POLICY: Under applicable regulations of the Rules of the City of New York, Article 175, Radiation Control OJ, and other applicable New York State and Federal statutes (2), it is the policy of the Columbia University to limit the radiation dose to the embryo/fetus of a declared pregnant woman to 5 mSv (0.5 rem) over the entire gestation period. The Medical Center shall review the exposure history of the declared pregnant woman and adjust working conditions so as to avoid a monthly exposure of more than 0.5 mSv (0.05 rem) to the declared pregnant woman (3).

Further, it is the policy of the Columbia University to provide counseling and education to the declared pregnant woman with regard to the risks of radiation exposure and to consult with her regarding recommendations for maintaining the radiation dose to the embryo/fetus within the above limits and As low As Reasonably Achievable (ALARA). Declarations and records under this policy are confidential. The declared pregnant woman is specifically protected from discharge or discrimination by her employer resulting from her pregnancy.

A copy of this policy shall be distributed to each department or laboratory at Columbia University using radiation or radioactive materials. This policy shall be incorporated into their QA Manual and a copy of this policy prominently posted in each such department or laboratory.

RESPONSIBILITY:

The Columbia University Radiation Safety Committee is responsible for administering the above policy at the Columbia University and associated Columbia University facilities. In administering and all other radiation safety policies the Columbia University Radiation Safety Committee shall be provided sufficient authority and organizational freedom to identify radiation safety problems, initiate, recommend, or provide corrective actions and verify implementation of corrective actions (5). Day to day implementation of this policy has been delegated to the Columbia University Radiation Safety Office. This Office can be contacted at:

Radiation Safety Office
Columbia University
500 west 120th street,
350 Mudd
Tel (212) 854-4442 Fax (212) 316-4937

PROCEDURE: The Columbia University Radiation Protection For Pregnant Workers shall be implemented as follow (6):

1. Method of instruction to workers:

As part of their initial employment (7), all radiation workers are required to receive from the Radiation Safety Office, instructions in radiation protection. These instructions may be given at a
new employee orientation or at a scheduled radiation safety lecture for new employees. These instructions should include: the effects of radiation to the embryo/fetus, a statement of the special limit for protection of the embryo/fetus of a declared pregnant woman, the responsibility of the pregnant woman to declare her condition to the Radiation Safety Office and the importance of her doing so. A copy of this policy should be distributed to each new radiation worker at his or her initial radiation safety orientation.

Instruction in the special limit for protection of the embryo/fetus of a declared pregnant woman and the Columbia University pregnancy policy should be included in all annual refresher training. Copies of this policy, the US.N.R.C. Regulatory Guide 8.13, Instruction Concerning Prenatal Radiation Exposure and the Declaration of Pregnancy Form shall be made available at all refresher-training sessions and in the Radiation Safety Office.

At the time of her Declaration of Pregnancy, the declared pregnant woman will receive individual counseling from the Radiation Safety Officer.

2. **Responsibility of workers:**

Federal statute (8) mandates that; "It is the fundamental responsibility of the pregnant worker to decide when or whether she will formally declare her condition to her employer." It is the policy of Columbia University that formal declaration is defined as filing a completed, signed and dated Declaration Of Pregnancy form with the Radiation Safety Office. A copy of the Declaration of Pregnancy Form is attached as APPENDIX A. If she chooses not to declare her pregnancy, the Radiation Safety Office will continue to ensure that she receives all normal occupational protections - the annual occupational dose limit of 50 mSy (5.0 rem) (9) and all ALARA (10) requirements will be in effect. All rights of declaration rest with the pregnant woman. The declaration of pregnancy may withdrawn at any time by a signed, dated, written statement of withdrawal filed with the Radiation Safety Office.

In addition, all radiation workers have an individual responsibility to comply with RCNY Article 175 requirements. The Rules of the City of New York, Article 175 (11) states that "the supervised individual. ..shall follow the instructions of the supervising authorized user; follow the procedures established by the radiation safety officer; and comply with this Code and with the license conditions with respect to the use of radioactive material ".

**Regarding work assignments for pregnant workers:**

In order to insure that the dose to an embryo/fetus (12) during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 5 mSv (0.5 rem), the Radiation Safety Office shall review the exposure history and the present job duties of the declared pregnant woman and require the adjustment in working conditions so as to avoid a monthly exposure of more than 0.5 mSv (0.05 rem) to a declared pregnant woman (13). This adjustment would range from requiring the wearing of a personnel radiation dosimeter as an assigned fetal monitor to a prohibition of participation in certain procedures.

If, by the time the pregnant worker declares pregnancy to the Radiation Safety Office, the dose to the embryo/fetus has exceeded
4.5 mSv (0.45 rem), the Radiation Safety Office shall ensure that additional occupational dose to the embryo/fetus does not exceed 0.5 mSv (0.05) rem during the remainder of the pregnancy (14). The radiation dose to the embryo/fetus is defined as the sum of the deep dose equivalent to the declared pregnant woman from external sources of radiation, such as X-rays and gamma-rays or neutrons and the internal dose to the embryo/fetus from the uptake of Radionuclides by the declared pregnant woman and by the embryo/fetus (15).

