

## APPENDIX TO REGULATORY GUIDE 8.13

### INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

#### Basic Radiation Exposure Limits

As a worker in an activity licensed by the Nuclear Regulatory Commission (NRC), you may be exposed to more radiation than the general public. The amount of radiation an individual receives is called the "dose" and it is measured in "rems."<sup>1</sup> The average individual in the United States accumulates a dose of 1 rem from natural radiation sources<sup>2</sup> every 12 years. The NRC has established a basic radiation exposure limit<sup>3</sup> for all occupationally exposed adults of 1.25 rems per calendar quarter, which is 5 rems per year. If a licensee has records of your previous radiation exposure history and your total radiation exposure does not exceed an average of 5 rems per year, the regulations currently allow a maximum of 3 rems per calendar quarter (a total annual dose of 12 rems per year).<sup>4</sup> Individuals under 18 years of age and members of the general public are permitted to be exposed to only 0.125 rem per calendar quarter or one-tenth of the occupational limits.

It must be remembered, however, that these limits are for adults. Internationally recognized groups of scientists have considered the special situation that exists when an unborn child may be exposed to radiation as a result of occupational exposure of the mother.

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<sup>1</sup>Note: A rem is a measure of radiation dose just as the mile is a measure of distance and the pound is a measure of weight.

<sup>2</sup>Exposure to natural or background radiation comes from cosmic rays (from outer space), from radioactive materials that occur naturally in rock or brick structures, and from radioactive elements present naturally in the food and water we eat and drink.

<sup>3</sup>In the Code of Federal Regulations, Title 10, Part 20, "Standards for Protection Against Radiation," Section 20.101, "Radiation Dose Standards for Individuals in Restricted Areas."

<sup>4</sup>Recent guidance from the Environmental Protection Agency recommends a maximum allowed dose of 5 rems per year rather than 12. This recommendation is included in a proposed rule change by the NRC, which was published for public comment in the Federal Register (44 FR 10388, February 20, 1979).

## Recommendations of Scientific Organizations

The scientific organization called the National Council on Radiation Protection and Measurements (NCRP) has recommended that because the unborn<sup>5</sup> are more sensitive to radiation than adults, their radiation dose from occupational radiation exposure of the mother should not exceed 0.5 rem (Ref. 1). The International Commission on Radiological Protection (ICRP) recommends that occupational radiation exposure of women of reproductive capacity be received gradually in small increments so that it would be unlikely for an unborn baby to receive more than 0.5 rem in the first 2 months when a woman may not be aware that she is pregnant (Ref. 2). After a woman knows she is pregnant, the ICRP recommends that she not work in areas where the annual exposure would probably exceed 1.5 rems.

## NRC Requirements

All Nuclear Regulator Commission licensees are required<sup>6</sup> to inform all individuals who work in a restricted radiation area of the risks associated with radiation exposure. This instruction should include information on the risks to the unborn. The regulations also require<sup>7</sup> licensees to keep radiation exposures as low as is reasonably achievable. For radiation protection purposes, the NRC assumes that there is some risk associated with any amount of radiation exposure (down to zero). According to the NCRP, vigorous efforts should be made to keep the radiation exposure of the unborn at the very lowest practicable level during the entire pregnancy.

Therefore, it is the responsibility of your employer to take all practicable steps to reduce your radiation exposure and to keep you informed of the exposures you are receiving.

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<sup>5</sup>Specifically, from conception to about 15 days an unborn child is referred to as a zygote; from 15 days until 2 months as an embryo; and from 2 months until birth as a fetus. In this appendix, the term unborn is used to include all three stages.

<sup>6</sup>By the Code of Federal Regulations, Title 10, Part 19, "Notices, Instructions and Reports to Workers; Inspections."

<sup>7</sup>In the Code of Federal Regulations, Title 10, Part 20, "Standards for Protection Against Radiation, "Section 20.1, "Purpose."

