Radiation Safety Concerns for Pregnant or Breast Feeding Patients

The Positions of the NCRP and the ICRP

Prepared by
C. B. Meinhold

Brookhaven National Laboratory

Prepared for
U.S. Nuclear Regulatory Commission

DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED
AVAILABILITY NOTICE

Availability of Reference Materials Cited in NRC Publications

Most documents cited in NRC publications will be available from one of the following sources:

1. The NRC Public Document Room, 2120 L Street, NW., Lower Level, Washington, DC 20555-0001

2. The Superintendent of Documents, U.S. Government Printing Office, P. O. Box 37082, Washington, DC 20402-9328

3. The National Technical Information Service, Springfield, VA 22161-0002

Although the listing that follows represents the majority of documents cited in NRC publications, it is not intended to be exhaustive.

Referenced documents available for inspection and copying for a fee from the NRC Public Document Room include NRC correspondence and internal NRC memoranda; NRC bulletins, circulars, information notices, inspection and investigation notices; licensee event reports; vendor reports and correspondence; Commission papers; and applicant and licensee documents and correspondence.

The following documents in the NUREG series are available for purchase from the Government Printing Office: formal NRC staff and contractor reports, NRC-sponsored conference proceedings, international agreement reports, grantee reports, and NRC booklets and brochures. Also available are regulatory guides, NRC regulations in the Code of Federal Regulations, and Nuclear Regulatory Commission Issuances.

Documents available from the National Technical Information Service include NUREG-series reports and technical reports prepared by other Federal agencies and reports prepared by the Atomic Energy Commission, forerunner agency to the Nuclear Regulatory Commission.

Documents available from public and special technical libraries include all open literature items, such as books, journal articles, and transactions. Federal Register notices. Federal and State legislation, and congressional reports can usually be obtained from these libraries.

Documents such as theses, dissertations, foreign reports and translations, and non-NRC conference proceedings are available for purchase from the organization sponsoring the publication cited.

Single copies of NRC draft reports are available free, to the extent of supply, upon written request to the Office of Administration, Distribution and Mail Services Section, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Copies of Industry codes and standards used in a substantive manner in the NRC regulatory process are maintained at the NRC Library, Two White Flint North, 11545 Rockville Pike, Rockville, MD 20852-2738, for use by the public. Codes and standards are usually copyrighted and may be purchased from the originating organization or, if they are American National Standards, from the American National Standards Institute, 1430 Broadway, New York, NY 10018-3308.

DISCLAIMER NOTICE

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, makes any warranty, expressed or implied, or assumes any legal liability or responsibility for any third party's use, or the results of such use, of any information, apparatus, product, or process disclosed in this report, or represents that its use by such third party would not infringe privately owned rights.
Radiation Safety Concerns for Pregnant or Breast Feeding Patients

The Positions of the NCRP and the ICRP

Manuscript Completed: March 1996
Date Published: January 1997

Prepared by
C. B. Meinhold

Brookhaven National Laboratory
Upton, NY 11973

S. Z. Jones, NRC Project Manager

Prepared for
Division of Regulatory Applications
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
NRC Job Code L2617
DISCLAIMER

Portions of this document may be illegible in electronic image products. Images are produced from the best available original document.
DISCLAIMER

This report was prepared as an account of work sponsored by an agency of the United States Government. Neither the United States Government nor any agency thereof, nor any of their employees, make any warranty, express or implied, or assumes any legal liability or responsibility for the accuracy, completeness, or usefulness of any information, apparatus, product, or process disclosed, or represents that its use would not infringe privately owned rights. Reference herein to any specific commercial product, process, or service by trade name, trademark, manufacturer, or otherwise does not necessarily constitute or imply its endorsement, recommendation, or favoring by the United States Government or any agency thereof. The views and opinions of authors expressed herein do not necessarily state or reflect those of the United States Government or any agency thereof.
ABSTRACT

For many years, protecting the fetus has been a concern of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). Early recommendations focused on the possibility of a wide variety of detrimental developmental effects while later recommendations focused on the potential for severe mental retardation and/or reduction in the intelligence quotient (I.Q.). The latest recommendations also note that the risk of cancer for the fetus is probably two to three times greater per Sv than in the adult.

