

**Bon Secours St. Mary's Hospital  
EMPLOYEE DECLARATION OF PREGNANCY**

Name (print): \_\_\_\_\_

Participant number: \_\_\_\_\_

Date of Declaration: \_\_\_\_\_

Date of Conception or Weeks of pregnancy: \_\_\_\_\_

Department: **Radiology/School of Medical imaging**

Position: **Radiology Student**

By providing this information to my immediate supervisor, in writing, I am declaring myself to be pregnant as of the date shown above. I understand the provision of 10 CFR Part 20.1208, total exposure to my unborn child from occupational exposure to radiation will not be allowed to exceed 5 mSv (500 mrem) during the entire pregnancy (The dose to my unborn child shall be taken as the sum of my deep dose equivalent and the dose resulting from the intake of any radionuclides). I also understand that this limit includes any exposures I have received since conception, and that if the dose to my unborn child has already exceeded 500 mrem, the dose for the remainder of my pregnancy must be limited to 0.5 mSv (50mrem). I further understand that if I should find out that I am not pregnant, or if for any reason my pregnancy is terminated, I will inform my supervisor as soon as practical. I may obtain information regarding my past personnel radiation monitoring record, and guidance concerning radiation protection measures from the Radiation Safety Officer, or his/her designee.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Supervisor's Receipt of Declaration of Pregnancy**

By signing this statement, I acknowledge receipt of the declaration of the above individual; have provided her with an outline of potential risks from exposure to the unborn child which uses the information provided in Regulatory Guide 8.13; and have evaluated her prior exposure (internal and external) to establish appropriate limits to control the dose to her unborn child in accordance with the above stated limitations and the ALARA program. I understand it is my responsibility to forward this form to the Radiation Safety Officer.

Name (print): \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**Radiation Safety Officer's Receipt of Declaration of Pregnancy**

By signing this statement, I acknowledge receipt of the declaration of the above individual; have evaluated her prior exposure (internal and external) to ensure appropriate limits to control the dose to her unborn child in accordance with the above stated limitations and the ALARA program have been established and that appropriate monitoring is being provided.

Name(print): Douglas E. Cook M.D.

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

## Specific Controls Being Applied to the Unborn Child

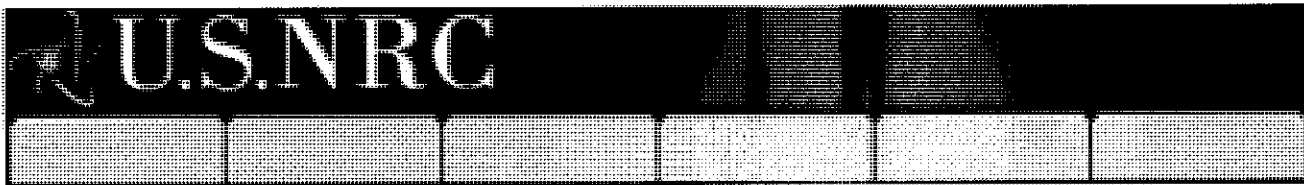
To be completed by supervisor with consultation from the RSO if necessary. A written evaluation must be entered and initialed by the employee in order to document assessment of exposure and understanding of specific controls even if no specific controls are recommended.

Based on prev exposures no controls at this time. Will monitor.

Series/Name/Number	Dose Period	Deep	Lens	Shallow	Beta	Neutron	Extremity	Exceeded	Exceeded Limit
	QTD								
	YTD09								
	YDT08								
	LIFE								

\_\_\_\_\_  
Initials of Employee

\_\_\_\_\_  
Date



## **Regulatory Guide 8.13 - Instruction Concerning Prenatal Radiation Exposure**

(Draft was issued as DG-8014)

Revision 3  
June 1999

Availability Notice

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### **A. INTRODUCTION**

The Code of Federal Regulations in 10 CFR Part 19, "Notices, Instructions and Reports to Workers: Inspection and Investigations," in Section 19.12, "Instructions to Workers," requires instruction in "the health protection problems associated with exposure to radiation and/or radioactive material, in precautions or procedures to minimize exposure, and in the purposes and functions of protective devices employed." The instructions must be "commensurate with potential radiological health protection problems present in the work place."

