

ACR–SPR PRACTICE PARAMETER FOR IMAGING PREGNANT OR POTENTIALLY PREGNANT PATIENTS WITH IONIZING RADIATION

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PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

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The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ *Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing*, 831 N.W.2d 826 (Iowa

2013) Iowa Supreme Court refuses to find that the "ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures (Revised 2008)" sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, *Stanley v. McCarver*, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR).

Radiation exposure to a pregnant or potentially pregnant patient from a medical imaging procedure and the management of such patients are complex topics [1]. Patients, their families, and medical staff are understandably concerned about the possible detrimental effects of radiation exposure to the developing conceptus. On the other hand, overly concerned pregnant patients might decide to forgo necessary imaging procedures, which may put the patient and the conceptus at risk. Clearly, an appropriate benefit/risk perspective is necessary to properly care for the ill or injured pregnant patient.

Because there is no universally recognized threshold for some radiation effects (stochastic effects), it has been argued that there is "no safe level" of radiation exposure. The risk of adverse effects from ionizing radiation should always be weighed against the risk of not performing the procedure and the benefit derived from the procedure. Many people are exposed to higher amounts of natural background radiation, including people who live at mountain elevations or those who frequently use air travel. These lifestyle-related activities are generally not considered risky. Even during pregnancy, the majority of the population does not avoid activities with natural background radiation over concern of ionizing radiation exposure. The use of the term "safe" in any setting, clinical or nonclinical, should be understood within the context of benefit versus risk. Safety is a matter of taking appropriate actions to limit risk to a level justified by the benefit. To maintain a high standard of safety, particularly when imaging pregnant or potentially pregnant patients, the degree of medical benefit should outweigh the well-managed levels of risk.

This practice parameter has been developed to provide current practical information to radiologists, nuclear medicine physicians, other physicians, and medical practitioners implementing policies for imaging pregnant and potentially pregnant patients. Individual institutions and facilities should develop their own policies. As with all imaging procedures, the specifics of an individual case may necessitate deviation from even the most strongly worded guidelines.

Throughout this practice parameter, the radiologic or nuclear medicine/positron emission tomography (NM/PET) technologist is referred to as the most likely person to communicate potential risks to pregnant patients. Nurses, registered radiologist assistants, physician assistants, physicians, and other staff may also fill this role. Therefore, whenever this practice parameter refers to technologists, it should be understood that others may share or be assigned this responsibility.

When managing a pregnant patient potentially exposed to a high dose of radiation, the radiologist or nuclear medicine physician should involve a Qualified Medical Physicist or Radiation Safety Officer to estimate absorbed dose to the conceptus from the diagnostic or interventional procedure(s). This can be completed either prospectively or retrospectively. The Qualified Medical Physicist should also advise the radiologist means by which risk can be reasonably limited.

This practice parameter addresses the imaging of pregnant and possibly pregnant patients with ionizing radiation (ie, radiography, fluoroscopy, computed tomography [CT], and diagnostic NM/PET). It does not address issues related to imaging the lactating patient, the use of contrast agents during imaging, or magnetic resonance imaging (MRI) (see the [ACR Manual on Contrast Media](#) [2] and the [ACR Manual on MR Safety](#) [3]). Furthermore, this practice parameter addresses neither pregnant or potentially pregnant patients undergoing radiation or

radionuclide therapy nor pregnant or potentially pregnant personnel working with ionizing radiation.

The objective of this practice parameter is to assist practitioners in identifying pregnant patients, preventing unnecessary radiation exposure, tailoring examinations to effectively manage radiation dose, and developing strategies to quantify and evaluate the potential effects of radiation delivered to pregnant patients. This practice parameter 1) outlines the body of knowledge on the risks to the conceptus from ionizing radiation during the various stages of pregnancy, 2) provides guidance on when and how to screen for pregnancy prior to imaging examinations using ionizing radiation, 3) recommends means to control, manage, and minimize radiation dose to pregnant or potentially pregnant patients, and 4) discusses evaluation of dose assessment, risk assessment, and communication issues following exposure of pregnant patients.

II. RADIATION RISKS TO THE CONCEPTUS

Potential effects of radiation have been extensively researched, resulting in a broad body of knowledge. As with any body of knowledge, uncertainties exist. The purpose of reviewing radiation research and the underlying uncertainties is to build a knowledge base from which reasonably informed clinical decisions can be reached regarding risks of radiological examinations in pregnant or potentially pregnant patients. The risk assessment should address the likelihood of an adverse outcome and the severity of that outcome. These should be weighed against potential benefits to the pregnant patient and the conceptus.

The following information ([Table 1](#)) can be used to gain perspective and develop clinical guidelines in the management of pregnant or potentially pregnant patients. A more complete review is provided in [Appendix A](#).

Table 1. Summary of suspected in utero induced deterministic radiation effects*[4,5]

Menstrual or Gestational age	Conception age	<50 mGy (<5 rad)	50–100 mGy (5–10 rad)	>100 mGy (>10 rad)
0–2 weeks (0–14 days)	Prior to conception	None	None	None
3rd and 4th weeks (15–28 days)	1st–2nd weeks (1–14 days)	None	Probably none	Possible spontaneous abortion.
5th–10th weeks (29–70 days)	3rd–8th weeks (15–56 days)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable.	Possible malformations increasing in likelihood as dose increases
11th–17th weeks (71–119 days)	9th–15th weeks (57–105 days)	None	Potential effects are scientifically uncertain and probably too subtle to be clinically detectable.	Risk of diminished IQ or of mental retardation, increasing in frequency and severity with increasing dose
18th–27th weeks (120–189 days)	16th–25th weeks (106–175 days)	None	None	IQ deficits not detectable at diagnostic doses

>27 weeks (>189 days)	>25 weeks (>175 days)	None	None	None applicable to diagnostic medicine
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**Stochastic risks are suspected, but data are not consistent [6]. For exposure to a newborn child, the lifetime attributable risk of developing cancer is estimated to be 0.4% per 10 mGy (1 rad) dose to the baby. The potential risks in utero for the second and third trimesters and part of the first trimester may be comparable, but the uncertainties in this estimate are considerable.*

III. SCREENING FOR PREGNANCY

According to the International Commission on Radiological Protection, thousands of pregnant patients are exposed to medically indicated ionizing radiation each year [4]. The frequency at which pregnant patients are unintentionally exposed to ionizing radiation is unknown. One study reported that 1% of patients of childbearing potential who underwent abdominal imaging were unknowingly pregnant in their first trimester [7]. Another study of female trauma patients reported that 2.9% were pregnant and that the unidentified pregnancy rate was 0.3% [8].