For all these reasons, the NCRP and the ICRP have provided guidance to physicians on taking all reasonable steps to ascertain whether any woman requiring a radiological or nuclear medicine procedure is pregnant or nursing a child. The NCRP and the ICRP also advise the clinician to postpone such procedures until after delivery or cessation of nursing, if possible.
CONTENTS

ABSTRACT ........................................................................................................ iii

1 POSITIONS OF THE NCRP AND THE ICRP ............................................. 1
  1.1 Introduction .................................................................................................. 1
  1.2 The NCRP Position and Guidance ................................................................. 1
  1.3 The ICRP Position and Guidance .................................................................. 6

2 REFERENCES .................................................................................................. 14
FOREWORD

The purpose of this report is to compile in one document the positions of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP) regarding the radiation safety concerns associated with the administration of radiation or radioactive materials to patients or human research subjects who may be pregnant or breast-feeding a child.

The positions of the NCRP and the ICRP provided in this report are for information only. Publication of this report does not necessarily constitute NRC approval of, or agreement with, the positions provided herein.

Cheryl A. Trottier, Acting Chief
Radiation Protection and Health Effects Branch
Division of Regulatory Applications
Office of Nuclear Regulatory Research
1 POSITIONS OF THE NCRP AND THE ICRP

1.1 Introduction

The publications of the NCRP and ICRP were reviewed to establish their respective positions and guidances on the radiation safety concerns associated with administering radiation or radioactive materials to women patients or research subjects who may be pregnant or breast feeding.

The relevant publications of the NCRP are:

- NCRP Commentary No. 11 on *Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients* (NCRP, 1995)
- NCRP Commentary No. 9 on *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, and Nursing Child* (NCRP, 1994)
- NCRP Report 116 on *Limitation of Exposure to Ionizing Radiation* (NCRP, 1993)
- NCRP Report 70 on *Nuclear Medicine -- Factors Influencing the Choice and Use of Radionuclides in Diagnosis and Therapy* (NCRP, 1982)
- NCRP Report 54 on *Medical Radiation Exposure of Pregnant and Potentially Pregnant Women* (NCRP, 1977)

The relevant publications of the ICRP are:

- ICRP Publication 62 on *Radiological Protection in Biomedical Research* (ICRP, 1993)
- ICRP Publication 52 on *Protection of the Patient in Nuclear Medicine* (ICRP, 1987)
- ICRP Publication 44 on *Protection of the Patient in Radiation Therapy* (ICRP, 1985)
- ICRP Publication 34 on *Protection of the Patient in Diagnostic Radiology* (ICRP, 1982)

1.2 The NCRP Position and Guidance

Corollary to the topic of this publication, the NCRP Commentary No. 11 on *Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients* (NCRP, 1995) contains two paragraphs of interest:

5.3.3 Considerations of Patient’s Family

Members of a radionuclide therapy patient’s family are likely to perceive that they will benefit from the family member’s treatment, and they are likely to be willing to bear greater risks in order to achieve that benefit.

*Children and Pregnant Women.* The doses to children in the family and pregnant members of the family should not exceed 1 mSv in a year.
Positions

Adults. The dose limit for adult family members exposed to a radionuclide therapy patient should not exceed 50 mSv annually. When family members are likely to receive exposures in excess of 5 mSv annually, they should receive appropriate training and individual monitoring.

And Appendix A Section A.2.2.1 concludes with the following paragraph:

In addition to the common administrative restrictions described for brachytherapy (Section A.1), family members should be cautioned about the likely presence of $^{131}$I on items contaminated by the patient’s sweat, urine and mucous secretions. Since $^{131}$I can appear in breast milk, breast-feeding should be discontinued until the treating physician is assured that no $^{131}$I is present in freshly-expressed milk (Culver and Dworkin, 1991).