The Nuclear Regulatory Commission's (NRC's) regulations on radiation protection are specified in 10 CFR Part 20, "Standards for Protection Against Radiation"; and Section 20.1208, "Dose to an Embryo/Fetus," requires licensees to "ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv)." Section 20.1208 also requires licensees to "make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman." A declared pregnant woman is defined in 10 CFR 20.1003 as a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.


This regulatory guide is intended to provide information to pregnant women, and other personnel, to help them make decisions regarding radiation exposure during pregnancy. This Regulatory Guide 8.13 supplements Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure" (Ref. 1), which contains a broad discussion of the risks from exposure to ionizing radiation.

Other sections of the NRC's regulations also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. In 10 CFR 20.1502, "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," licensees are required to monitor the occupational dose to a declared pregnant woman, using an individual monitoring device, if it is likely that the declared pregnant woman will receive, from external sources, a deep dose equivalent in excess of 0.1 rem (1 mSv). According to Paragraph (e) of 10 CFR 20.2106, "Records of Individual Monitoring Results," the licensee must maintain records of dose to an embryo/fetus if monitoring was required, and the records of dose to the embryo/fetus must be kept with the records of dose to the declared pregnant woman. The declaration of pregnancy must be kept on file, but may be maintained separately from the

dose records. The licensee must retain the required form or record until the Commission terminates each pertinent license requiring the record.

The information collections in this regulatory guide are covered by the requirements of 10 CFR Parts 19 or 20, which were approved by the Office of Management and Budget, approval numbers 3150-0044 and 3150-0014, respectively. The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

## **B. DISCUSSION**

As discussed in Regulatory Guide 8.29 (Ref. 1) , exposure to any level of radiation is assumed to carry with it a certain amount of risk. In the absence of scientific certainty regarding the relationship between low dose exposure and health effects, and as a conservative assumption for radiation protection purposes, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects and that the likelihood of these effects increases as the dose increases. At the occupational dose limit for the whole body of 5 rem (50 mSv) per year, the risk is believed to be very low.

The magnitude of risk of childhood cancer following in utero exposure is uncertain in that both negative and positive studies have been reported. The data from these studies "are consistent with a lifetime cancer risk resulting from exposure during gestation which is two to three times that for the adult" (NCRP Report No. 116, Ref. 2). The NRC has reviewed the available scientific literature and has concluded that the 0.5 rem (5 mSv) limit specified in 10 CFR 20.1208 provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions specified in 10 CFR Part 20, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring pregnancy is provided in this guide or the licensee may use its own form letter for declaring pregnancy. A separate written declaration should be submitted for each pregnancy.

## **C. REGULATORY POSITION**

### **1. Who Should Receive Instruction**

Female workers who require training under 10 CFR 19.12 should be provided with the information contained in this guide. In addition to the information contained in Regulatory Guide 8.29 (Ref. 1), this information may be included as part of the training required under 10 CFR 19.12.

### **2. Providing Instruction**

The occupational worker may be given a copy of this guide with its Appendix, an explanation of the contents of the guide, and an opportunity to ask questions and request additional information. The information in this guide and Appendix should also be provided to any worker or supervisor who may be affected by a declaration of pregnancy or who may have to take some action in response to such a declaration.

Classroom instruction may supplement the written information. If the licensee provides classroom instruction, the instructor should have some knowledge of the biological effects of radiation to be able to answer questions that may go beyond the information provided in this guide. Videotaped presentations may be used for classroom instruction. Regardless of whether the licensee provides classroom training, the licensee should give workers the opportunity to ask questions about information contained in this Regulatory Guide 8.13. The licensee may take credit for instruction that the worker has received within the past year at other licensed facilities or in other courses or training.

### **3. Licensee's Policy on Declared Pregnant Women**

The instruction provided should describe the licensee's specific policy on declared pregnant women, including how those policies may affect a woman's work situation. In particular, the instruction should include a description of the licensee's policies, if any, that may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy consistent with 10 CFR 20.1208.

