Administrative Policy Title:	**PATIENT RADIATION PROTECTION & SAFETY (INCLUDING PREGNANCY)**	**Manual Code:**	**I.12**
Original Policy Date	3/05, 9/06, 2/08, 10/08, 3/11, 7/11, 2/12, 9/12, 9/13, 9/14, 9/15	**Revised/ Reviewed**	3/16
Approved By:	**Cheryl Granucci, Director** **Rob Goodman, MD, Executive Vice Chairman** **Adel Mustafa, Chief Physicist**	Pages	1 of 9

I. POLICY

It is the objective of the department of radiology and biomedical imaging to minimize patient dose and to avoid embryo/fetal radiation exposure to the greatest extent possible.

II. PROCEDURE

A. General Patient Radiation Protection and Safety Guidelines

1. All YNHH patients (adult and pediatric) will be provided with gonadal shielding and other appropriate lead shielding whenever applicable; *Attachment I.12 A - Patient Shielding Guidelines in CT.*
2. Optimal study acquisition parameters will be used, taking into consideration achieving the highest image quality at the lowest possible radiation dose.
3. *Attachment I.12C-Table of Estimated Fetal Radiation Exposure* for various radiology exams will be consulted as a reference on potential fetal doses.

B. Pregnancy Guidelines;
Per YNHH Clinical Practice Manual: *Pre-procedure Pregnancy Testing for Non-Emergent Case. https://ynhh.ellucid.com/documents/view/7929*

1. All Female inpatients, outpatients and ED patients who have started their menses or are between the ages of 10 and 60 undergoing a non-emergent radiology exam listed in Appendix A below (which may impart > 50 mGy to the embryo/fetus, involve intravenous contrast for MRI or radiopharmaceuticals) will be required to take a pregnancy test, unless:
    a. The patient is 18 years or older, has capacity to provide informed consent, and does not want to have a pregnancy test done then they may sign a waiver. *Yale New Haven Hospital Waiver for Pregnancy Testing (F6460).* Pediatric patients ages 10-17 (or their parent/guardian) cannot waive testing.
    b. The patient has a history of hysterectomy or bilateral ovarian removal. All other female patients will follow 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 urine test within 24 hours of the procedure is available for ED or outpatients. In-patients do not

need repeat testing if a negative serum or urine pregnancy test is available from the current admission.

d. A test for an inpatient or ED patient 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.

For ED and in-patients, a urine or serum pregnancy test should be performed on their inpatient or ED unit prior to the radiology test (however urine pregnancy testing in the radiology department may also be permitted if necessary). For outpatients, a point of care urine test will be performed while in the radiology department.

Either the referring physician or radiologist will place an order for the pregnancy test. Dept of Lab Medicine *Attachment I.12D. Procedure for Point of Care Urine hCG Pregnancy Testing.* *https://ynhh.ellucid.com/documents/view/200*

e. In the case of positive test findings, please call Labor & Birth for guidance and assistance with informing the patient and their referring physician of the test results. This service is available 24/7, and for all imaging sites.
(a) The York Street campus – via Labor & Birth at 688-2309
(b) The Saint Raphael campus – via beeper 0633

2. Female <u>outpatients</u> who are between the ages of 10 and 60 undergoing radiology exams <u>not</u> listed in Appendix A will be discretely asked if they are or might be pregnant. If yes, appropriate steps will be taken as outlined in section lll.A of this policy and related attachments.

Appendix A.

- CT involving the abdomen and/or pelvis including CT lumbar spine
- Any exam involving intravenous MRI contrast
- Fluoroscopic exams which include the pelvis e.g.: VCUG, hysterosalpinogram, barium enema, small bowel series, lumbar puncture, Interventional Radiology procedures
- Invasive/surgical radiology procedures with anesthesia/conscious sedation; 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 <u>therapy</u> procedures require a Beta HCG; patients may not sign a waiver.

III. PREGNANCY STATUS AND ACTION

A. If a patient is determined to be <u>pregnant</u>, the procedure below is followed:

1. For those exams listed in Appendix A, the exam should not be performed except in life threatening emergencies.
    a. The technologist will inform the radiologist that the patient is pregnant.
    b. 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. The YNHH Radiation Safety Officer or radiology physicist is available for consult or to calculate fetal dose for any exams requested, especially CT and Nuclear Medicine exams.
    c. 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.
    d. If possible, both the patient and radiologist will sign form F1696 Consent for Operation or Special Procedure
    e. The technologist is responsible to document the pregnancy status and the radiologist or physician who authorized to proceed with the exam in the RIS Study Notes, and to scan in the YNHH consent form.
    f. The radiologist dictating the exam will include the pregnancy status and the decision to proceed with the exam in the report for documentation in the patient's medical record.