NCRP Commentary No. 9 (NCRP, 1994) on Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child should be considered in its entirety. The recommendation and conclusion section is quoted below:

Given the various factors discussed in earlier sections, it seems clear that exposures resulting in doses to the whole-body (i.e., effective dose) of 100 mSv or less will not cause detectable deterministic effects in the embryo or fetus, with the possible exception of the induction of small head size with a threshold perhaps as low as 50 mSv. Also no detectable deterministic effects would be expected in the nursing child. Stochastic effects, such as cancer induction, should not exceed about one percent at 100 mSv for the embryo, fetus or nursing child (NCRP, 1993). Therefore, setting requirements for action after radiation exposure of the embryo, fetus or nursing child at some level below an effective dose of 100 mSv to allow for a margin of safety, should enable all such incidents with the potential for harm to be dealt with appropriately.

With regard to exposure of the embryo, fetus or nursing child during a medical procedure to the mother involving radioactive material, if the physician is aware that the patient is pregnant or breast feeding and the risk/benefit has been fully discussed with the patient before the procedure is undertaken, no unintended exposure will have occurred.

Unintended exposure of the embryo, fetus or nursing child as a result of medical procedures to the mother involving radioactive material results when the physician is unaware of the patient’s pregnancy, or that she is breast or bottle feeding at the time of the procedure or a misadministration has occurred. When the physician becomes aware of the situation after the fact, he or she needs to have procedures available regarding appropriate action (see below).

If the dose to the embryo, fetus or nursing child from an unintended exposure is less than or equal to an effective dose of 50 mSv, there is no harm from deterministic effects and the risk of stochastic effects is less than one percent.
A full record of the exposure and circumstances and the doses involved must be developed so that procedures can be implemented to reduce the chance of future unintended exposures, but no action regarding the embryo, fetus or nursing child other than assurance of the accuracy of the dose is warranted.

If the dose to the embryo, fetus or nursing child from an unintended exposure exceeds an effective dose of 50 mSv, since the possibility of harm increases with the dose, it is recommended that action be instituted to assure that the dose estimation is accurate, and in addition, that expert medical evaluation, advice and follow-up be utilized on a case-by-case basis.

In its Report 116 (NCRP, 1993), the NCRP provided the following information on embryo and fetal risks in Section 10, Protection of the Embryo-Fetus:

In rats and mice, irradiation of the embryo-fetus to substantial doses has been shown to produce a wide spectrum of developmental anomalies (UNSCEAR, 1986). The only excess incidence of anomalies that has been reported in detail in the atomic bomb survivors involves the central nervous system, small head size, severe mental retardation and deficits in intelligence (Otake and Schull, 1984). The absence of a wide spectrum of developmental anomalies in the Japanese survivors may reflect the very low LD_{50} for the human embryo, the very short period of sensitivity for the induction of central nervous system effects and/or that the doses may not have been high enough to induce other developmental anomalies.

Among atomic bomb survivors exposed in utero, a dose-dependent increase in the incidence of severe mental retardation occurred in the gestational age group of 8 to 15 weeks after conception, and, to a lesser extent, in the gestational age group of 16 to 25 weeks after conception. Subjects exposed to radiation at less than 8 weeks or after 26 weeks of gestational age were not observed to have an excess of mental retardation. The data are consistent with a linear relationship between the incidence of mental retardation and dose with a slope of 0.4 Gy^{-1} and a threshold of 0.1 to 0.2 Gy, if all cases of severe mental retardation are included. If two children with Down’s Syndrome are excluded (they clearly had a nonradiation etiology since their genetic condition existed prior to exposure), the threshold is about 0.4 Gy. These data strongly suggest a threshold for severe mental retardation even in the most sensitive stages of gestation. The relative risk for exposure during the 16 to 25 week period is at least four times less than that for exposure at 8 to 15 weeks after conception, with an even clearer indication of a threshold.

For exposures during the most sensitive period, 8 to 15 weeks, more recent data from Japan also indicate a reduction in intelligence scores of 21 to 29 points at 1 Gy, although the data show great variability (Otake et al., 1988; Schull et al., 1988).
Small head size was observed over a wider range of doses and in some cases over a wider range of gestational age than for severe mental retardation, although the majority of the cases cluster around the 8 to 15 week period. There is not a one-to-one correlation between small head size and severe mental retardation, since one may occur in the absence of the other, with small head size being more common than mental retardation.