The purpose of screening patients for the possibility of pregnancy is to minimize radiation exposure to the conceptus . It should be realized that no screening policy will guarantee 100% detection. In every case, the effort needed to identify unsuspected pregnancy should be weighed against the risk of not detecting a pregnancy. Therefore, different screening policies might apply for higher-dose versus lower-dose procedures. The vast majority of routine diagnostic studies (including nuclear medicine studies) typically deliver far less than 20 mGy to the uterus. However, some procedures, such as fluoroscopically guided interventional procedures of the pelvic area, may deliver doses above the teratogenic threshold (~100 mGy). In these cases, a stricter method of screening for pregnancy should be applied.

III. SCREENING FOR PREGNANCY

A. Determining pregnancy status

Verification of pregnancy status is not necessary for many common imaging procedures. In certain situations, however, pregnancy status is a fundamental part of the clinical history that should be obtained before performing imaging studies that may expose the conceptus to ionizing radiation. Early-in-pregnancy patients may be unaware they are pregnant. Laboratory pregnancy testing may be used to determine a patient’s pregnancy status.

1. Examinations that do not require verification of pregnancy status

- In general, X-ray–based examinations that do not directly expose the pelvis or gravid uterus to the X-ray beam do not require verification of pregnancy status. Such studies include, but are not limited to:
- a. Chest radiography
 - b. Extremity radiography
 - c. Any diagnostic examination of the head or neck
 - d. Mammography
 - e. Any CT imaging outside of the abdomen or pelvis (with the possible exception of the hip)

Chest radiography in the third trimester can expose part of the fetus to the direct X-ray beam. This may proceed if it is justified and optimized (appropriate technique is used). The dose to the fetus remains very low, and the third trimester fetus is less radiosensitive compared with earlier in pregnancy. Performing a frontal view only (and omitting the lateral view) is an example of optimization .

Mammography can be performed safely at any time during pregnancy. Radiation exposure to the conceptus from a properly performed screening mammogram is expected to be inconsequential [9]. Therefore, the decision to proceed with the examination should be based on clinical considerations, not radiation dose to the fetus [10].

The use of shielding, historically offered to patients to reassure them, has been shown to potentially increase internal scatter [11] and, therefore, likely radiation dose to the fetus. More than that, relative risk to the fetus from radiation exposure is much less than previously thought [12]. In the past, the use of shielding was optional but not required. In light of the new data, the use of protective shielding for the pelvis, when it is outside the field of view, is not recommended [13].

2. Examinations that may require verification of pregnancy status

- a. Interventional fluoroscopic procedures of the abdomen or pelvis
- b. Diagnostic angiography of the abdomen or pelvis
- c. Hysterosalpingography [14]
- d. Standard-dose CT protocols of the abdomen or pelvis
- e. Diagnostic nuclear medicine studies

Determination of pregnancy status has 2 components: clinical history and pregnancy testing.

In some circumstances, clinical history may be sufficient to exclude pregnancy. For example, it may be sufficient for patients who have a history of hysterectomy or tubal ligation, ongoing oncologic therapy, etc. If clinical history is insufficient to exclude pregnancy, testing may be required. Consider informing all patients of childbearing potential about potential risks to a conceptus from the expected radiation exposure of the examination they are undergoing. Counseling can be provided as needed.

In the case of diagnostic nuclear medicine, all radiopharmaceuticals used for diagnostic purposes (except Iodine-131) have short half-lives (ranging from 68 minutes to 78 hours) and low administered activities resulting in low radiation doses that pose extremely low radiation risks (Table 2). In this case, a clinical history that the patient cannot reasonably be pregnant is sufficient. Except for when clinical history is insufficient, pregnancy tests are not routinely required for these diagnostic nuclear medicine studies.

An exception for not performing a pregnancy test is for longer half-life radionuclides that will expose the fetus to >0.50 mGy [15]. For diagnostic nuclear medicine studies, this threshold could be attained when using iodine-131 whole-body imaging for thyroid cancer (usually 74–185 MBq [2–5 mCi] administered activity). In this case, nuclear medicine facilities may require pregnancy testing in addition to the clinical history to verify pregnancy status. Note: iodine-123 has a low energy and short half-life, so pregnancy tests are not routinely required for iodine-123 whole-body scans.

In many cases, especially with inpatients, pregnancy history is available in the medical record. In some facilities pregnancy status must be documented before an order for radiological or nuclear medicine examination is accepted. Although this information is helpful in screening for pregnant patients, it should not be the sole determinant of pregnancy for patients in whom pregnancy has not been diagnosed. Assessment of reproductive status just prior to an examination will help decrease the likelihood of imaging patients with an unsuspected pregnancy. When possible, an interactive electronic order entry system should embed a query about pregnancy status when ordering imaging studies that include the abdomen and/or pelvis of a patient of childbearing potential .