The instruction should also identify who to contact for additional information as well as identify who should receive the written declaration of pregnancy. The recipient of the woman's declaration may be identified by name (e.g., John Smith), position (e.g., immediate supervisor, the radiation safety officer), or department (e.g., the personnel department).

### **4. Duration of Lower Dose Limits for the Embryo/Fetus**

The lower dose limit for the embryo/fetus should remain in effect until the woman withdraws the declaration in writing or the woman is no longer pregnant. If a declaration of pregnancy is withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time the declaration is withdrawn. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

### **5. Substantial Variations Above a Uniform Monthly Dose Rate**


According to 10 CFR 20.1208(b), "The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman so as to satisfy the limit in paragraph (a) of this section," that is, 0.5 rem (5 mSv) to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a monthly equivalent dose limit of 0.05 rem (0.5 mSv) to the embryo/fetus once the pregnancy is known (Ref. 2). In view of the NCRP recommendation, any monthly dose of less than 0.1 rem (1 mSv) may be considered as not a substantial variation above a uniform monthly dose rate and as such will not require licensee justification. However, a monthly dose greater than 0.1 rem (1 mSv) should be justified by the licensee.

## **D. IMPLEMENTATION**

The purpose of this section is to provide information to licensees and applicants regarding the NRC staff's plans for using this regulatory guide.

Unless a licensee or an applicant proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods described in this guide will be used by the NRC staff in the evaluation of instructions to workers on the radiation exposure of pregnant women.

## **REFERENCES**

1. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1 , February 1996.
2. National Council on Radiation Protection and Measurements, *Limitation of Exposure to*

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## **APPENDIX: QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE**

1. Why am I receiving this information?

The NRC's regulations (in 10 CFR 19.12, "Instructions to Workers") require that licensees instruct individuals working with licensed radioactive materials in radiation protection as appropriate for the situation. The instruction below describes information that occupational workers and their supervisors should know about the radiation exposure of the embryo/fetus of pregnant women.

The regulations allow a pregnant woman to decide whether she wants to formally declare her pregnancy to take advantage of lower dose limits for the embryo/fetus. This instruction provides information to help women make an informed decision whether to declare a pregnancy.

2. If I become pregnant, am I required to declare my pregnancy?

No. The choice whether to declare your pregnancy is completely voluntary. If you choose to declare your pregnancy, you must do so in writing and a lower radiation dose limit will apply to your embryo/fetus. If you choose not to declare your pregnancy, you and your embryo/fetus will continue to be subject to the same radiation dose limits that apply to other occupational workers.

3. If I declare my pregnancy in writing, what happens?

If you choose to declare your pregnancy in writing, the licensee must take measures to limit the dose to your embryo/fetus to 0.5 rem (5 millisievert) during the entire pregnancy. This is one-tenth of the dose that an occupational worker may receive in a year. If you have already received a dose exceeding 0.5 rem (5 mSv) in the period between conception and the declaration of your pregnancy, an additional dose of 0.05 rem (0.5 mSv) is allowed during the remainder of the pregnancy. In addition, 10 CFR 20.1208, "Dose to an Embryo/Fetus," requires licensees to make efforts to avoid substantial variation above a uniform monthly dose rate so that all the 0.5 rem (5 mSv) allowed dose does not occur in a short period during the pregnancy.

This may mean that, if you declare your pregnancy, the licensee may not permit you to do some of your normal job functions if those functions would have allowed you to receive more than 0.5 rem, and you may not be able to have some emergency response responsibilities.

4. Why do the regulations have a lower dose limit for the embryo/fetus of a declared pregnant woman than for a pregnant worker who has not declared?

A lower dose limit for the embryo/fetus of a declared pregnant woman is based on a consideration of greater sensitivity to radiation of the embryo/fetus and the involuntary nature of the exposure. Several scientific advisory groups have recommended (References 1 and 2) that the dose to the embryo/fetus be limited to a fraction of the occupational dose limit.