Epidemiological data suggest an association between diagnostic x rays received in utero and excess incidence of childhood cancer, which implies that susceptibility to radiation carcinogenesis from exposure during prenatal life may be higher than in the adult. However, there is also evidence against this conclusion. An excess in childhood cancer was not observed in the atomic bomb survivors that were exposure in utero. In a follow-up through 1984, cancer incidence data suggested that excess cancer in adulthood might result from irradiation in utero, although there was no evidence of excess cancer risk for more recent years, 1985-89 (Yosimoto et al., 1992). The present data are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult (i.e., about $1 \times 10^{-1}$ Sv$^{-1}$) (UNSCEAR, 1986).

The sensitivity of the embryo-fetus for both mental retardation and cancer should be considered in all situations involving irradiation of the embryo-fetus.

The following guidance is found in the Recommendations section of NCRP Report 70 (NCRP, 1982):

Radionuclides in Women in Reproductive Years

(a) **Diagnostic Studies.** Elective procedures, especially those involving radiation doses in excess of 0.5 rad (whole body dose) or with agents having a propensity of localization in the conceptus, e.g. radioiron incorporated in erythropoietic cells of the fetus and colloids that concentrate in reticuloendothelial cells of the placenta, should be avoided whenever possible during pregnancy. See Report No. 39 (paragraphs 265,266) and Report No. 55 (NCRP, 1971, 1977).

(b) **Therapeutic Procedures.** Therapeutic procedures with radiopharmaceutical drug products should be avoided during pregnancy unless abortion of the pregnancy is planned. Based on radiobiological data on genetic effects in mice (Russell, 1965), in order to minimize the possibility of genetic hazards after radiation therapy of non-pregnant females in the child-bearing years, it is prudent that the patient should be advised to postpone possible pregnancies for at least several months to permit repair to such genetic damage as may have occurred.
For volunteers receiving radionuclides for investigative purposes, NCRP Report 70 (NCRP, 1982) states the following:

A further requirement for the interpretation of all clinical investigations designed to detect abnormality is that measurements be obtained in subjects who are known to be normal in the relevant respect. This procedure establishes the normal ranges for test results. This requirement is equally true for investigations involving radionuclides; and hence, there is a need for investigations involving matched control individuals who may not themselves benefit from the investigation. For investigations where the range of values within the normals is small, these volunteer groups can ordinarily be limited in number. The source of such control groups may be individuals seeking medical attention for other purposes, but if so, care must be taken that they are normal in regard to the particular procedure that is under investigation and that they are not pregnant.

From the summary of conclusions and recommendations in NCRP Report No. 54 (NCRP, 1977) the following is their position and guidance:

Sensitivity to ionizing radiation is greater during intrauterine stages of development than at other stages in the life of the mammalian organism. For this reason, the NCRP recommends special care in patient selection in certain cases of diagnostic radiology and nuclear medicine diagnostic procedures. For women of child-bearing capacity, the physician requesting a radiological or nuclear medicine examination involving the lower abdominal or pelvic region should ascertain whether the patient is, or could be, pregnant.

Further, the NCRP recommends that physicians tell their premenopausal patients that, if they are likely to have nuclear medicine studies or x-ray examinations of the lower abdomen, it is generally advisable that they not run a risk of pregnancy until two months after the studies are carried out.

If, in the best judgment of the attending physician, a diagnostic examination or nuclear medicine procedure, at that time, is deemed advisable to the medical well-being of the patient, it should be carried out without delay, special efforts being made, however, to minimize the dose received by the lower abdomen (uterus). For example, such an examination should be conducted under conditions designed to limit the radiation exposure to the amount necessary for adequate examination. Filtration, collimation of the radiation beam to the anatomical region of interest, and careful selection of technical exposure factors can significantly contribute to good radiological practice and to the reduction of radiation exposure to all tissues. Such caution will automatically limit radiation effects on the embryo-fetus, if present. Modification of an examination for dose reduction is warranted only if it reasonably can be done without significant jeopardy to the medical care of the patient and/or her unborn child.