Table 2. Examples of diagnostic nuclear medicine examinations that do NOT require routine pregnancy testing prior to radiopharmaceutical administration

Radiopharmaceutical	Type of scan
Single Photon Emitters	
99mTc-DTPA	Renal scan, Ventilation, Gastric emptying, VP/VA shunt

99mTc-MDP	Bone scan
99mTc-Sulfur Colloid	Gastric emptying, Bone marrow mapping, Splenule/splenosis localization, Sentinel node localization, lymphoscintigraphy
99mTc-Pertecnetate	Thyroid scan, Meckel's diverticulum
99mTc-MAA	Lung perfusion, Right-to-Left shunt assessment, Liver shunt assessment
99mTc-labeled RBC	GI bleeding, MUGA, Hemangioma
99mTc-HIDA	Cholecystitis, Bile leak, Functional gallbladder disorder
99mTc-Sestamibi	Cardiac stress test, parathyroid localization, Molecular Breast Imaging
99mTc-HMPAO	Brain Death scan
111In-WBC	Infection, inflammatory bowel disease
111In-Octreoscan	Neuroendocrine tumor imaging
111In-DTPA	Cisternography, CSF leak
133Xe	Lung ventilation
67Ga	Spine infection
201Tl*	Cardiac perfusion scan stress/rest
133Xe	Ventilation
Positron Emitters	
18F-FDG	Tumor imaging
68Ga-DOTATATE	Neuroendocrine tumor imaging
Abbreviations	

**Not commonly used at present time.*

III. SCREENING FOR PREGNANCY

B. Patient history

Patients usually can supply adequate information to help assess the possibility of pregnancy [4]. All patients of childbearing potential [16] should be questioned about pregnancy status using a standardized form and/or through direct questioning by the technologist, preferably in private without an accompanying person. The guidance is based on a minimum practical and balanced approach that considers patient and facility convenience, fertility (extremely rare without medical intervention beyond age 50 despite menstruation status), safety, and efficiency. A standardized form has the advantage of ensuring uniformity and can serve as documentation of pregnancy status for the medical record (see Appendix B).

III. SCREENING FOR PREGNANCY

C. Pregnancy tests

If the results of a pregnancy test are positive, the information must be brought to the attention of a radiologist or nuclear medicine physician, with the exception of an imminently life-threatening emergency, prior to proceeding with an examination. A negative pregnancy test should not be a reason to forgo standard screening procedures for pregnancy. If, after questioning the patient, there is uncertainty in regard to their pregnancy status, the radiologist or nuclear medicine physician should be notified prior to performing the study. The date of the negative pregnancy test should be included in the notification.

Procedures that require a pregnancy test should be documented in the department policies

III. SCREENING FOR PREGNANCY

D. Patients who are minors

The definition and age of a minor may vary depending on state law; typically a person under the age of 18 is a minor. Generally, a minor is considered emancipated if married, on active duty in the armed forces, or otherwise living apart from their parents and managing their own finances. Although a parent or guardian is usually responsible for consenting to a minor's health care, in addition to the exceptions mentioned above, all states have specific laws for minors receiving medical treatment. Most states have laws that allow minors to have a pregnancy test without obtaining parental consent or notification. It is unclear, however, if those provisions apply only to situations in which the minor is receiving prenatal care. It is important to be familiar with applicable state requirements.

In 1996, the US Congress passed the Health Insurance Portability and Accountability Act (HIPAA). The resulting regulations contain numerous provisions that affect patients' health care privacy rights, including those of minors. The regulations recognize that, in specific circumstances, parents are not necessarily the personal representatives of their minor children 1) when under state law the minor is legally able to consent to their care; 2) when the minor may legally receive the care without the consent of a parent, and the minor or someone else has consented to the care; or 3) when a parent or guardian assents to a confidential relationship between a health care provider and the minor. In these situations, the radiologic or nuclear medicine technologist may ask a minor about their pregnancy status prior to an imaging procedure involving ionizing radiation. The minor may exercise most of the same rights as an adult under the regulations including limiting access of the parent or guardian to the minor's health care information. However, the regulations should be deferred to state laws, which might negate this aspect for specific states.

The minor is also particularly vulnerable to social and parental pressures that can potentially result in the patient providing misinformation about their reproductive status. One approach to rectify this situation is for the technologist to ask the parent or guardian for permission to prepare the patient in the examination room privately prior to the examination. In the private setting, the technologist can either ask the patient the standard questions or ask the patient to fill out the standard form about menstrual history and the potential for pregnancy. If the parent refuses, then a backup screening policy may be put in place. If the responses indicate that the patient is or could be pregnant, verbal consent for a pregnancy test should be obtained from the patient and, when

appropriate or when required by law, from the minor's parent or guardian. The order for the pregnancy test can be initiated by the technologist working under written protocol, by the radiologist, or by the provider ordering the examination. If consent is declined, the radiologist should be informed of the circumstance before any examination is conducted. It should be documented in the patient's medical record that the patient and/or the guardian declined the pregnancy test.

Alternatively, the institutional policy might indicate that:

All minors who are not known to be pregnant are to undergo a pregnancy test prior to the following procedures:

- Pelvic CT
- Angiography and other interventions of the pelvis under fluoroscopy (eg, contrast enema)

The pregnancy test should be ordered by the appropriate clinician.

If a pregnancy test is refused, this should be documented in the patient's medical record and the radiologist should be notified.

Such a policy has the advantage of:

- Avoiding questions that might confuse minors or be objectionable to parents or guardians
- Providing a stricter method of screening for some higher-dose procedures

III. SCREENING FOR PREGNANCY

E. Deciding to proceed with the examination

If a patient can reasonably attest that they are not pregnant (not sexually active, on birth control, or biologically incapable of conceiving), then the examination can be performed.

When the patient does not meet these criteria, and when the need for the examination is not critically urgent, the technologist should contact the radiologist or nuclear medicine physician for further guidance. The technologist may also follow procedural instructions defined in a written protocol [1].

If pregnancy is established, the patient should be informed in a timely manner. Although it is preferable that the referring physician inform the patient, this might not be practical, and the radiologist or nuclear medicine physician should ensure the patient is informed. The patient, referring physician, and radiologist/nuclear medicine physician can then make decisions on the optimal patient management and imaging needs.

If the procedure is critically urgent, it must be performed without determining the patient's pregnancy status. That the determination of the pregnancy status was waived must be documented in the patient's record [17]. Documentation that is consistent with institutional policies must be entered in the patient's medical record, indicating the circumstances of the waiver and the physician who directed the waiver.