5. What are the potentially harmful effects of radiation exposure to my embryo/fetus?

The occurrence and severity of health effects caused by ionizing radiation are dependent upon the type and total dose of radiation received, as well as the time period over which the exposure was received. See Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Exposure" (Ref. 3), for more information. The main concern is embryo/fetal susceptibility to the harmful effects of radiation such as cancer.

6. Are there any risks of genetic defects?

Although radiation injury has been induced experimentally in rodents and insects, and in the experiments was transmitted and became manifest as hereditary disorders in their offspring, radiation has not been identified as a cause of such effect in humans. Therefore,

the risk of genetic effects attributable to radiation exposure is speculative. For example, no genetic effects have been documented in any of the Japanese atomic bomb survivors, their children, or their grandchildren.

7. What if I decide that I do not want any radiation exposure at all during my pregnancy?

You may ask your employer for a job that does not involve any exposure at all to occupational radiation dose, but your employer is not obligated to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, your embryo/fetus will receive some radiation dose (on average 75 mrem (0.75 mSv)) during your pregnancy from natural background radiation.

The NRC has reviewed the available scientific literature and concluded that the 0.5 rem (5 mSv) limit provides an adequate margin of protection for the embryo/fetus. This dose limit reflects the desire to limit the total lifetime risk of leukemia and other cancers. If this dose limit is exceeded, the total lifetime risk of cancer to the embryo/fetus may increase incrementally. However, the decision on what level of risk to accept is yours. More detailed information on potential risk to the embryo/fetus from radiation exposure can be found in References 2-10.

8. What effect will formally declaring my pregnancy have on my job status?

Only the licensee can tell you what effect a written declaration of pregnancy will have on your job status. As part of your radiation safety training, the licensee should tell you the company's policies with respect to the job status of declared pregnant women. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer and ask what a declaration of pregnancy would mean specifically for you and your job status.

In many cases you can continue in your present job with no change and still meet the dose limit for the embryo/fetus. For example, most commercial power reactor workers (approximately 93%) receive, in 12 months, occupational radiation doses that are less than 0.5 rem (5 mSv) (Ref. 11). The licensee may also consider the likelihood of increased radiation exposures from accidents and abnormal events before making a decision to allow you to continue in your present job.

If your current work might cause the dose to your embryo/fetus to exceed 0.5 rem (5 mSv), the licensee has various options. It is possible that the licensee can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee do a small part of the job that accounts for some of your radiation exposure.

9. What information must I provide in my written declaration of pregnancy?

You should provide, in writing, your name, a declaration that you are pregnant, the estimated date of conception (only the month and year need be given), and the date that you give the letter to the licensee. A form letter that you can use is included at the end of these questions and answers. You may use that letter, use a form letter the licensee has provided to you, or write your own letter.

10. To declare my pregnancy, do I have to have documented medical proof that I am pregnant?

NRC regulations do not require that you provide medical proof of your pregnancy. However, NRC regulations do not preclude the licensee from requesting medical documentation of your pregnancy, especially if a change in your duties is necessary in order to comply with the 0.5 rem (5 mSv) dose limit.

11. Can I tell the licensee orally rather than in writing that I am pregnant?

No. The regulations require that the declaration must be in writing.

12. If I have not declared my pregnancy in writing, but the licensee suspects that I am pregnant, do the lower dose limits apply?

No. The lower dose limits for pregnant women apply only if you have declared your pregnancy in writing. The United States Supreme Court has ruled (in *United Automobile Workers International Union v. Johnson Controls, Inc.*, 1991) that "Decisions about the welfare of future children must be left to the parents who conceive, bear, support, and raise them rather than to the employers who hire those parents" (Reference 7). The

Supreme Court also ruled that your employer may not restrict you from a specific job "because of concerns about the next generation." Thus, the lower limits apply only if you choose to declare your pregnancy in writing.

13. If I am planning to become pregnant but am not yet pregnant and I inform the licensee of that in writing, do the lower dose limits apply?

No. The requirement for lower limits applies only if you declare in writing that you are already pregnant.

