



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 8.13
(Task OP 031-4)

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12, "Instructions to Workers," of 10 CFR Part 19, "Notices, Instructions, and Reports to Workers; Inspections," requires that all individuals working in or frequenting any portion of a restricted area¹ be instructed in the health protection problems associated with exposure to radioactive materials or radiation, in precautions or procedures to minimize exposure, and in the regulations that they are expected to observe. The present 10 CFR Part 20, "Standards for Protection Against Radiation," has no special limit for exposure of the embryo/fetus.² This guide describes the instructions an employer should provide to workers and supervisors concerning biological risks to the embryo/fetus exposed to radiation, a dose limit for the embryo/fetus that is under consideration, and suggestions for reducing radiation exposure.

This regulatory guide takes into consideration a proposed revision to 10 CFR Part 20, which incorporates the radiation protection guidance for the embryo/fetus approved by the President in January 1987 (Ref. 1). This revision to Part 20 was issued in January 1986 for comment as a proposed rule. Comments on the guide as it pertains to the proposed Part 20 are encouraged. If the new Part 20 is codified, this regulatory guide will be revised to conform to the new regulation and will incorporate appropriate public comments.

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Parts 19 or 20, which provide the regulatory

¹Restricted area means any area that has controlled access to protect individuals from being exposed to radiation and radioactive materials.

²In conformity with the proposed revision to 10 CFR Part 20, the term "embryo/fetus" is used throughout this document to represent all stages of pregnancy.

basis for this guide. The information collection requirements in 10 CFR Parts 19 and 20 have been cleared under OMB Clearance Nos. 3150-0044 and 3150-0014, respectively.

B. DISCUSSION

It has been known since 1906 that cells that are dividing very rapidly and are undifferentiated in their structure and function are generally more sensitive to radiation. In the embryo stage, cells meet both these criteria and thus would be expected to be highly sensitive to radiation. Furthermore, there is direct evidence that the embryo/fetus is radiosensitive. There is also evidence that it is especially sensitive to certain radiation effects during certain periods after conception, particularly during the first 2 to 3 months after conception when a woman may not be aware that she is pregnant.

Section 20.104 of 10 CFR Part 20 places different radiation dose limits on workers who are minors than on adult workers. Workers under the age of 18 are limited to one-tenth of the adult radiation dose limits. However, the present NRC regulations do not establish dose limits specifically for the embryo/fetus.

The NRC's present limit on the radiation dose that can be received on the job is 1,250 millirems per quarter (3 months).³ Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 125 millirems per quarter. (See § 20.101 of 10 CFR Part 20.)

Because of the sensitivity of the unborn child, the National Council on Radiation Protection and Measurements (NCRP) has recommended that the dose equivalent

³The limit is 3,000 millirems per quarter if the worker's occupational dose history is known and the average dose does not exceed 5,000 millirems per year.

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This guide was issued after consideration of comments received from the public. Comments and suggestions for improvements in these guides are encouraged at all times, and guides will be revised, as appropriate, to accommodate comments and to reflect new information or experience.

Written comments may be submitted to the Rules and Procedures Branch, DRR, ADM, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

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to the unborn child from occupational exposure of the expectant mother be limited to 500 millirems 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 proposed revision to Part 20) has proposed adoption of the above limits on dose and rate of exposure.

In 1971, the NCRP commented on the occupational exposure of fertile women (Ref. 2) and suggested that fertile women should be employed only where the annual dose would be unlikely to exceed 2 or 3 rems and would be accumulated at a more or less steady rate. In 1977, the ICRP recommended that, when pregnancy has been diagnosed, the woman work only where it is unlikely that the annual dose would exceed 0.30 of the dose-equivalent limit of 5 rems (Ref. 3). In other words, the ICRP has recommended that pregnant women not work where the annual dose might exceed 1.5 rem.

C. REGULATORY POSITION

Instructions on radiation risks should be provided to workers, including supervisors, in accordance with § 19.12 of 10 CFR Part 19 before they are allowed to work in a restricted area. In providing instructions on radiation risks, employers should include specific instruc-

tions about the risks of radiation exposure to the embryo/fetus.

The instructions should be presented both orally and in printed form, and the instructions should include, as a minimum, the information provided in Appendix A (Instructor's Guide) to this guide. Individuals should be given the opportunity to ask questions and in turn should be questioned to determine whether they understand the instructions. An acceptable method of ensuring that the information is understood is to give a simple written test covering the material included in Appendix B (Pregnant Worker's Guide). This approach should highlight for instructors those parts of the instructions that cause difficulties and thereby lead to appropriate modifications in the instructional curriculum.