For procedures expected to deliver high doses to a conceptus, a pregnancy test should be obtained within 72 hours prior to commencement of the procedure unless medical exigencies prevent it. If a patient is found to be pregnant, the procedure might be modified, canceled, or substituted with alternative imaging . If so, the referring provider should be notified.

IV. IMAGING THE PREGNANT PATIENT

A. Patient Consent

For an imaging examination of the abdomen or pelvis using ionizing radiation, obtaining consent from a confirmed pregnant patient is essential to provide comprehensive medical care . This process requires:

1. A realistic overview of the limited risk to the patient and conceptus from the examination.
2. Communicating the benefit of the imaging procedure in patient or fetal health evaluation.

Whether institutions use written consent forms or verbal consent, this interaction should be documented in the patient's medical record and in compliance with state law. If written consent is required, then the form should be retained in the medical record.

The format of the consent may vary based on the clinical situation and local institutional guidelines. Because a detailed quantitative list of risks may be beyond the comprehension of some patients, institutions may prefer a limited consent process in which generalized benefits and risks to the pregnant patient and conceptus are described (see Appendix C). Other facilities might prefer a detailed, numerically oriented consent form that lists the radiation risks and potential adverse effects. Regardless of the format, the information communicated should accurately convey benefits and risks posed by the procedure, in language understandable to the layperson.

Conveying information in a positive, rather than negative, manner is useful in helping a patient accurately understand the risks. Rather than telling the patient the likelihood of their child developing cancer later in life, a positive, accurate perspective is that the cancer risk is extremely small and it is likely the child will remain healthy with no adverse radiation effects (see Appendix C for sample consent form).

IV. IMAGING THE PREGNANT PATIENT

B. Preplanning

The most effective way to limit radiation exposure to the pregnant patient is by eliminating unnecessary scans, using alternative modalities (ultrasound and MRI) and, in cases in which a modality using ionizing radiation is appropriate, tailoring the examination to the clinical question while optimizing the radiation dose. For this to be achieved, discussion between the referring physician and the radiologist or the nuclear medicine physician may need to occur. The imaging technologist and the imaging physician should work together to assure the best benefit/risk for the patient and conceptus. Establishment of guidelines for imaging acute disease processes in pregnant patients can expedite patient evaluation.

It is best to have written imaging protocols in place before imaging pregnant patients to ensure uniform and optimized patient care. Protocols may be based on accumulated experience, literature reviews, and respected medical opinions. When necessary, dose estimation can be facilitated by documenting relevant technique factors [16] and machine-recorded dose surrogates, such as kerma-area product (also known as dose-area product) and cumulative reference-point air kerma [18]. For nuclear medicine procedures, the conceptus dose can be estimated from published tables of organ doses per unit of administered activity by radiopharmaceutical [19].

For radiological examinations, the highest radiation exposure to the conceptus occurs when the abdominal/pelvic region is exposed to the primary X-ray beam.

Radiation exposure parameters may be reduced. A degree of compromise in image quality is acceptable, although image quality must not fall below the level required for diagnosis. CT exposure parameters should be determined prior to imaging by radiologists in collaboration with a Qualified Medical Physicist.

Nearly all abdominal/pelvic radiologic procedures can be modified to reduce radiation exposure to a pregnant patient and conceptus, including reducing the number of images or limiting CT phases through the abdomen/pelvis. When possible, imaging should be confined to the area of interest to avoid unnecessary pelvic exposure.

Improvements in imaging equipment can also aid in reducing radiation exposure to the conceptus. One example is automatic exposure control software on multirow-detector CT (MDCT) scanners, which limit patient exposure by instantaneously modifying X-ray tube output to produce diagnostic images at a preset noise level. In the MDCT assessment of abdominal/pelvic trauma, the data from a single phase through the patient's body provide both a comprehensive evaluation of the abdominal contents and diagnostic-quality reconstructed images of the spine, eliminating the need for additional series. CT scanners with iterative reconstruction techniques have improved image quality and reduced radiation dose in CT relative to the filtered back-projection techniques. Historically shielding was provided to wrap the pelvis of the pregnant patient during nonpelvic CT may reassure and support the emotional well-being of the patient. The dose to the gravid uterus is primarily from internal scatter and can

actually be increased by the use of shielding. The use of shielding is no longer recommended [12,13,20,21].

For nuclear medicine/PET procedures, the patient and fetal radiation dose depends on administered activity, the radiopharmaceutical's physical and biological half-lives, particle and photon energies, their relative abundance, radiopharmaceutical biological distribution, and biokinetics. Reduction of the patient and fetal dose can be achieved by decreasing the administered activity and employing means that promote radiopharmaceutical excretion of the administered compound. Reduced count rate caused by reduced administered activity can be offset by increasing scan time. Additionally, the use of more efficient scanners that employ novel detectors, collimator designs, larger axial extent, and improved image reconstruction techniques has allowed for a reduction of injected activity (and hence organ doses) by about 50% without affecting image quality [22,23]. Discharge instructions for nuclear medicine diagnostic examination patients do not require any special instructions regarding radiation risk to the patient's family or friends or to the public.

All protocols for imaging the pregnant patient should be evaluated by imaging physicians and qualified medical physicists to estimate dose to a conceptus prior to implementation. This can determine whether the dose savings have been achieved and calculate the magnitude of the risk relative to the anticipated benefits.

Further imaging should only be obtained after collaborative consultation of the interpreting radiologist and the referring physician.