## Your Responsibility

It is your responsibility to decide whether the risks to you or to a potential unborn child are acceptable. The following facts will help you make your decision:

1. The first 3 months pregnancy are the most important, so you should make your decision early.
2. In most work situations, the actual dose received by an unborn child would be less than the dose you would receive yourself because some of the dose would be absorbed by your body.
3. The dose to the unborn child can be reduced, where possible, (a) by decreasing the amount of time you spend in an area where you will be exposed to radiation, (b) by increasing the distance between yourself and the source of radiation, and (c) by shielding your abdominal area.
4. If you do become pregnant, you could ask your employer to reassign you to areas involving less exposure to radiation.
5. When your occupational exposure is below the 5 rems per year limit, the risk to an unborn child may be small in relation to other day-to-day risks to the unborn during pregnancy. Experts disagree on the exact amount.
6. There is no need to be concerned about sterility, that is, loss of your ability to bear children. The radiation dose required to produce this effect is more than 100 times greater than the Nuclear Regulatory Commission's basic dose limits for adults of 5 rems per year, 1.25 rems per calendar quarter.
7. Even if you work in an area where you receive only 0.5 rem per 3-month period, in 9 months you could receive 1.5 rems, and your unborn baby could therefore, if you decide to restrict your unborn baby's radiation exposure as recommended by the NCRP, be aware that the 0.5 rem limit to the unborn applies to the full 9-month pregnancy.

## Your Additional Rights as a Worker

It is up to you to compare the benefits of your employment against the possible risks involving occupational radiation exposure to a known or potential unborn child. You should know that the Pregnancy Discrimination Act, an amendment of Title VII of the Civil Rights Act of 1964, states that ". . . women affected by pregnancy, childbirth, or related medical conditions; shall be treated the same for all employment-related purposes, including receipt of benefits under fringe benefit programs, as other persons not so affected but similar in their ability or inability to work . . ." (Ref. 3). In addition, the Equal Employment Opportunity Commission (a Federal agency) is responsible for examining cases for compliance with this Act.

## Why the Unborn are More Sensitive

The remainder of this appendix contains a brief explanation of prenatal<sup>8</sup> exposure to radiation in relation to other risks to the unborn during pregnancy.

The unborn baby is more sensitive to radiation than the adult because of its rapid rate of development. At certain times during development, those cells forming a specific organ or body function are not yet developed (Ref.4).

Four to six percent of the live births show some birth defect. Most often it is not possible to say what caused a particular birth defect. Out of 100 children born with birth defects, 2 to 3 can be attributed to drugs and chemicals. Defects in the genetic material<sup>9</sup> of the parents are thought to cause another 25 out of 100 birth defects (Ref. 5). About 1 out of 3 naturally aborted fetuses show abnormal genetic material (Ref. 6). Other factors in the mother's life (including the exposure of the unborn to naturally-occurring radiation) are thought to cause another 6 out of 100 birth defects. However, it is not known what causes the remaining birth defects, that is, about 65 out of 100 (Ref. 5). It is estimated that 70 out of 100 fertilized eggs will not result in the birth of a living infant (Ref. 7).

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<sup>8</sup>Prenatal means prior to birth, while the unborn child is in the mother's uterus.

<sup>9</sup>Substance involved in reproduction or the passing down of traits from parents to their children.

## Prenatal Radiation Risk Compared to Other Risks

Some common activities once considered safe have now been shown to be harmful during pregnancy (see Table 1). Alcohol has been said to be most common chemical causing infant malformation and mental retardation (Ref. 8). The full "fetal alcohol syndrome" seen in 30 to 50 out of 100 mothers who were heavy (8 or more drinks per day) shows greater problems, brain dysfunction, and subtle facial signs. Symptoms of the fetal alcohol syndrome were seen in the children of 11 out of 100 women who drank 2 to 4 drinks a day during pregnancies, and in children of 19 out of 100 women who drank 4 or more drinks a day during their pregnancies.

