

REGULATORY GUIDE

OFFICE OF STANDARDS DEVELOPMENT

REGULATORY GUIDE 8.13

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 19.12 of 10 CFR Part 19 states that all individuals working in or frequenting any portion of a restricted area must be instructed in the health protection problems associated with exposure to radioactive materials or radiation. This guide describes the instruction that should be provided concerning biological risks to embryos or fetuses resulting from prenatal exposure.*

B. DISCUSSION

Since the Law of Bergonie and Tribondeau was published in 1906** it has been known that the sensitivity of cells to radiation damage is related to their reproductive activity and inversely related to their degree of differentiation. It follows that children could be expected to be more radiosensitive than adults, fetuses more radiosensitive than children, and embryos even more radiosensitive.

This principle has long been a factor in the development of radiation exposure standards. Section 20.104 of 10 CFR Part 20 places different limits on minors than on adult workers. Specifically, it limits anyone under the age of 18 to exposures not exceeding 10% of the limits for adult workers. However, §20.104 does not relate to embryos or fetuses.

A special situation arises when an occupationally exposed woman is pregnant. Exposure of the abdomen of such a worker to penetrating radiation from either external or internal sources would also involve exposure of the embryo or fetus. Because a number of studies have indicated that the embryo or fetus is more sensitive

than an adult, particularly during the first three months after conception, when a woman may not be aware that she is pregnant, the National Council on Radiation Protection and Measurements (NCRP) recommended in its Report No. 39 that special precautions be taken to limit exposure when an occupationally exposed woman could be pregnant.

C. REGULATORY POSITION

Instruction to workers performed under §19.12 should be given prior to assignment to work in a restricted area. In providing instruction about health protection problems associated with radiation exposure, female workers and those who may supervise or work with them should be given specific instruction about prenatal exposure risks to the developing embryo and fetus.

The instruction should ensure that the employees understand:

1. That the NCRP has recommended that, during the entire gestation period, the maximum permissible dose equivalent to the fetus from occupational exposure of the expectant mother should not exceed 0.5 rem and

2. The reasons for this recommendation.

The instruction should include the information provided in the Appendix to this guide. It should be presented to the employee, her supervisors, and her co-workers both orally and in written form. Each individual should be given an opportunity to ask questions, and each individual should be asked to acknowledge in writing that the instruction has been received.

D. IMPLEMENTATION

The purpose of this section is to provide information to licensees regarding the use of this guide.

*This revision of the guide includes minor changes of a clarifying nature incorporated as a result of public comments. No substantive changes have been made.

***Comptes Rendus des Seances de l'Academie des Sciences*, Vol. 143, pp. 983-985, 1906.

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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. This guide was revised as a result of substantive comments received from the public and additional staff review.

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Except in those cases in which the licensee chooses to propose an alternative method for complying with the portion of the Commission's regulations previously specified, the methods described herein should be used immediately to instruct female employees working in or

frequenting any portion of a restricted area, and those who may supervise or work with such employees, concerning the health protection problems associated with prenatal radiation exposure.

U.S. NUCLEAR REGULATORY COMMISSION

APPENDIX TO REGULATORY GUIDE 8.13

POSSIBLE HEALTH RISKS TO CHILDREN OF WOMEN WHO ARE EXPOSED TO RADIATION DURING PREGNANCY

Some recent studies have shown that the risk of leukemia and other cancers in children increases if the mother is exposed to a significant amount of radiation during pregnancy. According to a report by the National Academy of Sciences, the incidence of leukemia among children from birth to 10 years of age in the United States could rise from 3.7 cases in 10,000 children to 5.6 cases in 10,000 children if the children were exposed to 1 rem of radiation before birth (a "rem" is a measure of radiation). The Academy has also estimated that an equal number of other types of cancers could result from this level of radiation. Although other scientific studies have shown a much smaller effect from radiation, the Nuclear Regulatory Commission wants women employees of its licensees to be aware of any possible risk so that the women can take steps they think appropriate to protect their offspring.