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

When a patient is discovered to be pregnant after having undergone an imaging procedure using ionizing radiation, counseling should be conducted to provide information to allow objective assessment of the possible risk to the conceptus. Most potential risks are very small and are similar to normally accepted risks of pregnancy, below the threshold for serious concern. Counseling statements such as, "There is a small chance your child will develop cancer or a birth defect" are honest but unnecessarily alarming because they are void of any indication the child will be healthy. To be less alarming and more complete, one may say, "Your child will have nearly the same chances of living a healthy life as any other child under similar medical circumstances. The risk your child might develop cancer from this imaging procedure is very small. The risk of a birth defect from this imaging procedure is negligible or nonexistent." If a quantitative evaluation is requested, it is reasonable to say, "Compared to any other child in similar medical circumstances, the chances of being healthy are about or better than 99% of the chances that others have." (Note: this does not mean that the chances of being healthy are better than 99% because, for example, the risk of nonradiation-related congenital malformation is 3% or higher.)

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

A. Risk Assessment

Before meaningful risk assessment can take place, certain information should be gathered, including:

1. The age of the conceptus at the time of the examination.
2. A reasonable estimate of the absorbed dose to the conceptus.

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

B. Radiation exposure prior to conception

For exposures to ionizing radiation prior to conception, genetically heritable risks have not been documented in the human population. The heritable risks to progeny from diagnostic levels of radiation are not a realistic concern [24].

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

C. Radiation exposure to at less than 2 weeks postconception

In the first 10 to 14 days after conception, the only potential risk is induced termination of the pregnancy. Doses normally delivered from diagnostic radiologic and nuclear medicine procedures have not been associated with such an effect [4,5]. Doses from diagnostic fluoroscopy of the pelvis, CT, or multiple pelvic radiographic

examinations are not likely to induce termination of pregnancy [4]. Furthermore, numerous cases of exposures involving typical radiological, nuclear medicine, and PET procedures during this conceptus development interval have not documented any corresponding increase in the rate of fetal anomalies [17]. However, in the population of patients not exposed to radiation, approximately 50% of all conceptions are not viable and are spontaneously lost [25]. This is exhibited typically as a late or missed menstrual period, and the patient might not have known that they were pregnant. There is no recommended medical intervention for this situation. Medical advice to the patient should be to seek standard obstetrical care.

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

D. Radiation exposure between 3 weeks and 15 weeks postconception

During this period, the risk to the conceptus should be evaluated based on the imaged body part(s) and the delivered dose.

1. Radiologic procedures outside the abdomen/pelvis

For diagnostic radiologic procedures outside the abdomen/pelvis, conceptus is exposed only to scattered radiation characteristically resulting in a very low dose. Only under unusual circumstances does the conceptus incur significant radiation exposure. When standard precautions are taken to avoid direct irradiation of the abdomen/pelvis through the use of proper patient positioning and X-ray beam collimation, the dose delivered does not pose significant risk to the conceptus.

2. Radiologic procedures of the abdomen/pelvis

For typical radiologic examinations of the abdomen and/or pelvis, the dose to the conceptus is usually well below any threshold that may induce developmental abnormalities. The only potential risk might be a slight increase in the risk for cancer later in life. Such a risk is very small and under normal circumstances would not justify any medical intervention.

Most radiographic examinations deliver much less than 20 mGy to a conceptus. A dose of 20 mGy represents an additional projected lifetime risk of not greater than 40 additional cancers per 5,000 babies, or about 0.8%. In other words, there is above 99% likelihood the conceptus will be unaffected by the radiation. Most scientific research show this level of risk to be negligible.

For diagnostic fluoroscopy of the abdomen/pelvis, doses may be more substantial but are not likely to exceed the threshold for induced malformation (more than 100 mGy) in all but exceptional cases. A calculation of the absorbed dose by a Qualified Medical Physicist is recommended. An assessment of the risk based on absorbed dose and gestational age is recommended before definitive discussion with the patient.

CT studies can confer significant radiation exposure. Currently, the conceptus dose under well-managed conditions for a single-phase study of the abdomen/pelvis is less than 35 mGy and typically about 10 to 25 mGy. This low exposure would not warrant interruption of pregnancy. Calculation of the dose by a Qualified Medical Physicist is appropriate.

Prior to definitive counseling of the patient, a radiation dose calculation by a Qualified Medical Physicist is recommended for patients with pregnancies between 3 and 15 weeks postconception who underwent multiple abdominal and pelvic CT examinations that directly exposed the conceptus.

For doses under 100 mGy, there are no identifiable induced developmental defects, and interruption of pregnancy is not warranted based on radiation effects [26]. At doses above 100 mGy, there is a low risk for developmental deficits (eg, gross malformations, growth retardation, mental retardation, small head size). Radiation levels in excess of 150–200 mGy carry higher and more significant risk of developmental malformations [4,26].

Consideration of intervention should include additional factors associated with the pregnancy. Situations that cumulatively lead to high doses (more than 100 mGy) are very rare and likely entail patient circumstances that further complicate, or are complicated by, the pregnancy. In these cases, a Qualified Medical Physicist should

calculate a radiation dose. The overall medical picture includes an assessment of other risks associated with normal pregnancies, risks specifically associated with the genetic background of the parents, and specific medical issues of the pregnant patient. Counseling should take into account all factors of the individual patient's circumstances, including medical, social, and personal factors.

3. Nuclear Medicine and PET procedures

The estimated radiation exposure to the conceptus from the vast majority of diagnostic NM/PET examinations is well below 20 mGy, and thus the likelihood of deterministic effects from such examinations is extremely small. A conceptus dose estimate should be provided to educate and reassure all stakeholders (including the radiologist, referring physician, and patient) In addition, these calculations will help identify rare instances when a procedure might pose a risk if performed using the standard amount of injected activity. Dose estimates should also be provided for hybrid (PET/CT and single-photon emission computed tomography/CT) examinations [16,27-30].