**TABLE 1**

**EFFECT AND FREQUENCY OF CERTAIN MATERNAL FACTORS ON PREGNANCY OUTCOME**

<b>MATERNAL FACTOR</b>	<b>PREGNANCY OUTCOME</b>	<b>RATE OF OCCURRENCE</b>
<b><u>German Measles</u><sup>a</sup></b>	Defects of: heart, lens of the eye, skeletal muscles, inner ear, teeth.	2 in 3
<b><u>Cigarette Smoking</u><sup>b</sup></b>	In general, babies weigh 5 to 9 ounces less than average babies.	
Less than 1 pack per day	Infant death	1 in 5
Pack or more per day	Infant death	1 in 3
<b><u>Alcohol Consumption</u><sup>c</sup></b>		
2 drinks per day	Babies weigh 2 to 6 ounces less than average babies	
2 to 4 drinks per day	Signs of fetal alcohol syndrome (growth deficiency, brain dysfunction, characteristic facial signs)	1 in 10
4 or more drinks per day		1 in 5
Chronically alcoholic		1 in 3 to 1 in 2
<b><u>Maternal Age</u><sup>d</sup></b>		
20 years	Down's Syndrome (Mental and physical growth retardation)	1 in 2300
35 to 39 years		1 in 64
40 to 44 years		1 in 39
<b><u>Aspirin</u><sup>e</sup></b> (Salicylates)	Clubfoot	1 in 13
<b><u>High Altitude</u><sup>f</sup></b>		
Mean altitude		
263 feet	Low birth weight (higher risk); babies weigh less than 5 1/2 pounds	1 in 25
5000 feet		1 in 10
10,500 feet		1 in 4

MATERNAL FACTOR	PREGNANCY OUTCOME	RATE OF OCCURRENCE
<b><u>Radiation<sup>g</sup></u></b>		
Childhood Cancer: 1 rem	Childhood leukemia deaths before the age of 12 years	1 in 3333
1 rem	Deaths from other childhood cancers before the age of 10	1 in 3571
Bomb exposure at 4-13 weeks gestation		
From 15 to greater than 100 rads <sup>h</sup> (Hiroshima)	Small head size with severe mental retardation at exposures greater than 25 rads	
Greater than 150 rads (Nagasaki)		

a. G. Tondury, "The Virus as a Danger to Human Embryos," Teratology Symposium, Como, Italy, October 1967, edited by A. Bertelli, L. Donati, Excerpta Medica Foundation, Amsterdam, 1969.

b. M. B. Meyer and J. A. Tonascia, "Maternal Smoking, Pregnancy Complications, and Perinatal Mortality," American Journal of Obstetrics and Gynecology, Vol. 128, no. 5, pp. 494-502, July 1, 1977.

c. D. W. Smith, "Alcohol Effects on the Fetus," Progress in Clinical and Biological Research, edited by K. Adamson and H. A. Fox, Alan R. Liss, Inc., New York, 1975.

d. "Preventability of Perinatal Injury," Progress in Clinical and Biological Research, edited by K. Adamson and H.A. Fox, Alan R. Liss, Inc., New York, 1975.

e. I. D. Richards, "A Retrospective Inquiry into Possible Teratogenic Effects of Drugs in Pregnancy," Advances in Experimental Medical Biology, Vol 27, p. 441, 1972.

f. D. Grahn and J. Kratchman, "Variation in Neonatal Death Rate and Birth Weight in the United States and Possible Relations to Environmental Radiation, Geology and Altitude," American Journal of Human Genetics, Vol 15, pp. 329-351, 1963.

g. National Academy of Sciences, Report of the Committee on the Biological Effects of Ionizing Radiation (BEIR-80 Report), "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation," Washington, D.C., November 1980.

h. Rads and rems are measurements of radiation dose. For some types of radiation, such as those present at the bombings, a given dose of rads might equal a larger dose of rems. The experts are not sure.

Babies born to women who smoked cigarettes while they were pregnant weighed less than average babies, which contributes to a higher risk of early death. In addition, higher numbers of natural abortions were seen with these mothers and lower performance and physical well being were seen in their children when tested at age 7 (Ref. 9). Aspirin, antihistamines, cold remedies, barbiturates, and amphetamines are a few drugs suspected of having harmful effects on the developing baby (Ref. 10). The Food and Drug Administration has warned pregnant women to avoid or reduce their intake of caffeine (found in coffee, tea, and cola drinks) because of animal studies showing related birth defects (Ref. 11).

Radiation also can be harmful to an unborn baby at doses that would have little or no effect on adults.<sup>10</sup> Large doses of radiation (greater than 100 rems) to unborn babies can cause growth retardation, severe birth defects, and even death. Which organ is most seriously affected by radiation depends on the stage of growth at the time of the exposure. For growth defects, the period of the greatest sensitivity is between weeks 2 and 12 of a woman's pregnancy. During a large part of this time, a woman may not be aware that she is pregnant.