D. IMPLEMENTATION

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

Except in those cases in which an applicant or licensee proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the NRC will use the material described in this guide to evaluate the instructional program presented to individuals, including supervisors, working in or frequenting any portion of a restricted area.

APPENDIX A

INSTRUCTOR'S GUIDE

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 nonradiation 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 0.6 death per thousand children (Ref. 4).

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. NONRADIATION 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 chemical industry, medical technology, the wood 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 had 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).

TABLE 1
EFFECTS OF RISK FACTORS ON PREGNANCY OUTCOME

Effect	Number Occurring from Natural Causes	Risk Factor	Excess Occurrences from Risk Factor
RADIATION RISKS			
Childhood Cancer			
Cancer death in children	1.4 per thousand (Ref. 5)	Radiation dose of 1000 millirems received before birth	0.6 per thousand (Ref. 4)
Abnormalities			
Radiation dose of 1000 millirads received during specific periods after conception:			
Small head size	40 per thousand (Ref. 6)	4-7 weeks after conception	5 per thousand (Ref. 7)
Small head size	40 per thousand (Ref. 6)	8-11 weeks after conception	9 per thousand (Ref. 7)
Mental retardation	4 per thousand (Ref. 8)	Radiation dose of 1000 millirads received 8 to 15 weeks after conception	4 per thousand (Ref. 8)
NONRADIATION RISKS			
Occupation			
Stillbirth or spontaneous abortion	200 per thousand (Ref. 9)	Work in high-risk occupations (see text)	90 per thousand (Ref. 9)
Alcohol Consumption (see text)			
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	2-4 drinks per day	100 per thousand (Ref. 11)
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	More than 4 drinks per day	200 per thousand (Ref. 11)
Fetal alcohol syndrome	1 to 2 per thousand (Ref. 10)	Chronic alcoholic (more than 10 drinks per day)	350 per thousand (Ref. 12)
Perinatal infant death (around the time of birth)	23 per thousand (Refs. 13, 14)	Chronic alcoholic (more than 10 drinks per day)	170 per thousand (Ref. 15)
Smoking			
Perinatal infant death	23 per thousand (Refs. 13, 14)	Less than 1 pack per day	5 per thousand (Ref. 13)
Perinatal infant death	23 per thousand (Refs. 13, 14)	One pack or more per day	10 per thousand (Ref. 13)

For mothers who consume 2 to 4 drinks 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).

APPENDIX B

PREGNANT WORKER'S GUIDE

POSSIBLE HEALTH RISKS 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. For those of you who 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 three sources:

	Average Annual Dose
Terrestrial - radiation from soil and rocks	50 millirem
Cosmic - radiation from outer space	50 millirem
Radioactivity normally found within the human body	25 millirem
	125 millirem*
Dosage range (geographic and other factors)	75 to 5,000 millirem

The first two of these sources expose the body from the outside, and the last one exposes it from the inside. The average person is thus exposed to a total dose of about 125 millirems 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.

*Radiation doses in this document are described in two different units. The rad is a measure of the amount of energy absorbed in a certain amount of material (100 ergs per gram). Equal amounts of energy absorbed from different types of radiation may lead to different biological effects. The rem is a unit that reflects the biological damage done to the body. The millirad and millirem refer to 1/1000 of a rad and a rem, respectively.

X-Ray Procedure	Average Dose*
Normal chest examination	10 millirem
Normal dental examination	10 millirem
Rib cage examination	140 millirem
Gall bladder examination	170 millirem
Barium enema examination	500 millirem
Pelvic examination	600 millirem

*Variations by a factor of 2 (above and below) are not unusual.

NRC POSITION

NRC 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 rad would have any effect at all." Although it is known that the unborn child is more sensitive to radiation than adults, particularly during certain stages of development, the NRC has not established a special dose limit for protection of the unborn child. Such a limit could result in job discrimination for women of child-bearing age and perhaps in the invasion of privacy (if pregnancy tests were required) if a separate regulatory dose limit were specified for the unborn child. Therefore, the NRC has 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 the NRC 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.