V. COUNSELING THE PATIENT NOT KNOWN TO BE PREGNANT AT THE TIME OF EXPOSURE

E. Radiation exposure at more than 15 weeks postconception

Potential risks to the developing central nervous system of fetuses that are more than 15 weeks postconception exist only at high doses (eg, more than 200 mGy). This exceeds the dose commonly delivered in multiple radiological, nuclear medicine, and PET examinations. During this period, the only risk to the fetus from diagnostic doses of radiation is induced cancer. The cancer risk from well-managed radiologic, nuclear medicine, and PET procedures is too small to warrant medical intervention. The lifetime attributed cancer incidence for a fetal dose of 50 mGy in this gestational period is roughly estimated at 2%; a more accurate quantification is impossible [26,31]. Conversely, there is a nearly 98% likelihood the child will be unaffected by the radiation. Most diagnostic examinations result in much lower doses to the fetus. Abdominal/pelvic CT imaging and FDG PET/CT examinations are some of the higher-dose examinations, typically delivering 10 to 35 mGy.

VI. DOCUMENTATION

Reporting should be in accordance with the [ACR Practice Parameter for Communication of Diagnostic Imaging Findings](#) [32]. Pregnancy status and the method used to determine it should be included as part of the patient's medical record in the radiology information system.

If a fetal dose estimate is required, it should be performed by a Qualified Medical Physicist and appropriately documented.

VII. EQUIPMENT SPECIFICATIONS

Equipment performance monitoring should be in accordance with the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Radiographic Equipment](#) [33], the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment](#) [34], and the [ACR–AAPM Technical Standard for Diagnostic Medical Physics Performance Monitoring of Computed Tomography \(CT\) Equipment](#) [35].

VIII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement>).

To provide foreknowledge of the potential radiation doses delivered, an evaluation of the likely doses delivered to the conceptus of a patient in early pregnancy by protocols involving diagnostic examination of the abdomen/pelvis should be performed to ensure that the delivered dose is within acceptable standards for that type of examination. For example, the conceptus dose from a CT protocol of the pelvis should not exceed 50 mGy

and preferably should be below 30 mGy. (Note: testing a protocol requires that the cumulative dose from all exposures of the protocol be assessed, not just that from a single view, single procedure, or single phase of that protocol.)

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APPENDIX A

Potential Radiation Effects to a Conceptus/Fetus

Radiation effects can be classified into 2 categories, deterministic and stochastic.

A. Deterministic Effects

Deterministic effects are observed only if relatively large doses are applied and multiple cells are involved. Deterministic effects are the result of cell damage and do not occur at doses below certain threshold levels that are determined by factors such as type of effect and the developmental stage of the organism. The severity of deterministic effects increases with increased radiation dose above the threshold. An example of a deterministic effect is radiation-induced malformations of a developing organ. Another example is skin injury, with severities ranging from skin erythema to ulceration and necrosis.

Although exceeding a threshold dose is necessary to incur a deterministic effect, available data do not always allow for a clear identification of the value for that threshold. Furthermore, for some effects thought to be deterministic, the existence of a threshold dose cannot even be established. These uncertainties arise due to limited available data involving small numbers of human subjects. Therefore, caution should be exercised so as to avoid inappropriate conclusions based on limited imprecise data.

B. Stochastic Effects

Stochastic effects can result from induced changes in a single cell and can potentially result in neoplasia or changes to reproductive genes. In contrast to deterministic effects, the severity of stochastic effects does not necessarily increase as the radiation dose increases. Stochastic effects are believed to be possible at any level of radiation exposure, with the likelihood increasing as dose increases.

C. Conceptus Age at Time of Exposure

When addressing risk to the ovum prior to and during ovulation, to the conceptus after fertilization, and to the developing fetus prior to birth, the type and the severity of potential deterministic effects and the likelihood of stochastic effects vary with the stage at the time of exposure and with the dose of radiation delivered to the uterus [36]. To adequately assess the benefit versus risk, the radiologist responsible for conducting a given examination should be aware of the potential vulnerabilities of the ovum or conceptus and the level of risk involved for a given patient undergoing a specific examination. This information should be founded on explicit existing experimental and clinical data and on well-informed recommendations. During discussions between the patient and the radiologist, this information can be used to assuage any alarm that might arise from misconceptions related to relative risk during pregnancy. It can also be used in discussions between the referring physician and the radiologist when assessing the proper course of action

for patients. The potential risks are summarized in the following sections and are outlined in Table 1.

1. The weeks prior to conception

During the preconception interval, between last menstruation and just prior to conception, the ovum is potentially susceptible to the genetic effects of radiation, a stochastic effect. Although heritable effects have been demonstrated in experiments involving large doses of radiation to populations of mice and insects, the results of these investigations demonstrate the likelihood of inducing a harmful effect from a typical dose of radiation from imaging is so small as to be undetectable in human populations. In fact, no statistically significant heritable genetic effect has ever been observed in a human population, not even in those exposed to atomic bomb radiation (mean dose approximately 200 mGy), to radiation received in radiation accidents, or as a result of medical radiation treatment. Any potential adverse effect to human progeny resulting from irradiation during the preconception interval is extremely unlikely and has not been documented as a result of imaging examinations.

2. Conception to implantation and preorganogenesis

For about 2 weeks after conception, the only established deterministic effect of radiation is induced abortion [4]. Much of the experimental data assessing this effect involved rodents. Although doses of 1,000 mGy (1 Gy) or more result in a high rate of lethality, the likelihood of inducing this effect at doses less than 50 mGy (0.05 Gy), in the upper range of diagnostic examinations, is low and not distinguishable from zero [26]. Data from animal experiments suggest the risk of embryonic loss at this stage increases incrementally between 0.5% and 1% per 10 mGy. Surviving conceptuses develop normally. Because of this "all-or-none" phenomenon, this stage of gestation is sometimes called the period of the "all-or-none effect."

If teratogenic effects exist in surviving embryos they have not been observed at doses typical of imaging examinations.