The BEIR-80<sup>11</sup> report (Ref. 12) discusses the effects of radiation on the growing baby. Small head size was seen in the studies of Japanese children who were in the womb when their mothers received doses of atomic bomb radiation over a very short period, greater than 10 rads at Hiroshima and greater than 150 rads at Nagasaki.<sup>12</sup> The reason for the different degree of effect

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<sup>10</sup>For a general discussion of risks to adults from occupational radiation exposure, see Regulatory Guide 8.29, "Instruction Concerning Risks from Occupational Radiation Exposure." A list of additional publications on the biological risks of radiation exposure can be found in the bibliography of this appendix.

<sup>11</sup>The Committee on the Biological Effects of Ionizing Radiation (BEIR) was established by the National Academy of Sciences to report on the effects on populations from exposure to low levels of radiation.

<sup>12</sup>A rad is a measure of radiation dose similar to the rem. The radiation dose in rads may be converted to the dose in rems. For example, 10 rads at Hiroshima may have been more than 10 rems; the experts are not sure, but the matter is under study.

at the two cities is not known. At higher doses, greater than 25 rads, mental retardation was associated with the small head size.

The BEIR-80 report also discussed several studies performed to evaluate an increased risk of cancer (especially leukemia) in children whose mothers had received medical x-ray examinations while pregnant. The BEIR Committee concluded that if 100,000 unborn babies were each exposed to 1 rem, up to 62 of the children could get leukemia before reaching 10 years of age. Of these, 37 cases would occur normally regardless of radiation exposure. Therefore, the number of cancers assumed to be caused by radiation would be 25. An equal number of other cancers could result from this level of radiation. Hence, it is not certain that the low doses of radiation actually caused the childhood cancers or if the babies that later developed cancer were for some reason more likely to be x-rayed while in the womb.

The National Council on Radiation Protection and Measurements (NCRP Report No. 53, Ref. 13) questions whether a dose of 5 to 10 rems, received at critical stages in the baby's development (2 to 12 weeks), can cause birth defects or an increased risk of childhood cancer. Therefore, the NCRP recommends that a radiation exposure limit of 0.5 rem to the unborn during the entire pregnancy be set to ensure a reasonable safety factor. The International Commission on Radiation Protection (ICRP) in their report No. 26 gives a similar recommendation (Ref. 2).

### Some Radioactive Material Can Be Inhaled or Swallowed

Special care should be taken when a potentially pregnant woman is working with radioactive material that can be inhaled or swallowed. If you are pregnant, this type of radioactive material may enter your body and cross into your baby's body.<sup>13</sup> If you are working with such material, you should talk to the person responsible for radiation protection at your place of work (such as the radiation safety officer or health physicist, if available) about the following questions:

1. Will the radioactive material be retained in my body?
2. Will the radioactive material cross from my body to my baby's body?

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<sup>13</sup>Much of this information was presented by Steven A. Book in "Health Physics Education for the Pregnant Worker" at the 1980 Health Physics Society Meeting in Honolulu, Hawaii, December 1979.

3. How can I avoid breathing or swallowing this radioactive material?
4. How can I get rid of this radioactive material if I get it into my body?

Radioiodine, a radioactive medicine widely used in hospitals for diagnostic and therapeutic purposes and in research laboratories, is a good example of the type of radioactive material that can enter your body. Radioiodine is important in this regard because it easily crosses into the unborn baby's body and may affect its thyroid gland, which starts to function at about the tenth week of pregnancy (Ref. 14). By the time of birth, the amount of radioiodine in each ounce of the baby's thyroid would be higher than that in the mother's thyroid (Ref. 14). In addition, the baby's thyroid is more sensitive than the adult thyroid (Ref. 15). Radioiodine as a gas-easily mixes with the air and has been reported to be present in nuclear medicine workers in concentrations several times higher than workers who did not usually work directly with radioiodine (Ref. 16).

### Summary of Risks

Occupational exposures to radiation are for most workers in NRC-licensed activities, well below the established limits. However, qualified scientists have recommended that the radiation dose to the unborn as a result of occupational exposure of the expectant mother should not exceed 0.5 rem because of possible effects on development of the unborn child and an increased risk of childhood leukemia and cancer. Since 0.5 rem per 9 months is lower than the dose generally permitted for adult radiation workers, woman workers may want to take special actions to avoid receiving exposures higher than 0.5 rem per 9 months. Similarly, women may stop smoking and drinking during pregnancy or may restrict their intake of drugs and caffeinated beverages -- all to reduce risks to their developing babies.

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