As an employee of a Nuclear Regulatory Commission licensee, you may be exposed to more radiation than the general public. However, the Nuclear Regulatory Commission has established a basic exposure limit for all occupationally exposed adults of 1.25 rems per calendar quarter, or 5 rems per year. No clinical evidence of harm would be expected in an adult working within these levels for a lifetime. Because the risks of undesirable effects may be greater for young people, individuals under 18 years of age are permitted to be exposed to only 10 percent of the adult occupational limits. (This lower limit is also applied to members of the general public.)

The scientific organization called the National Council on Radiation Protection and Measurements has recommended that because unborn babies may be more sensitive to radiation than adults, their radiation dose as a result of occupational exposure of the mother should not exceed 0.5 rem. Other scientific groups, including the International Commission on Radiation Protection, have also stressed the need to keep radiation doses to unborn children as low as is reasonably achievable.

All Nuclear Regulatory Commission licensees are now required* to inform all individuals who work in a restricted area of the health protection problems associated with radiation exposure. This instruction would in many cases include information on the possible risks to unborn babies. The regulations also state** that licensees should keep radiation exposures as low as is reasonably achievable. According to the National Council on Radiation Protection and Measurements, vigorous efforts should be made to keep the radiation exposure of an embryo or fetus at the very lowest practicable level during the entire period of pregnancy.

Thus it is the responsibility of your employer to take all practicable steps to reduce your radiation exposure. Then it is your responsibility to decide whether the exposure you are receiving is sufficiently low to protect your unborn child. The advice of your employer's health physicist or radiation protection officer should be obtained to determine whether radiation levels in your working areas are high enough that a baby could receive 0.5 rem or more before birth. If so, the alternatives that you might want to consider are:

(a) If you are now pregnant or expect to be soon, you could decide not to accept or continue assignments in these areas.

(b) You could reduce your exposure, where possible, by decreasing the amount of time you spend in the radiation area, increasing your distance from the radiation source, and using shielding.

(c) If you do become pregnant, you could ask your employer to reassign you to areas involving less exposure to radiation. If this is not possible, you might consider

* By Title 10, Part 19 of the Code of Federal Regulations.

**In Title 10, Part 20.

leaving your job. If you decide to take such steps, do so without delay. The unborn child is most sensitive to radiation during the first three months of your pregnancy.

(d) You could delay having children until you are no longer working in an area where the radiation dose to your unborn baby could exceed 0.5 rem.

You may also, of course, choose to:

(e) Continue working in the higher radiation areas, but with full awareness that you are doing so at some small increased risk for your unborn child.

The following facts should be noted to help you make a decision:

1. The first three months of pregnancy are the most important, so you should make your decision quickly.

2. In most cases of occupational exposure, the actual dose received by the unborn baby is less than the dose received by the mother because some of the dose is absorbed by the mother's body.

3. At the present occupational exposure limit, the actual risk to the unborn baby is small, but experts disagree on the exact amount of risk.

4. There is no need to be concerned about sterility or loss of your ability to bear children. The radiation dose required to produce such effects is more than 100 times larger than the Nuclear Regulatory Commission's dose limits for adults.

5. Even if you work in an area where you receive only 0.5 rem per three-month period, in nine months you could receive 1.5 rems, and the unborn baby could receive more than 0.5 rem, the full-term limit suggested by the NCRP. Therefore, if you decide to restrict your unborn baby's exposure as recommended by the NCRP, be aware that the 0.5 rem limit to the unborn baby applies to the full nine-month pregnancy.

The remainder of this document contains a brief explanation of radiation and its effects on humans. As you will see, some radiation is present everywhere and the levels of radiation most employees of Nuclear Regulatory Commission licensees receive are not much larger than these natural levels. Because the radiation levels in the facility where you will be working are required by law to be kept quite low, there is not considered to be a significant health risk to individual adult employees.

Discussion of Radiation

The amount of radiation an individual receives is called the "dose" and is measured in "rems." The average individual in the United States accumulates a dose of one rem from natural sources every 12 years. The dose from natural radiation is higher in some states, such as Colorado, Wyoming, and South Dakota, primarily because of cosmic radiation. There the average individual gets one rem every 8 years.