3. Organogenesis

There is increased radiosensitivity to potential teratogenic effects during the period of organogenesis. These are deterministic effects and therefore do not occur unless the dose to the embryo exceeds the threshold necessary to induce the effect. Organogenesis occurs after implantation and throughout the remainder of gestation and can be divided into 4 distinct intervals with different vulnerabilities.

a. Embryonic stage or major organogenesis (~15–56 days after conception)

In the embryonic stage, beginning near the end of the second postconception week and extending through the eighth week postconception (about 4–10 weeks menstrual age), major organogenesis occurs. This period is subject to radiation-mediated malformation of most organs and to generalized growth retardation, believed to result from cell depletion. The threshold for major effects during this period is about 100 to 200 mGy [4]. At doses in the vicinity of the threshold dose, the likelihood of observing an induced effect is relatively small. The type of vulnerability depends on the timing of radiation delivery and the developmental stage of differentiated and differentiating cells. The likelihood and severity of the effect increase as the dose increases beyond the threshold.

A finding of small head circumference, without cognitive defect, has also been reported in atomic-bomb survivors exposed during the organogenesis stage of intrauterine life [37]. There was no discernible threshold for this effect. The mechanism for such an effect is unclear, and the finding has been hypothesized to be a result of generalized growth retardation. In the dose range of diagnostic examinations (less than 0.1 Gy), the effect, if truly existing, is subtle. Small head circumference resulting from exposure to radiation secondary to diagnostic

imaging has only been identified under statistical analysis of physical characteristics in a study population. No cognitive or behavioral abnormalities have been identified [38].

b. Early fetal stage

In the early fetal stage, after the eighth and through the 15th week postconception (after the 10th and through the 17th weeks menstrual age or approximately days 56–105 postconception), the central nervous system (CNS) is very radiosensitive, due to the high neuronal mitotic rate and organized neuronal migration occurring during this time [37]. Radiation-induced CNS effects, particularly mental retardation (defined as inability to care for oneself or to make simple calculations or conversation), are among the most frequently identified teratogenic effects associated with intrauterine radiation exposure during this stage of development. The threshold dose for mental retardation has been estimated at 60 to 310 mGy, using the Japanese DS86 radiation data [39]. The broad range of the threshold estimate is a consequence of the very small sample size at this radiation level. Furthermore, this threshold range is determined on the basis of one model for statistical analysis. Higher thresholds are predicted by other models. The lowest clinically documented dose producing severe mental retardation is 610 mGy. The putative threshold is an extrapolation from data observed at higher doses. The absolute risk of mental retardation is estimated at 44% for a 1,000 mGy exposure. The threshold range for CNS effects is significantly higher than the range of doses delivered from a single well-managed imaging examinations (less than 50 mGy).

Dose-dependent radiation-mediated deficits in Intelligence Quotient (IQ) have also been observed when irradiation occurs in this interval [39]. No effects on IQ have been observed below a 100 mGy dose. Above a dose of 100 mGy, the decline in IQ is estimated at 25 to 29 points per 1,000 mGy.

Radiation exposure during the fetal period is also associated with growth retardation. Thankfully this appears to only persist beyond birth into adulthood when doses are well beyond those normally delivered by radiological examinations.

c. Mid fetal stage

Beginning with the 16th week and extending through the 25th week postconception, the risk for mental retardation remains but is less pronounced than in the preceding 8–15-week stage. The estimated threshold dose for severe mental retardation is 250 to 280 mGy. The decline in IQ is also less pronounced compared with the early fetal stage. Beyond a dose of 100 mGy, the decline is estimated at 13 to 25 points per 1,000 mGy. The threshold dose during this period for other types of malformation is about 1,000 mGy.

d. Late fetal stage

After the 25th postconception week of pregnancy, exceptionally high doses of radiation are required to induce deterministic effects. During this stage of development the risks associated with medical imaging are exclusively stochastic risks, principally the potential for induced neoplasia. These are discussed below.

D. Risk of Cancer Induced by Imaging Procedures Using Ionizing Radiation

The relative risk of cancer development secondary to in utero exposure has been debated in the scientific literature for years [31]. From studies on the offspring of mothers who received diagnostic pelvic radiation during pregnancy, there appears to be an increased risk of childhood leukemia with exposures as low as 10 mGy, although firmly establishing causality has been difficult. The findings in offspring of Japanese atomic bomb survivors are not consistent with the case-control studies of medical in utero irradiation. After an

exposure of 10 mGy to a newborn, the lifetime risk of developing childhood malignancy, particularly leukemia, may increase from a background rate of 0.2%–0.3% to 0.3% to 0.7%, whereby the estimate varies depending on methods used to assess risk from statistical data.

The lifetime risk of developing radiation-induced cancer from in utero radiation exposure has been estimated to be similar, but due to significant uncertainties in the estimate, it is only possible to conclude that doses in the vicinity of 10 mGy are associated with a detectable increased risk of childhood cancer. The relationship of vulnerability to gestational age is also uncertain; available data currently show risk to be relatively constant from the beginning of major organogenesis to term.

APPENDIX B

Sample Policy and Form Regarding Pregnancy Determination

All technologists, prior to performing an abdominal or hip X-ray or abdominal or pelvic CT procedure, should query patients with reproductive potential about the possibility of pregnancy. The following or a similar form is suggested, to be filled out before any exposure and then entered into the medical record. The examination should proceed only if the patient's last complete menstrual period started less than 4 weeks prior to the examination date and if the patient responds "no" to the second question. If either condition is not met, a radiologist should be notified before proceeding with the study or consent should be acquired for a pregnancy test. The technologist should proceed according to verbal or written policy instructions of the radiologist. If a required pregnancy test is refused, the radiologist should provide instructions on how to proceed.

This form and the one in Appendix C are provided as EXAMPLES ONLY. They are not intended to be used without first consulting with legal counsel regarding your facility, local, or state law requirements.