2. For exams involving ionizing radiation listed in Appendix B, the technologist will inform the radiologist that the patient is pregnant.
    a. The radiologist will make a decision to proceed, limit or cancel the exam. The technologist will give the patient the option to discuss the exam with the radiologist if they have questions.
    b. The technologist will document the patient's pregnancy status and the radiologist's instructions in the Radiology Information System performing provider comments section.
    c. The radiologist dictating the exam will include the pregnancy status and the decision to proceed with the exam in the body of the report for documentation in the patient's medical record.
    d. For exams involving ionizing radiation not listed in Appendix A or B, the exam is performed in a normal manner using patient protective shielding of the abdominal area. The technologist will document the patient's pregnancy status in the RIS Study Notes. 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

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Appendix B

- X-rays of any region of the abdomen or pelvis, including L-S spine
- Hip x-rays
- CT of the chest in the second and third trimester

B. If an outpatient is unsure if they are pregnant, they can have a point of care

urine pregnancy test performed or reschedule the exam.

1. In the case of positive test findings, please call Labor & Birth for guidance and assistance with informing the patient and their referring physician of the test results. This service is available 24/7, and for all imaging sites.
   Ask for the on-call attending covering the General Obstetrics Service
   (a) The York Street campus – via Labor & Birth at 688-2309
   (b) The Saint Raphael campus – via Labor & Birth at 789-3461

C. If it is discovered that a patient is pregnant after the exam is performed:

1. The YNHH Radiation Safety Officer or radiology physicist should be contacted for calculating fetal dose.

2. A patient incident report must be completed in RL Solutions Event Reporter.

3. 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.

IV. DOCUMENTATION

A. Technologist: The technologist is responsible for documentation in the Radiology Information System Study Notes.

B. Radiologist: The radiologist is responsible for documentation in the body of the exam report.

Attachment 1.12 A

Patient Shielding Guidelines in CT

To alleviate patient/family anxiety the CT Technologist will shield the pediatric patient while performing CT Scans unless the area being imaged is in question.

The adult patients will not be routinely provided with shielding. In case of special instructions or per patient request, a lead apron may be used if it does not interfere with the imaged

area.

In all situations, the shield has to be carefully placed so that it will not interfere with the imaged area

Attachment I.12C

Estimated Fetal Exposure for Various Diagnostic Imaging Methods[2]

Examination type	*Estimated fetal dose per examination (mGy)*	*Number of examinations required for a cumulative 50 mGy dose*
Plain films		
Skul	0.04	1,250
Denta	0.001	50,000
Cervical spine	0.02	2,500
Upper or lower extremity	0.01	5,000
Chest (two views)	0.0007	71,429
Mammogram	0.20	250
Abdominal (multiple views)	2.45	20
Thoracic spine	0.09	555
Lumbosacral spine	3.59	13
Intravenous pyelogram	13.98	3
Pelvis	0.40	125
Hip (single view)	2.13	23
CT scans (slice thickness: 10 mm)		
Head (10 slices)	< 0.50	> 100
Chest (10 slices)	< 1.00	> 50
Abdomen (10 slices)	26.00	1
Lumbar spine (5 slices)	35.00	1
Pelvimetry (1 slice with scout film)	2.50	20
Fluoroscopic studies		
Upper GI series	0.66	89
Barium swallow	0.06	833
Barium enema	39.86	1
Nuclear medicine studies		
Most studies using technetium (^{99m}Tc)	< 0.500	> 10
Hepatobiliary technetium HIDA scan	1.50	33
Ventilation-perfusion scan (total)	2.15	23
• Perfusion portion: technetium	1.75	28
• Ventilation portion: xenon (^{133}Xe)	0.40	125
Environmental sources (for comparison)		
Environmental background radiation (cumulative dose over nine months)	1.00	N/A

Effects of Ionizing Radiation on Conceptus[3]