14. What if I have a miscarriage or find out that I am not pregnant?

If you have declared your pregnancy in writing, you should promptly inform the licensee in writing that you are no longer pregnant. However, if you have not formally declared your pregnancy in writing, you need not inform the licensee of your nonpregnant status.

15. How long is the lower dose limit in effect?

The dose to the embryo/fetus must be limited until you withdraw your declaration in writing or you inform the licensee in writing that you are no longer pregnant. If the declaration is not withdrawn, the written declaration may be considered expired one year after submission.

16. If I have declared my pregnancy in writing, can I revoke my declaration of pregnancy even if I am still pregnant?

Yes, you may. The choice is entirely yours. If you revoke your declaration of pregnancy, the lower dose limit for the embryo/fetus no longer applies.

17. What if I work under contract at a licensed facility?

The regulations state that you should formally declare your pregnancy to the licensee in writing. The licensee has the responsibility to limit the dose to the embryo/fetus.

18. Where can I get additional information?

The references to this Appendix contain helpful information, especially Reference 3, NRC's Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure," for general information on radiation risks. The licensee should be able to give this document to you.

For information on legal aspects, see Reference 7, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children--What Can the Employer Do?" which is an article in the journal *Radiation Protection Management*.

You may telephone the NRC Headquarters at (301) 415-7000. Legal questions should be directed to the Office of the General Counsel, and technical questions should be directed to the Division of Industrial and Medical Nuclear Safety.

You may also telephone the NRC Regional Offices at the following numbers: Region I, (610) 337-5000; Region II, (404) 562-4400; Region III, (630) 829-9500; and Region IV, (817) 860-8100. Legal questions should be directed to the Regional Counsel, and technical questions should be directed to the Division of Nuclear Materials Safety.

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## REFERENCES FOR APPENDIX

1. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.
2. International Commission on Radiological Protection, *1990 Recommendations of the International Commission on Radiological Protection*, ICRP Publication 60, Ann. ICRP 21: No. 1-3, Pergamon Press, Oxford, UK, 1991.
3. USNRC, "Instruction Concerning Risks from Occupational Radiation Exposure," Regulatory Guide 8.29, Revision 1, February 1996.<sup>(1)</sup> (Electronically available at <http://www.nrc.gov/reading-rm/doc-collections/reg-guides/>)



4. Committee on the Biological Effects of Ionizing Radiations, National Research Council, *Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V)*, National Academy Press, Washington, DC, 1990.
  5. United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.
  6. R. Doll and R. Wakeford, "Risk of Childhood Cancer from Fetal Irradiation," *The British Journal of Radiology*, 70, 130-139, 1997.
  7. David Wiedis, Donald E. Jose, and Timm O. Phoebe, "The Rock and the Hard Place: Employer Liability to Fertile or Pregnant Employees and Their Unborn Children--What Can the Employer Do?" *Radiation Protection Management*, 11, 41-49, January/February 1994.
  8. National Council on Radiation Protection and Measurements, *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child*, NCRP Commentary No. 9, Bethesda, MD, 1994.
  9. National Council on Radiation Protection and Measurements, *Risk Estimates for Radiation Protection*, NCRP Report No. 115, Bethesda, MD, 1993.
  10. National Radiological Protection Board, *Advice on Exposure to Ionising Radiation During Pregnancy*, National Radiological Protection Board, Chilton, Didcot, UK, 1998.
  11. M.L. Thomas and D. Hagemeyer, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities, 1996," Twenty-Ninth Annual Report, NUREG-0713, Vol. 18, USNRC, 1998.<sup>(2)</sup>
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## REGULATORY ANALYSIS

A separate regulatory analysis was not prepared for this regulatory guide. A regulatory analysis prepared for 10 CFR Part 20, "Standards for Protection Against Radiation" (56 FR 23360), provides the regulatory basis for this guide and examines the costs and benefits of the rule as implemented by the guide. A copy of the "Regulatory Analysis for the Revision of 10 CFR Part 20" (PNL-6712, November 1988) is available for inspection and copying for a fee at the NRC Public Document Room, 2120 L Street NW, Washington, DC, as an enclosure to Part 20 (56 FR 23360).