PRE-EXAMINATION PREGNANCY DETERMINATION

PATIENT:_MRN: DATE: TIME:

TECHNOLOGIST:

Pregnancy Check

For patients of reproductive age (postmenarche to menopause), indicate the patient's response to the following 2 questions:

1. What was the first day of your last complete menstrual period?

Month_Day_Year

2. To the best of your knowledge, are you pregnant (or do you think you could be)?

Yes_No_Possibly

Patient/guardian signature:_Date:

Pregnancy testing required (per department guideline)? Yes_No

Type: urine serum

Pregnancy Test Performed in Diagnostic Imaging

Verbal consent to test from:_Patient_Guardian (if appropriate) Results:_Negative_Positive

Testing tech/nurse initials:

Pregnancy Test Performed Outside the Radiology Practice

Test date:

Results:_Negative_Positive

Source of results:

APPENDIX C

Sample Consent Form for Radiologic Procedure in Patients Known to be Pregnant

(This informed consent form applies only to single examination diagnostic radiographic studies and single-phase abdominal-pelvic CT studies.)

INFORMED CONSENT FOR ABDOMINAL OR PELVIC X-RAY EXAMINATION OF PREGNANT OR POTENTIALLY PREGNANT PATIENT

PATIENT NAME: _____ MRN: _____

DATE: _____ TIME: _____

To the patient:

You are scheduled for an X-ray examination of your body. You and your unborn child will be exposed to X-rays. The risk to you is very small. The examination might slightly increase the possibility of cancer later in the child's life, but the actual potential for a healthy life is very nearly the same as that of other children in circumstances similar to yours but who are not provided the benefit of this medical examination. The examination does not add to risks for birth defects or miscarriage. Your physician has considered the risks associated with this examination and believes it is in your and your child's best interests to proceed. Any questions you have regarding this examination should be directed to the radiologist.

Radiologist or referring physician:_Date:

I,_, have read and fully understand the above and hereby give my consent to have an X-ray procedure performed. I have been informed of the estimated risks to my embryo or fetus.

Patient/guardian signature:_Date:

This signed informed consent form shall be placed in the patient's medical record.

APPENDIX D

Pregnancy Screening

A. General Criteria

1. Patients of childbearing potential will be screened for pregnancy.
2. Screening of patients <12 will be conducted at the discretion of the patient's care providers.

B. Policy Exceptions This policy does not apply to:

1. Emergency procedures and examinations
2. Patients for whom pregnancy is anatomically impossible
3. Patients receiving human chorionic gonadotropin (hCG) therapy
4. Patients undergoing diagnostic/therapeutic oncology procedures (eg, bone marrow biopsy, lumbar puncture, intrathecal chemotherapy) .

C. Defining Procedures and Examinations Subject to Pregnancy Screening

1. Radiologic procedures that pose a substantial risk to pregnancy or fetus

Based on the *American College of Radiology's ACR-SPR Practice Parameter for Imaging Pregnant or Potentially Pregnant Patients with Ionizing Radiation*, the risks of diagnostic exams that could

potentially harm the fetus or a pregnancy are:

a. Negligible Risk

These include all examinations that do not directly involve exposure of the pelvis (other than Interventional Radiology; IR).

b. Low Risk

i. No probable (ie, deterministic) radiation effect, but a theoretical (ie, stochastic) risk.

ii. These include abdomen/pelvic images and single-phase abdominal/pelvic CT.

c. Substantial Risk

i. Examinations with possible deterministic radiation effects during some portions of the pregnancy.

ii. In general, these include multiple-phase abdominal and/or pelvic CT scans and any examination that involves an unpredictable duration of fluoroscopy including all IR procedures.

d. See APPENDIX E: Imaging Examinations Requiring Pregnancy Testing.

2. Elective surgical procedures performed in the perioperative area

Note: Because of the operational complexity of limiting screening by laboratory test only to those procedures believed to pose a substantial risk (such as abdominal and pelvic procedures and procedures involving radiation exposure due to use of C arm), all patients of reproductive potential scheduled for elective procedures in the perioperative area (See section I.A.1.a-f above) will be screened for pregnancy by urine or serum test.

D. Pregnancy Screening Procedure

1. Negligible risk

For negligible risk examinations (eg, chest or extremity imaging), the pregnancy screening is unnecessary.

2. Low risk: Prior to the radiology examination involving ionizing radiation categorized as low risk to a pregnancy or fetus: (procedures expected to result in a conceptus dose < 50 mGy):

a. The patient should be asked, *Is there any possibility you could be pregnant? Have you had a period in the last 4 weeks?*

b. This question should be posed when the patient is by themselves, outside of hearing of those accompanying them.

c. Document response in the patient's chart.

d. If the patient response is other than "no" or is thought to be unreliable for any reason, an hCG test should be performed.

3. Substantial risk

a. Examinations with possible deterministic radiation effects during some portions of the pregnancy (ie, dual-phase abdominal and/or pelvic CT), and any examination that involves an unpredictable duration of fluoroscopy including IR procedures, procedures expected to exceed a conceptus dose of 50 mGy.

b. Obtain a urine hCG test prior to examination.

c. The results are valid for 7 days or the length of an inpatient stay.

d. If pregnancy testing is refused, contact the attending physician and Subsequent performance of the examination/procedure will be at the discretion of the attending physician or radiologist.

E. Positive Pregnancy Test Result

Note: The following may vary by jurisdiction, but in general, pediatric patients may have the right to control decisions regarding their sexuality/reproductive rights and therefore have a legal right to confidentiality. If so, test results cannot be disclosed to parents/guardians without the patient's permission.

The ordering provider and radiologist may recommend to the patient, parent, or guardian that the imaging examination may still be done; for example:

1. Low exposure examinations The benefit of providing the diagnostic imaging study outweighs the very low potential risk to the fetus during a well-shielded patient examination.

2. Examinations categorized as substantial risk Risk versus benefit dialogue provides rationale to move

forward with the examination (ie, no other study provides the needed information and it is not prudent to delay until after childbirth).

APPENDIX E

Substantial Risk Imaging Examinations for which Pregnancy Testing is Recommended

- Diagnostic, Interventional, or Intraoperative procedures involving fluoroscopy
- Multiphase CT or CT angiography of abdomen, pelvis, or both
- CT-guided interventional procedures of the abdomen
- Any procedure expected to result in a conceptus dose over 50 mGy

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised, or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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