

DEPARTMENT OF RADIOLOGY AND BIOMEDICAL IMAGING STANDARD OPERATING PROCEDURES

Administrative SOP:	Patient Radiation Protection & Safety (Including Pregnancy)		
Reviewed:	3/05, 9/06, 2/08, 10/08, 3/11, 7/11, 2/12, 9/12, 9/13, 9/14, 9/15, 3/16, 10/18, 7/19, 10/21, 11/22, 1/23, 5/23, 4/24	Revised / Reviewed	5/24
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PURPOSE:

The objective of performing medical imaging in a pregnant patient is to minimize patient and embryo/fetal radiation exposure to the greatest extent possible while still obtaining a diagnostic test. This Standard Operating Procedure (SOP) applies to all Yale New Haven Health System Radiology sites.

PREGNANCY TESTING APPLICATION/GUIDELINES

- I. Per YNHHS Clinical Practice Manual: Pre-procedure Pregnancy Testing for Non-Emergent Case:
 - a. All patients anatomically capable of bearing a child (female assigned sex at birth) who have started their menses or are between the ages of **10 and 55** undergoing a non-emergent radiology exam listed in Appendix A (which may impart >50 mGy to the embryo/fetus, involves intravenous contrast for MRI or involves radiopharmaceuticals) must have pregnancy testing. A urine hCG or serum hCG pregnancy test are both valid, including Point of Care (POC) Pregnancy testing where available.
 - b. **For ED and Inpatients**, a urine or serum pregnancy test should be performed in the inpatient or ED unit prior to the radiology test (however urine pregnancy testing in the radiology department may be permitted if necessary). **For outpatients**, a laboratory pregnancy test or POC urine pregnancy test can be performed prior to the radiology test. If the patient cannot provide a urine sample for testing, or if the result is equivocal, a radiologist should be informed. Exam should be delayed until serum hCG results are available (unless testing can be waived per below). Either the referring physician or radiologist can place an order for the pregnancy test if needed.
- II. Waivers
 - a. The patient who has decision making capacity and is anatomically capable of bearing a child aged 18 through 55 may decline pregnancy testing by completing the *Yale New Haven Health Waiver for Pregnancy Testing (F6460)*.
 - i. Pediatric patients ages 10-17 (or their parent/guardian) or adult patients that do NOT have decision making capacity (including their guardian/proxy) **cannot** waive testing unless a condition is met below to allow waiver of testing.
 - b. A pregnancy test or signed Waiver for Pregnancy Testing Form is NOT required if:
 - i. The patient has a documented hysterectomy or bilateral ovarian removal. Any patient anatomically capable of bearing a child who has an implanted IUD, Essure device or tubal ligation will follow standard protocol as these methods are not 100% effective in preventing a pregnancy.
 - ii. The patient is less than two (2) weeks after pregnancy completion (includes miscarriage and D+C procedure for pregnancy)
 - iii. A medical emergency exists whereas a pregnancy test would delay care, which is documented in patient's medical record
 - iv. The patient has received a documented pregnancy test in the past 24 hours (urine) or 72 hours (serum)
 - v. The patient has received a pregnancy test during their current hospitalization, whereas the test is not necessary to repeat.
 - vi. The radiology exam is deemed **medically emergent** by the referring clinician where the benefit of rapid imaging outweighs any loss of time for pregnancy testing and potential risk of fetal exposure to radiation, MRI contrast agent or radiopharmaceutical. This can also be discussed with the consulting radiologist

- and should be documented in the medical record.
- vii. The ordering provider may also selectively defer pregnancy testing in non-emergent situations and document medical condition(s) that preclude testing in the patient's medical record. This ONLY applies to patients with decision making capacity who are anatomically capable of bearing a child ages 18-55. Patients ages 10-17 or patients > 18 with a legal guardian **cannot** have testing waived with this exemption clause.
 - c. Pregnancy testing is only required for radiology exams listed below in Appendix A. Other Radiology exams do NOT require a pregnancy test, but if the patient is known to be pregnant and has questions about the examination the technologist should consult with a radiologist as needed.