In the case of abdominal radiological or nuclear medicine irradiations of pregnant
or potentially pregnant women that could be postponed without significantly jeopardizing the medical well-being of the patient, the physician should consider the fact that the probability of causing different types of effects varies with stage of pregnancy and with dose.

The final decision to proceed or not to proceed with the examination must depend on considerations of the patient's health, and on her wishes, and must reside with the attending physician in consultation with the radiological expert when such services are utilized; that is, the attending physician must retain full discretion to decide each case according to his judgment.

1.3 The ICRP Position and Guidance

From ICRP 62 (ICRP, 1993) we find the following discussion under the section on ethical aspects:

(11) Pregnant women should not be asked to take part in research projects involving irradiation of the fetus unless the pregnancy itself is central to the research, and then only if other techniques involving less risk cannot be used. The proposed benefit of the study should be clear and substantially exceed the possible detriment. In this case the full and informed consent of the pregnant patient must be obtained and it would usually be appropriate to seek the same from the father. In some investigations it would be prudent to consider the possibility that a woman may be pregnant but not know it. If so the protocol involved in the investigation should recognize this possibility.

From ICRP 60 (ICRP, 1991), under the section discussing the protection methods in medical exposure, the following statements are made:

5.4.4 Medical exposure of pregnant women

(184) As discussed in Section 3.4.4, exposure of the embryo in the first three weeks following conception is not likely to result in deterministic or stochastic effects in the liveborn child. A pregnant patient is likely to know, or at least suspect, that she is pregnant after one missed menstruation, so the necessary information on possible pregnancy can, and should, be obtained from the patient herself. If the most recent expected menstruation has been missed, and there is no other relevant information, the woman should be assumed to be pregnant. Diagnostic and therapeutic procedures causing exposures of the abdomen of women likely to be pregnant should be avoided unless there are strong clinical indications.
From the section on guidelines to good clinical practice, ICRP Publication 52 (ICRP, 1987) under the heading diagnosis, the following is stated:

2.1.11 Women of reproductive capacity

(51) In women of child-bearing age, the possibility of pregnancy should be taken into account and the justification for the examination considered in the light of this information. The recommended measures and precautions to ensure the prevention or minimization of exposure to an embryo or fetus include the following:

-- The patient must be carefully interviewed to assess the likelihood of pregnancy. Particular discretion is required to ascertain the possibility of pregnancy in an adolescent of child-bearing age.

-- It would be prudent to treat as pregnant any woman of reproductive age presenting for a nuclear medicine examination at a time when a menstrual period is overdue or missed, unless there is information that precludes pregnancy (e.g. hysterectomy). If the menstrual cycle is irregular, a pregnancy test may be indicated before proceeding.

-- In order to ensure maximum publicity and to minimize the frequency of unintentional exposure of the fetus, advisory notices should be posted at several places within the nuclear medicine department, and particularly at its reception area. For example:

IF YOU THINK THAT YOU MIGHT BE PREGNANT,
NOTIFY STAFF BEFORE TREATMENT

2.1.12 Avoidance of pregnancy after a diagnostic procedure

(52) Patients sometimes inquire about the time that should elapse between the completion of a diagnostic nuclear medicine procedure and attempts to become pregnant. Since there are no currently used diagnostic tests in which tissue radionuclide concentrations have sufficiently long effective half lives to expose a subsequent embryo significantly, there is no medical reason to wait, as the risk to the embryo would be negligible.