Natural background radiation levels are also much higher in certain local areas. A dose of one rem may be received in some areas on the beach at Guarapari, Brazil, in only about 9 days, and some people in Kerala, India, get a dose of one rem every 5 months.

Many people receive additional radiation for medical reasons. In 1970, an estimated 212 million X-ray examinations were performed in the United States. The estimated average surface skin dose from one radiographic chest X-ray is 0.027 rem. The estimated average surface skin dose per abdominal X-ray is 0.62 rem.*

Radiation can also be received from natural sources such as rock or brick structures, from consumer products such as television and glow-in-the-dark watches, and from air travel. The possible annual dose from working 8 hours a day near a granite wall at the Redcap Stand in Grand Central Station, New York City, is 0.2 rem, and the average annual dose in the United States from TV, consumer products, and air travel is 0.0026 rem.

Radiation, like many things, can be harmful. A large dose to the whole body (such as 600 rems in one day) would probably cause death in about 30 days, but such large doses result only from rare accidents. Control of exposure to radiation is based on the assumption that any exposure, no matter how small, involves some risk. The occupational exposure limits are set so low, however, that medical evidence gathered over the past 50 years indicates no clinically observable injuries to individuals due to radiation exposures when the established radiation limits are not exceeded. This was true even for exposures received under the early occupational exposure limits, which were many times higher than the present limits. Thus the risk to individuals at the occupational exposure levels is considered to be very low. However, it is impossible to say that the risk is zero. To decrease the risk still further, licensees are expected to keep actual exposures as far below the limits as is reasonably achievable.

*"Pre-Release Report: X-Ray Exposure Study (XES) Revised Estimates of 1964 and 1970 Genetically Significant Dose," February 4, 1975, U.S. Department of Health, Education, and Welfare, Public Health Service, Federal Drug Administration, Bureau of Radiological Health.

The current exposure limits for people working with radiation have been developed and carefully reviewed by nationally and internationally recognized groups of scientists. It must be remembered, however, that these limits are for adults. Special consideration is appropriate when the individual being exposed is, or may be, an expectant mother, because the exposure of an unborn child may also be involved.

Prenatal Irradiation

The prediction that an unborn child would be more sensitive to radiation than an adult is supported by observations for relatively large doses. Large doses delivered before birth alter both physical development and behavior in experimentally exposed animals. A report of the National Academy of Sciences states that short-term doses in the range of 10 to 20 rems cause subtle changes in the nerve cells of unborn and infant rats. The report also states, however, that no radiation induced changes in development have been demonstrated to result in experimental animals from doses up to about 1 rem per day extended over a large part of the period before birth.

The National Academy of Sciences also noted that doses of 25 to 50 rems to a pregnant human may cause growth disturbances in her offspring. Such doses substantially exceed, of course, the maximum permissible occupational exposure limits.

Concern about prenatal exposure (i.e., exposure of a child while in its mother's uterus) at the permissible occupational levels is primarily based on the possibility that cancer (especially leukemia) may develop during the first 10 years of the child's life. Several studies have been performed to evaluate this risk. One study involved the followup of 77,000 children exposed to radiation before birth (because of diagnostic abdominal X-rays made for medical purposes during their mother's pregnancy). Another study involved the followup of 20,000 such children. In addition, 1292 children who received prenatal exposure during the bombing of Hiroshima and Nagasaki were studied. Although contradictory results have been obtained, most of the evidence suggests a relationship between prenatal exposure and an increased risk of childhood cancer.

Summary

Occupational exposures to radiation are being kept low. However, qualified scientists have recommended that the radiation dose to an embryo or fetus as a result of occupational exposure of the expectant mother should not exceed 0.5 rem because of possible increased risk of childhood leukemia and cancer. Since this 0.5 rem is lower than the dose generally permitted to adult workers, women may want to take special actions to avoid receiving higher exposures, just as they might stop smoking during pregnancy or might climb stairs more carefully to reduce possible risks to their unborn children.

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The Genetic Effects of Radiation

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