PREGNANCY PHASE	WEEKS POST CONCEPTION	RADIATION EXPOSURE	POSSIBLE CONCEPTUS HEALTH EFFECTS
Pre-Implantation	0 to 2 weeks	Diagnostic exposure (less than 100 mGy (10 rad))	Embryo implantation failure; embryo death by cytogenic damage
		Greater than 100 mGy (10 rad)	Lethality
Organogenesis	2 to 7/8 weeks	Less than 50 mGy (5 rad)	No increase of significant congenital malformations above background incidence
		Greater than 100 mGy to 150 mGy (10 rad to 15 rad)	Malformations due to cell killing; growth retardation; cataracts; skeletal anomalies; central nervous system abnormalities: microcepholy, mental retardation (risk of severe mental retardation is not increased over background levels)
Fetal Development Early	8/9 weeks to 15 weeks	Less than 50 mGy (5 rad)	Cancer is the only detectable health risk
		50 mGy to 500 mGy (5 rad to 50 rad)	Dose dependent growth retardation; IQ reduction
		Greater than 500 mGy (50 rad)	Increased risk of growth retardation/spontaneous abortion; major malformation; IQ reduction; severe mental retardation
Mid	16 weeks to 25 weeks	Less than 50 mGy (5 rad)	Cancer is the only detectable health risk
		50 mGy to 500 mGy (5 rad to 50 rad)	Not likely to produce health risk except cancer
		Greater than 500 mGy (50 rad)	Increase in major malformations and spontaneous abortions; dose dependent growth retardation; IQ reduction; severe mental retardation
Late	26 weeks to delivery	Less than 500 mGy (50 rad)	Cancer is the only detectable health risk
		Greater than 500 mGy (50 rad)	Dose dependent neonatal death and spontaneous abortion; major functional anomalies or malformations unlikely

References

1. International Commission on Radiological Protection, editors. Annals of the ICRP, Publication 84: Pregnancy and Medical Radiation 30 (1). Tarrytown, New York: Pergamon, Elsevier Science, Inc.; 2000.
2. Safety of Radiographic Imaging During Pregnancy *Am Fam Physician.* 1999 Apr 1;59(7):1813-1818.
3. International Commission on Radiological Protection, editors. Annals of the ICRP, Publication 90: Biological Effects After Prenatal Irradiation (Embryo and Fetus) 33 (1-2). Tarrytown, New York: Pergamon, Elsevier Science, Inc.; 2003.
4. National Council on Radiation Protection and Measurements. NCRP Report No. 128: Radionuclide Exposure of the Embryo/Fetus. Bethesda, Maryland: NCRP; 1998.
5. ACR Practice Guideline for Imaging Pregnant or Potentially Pregnant Adolescents and Women with Ionizing Radiation, 2008

Attachment 1.12 D

DEPT OF LAB MEDICINE POC Policy and Procedure Manual

TITLE: Urine hCG using the Quidel Quickvue
https://ynhh.ellucid.com/documents/view/200

DOCUMENT # POC – 12.0A Page 1 of 1
WRITTEN BY: Peter Marone
EFFECTIVE DATE: May, 1996 REVISION: H-2 October, 2004 SUPERCEDES: H-1

PROCEDURE

1. REMOVE TEST CASSETTE FROM POUCH.
Place on a clean, dry, level surface.

2. DISPENSE THREE DROPS OF SPECIMEN INTO SAMPLE WELL.
The specimen should be at room temperature.

3. READ RESULTS AFTER THREE MINUTES

RESULTS REPORTING

1. POSITIVE RESULT INDICATED BY PINK-PURPLE LINE NEXT TO "T", ALONG WITH BLUE LINE NEXT TO "C" IN RESULTS WINDOW.

2. NEGATIVE RESULT INDICATED BY BLUE LINE NEXT TO "C"AND NO LINE NEXT TO "T" IN RESULTS WINDOW.

3. IF NO BLUE LINE APPEARS NEXT TO "C", THE TEST IS INVALID AND MUST BE REPEATED.

4. RECORD AND INITIAL RESULT IN PATIENT RECORD: URINE HCG(+) OR URINE HCG(-)

DO NOT USE KIT BEYOND EXPIRATION DATE ON OUTSIDE OF KIT CARTON.

Note: If any problems occur consult the full procedure or consult the unit Point-of-Care Testing coordinator at 688-5212.

UNIT NO.

NAME

BIRTH DATE:

VISIT NUMBER:

(If handwritten, record name, unit no., birth date, and visit no.)

Yale-New Haven Hospital

Waiver for Pregnancy Testing

I understand that pregnancy testing is offered to all female patients 18 through 60 years of age. I have been informed of the role of pregnancy testing in planning my treatment or procedure. I understand that the treatment/procedure may put a possible pregnancy at risk for harm. Identifying an unrecognized pregnancy will allow me and/or my physicians to make an informed decision before having a treatment/procedure that could be harmful to myself and/or my fetus.

Understanding this, I decline to have a pregnancy test performed.

_____ Date_____ Time _____

Patient Signature

_____

Printed Name