Appendix A: Radiology tests that require pregnancy testing (or exemption listed above)

- CT involving the abdomen and/or pelvis including lumbar spine
- Any exam involving intravenous MRI gadolinium based contrast
- Fluoroscopic exams which include the pelvis e.g.: VCUg, hysterosalpinogram, barium enema, small bowel series, lumbar puncture, Interventional Radiology procedures involving abdomen or pelvis
- Invasive/surgical or other radiology procedures with general anesthesia or MAC; excludes IV insertion for routine IV contrast exams
- All Nuclear Medicine and PET exams, except brain death scans which is optional. Note: all Nuclear Medicine therapy procedures require a SERUM Beta hCG within 48 hours. Patients may not sign a waiver. If a total hysterectomy or bilateral ovarian removal is clearly documented, the patient will be exempt from requiring a pregnancy test.

POSITIVE OR INDETERMINATE PREGNANCY RESULTS AND ACTIONS NEEDED

- I. If a patient is determined to be pregnant the procedure below is to be followed:
 - a. Contact the referring physician to inform them of the pregnancy test results
 - i. Results should be discussed directly with patient, not in presence of parent/guardian, who are under 17 years old as long as the patient is deemed cognitively mature enough to understand by the radiologist or ordering provider. The patient can request results to be disclosed to parent/guardian.
 - ii. Positive pregnancy tests in patients 12 or younger (in State of Connecticut) or 15 or younger (in State of Rhode Island) should be reported to Department of Children and Families (DCF). Radiologists should first consult with social worker (SW) or Case Manager (CM) who can assist in filing report with DCF. Positive pregnancy test results are considered potential markers of abuse in patients in these ages.
 - iii. If a YNHHS Radiologist requires guidance and/or assistance informing a minor patient, they can call Labor & Birth as listed below. This service is not available at other YNHHS sites.
 1. YNHHS YSC Labor & Birth: 203-688-2309
 2. YNHHS SRC Labor & Birth: 203-789-3461
 - b. For those exams listed in **Appendix A**, the exam should not be performed except in a medical emergency. If an emergency is presented and the patient is determined to be

pregnant (or indeterminate serum pregnancy test), the procedure below is to be followed:

- i. The technologist will inform the radiologist that the patient is pregnant or potentially pregnant.
 - ii. The radiologist will contact the referring physician to ascertain the emergent status of the exam and consult in the decision to proceed, limit, or cancel the exam. Site Radiation Safety Officer (RSO) or Physicist can be consulted to calculate fetal dose for any Fluoroscopic, CT or Nuclear Medicine exams.
 - iii. If a decision is made to proceed with the exam emergently as ordered or as modified by the radiologist, the radiologist will discuss with the patient the risk vs. benefit associated with the exam based on pregnancy status, if possible.
 - iv. Both the patient and radiologist will sign Standard Consent form for Operation or Special Procedure after reviewing risks/benefits of exam. **This can be waived if medical emergency or if patient unable to provide consent and test deemed medically necessary by radiologist and ordering clinician.**
 - v. The technologist is responsible for documenting the pregnancy status, and the authorizing MD or radiologist in the RIS Study Notes. Radiology staff will scan the signed YNHHS consent form into the patient's chart.
 - vi. The radiologist should include pregnancy status and the decision to proceed with the exam in the report for documentation in the patient's medical record whenever feasible.
- c. For exams involving ionizing radiation not listed in Appendix A, the exam is performed in a normal manner. See below on the use of shielding. Routine use of gonadal or pelvic shielding is not needed for any x-ray, flouroscopy or CT exam, but can be offered if patient requests.
- II. If it is discovered that a patient is pregnant **after** the exam is performed:
- a. The RSO or Physicist should be contacted for calculating fetal dose for exams listed in Appendix A. Dose calculation is optional for all other exams.
 - b. A patient incident report must be completed in RL Solutions event reporter.
 - c. The radiologist will be notified and an addendum will be added to the exam report to document discussions with the referring physician and/or patient, and fetal dose, if indicated
- III. If the patient has an indeterminate hCG result:
- a. Technologist will ask patient if there is any chance of pregnancy
 - i. If yes (chance of pregnancy), procedure for positive pregnancy status should be followed
 - ii. If no, Technologist can document no chance of pregnancy in study notes and proceed with exam OR have patient sign a standard consent form.

DOCUMENTATION

- I. Technologist
 - a. The Technologist is responsible for documentation in the Electronic Health Record (EHR)/Epic
- II. Radiologist
 - a. The radiologist is responsible for documentation in the exam report

PATIENT SHIELDING

- I. Routine use of gonadal/pelvic lead apron shielding for patients is not needed for any x-ray, fluoroscopy, or CT exams
 - a. Routine patient shielding is no longer the standard of care according to the American College of Radiology, American Association of Physicists in Medicine and National Council on Radiation Protection and Measurements. Shielding can be provided to the patient upon request for both pregnant and non-pregnant patients.