2.1.13 Pregnant women

(53) Irradiation of the fetus results from placental transfer and distribution of radio-pharmaceuticals in the fetal tissues, or from external irradiation from the radiopharmaceutical present in the mother's organs and tissues. The chemical and biological properties of the radiopharmaceutical are the critical factors in possible placental transfer. Some radio-pharmaceuticals cross the placenta freely and are taken up in fetal tissues, where they irradiate the tissues. This may, for
example, result from the concentration of I-131 as iodide or Tc-99m as pertechnetate in the fetal thyroid, occurring during the last two trimesters of pregnancy. Some analogues of natural metabolites (e.g. radiostrontium for calcium, and radiocesium for potassium) are not so readily transferred. Radiocolloids that are retained by the reticuloendothelial system of the mother, and do not cross the placenta, act only as external sources of irradiation to the fetus. After the administration of short-lived radiopharmaceuticals, frequent voiding should, therefore, be ensured. This contribution to the fetal dose can be further reduced by administering the radiopharmaceutical when the bladder is partially filled, rather than immediately after voiding. When a nuclear medicine examination is proposed for a pregnant woman, great care has to be taken to ascertain that the examination is indeed indicated. If, in consultation with the referring physician, it is deemed that the risk of not making a necessary diagnosis is greater than that of irradiating the fetus, the examination should be performed (Taylor, 1979). When ultrasound diagnostics are available and can provide useful information, radionuclide studies for localization of the placenta should be discouraged.

(54) Exposure of the pregnant patient, at a time when the pregnancy was unrecognized, often leads to her apprehension, because of concern about possible effects on the fetus, even though the absorbed doses to the conceptus are generally small. Such concern may even lead to a suggestion that the pregnancy be terminated. However, on the basis of relative risk increment, fetal irradiation from a diagnostic procedure rarely justifies terminating a pregnancy. When such a concern arises, an estimate of the absorbed dose, and the associated risk to the fetus, should be made by a qualified expert. With such expert and carefully worded advice, the patient should then be in a position to take a decision regarding abortion.

2.1.14 Breast-feeding women

(55) Since many radiopharmaceuticals are secreted in breast milk, it is safest to assume that, unless there are experimental data to the contrary, some radioactive compounds will be found in the breast milk when a radiopharmaceutical is administered to a lactating female. It then becomes necessary to consider the risk to the breast-fed child, who may be irradiated without direct benefit. Consideration should be given to postponing the procedure. However, this should be balanced against the benefit resulting from having the disease diagnosed and the mother cured. If the procedure is to be performed, the child should not be breast-fed until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable absorbed dose to the child. In order to minimize the exposure of the breast-fed child, advisory notices should be posted within the nuclear medicine department. An example of such a notice is:
(56) It is recommended that the following actions should then be taken for various radiopharmaceuticals (Ahlgren et al., 1985; Coakley and Mountford, 1985):

**Group I:** *Stop nursing for at least 3 weeks*
- All I-131- and I-125-radiopharmaceuticals except labeled hippuran
- Na-22, Ga-67, TI-201, Se-75-methionine

**Group II:** *Stop nursing for at least 12 hours*
- I-131-, I-125- and I-123-hippuran
- All Tc-99m-compounds except labeled red blood cells, -phosphonates and -DTPA

**Group III:** *Stop nursing for at least 4 hours*
- Tc-99m-red blood cells, -phosphonate and -DTPA

**Group IV:** *No necessity to stop nursing*
- Cr-51-EDTA

From the same section, under therapy, the following position is taken:

2.2.6 **Pregnancy**

(76) Because certain radiopharmaceuticals including I-131 as iodide and P-32 as phosphate, can rapidly cross the placenta, the possibility of pregnancy should be considered before such radionuclides are given for therapy. As a rule, a pregnant woman should not be treated with a radioactive substance unless the therapy is required to save her life; in that event, consideration should be given to terminating the pregnancy.

2.2.7 **Women of reproductive capacity**

(77) Precautions that need to be taken to avoid treatment with radionuclides of women with undiagnosed pregnancy are specified in paragraph 51. In the past, some women who were unaware of early pregnancy were treated with I-131 and there have been reports of hypothyroidism in the offspring of women treated with I-131 for hyperthyroidism in early pregnancy. There is no evidence of an increase in congenital anomalies nor in the rate of fetal loss (Sarkar et al., 1976).

(78) The question may arise as to the interval that should elapse after administration of therapeutic amounts of radiopharmaceuticals before a woman attempts to become pregnant. As a general rule, it would appear advisable that
1. Positions

no attempt should be undertaken until the activity remaining in the woman's body is such that it will not cause the absorbed dose in the conceptus to exceed about 1 mGy. This would usually mean delaying pregnancy after hyperthyroidism therapy with I-131 for about 6 months.