1. Single copies of regulatory guides, both active and draft, and draft NUREG documents may be obtained free of charge by writing the Reproduction and Distribution Services Section, OCIO, USNRC, Washington, DC 20555-0001, or by fax to (301)415-2289, or by email to (DISTRIBUTION@NRC.GOV). Active guides may also be purchased from the National Technical Information Service on a standing order basis. Details on this service may be obtained by writing NTIS, 5285 Port Royal Road, Springfield, VA 22161. Copies of active and draft guides are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

2. Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161. Copies are available for inspection or copying for a fee from the NRC Public Document Room at 2120 L Street NW., Washington, DC; the PDR's mailing address is Mail Stop LL-6, Washington, DC 20555; telephone (202)634-3273; fax (202)634-3343.

## **POSSIBLE HEALTH EFFECTS TO CHILDREN OF WOMEN WHO ARE EXPOSED TO RADIATION DURING PREGNANCY**

During pregnancy, you should be aware of things in your surroundings or in your style of life that could affect your unborn child. If you work in or visit areas designated as Restricted Areas (where access is controlled to protect individuals from being exposed to radiation and radioactive materials), it is desirable that you understand the biological risks of radiation to your unborn child.

Everyone is exposed daily to various kinds of radiation: heat, light, ultraviolet, microwave, ionizing, and so on. For the purposes of this guide, only ionizing radiation (such as x-rays, gamma rays, neutrons, and other high-speed atomic particles) is considered. Actually, everything is radioactive and all human activities involve exposure to radiation. People are exposed to different amounts of natural "background" ionizing radiation depending on where they live. Radon gas in homes is a problem of growing concern. Background radiation comes from four sources:

### Average Annual Dose

Terrestrial - radiation from soil and rocks 28 mrem

Cosmic - radiation from outer space 28 mrem

Radon - inhaled from air 200 mrem

Radioactivity normally found within the human body 40 mrem

300 mrem

Variability (geographic and other factors) 100 to 5,000 mrem

The first two of these sources expose the body from the outside, and the last two sources expose the body from the inside. The average person is thus exposed to a total dose of about 300 mrem per year from natural background radiation

In addition to exposure from normal background radiation, medical procedures may contribute to the dose people receive. The following table lists the average doses received by the bone marrow (the blood-forming cells) from different medical applications.

### Average X-Ray Procedure Dose

Normal chest examination 10 mrem

Normal dental examination 10 mrem

Rib cage examination 140 mrem

Gall bladder examination 170 mrem

Barium enema examination 500 mrem

Pelvic examination 600 mrem

### REGULATORY POSITION

Federal and State regulations and guidance are based on the conservative assumption that any amount of radiation, no matter how small, can have a harmful effect on an adult, child, or unborn child. This assumption is said to be conservative because there are no data showing ill effects from small doses; the National Academy of Sciences recently expressed "uncertainty as to whether a dose of, say, 1,000 mrem would have any effect at all." Since it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, the regulatory agencies have established a special dose limit for protection of the unborn child if the mother *declares* her pregnancy. Since this limit could result in job discrimination for women of child-bearing age and perhaps in the invasion of privacy (if pregnancy tests were required) it only applies to the unborn child of woman who *declare* their pregnancy. The regulatory agencies have taken the position that special protection of the unborn child should be voluntary and should be based on decisions made by workers and employers who are well informed about the risks involved.

For this position to be effective, it is important that both the employee and the employer understand the risk to the unborn child from radiation received as a result of the occupational exposure of the mother. This document tries to explain the risk as clearly as possible and to compare it with other risks to the unborn child during pregnancy. It is hoped this will help pregnant employees balance the risk to the unborn child against the benefits of employment to decide if the risk is worth taking. This document also discusses methods of keeping the dose, and therefore the risk, to the unborn child as low as is reasonably achievable.

The present limit on radiation dose that can be received on the job is 5,000 millirem per year. Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 500 millirem per year.