RELEVANT CONTACT INFORMATION

Delivery Network	Phone Number
Bridgeport (BH)	203-384-3186 (SW/CM) 203-384-3256 (ED)
Greenwich (GH)	203-863-3336 (CM) 203-863-3637 (ED)
Yale New Haven Hospital (YNHH)	203-688-2195 (SW) 203-688-2222 (Adult ED) 203-688-3333 (Pedi ED)
Lawrence + Memorial Hospital (LMH)	860-442-0711 ext. 2614 (CM/SW) 860-442-0711 ext. 2261 (ED)
Westerly Hospital (WH)	401-348-3258 (CM) 401-596-6000 ext. 1 (ED)

Connecticut DCF	Rhode Island DCF
860-550-6515 or 800-824-2288	1-800-742-4453

EFFECTS OF GESTATIONAL AGE AND RADIATION DOSE ON RADIATION-INDUCED TERATOGENESIS

Gestational Period	Effects	Estimated Threshold Dose*
Before implantation (0–2 weeks after fertilization)	Death of embryo or no consequence (all or none)	50–100 mGy
Organogenesis (2–8 weeks after fertilization)	Congenital anomalies (skeleton, eyes, genitals)	200 mGy
	Growth restriction	200–250 mGy
Fetal period	Effects	Estimated Threshold Dose*
8–15 weeks	Severe intellectual disability (high risk) [†]	60–310 mGy
	Intellectual deficit	25 IQ-point loss per 1,000 mGy
	Microcephaly	200 mGy
16–25 weeks	Severe intellectual disability (low risk)	250–280 mGy*

*Data based on results of animal studies, epidemiologic studies of survivors of the atomic bombings in Japan, and studies of groups exposed to radiation for medical reasons (eg, radiation therapy for carcinoma of the uterus).

[†]Because this is a period of rapid neuronal development and migration.

Modified from Patel SJ, Reede DL, Katz DS, Subramaniam R, Amorosa JK. Imaging the pregnant patient for nonobstetric conditions: algorithms and radiation dose considerations. *Radiographics* 2007;27:1705–22.

FETAL RADIATION DOSES ASSOCIATED WITH COMMON RADIOLOGIC EXAMINATIONS

Type of Examination	Fetal Dose* (mGy)
<i>Very low-dose examinations (<0.1 mGy)</i>	
Cervical spine radiography (anteroposterior and lateral views)	<0.001
Head or neck CT	0.001–0.01
Radiography of any extremity	<0.001
Mammography (two views)	0.001–0.01
Chest radiography (two views)	0.0005–0.01
<i>Low- to moderate-dose examinations (0.1–10 mGy)</i>	
Radiography	
Abdominal radiography	0.1–3.0
Lumbar spine radiography	1.0–10
Intravenous pyelography	5–10
Double-contrast barium enema	1.0–20
CT	
Chest CT or CT pulmonary angiography	0.01–0.66
Limited CT pelvimetry (single axial section through the femoral heads)	<1
Nuclear medicine	
Low-dose perfusion scintigraphy	0.1–0.5
Technetium-99m bone scintigraphy	4–5
Pulmonary digital subtraction angiography	0.5
<i>Higher-dose examinations (10–50 mGy)</i>	
Abdominal CT	1.3–35
Pelvic CT	10–50
¹⁸ F PET/CT whole-body scintigraphy	10–50

Abbreviations: CT, computed tomography; PET, positron emission tomography.

*Fetal exposure varies with gestational age, maternal body habitus, and exact acquisition parameters.

Note: Annual average background radiation = 1.1–2.5 mGy, ¹⁸F = 2-[fluorine-18]fluoro-2-deoxy-D-glucose.

Modified from Tremblay E, Therasse E, Thomassin-Naggara I, Trop I. Quality initiatives: guidelines for use of medical imaging during pregnancy and lactation. *Radiographics* 2012;32:897–911.

RELATED POLICIES

<https://www.acr.org/-/media/acr/files/practice-parameters/pregnant-pts.pdf>

<https://www.acog.org/Clinical-Guidance-and-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Guidelines-for-Diagnostic-Imaging-During-Pregnancy-and-Lactation?IsMobileSet=fals>

[NCRP Recommends Against Routine Gonadal Shielding | American College of Radiology \(acr.org\)](#)

REFERENCES

Guidelines for Diagnostic Imaging During Pregnancy and Lactation. Committee Opinion No. 723. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017; 130:e210-6.