Due to privacy provisions noted in the following section, if an adjustment of working conditions is necessary, the Radiation Safety Office will consult with the declared pregnant woman; discuss with her any adjustment of working conditions that may be required; and obtain her written authorization prior to discussing such adjustments with her supervisor or Responsible Investigator.

The employment status of the declared pregnant woman is explicitly protected. The Rules of the City of New York, Article 175 (16) states that: "No licensee, registrant, or contractor or subcontractor of a licensee or registrant shall discharge or in any manner discriminate against any worker because... of the exercise by such worker on behalf of such worker or others of any option afforded by this Code". A notice of alleged violation of this or any other requirement of RCNY Article 175 may be filed in writing with the City of New York, Department of Health, Bureau of Radiological Health which is empowered to inspect the licensee and levy penalties if a violation is determined to exist.

**Records, informing workers of exposure received during gestation, reports:**

**A) Records**

Declarations and records required under this policy should be protected from public disclosure because of their personal privacy nature. These records are protected by New York State and Federal privacy statutes (17). The Declaration Of Pregnancy Form, including the estimated date of conception will be maintained in a separate file from the dose records of the declared pregnant woman and the embryo/fetus (18). The Declaration Of Pregnancy Form will be over-stamped or bear the prominent heading, "CONFIDENTIAL". Such records shall be retained until the City of New York, Bureau of Radiological Health authorizes disposition.

**B) Informing workers of exposure received during gestation**

The Radiation Safety Office shall advise each worker annually of the worker's exposure to radiation (20) and shall furnish a report of the worker's (or former worker's) exposure to sources of radiation at their request (21). If the Radiation Safety Office is required to report to the City of New York, Bureau of Radiological Health any exposure of an individual to radiation or radioactive material, the Radiation Safety Office shall also notify the individual at a time not later than the transmittal to the Bureau of Radiological Health (22).

Notification or report to a worker shall be in writing, shall include appropriate identification of the licensed institution, Columbia University, the name and social security number of the individual worker, their exposure information and shall contain the statement, "This report is furnished to you under the provisions of Para.175.04 of the New York City Health Code. You should preserve this report for further reference." (23).

**C) Reports**
The Radiation Safety Office shall submit a written report to the City of New York Bureau of Radiological Health within thirty days after learning that the 5 mSv (0.5 rem) dose limit for an embryo/fetus of a declared pregnant woman has been exceeded (24). The report shall describe the extent of exposure of the embryo/fetus and the declared pregnant woman to radiation and radioactive materials and include as appropriate; estimates of each individual's dose, the levels of radiation and concentrations of radioactive materials involved; the cause of the elevated exposures, dose rates and concentrations; and corrective steps taken or planned to ensure against a recurrence (25). This report shall be prepared so that identifiers such as name, social security number and date of birth are stated in a separate and detachable portion of the report in order to conform to privacy laws (26).

ALARA review (27) of the declared pregnant woman's Personnel Radiation Dosimetry Report will be performed on a monthly basis to avoid a monthly exposure of more than 0.5 mSv (0.05 rem). Records will be kept in the form specified above. The declared pregnant woman will be notified in writing if her monthly radiation dose exceeds the 0.05 rem ALARA level and an appropriate ALARA investigation will be performed. The Columbia University Radiation Safety Committee will receive ALARA reports for declared pregnant women with identifiers such as name, social security number and date of birth in a separate and detachable portion of the report.

Provision of further information:

Any individual or group having questions related to the radiation protection of the embryo/fetus is strongly encouraged to contact the Radiation Safety Office, telephone number (212) 8544442, at the location cited above. The Radiation Safety Office will provide appropriate and confidential education and counseling.

Further information may be found in the following publications:


Applicable City of New York, State of New York and Federal statutes referenced:

1. Rules of the City of New York - (RCNY), Article 175 - Radiation Control, 175.03(c)(8), Dose to an embryo/fetus.

2. State of New York, Department of Health, State Sanitary Code, Chapter 1, 10NYCRR16, l6.6(h),
Dose to an embryo/fetus.

Federal Register, Vol. 56, No. 98, Tuesday, May 21, 1991, Rules and Regulations, Final Rule, 10CFR20, Standards for Protection Against Radiation, p. 23397, 2,,0.1208, Dose to an embryo/fetus.

3. RCNY, 175.03(c)(8)(ii).

N.Y. S.D.O.H., 10NYCRR16.6(h)(2).