2.2.8 Protection of the Family

A patient treated with gamma-emitting radionuclides should be advised not to hold children or otherwise be in intimate contact with family members for an appropriate time interval after having left the hospital. If the patient is a nursing mother, breast-feeding may have to be stopped for an appropriate time after administration of a therapeutic amount of activity (see paragraphs 55 and 56). The physician responsible for the care of a patient receiving radioactive material for therapeutic purposes should provide necessary information to family members for their protection (Nishizawa et al., 1980). Concern for the protection of the family should not deprive the patient of family support at a critical time; however, certain groups (e.g., children and pregnant women) may need to avoid close proximity to the patient.

The following information was taken from the section on the expected risk to specific organs and tissues from therapeutic irradiation, ICRP Publication 44 (ICRP, 1985):

Fetus

(119) Irradiation of the pregnant woman is to be avoided. There may, however, be exceptional circumstances in the treatment of a life-threatening malignancy in which the therapeutic irradiation is the method of treatment that carries the lowest risk to the patient and fetus. In order to evaluate the relative risks of available therapies a knowledge of the dose to be received by the fetus is required (see paras. 123-127). It is also essential that any such treatment be planned in a way that minimizes the dose to the fetus; this includes the use of all relevant measures, e.g., minimum target volume, minimum effective dose, and appropriate shielding. This is a special circumstance in which full, informed discussion with the patient is necessary.

(120) With increasing dose to the fetus there is an increasing risk of abortion at all times through pregnancy. This risk is quantitatively greatest in the period of implantation of the embryo in the uterine wall, 5 or 6 days after fertilization, and during the first embryonic divisions from the zygote through the morula, blastula, and gastrula stages. However, a dose of 0.5 Gy or more may cause abortion at any stage of pregnancy (BEIR, 1972).

(121) The greatest risk of abnormal development following irradiation of the fetus occurs during the period of organogenesis. There is ample evidence that malformations are induced by radiation in laboratory animals at corresponding
stages of development. In humans, the greatest risk of severe mental retardation (on the order of 0.4 Gy) occurs during the period of forebrain development (10-17 weeks after the last menstrual period, 8-15 weeks after conception) (Otake and Schull, 1984).

(122) Ante-natal irradiation has been correlated with a higher risk of development of subsequent malignancy in childhood. From data obtained retrospectively by examining the obstetric histories of children with and without leukemia or other malignancies (Stewart et al., 1958), it has been suggested that radiation doses as low as a few tens of mGy may increase the risk of childhood malignancy to an extent comparable with, or perhaps rather higher than, the risk per unit dose in adults.

Finally, the ICRP position and guidance was taken from the section on specific types of radiological procedures, ICRP Publication 34 (ICRP, 1982):

5.2 Examination of Women of Reproductive Capacity

In addition to any risk to the woman, there may be additional risk to an unborn child if the woman is pregnant at the time of the examination. During the first ten days following a true menstruation there is no conceptus, and therefore there is clearly no such additional risk. The biological information summarized in Section 1.3 suggests that the risk of maldevelopment as a result of irradiation in utero begins about one month after the last menstruation and continues for the next 4-5 months. This information reduces the importance of the Commission’s earlier advice to confine to the 10 day period following menstruation any examination that could, if necessary, be postponed for the full duration of the pregnancy (15). This advice may be unnecessarily restrictive. The Commission will continue to review the need for, and form of, this advice as more information becomes available.

After exposure during the second month, detriment may be expressed as malformation of specific organs; after exposure during the third and fourth months the detriment is mainly in the form of defective development of the forebrain, resulting in mental retardation.

It can be said now that it would be prudent to treat as pregnant any woman presenting for radiography at a time when a period is overdue or clearly missed, unless there is information indicating the absence of pregnancy. If, however, the cycle is so irregular that it is difficult to know whether a period has been missed, then a pregnancy test may help to decide whether the patient is pregnant.