Because of the sensitivity of the unborn child, the National Council on Radiation Protection and Measurements (NCRP) has recommended that the dose equivalent to the unborn child from occupational exposure of the expectant mother be limited to 500 millirem for the entire pregnancy (Ref.2). The 1987 Presidential guidance (Ref.1) specifies an effective dose equivalent limit of 500 millirems to the unborn child if the pregnancy has been declared by the mother; the guidance also recommends that substantial variations in the rate of exposure be avoided. The NRC (in § 20.208 of its revision to Part 20, effective 1/1/94) requires the employer to ensure that the dose to an

embryo/fetus during the entire pregnancy, due to occupational exposure of a "declared pregnant woman", does not exceed 0.5 rem (5 mSv)..

### **ADVICE FOR EMPLOYEE AND EMPLOYER**

Although the risks to the unborn child are small under normal working conditions, it is still advisable to limit the radiation dose from occupational exposure to no more than 500 millirems for the total pregnancy. Employee and employer should work together to decide the best method for accomplishing this goal. Some methods that might be used include reducing the time spent in radiation areas, wearing some shielding over the abdominal are, and keeping an extra distance from radiation sources when possible. The employer or medical physicist will be able to estimate the probable dose to the unborn child during the normal nine-month pregnancy period and to inform the employee of the amount. If the predicted dose exceeds 500 millirems, the employee and employer should work out schedules or procedures to limit the dose to the 500-millirem recommended limit.

It is important that the employee inform the employer of her condition as soon as she realizes she is pregnant if the dose to the unborn child is to be minimized. By definitions (§ 20.1003), a "declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

### **INTERNAL HAZARDS**

This document has been directed primarily toward a discussion of radiation doses received from sources outside the body. Workers should also be aware that there is a risk of radioactive material entering the body in workplaces where unsealed radioactive material is used. Nuclear medicine clinics, laboratories, and radiation therapy may use radioactive material in bulk form, often as a liquid or a gas. A list of the commonly used materials and safety precautions for each is beyond the scope of this document, but certain general precautions might include the following:

1. Do not smoke, eat, drink, or apply cosmetics around radioactive material.
2. Do not pipette solutions by mouth
3. Use disposable gloves while handling radioactive material.
4. Wash hands after working around radioactive material.
5. Wear lab coats or other protective clothing whenever there is a possibility of spills.

Remember that the employer is required to have demonstrated safe procedures and practices are in before the Regulatory issues a license to use radioactive material or radiation producing devices. Workers are urged to follow established procedures and

consult the employer's radiation safety officer or medical physicist whenever problems or questions arise.

## **EFFECTS ON THE EMBRYO/FETUS OF EXPOSURE TO RADIATION AND OTHER ENVIRONMENTAL HAZARDS**

In order to decide whether to continue working while exposed to ionizing radiation during her pregnancy, a woman should understand the potential effects on an embryo/fetus, including those that may be produced by various environmental risks such as smoking and drinking. This will allow her to compare these risks with those produced by exposure to ionizing radiation.

Table 1 provides information on the potential effects resulting from exposure of an embryo/fetus to radiation and non radiation risks. The second column gives the rate at which the effect is produced by natural causes in terms of the number per thousand cases. The fourth column gives the number of additional effects per thousand cases believed to be produced by exposure to the specified amount of the risk factor.

The following section discusses the studies from which the information in Table 1 was derived. The results of exposure of the embryo/fetus to the risk factors and the dependence on the amount of the exposure are explained.

### **1. RADIATION RISKS**

#### **1.1 Childhood Cancer**

Numerous studies of radiation-induced childhood cancer have been performed, but a number of them are controversial. The National Academy of Science (NAS) BEIR report reevaluated the data from these studies and even reanalyzed the results. Some of the strongest support for a causal relationship is provided by twin data from the Oxford survey (Ref.4). For maternal radiation doses of 1,000 millirems, the excess number of deaths (above those occurring from natural causes) was found to be 0.2 to 0.25 death per thousand children (Ref. 20).

