

DEPARTMENT OF RADIOLOGY AND BIOMEDICAL IMAGING STANDARD OPERATING PROCEDURES

<b>Administrative SOP:</b>	<b>Patient Radiation Protection &amp; Safety (Including Pregnancy)</b>		
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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 female inpatients, outpatients and ED patients 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.
    - i. For all other diagnostic radiology exams involving ionizing radiation NOT listed in Appendix A, pregnancy status verification by performing technologist via signed waiver or urine/serum hCG is NOT required.
  - 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. Pregnancy testing can be waived if:
  - a. The patient is 18 years or older, has capacity to provide informed consent, and does not want to have a pregnancy test done. A waiver may be signed in this setting. *Yale New Haven Health Waiver for Pregnancy Testing (F6460)*. \*Pediatric patients ages 10-17 (or their parent/guardian) **cannot** waive testing.
  - b. The patient has a documented hysterectomy or bilateral ovarian removal or meets medical definition of post-menopausal (no menses for over one year and NOT taking any type of hormone contraception). All other female patients will allow standard protocol including those with IUD, Essure device or tubal ligation as they are not 100% effective.
  - c. A negative **serum** pregnancy test within 72 hours or negative **urine** test within 24 hours of the exam is already available for ED or outpatients. Inpatients do not need repeat testing if a pregnancy test is available from the current admission.
  - d. The test 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.
  - e. The ordering provider may selectively defer pregnancy testing and document medical condition(s) that preclude testing in the patient's medical record. This **ONLY** applies to competent females ages 18-55. Female patients ages 10-17 or patients > 18 with a legal guardian **cannot** have testing waived with this exemption clause.

- f. The patient is undergoing a test that does NOT require pregnancy testing. Exams that require testing are listed below in Appendix A. Other tests do NOT require a test **but** if patient is known to be pregnant and has questions on the examination the technologist can 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 anesthesia or monitored anesthesia care (MAC); excludes IV insertion for routine IV contrast exams. Note: pregnancy testing is NOT required if patient is getting moderate sedation provided by Radiology team.
- 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, documented post-menopausal, 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 or potentially pregnant (resulted indeterminate hCG), the procedure below is to be followed:
- a. Contact the referring physician to inform them of the 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. The patient can request results also disclosed to parent/guardian.
    - ii. Positive pregnancy tests in women 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 YNHH 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. YNHH YSC Labor & Birth: 203-688-2309
      - 2. YNHH 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 dictating the exam will include pregnancy status and the decision to proceed with the exam in the report for documentation in the patient's medical record.
- c. For exams not listed in Appendix A involving ionizing radiation of the abdominal/pelvic regions (i.e. XR KUB, XR Lumbar Spine), the Technologist will inform the radiologist that the patient is pregnant. The following steps are to be followed:
    - i. The radiologist will decide whether to proceed, limit or cancel the exam. Written informed consent is not necessary given insignificant fetal exposure for these exams, however a radiologist will be available to discuss the exam if needed.
    - ii. The technologist will document the patient's pregnancy status and the radiologist's instructions in the RIS study notes.
    - iii. The radiologist dictating the exam will include pregnancy status and the decision to proceed with the exam in the report for documentation in the patient's medical record.
  - d. For all other exams involving ionizing radiation not listed in Appendix A or including the abdominal/pelvic region, 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 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

## DOCUMENTATION OF RESULTS

- 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 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.
  - b. Shielding can be provided to the patient upon request for both pregnant and non-pregnant patients.

**RELEVANT CONTACT INFORMATION**

<b>Delivery Network</b>	<b>Phone Number</b>
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)

<b>Connecticut DCF</b>	<b>Rhode Island DCF</b>
860-550-6515 or 800-824-2288	1-800-742-4453

**EFFECTS OF GESTATIONAL AGE AND RADIATION DOSE ON RADIATION-INDUCED TERATONGENESIS**

<b>Gestational Period</b>	<b>Effects</b>	<b>Estimated Threshold Dose*</b>
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
<b>Fetal period</b>	<b>Effects</b>	<b>Estimated Threshold Dose*</b>
8–15 weeks	Severe intellectual disability (high risk) <sup>†</sup>	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).

<sup>†</sup>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 (&lt;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
<sup>18</sup> 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, <sup>18</sup>F = 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.