In order to minimize the frequency of unintentional exposure of the foetus it is recommended that notices should be posted at several places within diagnostic x-ray departments and other areas where diagnostic x-ray equipment is used, other than for dentistry. For example:
5.3 Obstetric Radiography

The protection of patients during pregnancy is particularly important because radiological examinations of the abdominal region of a pregnant woman frequently result in whole body irradiation of the foetus. Such radiation may contribute to the incidence of childhood cancer and foetal abnormalities, including mental retardation (see Section 1.3).

Ultrasonic examinations can give much useful information for evaluation of the foetus and placenta. In many instances, particularly in the evaluation of foetal maturation and placental localization, they are preferable to radiological examinations, since they do not use ionizing radiation and are more reliable. The use of ultrasound has greatly reduced the need for x rays of the gravid uterus (K2). If radiographs are performed for foetal examination, a film obtained with some compression, such as an oblique PA or a simple PA view, will reduce the foetal dose and give better visualization of detail.

While pelvimetry is sometimes of great value, it should be undertaken only on the rare occasion when this is likely to be so and should certainly not be carried out on a routine basis. In particular, the super-inferior projection for the pelvic inlet (sometimes called the brim view) should not be used in view of the high doses delivered to the foetus.

The obstetric radiological examination should be individually planned to answer the clinical problem. Ideally, one film should be taken at a time and checked to see that the information required is on it and only then should an additional film be taken. For example, in foetal evaluation only one projection may be needed and an additional one should be obtained only if the first one does not show the required information.

Strict beam collimation is important in obstetric radiology. Alternatively, special apertures can be used with some techniques that do not require irradiation of the entire pelvis. High speed films and screens are usually used to minimize dose. The use of a gridless technique and partial shielding of the foetus on antero-posterior and lateral views can be used to minimize foetal exposure (R6).
5.4 Other Radiological Procedures During Pregnancy

When pregnant women require other radiological examinations, in which the primary beam irradiates the foetus, care has to be taken to ascertain that the examination is indeed indicated. Sometimes the risk of irradiating the foetus is much less than that of not making a necessary diagnosis, so that the examination should still be done for proper medical indications. In such cases, greater than usual care should be made to minimize the number of views and to minimize the absorbed dose per view. However, these alterations of technique should not be done to the undue detriment of the diagnostic value of the examination.

When radiography of areas remote from the foetus is needed, such as, for example, the chest, skull or hand, these can be done safely at any time during pregnancy if proper collimation is used and if the equipment is properly shielded. The dose to the region of the uterus in a female having a chest x ray is usually less than 10 \( \mu \text{Gy} \).
2 REFERENCES


2. TITLE AND SUBTITLE
Radiation Safety Concerns for Pregnant or Breast-Feeding Patients: The Positions of the NCRP and the ICRP

5. AUTHOR(S)
C. B. Meinhold

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)
Brookhaven National Laboratory
Upton, NY 11973

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)
Division of Regulatory Applications
Office of Nuclear Regulatory Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

10. SUPPLEMENTARY NOTES
S.Z. Jones, NRC Project Manager

11. ABSTRACT (200 words or less)
For many years, protecting the fetus has been a concern of the National Council on Radiation Protection and Measurements (NCRP) and the International Commission on Radiological Protection (ICRP). Early recommendations focused on the possibility of a wide variety of detrimental developmental effects while later recommendations focused on the potential for severe mental retardation and/or reduction in the intelligence quotient (I.Q.). The latest recommendations also note that the risk of cancer for the fetus is probably two to three times greater per Sv than in the adult.

For all these reasons, the NCRP and the ICRP have provided guidance to physicians on taking all reasonable steps to ascertain whether any woman requiring a radiological or nuclear medicine procedure is pregnant or nursing a child. The NCRP and the ICRP also advise the clinician to postpone such procedures until after delivery or cessation of nursing, if possible.

12. KEY WORDS/DESCRIPTIONS (List words or phrases that will assist researchers in locating the report)
embryo, fetus, nursing child, radiation, pregnant, breast-feeding, unintended radiation exposure, pregnant women, breast-feeding women