4. RCNY, 175.03 (b)(iii), (iv).

5. RCNY, 175.03(b)(4),(i).


9. RCNY, 175.03(c)(1)(i)(A).

10. RCNY, 175.03(b)(i). RCNY, 175.103(b)( 1).

11. RCNY,175.103(b)(5)(D)(ii)

12. RCNY, 175.02(a)(74).

13. RCNY, 175.03(c)(8)(i),(ii).

14. RCNY, 175.03(c)(8)(iv).

15. 15 RCNY, 175.03(c)(8)(iii).

RCNY, 175.03 (c)(1)(iii).

16. RCNY, 175.04(g)(3).

17. Federal Register, Vol. 56, No. 98, Tuesday, May 21, 1991, Rules and Regulations, Final Rule, 10CFR20, Standards for Protection Against Radiation, p. 23405,


19. RCNY, 175.03(k)(8)(F(iv).


21. 10CFR 20.2 106(e).
22. RCNY, 175.03(k)(8)(F)(v).
23. RCNY, 175.04(d)(2).
24. RCNY, 175.04(d)(3).
25. RCNY, 175.03(l)(6)(i),(ii).
26. RCNY, 175.04(d)(1).
27. RCNY, 175.03(l)(3)(i)(B)(c).
28. RCNY, 175.03(1)(3)(ii)(A).
29. RCNY, 175.03(1)(3)(ii)(B).
30. RCNY, 175.103(b).
DECLARATION OF PREGNANCY

Under applicable regulations of the Rules of the City of New York, Article 175, Radiation Control, there is a requirement for increased protection from ionizing radiation for declared pregnant radiation workers. The radiation dose to the embryo/fetus of a declared pregnant worker is limited to 5 mSv (0.5 rem) over the entire gestation period. CPMC is required to review the exposure history of the declared pregnant worker and adjust working conditions so as to avoid a monthly exposure of more than 0.5 mSv (0.05 rem). Declaration of pregnancy is not mandatory. Pregnant individuals who do not declare their pregnancy will continue to receive the protection of the occupational dose limit of 50 mSv (5.0 rem). The CPMC Radiation Safety Office will provide education and counseling with regard to this policy. Declarations and records under this policy are confidential and will be maintained in a separate file from personnel radiation dosimetry records. All workers are specifically protected from discharge or discrimination by their employer resulting from exercise of any option afforded by this Code.

ATTENTION: RADIATION SAFETY OFFICER, CPMC.

This is to notify you that I am pregnant and request increased protection under the requirements of RCNY, 175.03 (c)(8).

My estimated date of conception was: ___/___/____

My estimated due date is: ___/___/____

I work in the department of: _________________________________

My work address/location and telephone are: _________________________________

I may be contacted at this additional phone number: _________________________

My Responsible Investigator is:

By signing this form I make a declaration of pregnancy and consent to a review of my radiation exposure history and working conditions. Upon completion of this review, I will be informed of my previous occupational exposure. If an adjustment of my working conditions is necessary to avoid a monthly exposure of more than 0.5 mSv (50 mRem), my supervisor will not be notified prior to my written approval.

Print Name _______________________ Social Security Number _________________

Signature _______________________ Date ________________________________
**Review of Radiation Exposure of Declared Pregnant Radiation Worker**

Acct. No. ________ Series ________ Badge No. ________ Frequency: BiWk Mo QTR

Inception Date: ____/ ____/_____

Temp. Badge Issued? Y or N ________ Serial Number ______________

[ ] Badge company notified. Assigned on: ___/ ____/___ Initials: ____

OCCUPATION ________________________________________ ______

AVERAGE OR TYPICAL MONTHLY DOSE ____________________________ DDE

ESTIMATED DOSE FROM CONCEPTION TO DECLARATION: ____________________ DDE

_____________________________________________________        ________________

Radiation Safety Officer Signature Date

1) **Work-related Radiation Exposure Adjustment Not Indicated**

Given the aforementioned radiation exposure history and occupation, the Radiation Safety Office has determined that an adjustment of working conditions to avoid a monthly dose to the embryo/fetus of more than 0.5 mSv (0.05 rem) is not indicated.

I understand that if my working conditions change during the gestation period, I will notify the Radiation Safety Office.

Signature Radiation Worker: __________________________     Date: ___________________

Signature R.S.O. conducting review: ____________________    Date: ___________________

2) **Work-related Radiation Exposure Adjustment Indicated**

Given the aforementioned radiation exposure history and occupation, the Radiation Safety Office has determined that an adjustment of working conditions to avoid a monthly dose to the embryo/fetus of more than 0.5 mSv (0.05 rem) is indicated.

I authorize the R.S.O. to discuss the adjustment of my working conditions with my Responsible Investigator or Supervisor. I understand that RCNY Article 175 provides specific protection against discrimination or discharge by my employer due to exercise of my options under the Code. I understand that if my working conditions change during the gestation period, I will notify the Radiation Safety Office.

Signature Radiation Worker: __________________________     Date: ___________________

Signature R.S.O. conducting review: ____________________    Date: ___________________

**Columbia University Office of Radiation Safety** RSO: George Hamawy gh81@columbia.edu