pregnancy is a personal issue that needs to be decided by the affected individual with appropriate information. In other countries, a declaration of pregnancy may be mandatory.

All individuals likely to receive an annual effective dose of 1 mSv or more from FGI-related work must be instructed in the health protection issues associated with exposure to radiation. Female radiation workers should be informed about radiation doses during pregnancy as well as accurate information on risks to arrive at prudent decisions regarding their career and family planning.

No specific controls (or limits), other than those already required for all radiation workers, are required for occupationally exposed women who are not known to be pregnant. After a worker has declared her pregnancy, her working conditions should ensure that the additional dose to the conceptus is maintained below 0.5 mSv per month during the pregnancy. The aim should be to control exposure during the entire gestation period so that it is ALARA, but in any case below 5 mSv (in the United States) or 1 mSv (in the European Union).

Occupationally exposed radiation workers who have declared their pregnancy should be monitored monthly and provided with their monthly dose record. Conformance to the dose limits should be demonstrated through the use of a personal dosimeter worn by the pregnant worker at waist level under any protective apron from the date the pregnancy is declared until delivery. When such dosimeters show an average value for personal dose equivalent, $H_p(10)$, of less than 0.1 mSv per month, the equivalent dose to the conceptus would be

in conformity with the applicable ICRP and NCRP recommendations. The employee has the option to request and wear an abdominal/waist dosimeter regardless of whether a pregnancy declaration has been made.

Exclusion of pregnant workers from fluoroscopic procedures solely on the basis of radiation risks to the conceptus cannot be justified on scientific grounds. A pregnant worker may request a change to a job that does not involve fluoroscopy or computed tomography (CT). However, this approach is typically not required on the basis of radiation protection, and its implementation depends on the facility being sufficiently large and flexible to be able to accommodate the change without adversely affecting patient care.

Workers need to know their occupational dose to ensure that they are working safely and within regulatory limits. Dose data will not be accurate unless workers always wear their dosimeters, wear them correctly, and turn them in to be read at each monitoring frequency (typically monthly). The proper placement and careful monitoring of these radiation badges should be emphasized, especially during pregnancy.

With proper radiation safety measures, current data do not justify precluding pregnant workers from performing FGI or CT-guided procedures. An assessment of anticipated conceptus doses should be performed based on current practice in the interventional radiology suite or laboratory. Qualified medical physicists/medical physics experts should assist in estimating radiation dose to the conceptus for pregnant or potentially pregnant workers. An estimation of maximum workload allowed for each month of gestation period following pregnancy declaration can help to ensure compliance with the conceptus dose limits and application of the ALARA principle.

The pregnant or potentially pregnant worker and her conceptus are best protected in a facility that uses best practices for radiation safety. Techniques that reduce patient dose will generally also reduce dose to the conceptus of pregnant workers. All FGI procedures should be optimized to achieve the clinical purpose with no more radiation than is necessary, given the available resources and technology. To that end, appropriate dose reduction techniques, as outlined in Table 1, should be employed.

Protective wraparound aprons with thyroid shields are the principal personal radiation protection tools for FGI workers. Properly fitted aprons are of particular importance for female operators and staff to provide adequate shielding of breast tissue and, during pregnancy, for the conceptus. A minimum of 0.25–0.5-mm lead-equivalent coverage should be provided. Consideration should be given to the overall weight of the lead apron (or additional personal protective shielding employed), as the weight can cause fatigue and strain and increase the potential for musculoskeletal and back issues, which are already more likely as a result of the pregnancy.

All equipment should be properly maintained and periodically inspected for radiation safety. Radiation output should be monitored and radiation scatter surveys conducted by a qualified medical physicist/medical physics expert according to local regulations and hospital policy.

Counseling by a qualified medical physicist/medical physics expert regarding radiation exposure and potential risks to the conceptus should be available at all institutions.

Termination of pregnancy as a result of radiation exposure is an individual decision affected by many factors. An evaluation of overall risks should be undertaken at all dose levels. Conceptus doses less than 100 mGy should not be considered a reason for terminating a pregnancy.

Women should not be deterred from entering professions and specialties that require occupational exposure to radiation from fluoroscopy or CT. As with all radiation workers, they should know the risks and should take appropriate measures to optimize radiation protection. Women should be aware that conceptus doses maintained below the regulatory requirement of 5 mSv (in the United States) or 1 mSv (in the European Union) over the course of a pregnancy present no measurably increased risk to the conceptus.

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SIR DISCLAIMER

The clinical practice guidelines of the Society of Interventional Radiology (SIR) attempt to define practice principles that generally should assist in producing high quality medical care. These guidelines are voluntary and are not rules. A physician may deviate from these guidelines, as necessitated by the individual patient and available resources. These practice guidelines should not be deemed inclusive of all proper methods of care or exclusive of other methods of care that are reasonably directed towards the same result. Other sources of information may be used in conjunction with these principles to produce a process leading to high quality medical care. The ultimate judgment regarding the conduct of any specific procedure or course of management must be made by the physician, who should consider all circumstances relevant to the individual clinical situation. Adherence to the SIR Quality Improvement Program will not assure a successful outcome in every situation. It is prudent to document the rationale for any deviation from the suggested practice guidelines in the department policies and procedure manual or in the patient's medical record.