#### **1.2 Mental Retardation and Abnormal Smallness of the Head (Microcephaly)**

Studies of Japanese children who were exposed while in the womb to the atomic bomb radiation at Hiroshima and Nagasaki have shown evidence of both small head size and mental retardation. Most of the children were exposed to radiation doses in the range of 1 to 50 rads. The importance of the most recent study lies in the fact that investigators were able to show that the gestational age (age of the embryo/fetus after conception) at the time the children were exposed was a critical factor (Ref.7). The approximate risk of small head size as a function of gestational age is shown in Table 1. For a radiation dose of 1,000 millirems at 4 to 7 weeks after conception, the excess cases of small head size was 5 per thousand; at 8 to 11 weeks, it was 9 per thousand (Ref. 7).

In another study, the highest risk of mental retardation occurred during the 8 to 15 week period after conception (Ref. 8). A recent EPA study (Ref. 16) has calculated that excess cases of mental retardation per live birth lie between 0.5 and 4 per thousand per rad.

### **1.3 Genetic Effects**

Radiation-induced genetic effects have not been observed to date in humans. The largest source of material for genetic studies involves the survivors of Hiroshima and Nagasaki, but the 77,000 births that occurred among the survivors showed no evidence of genetic effects. For doses received by the pregnant worker in the course of employment considered in this guide, the dose received by the embryo/fetus apparently would have a negligible effect on descendants (Refs. 17 and 18)

## **2. NON RADIATION RISKS**

### **2.1 Occupation**

A recent study (Ref.9) involving the birth records of 130,000 children in the State of Washington indicates that the risk of death to the unborn child is related to the occupation of the mother. Workers in the metal industry, the textile industry, and farms exhibited stillbirths or spontaneous abortions at a rate of 90 per thousand above that of workers in the control group, which consisted of workers in several other industries.

### **2.2 Alcohol**

It has been recognized since ancient times that alcohol consumption has an effect on the unborn child. Carthaginian law forbade the consumption of wine on the wedding night so that a defective child might not be conceived. Recent studies have indicated that small amounts of alcohol consumption have only the minor effect of reducing the birth weight slightly, but when consumption increases to 2 to 4 drinks per day, a pattern of abnormalities called the fetal alcohol syndrome (FAS) begins to appear (Ref. 11). This syndrome consists of reduced growth in the unborn child, faulty brain function, and abnormal facial features. There is a syndrome that has the same symptoms as full-blown FAS that occurs in children born to mothers who have not consumed alcohol. This naturally occurring syndrome occurs in about 1 to 2 cases per thousand (Ref. 10).

For mothers who consume 2 to 4 per day, the excess occurrences number about 100 per thousand; and for those who consume more than 4 drinks per day, excess occurrences number 200 per thousand. The most sensitive period for this effect of alcohol appears to be the first few weeks after conception, before the mother-to-be realizes she is pregnant (Refs.10 and 11). Also, 17% or 170 per thousand of the embryo/fetuses of chronic alcoholics develop FAS and die before birth (Ref 15.). FAS was first identified in 1973 in the United States where less than full-blown effects of the syndrome are now referred to as fetal alcohol effects (FAE) (Ref.12).

### 2.3 Smoking

Smoking during pregnancy causes reduced birth weights in babies amounting to 5 to 9 ounces on the average. In addition, there is an increased risk of 5 infant deaths per thousand for mothers who smoke less than one pack per day and 10 infant deaths per thousand for mothers who smoke one or more packs per day (Ref. 13).

### 2.4 Miscellaneous

Numerous other risks affect the embryo/fetus, only a few of which are touched upon here. Most people are familiar with the drug thalidomide (a sedative given to some pregnant women), which causes children to be born with missing limbs, and the more recent use of the drug diethylstilbestrol (DES), a synthetic estrogen given to some women to treat menstrual disorders, which produced vaginal cancers in the daughters born to women who took the drug. Living at high altitudes also gives rise to an increase in the number of low-birth-weight children born, while an increase in Down's Syndrome (mongolism) occurs in children born to mothers who are over 35 years of age. The rapid growth in the use of ultrasound in recent years has sparked an ongoing investigation into the risks of using ultrasound for diagnostic procedures (Ref. 19).