RADIATION DOSE LIMITS

The NRC's present limit on the radiation dose that can be received on the job is 1,250 millirems per quarter (3 months). * Working minors (those under 18) are limited to a dose equal to one-tenth that of adults, 125 millirems per quarter. (See § 20.101 of 10 CFR Part 20.)

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 millirems 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 proposed revision to Part 20) has proposed adoption of the above limits on dose and rate of exposure.

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 area, and keeping an extra distance from radiation sources when possible. The employer or health 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 proce-

*The limit is 3,000 millirems per quarter if the worker's occupational dose history is known and the average dose does not exceed 5,000 millirems per year.

dures 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.

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 certain manufacturers 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 when feasible.
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 that it will have safe procedures and practices before the NRC issues it a license to use radioactive material. Workers are urged to follow established procedures and consult the employer's radiation safety officer or health physicist whenever problems or questions arise.

REFERENCES

1. "Federal Radiation Protection Guidance for Occupational Exposure," *Federal Register*, p. 2822, January 27, 1987.
2. National Council on Radiation Protection and Measurements, "Basic Radiation Protection Criteria," NCRP Report No. 39, 1971.
3. International Commission on Radiological Protection, "Recommendations of the International Commission on Radiological Protection," ICRP Publication No. 26, Vol. 1, No. 3, 1977.
4. National Academy of Sciences, "The Effects on Populations of Exposure to Low Levels of Ionizing Radiation (BEIR III)," National Academy Press, Washington, DC, 1980.
5. J. L. Young and R. W. Miller, "Incidence of Malignant Tumors in U.S. Children," *Journal of Pediatrics*, pp. 254-258, 1975.
6. W. J. Blot, "Growth and Development Following Prenatal and Childhood Exposure to Atomic Radiation," *Journal of Radiation Research (Supplement)*, pp. 82-85, 1975.
7. R. W. Miller and J. J. Mulvihill, "Small Head Size After Atomic Radiation," *Teratology*, Vol. 14, pp. 355-358, 1976.
8. M. Otake and W. J. Schull, "In Utero Exposure to A-bomb Radiation and Mental Retardation; a Reassessment," *The British Journal of Radiology*, Vol. 57, pp. 409-414, 1984.
9. T. L. Vaughan et al., "Fetal Death and Maternal Occupation," *Journal of Occupational Medicine*, Vol. 26, No. 9, pp. 676-678, 1984.
10. J. W. Hanson, A. P. Streissguth, and D. W. Smith, "The Effects of Moderate Alcohol Consumption During Pregnancy on Fetal Growth and Morphogenesis," *Journal of Pediatrics*, Vol. 92, pp. 457-460, 1978.
11. D. W. Smith, "Alcohol Effects on the Fetus," *Progress in Clinical and Biological Research*, Vol. 36, pp. 73-82, 1980.
12. L. B. Robe, "Alcohol and Pregnancy," The American Medical Association, Box 10946, Chicago, 1984.
13. 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, 1977.
14. R. H. Mole, "Radiation Effects on Pre-Natal Development and Their Radiological Significance," *The British Journal of Radiology*, Vol. 52, No. 614, pp. 89-101, February 1979.
15. D. A. Roe, *Alcohol and the Diet*, AVI Publishing Company Inc., Westport, Connecticut, 1979.
16. Environmental Protection Agency, "Radionuclides," Background Information Document EPA 520/1-84-022-1, pp. 8-56 - 8-63.
17. G. W. Beebe, "The Atomic Bomb Survivors and the Problem of Low-Dose Radiation Effects," *American Journal of Epidemiology*, Vol. 114, No. 6, pp. 761-783, 1981.
18. W. J. Blot et al., "Reproductive Potential of Males Exposed in Utero or Prepubertally to Atomic Radiation," in *Atomic Bomb Casualty Commission Technical Report TR-39-72*, Radiation Effects Research Foundation, Hiroshima, Japan, 1972.
19. National Council on Radiation Protection and Measurements, "Protection in Nuclear Medicine and Ultrasound Diagnostic Procedures in Children," NCRP Report No. 73, 1983.

VALUE/IMPACT STATEMENT

A draft value/impact statement was published with the proposed Revision 2 to Regulatory Guide 8.13 (Task OP 031-4) when the draft guide was published for public comment in August 1981. No changes were necessary, so a separate value/impact statement for the

final guide has not been prepared. A copy of the draft value/impact statement is available for inspection and copying for a fee at the Commission's Public Document Room at 1717 H Street NW., Washington, DC, under Task OP 031-4.

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