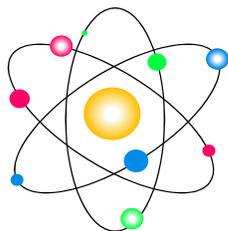
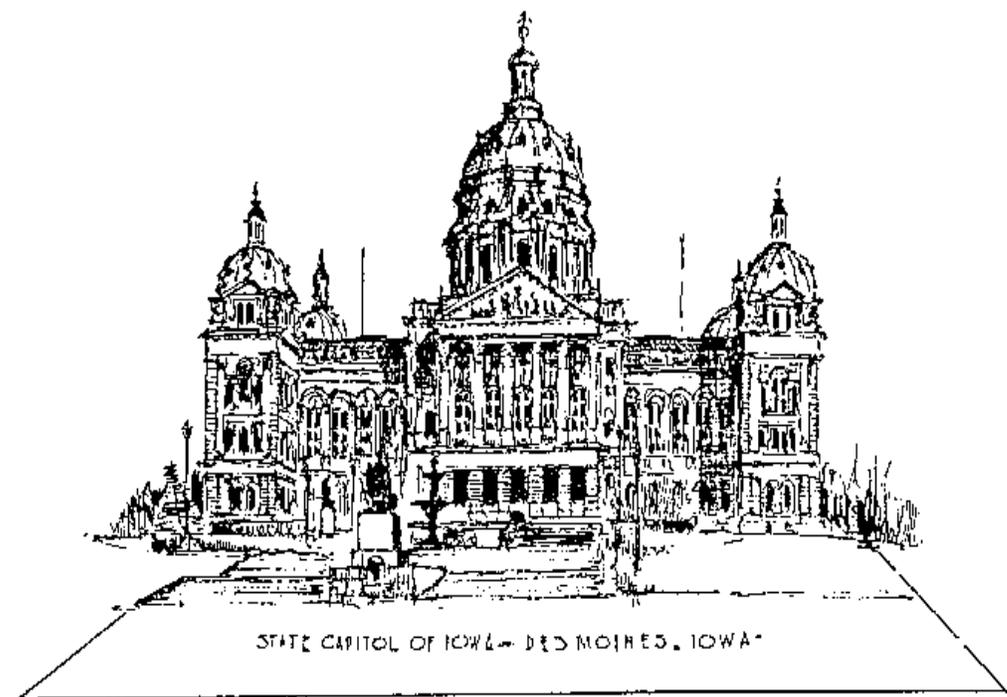

IOWA DEPARTMENT OF PUBLIC HEALTH

**INSTRUCTION CONCERNING PRENATAL
RADIATION EXPOSURE**



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INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

The Radiation Machines and Radioactive Materials Rules of the Iowa Department of Public Health (IDPH) require instruction for all individuals who in the course of their employment are likely to receive an occupational exposure in excess of 100 millirem (1 mSv) in a year. The instructions should include the health protection problems associated with exposure to radiation and/or radioactive material; precautions or procedures to minimize exposure; and 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 IDPH rules on radiation protection are specified in Chapter 40, "Standards for Protection Against Radiation". Section 641-40.22 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 500 millirem (5 mSv)". IDPH rule 40.22(2) 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 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 supplements "*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 IDPH rules also specify requirements for monitoring external and internal occupational dose to a declared pregnant woman. Licensees are required by 40.37(1)"b" 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 100 millirem (1 mSv). 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 IDPH terminates each pertinent license requiring the record.

B. DISCUSSION

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, the scientific community generally assumes that any exposure to ionizing radiation may cause undesirable biological effects. In addition, the assumption is that the likelihood of these effects increases as the dose increases. For radiation protection purposes, these assumptions represent a conservative approach. 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 available scientific literature indicates that the 500 millirem (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 associated with radiation exposure during pregnancy.

In order for a pregnant worker to take advantage of the lower exposure limit and dose monitoring provisions, the woman must declare her pregnancy in writing to the licensee. A form letter for declaring pregnancy is provided in this guide. 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 40.111 should be provided with the information contained in this guide. In addition to the information contained in *"Instruction Concerning Risks from Occupational Radiation Exposure"* (Ref. 1), this information may be included as part of the training provided to employees.

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 act 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 the information. 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, which may affect the declared pregnant woman's work situation after she has filed a written declaration of pregnancy.

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

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 were withdrawn, the dose limit for the embryo/fetus would apply only to the time from the estimated date of conception until the time that 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 40.22(2), "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, 500 millirem (5 mSv) to the embryo/fetus. The National Council on Radiation Protection and Measurements (NCRP) recommends a **monthly** dose limit of 50 millirem (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 100 millirem (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, the licensee should justify a monthly dose greater than 100 millirem (1 mSv).

D. IMPLEMENTATION

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

Unless a licensee or an applicant proposes an acceptable alternative for complying with the specified regulations, IDPH will use the methods described in this guide to evaluate instructions to workers on the radiation exposure of pregnant women.

REFERENCES

1. IDPH Regulatory Guide, "Instruction Concerning Risks from Occupational Radiation Exposure."
2. National Council on Radiation Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, NCRP Report No. 116, Bethesda, MD, 1993.

APPENDIX

QUESTIONS AND ANSWERS CONCERNING PRENATAL RADIATION EXPOSURE

1. Why am I receiving this information?

IDPH rule 641-40.111, "Instructions to Workers" requires that licensees instruct individuals in radiation protection as appropriate for the situation if in the course of employment they are likely to receive in a year an occupational dose in excess of 100 millirem (1 mSv). 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 formally to 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 of whether or not to declare your pregnancy is voluntary. If you choose to declare your pregnancy, you must do so in writing. A lower radiation dose limit will then 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 500 millirem (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 500 millirem (5 mSv) in the period between conception and the declaration of your pregnancy, an additional dose of 50 millirem (0.5 mSv) is allowed during the remainder of the pregnancy. In addition, 641-40.22, "Dose to an Embryo/ Fetus", requires licensees to make efforts to avoid substantial variation above a uniform monthly dose rate. All the 500 millirem (5 mSv) allowed dose should 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 500 millirem. You also 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. The lower dose limit is not required to be implemented unless the worker declares her pregnancy.

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 over which the exposure was received. See Regulatory Guide "*Instruction Concerning Risks from Occupational Exposure*" (Ref. 3) for more information. The main concern is embryo/fetal susceptibility to the harmful long-term 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 millirem (0.75 mSv)) during your pregnancy from natural background radiation.

IDPH, other Agreement States, and the NRC have reviewed the available scientific literature and concluded that the 500 millirem (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 through 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 woman. In addition, before you declare your pregnancy, you may want to talk to your supervisor or your radiation safety officer. You may want to ask how a declaration of pregnancy would affect 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 workers at commercial power reactors (approximately 93%) receive occupational radiation doses that are less than 500 millirem (5 mSv) in 12 months (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 500 millirem (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, your employer may have 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?

IDPH regulations do not require that you provide medical proof of your pregnancy. However, 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 500 millirem (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, does 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 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 might 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 non-pregnant 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 at a licensed facility under a contract?

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, IDPH Regulatory Guide, "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 contact the Iowa Department of Public Health, Bureau of Radiological Health at (515) 281-3478.

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. IDPH, "Instruction Concerning Risks from Occupational Radiation Exposure," (Electronically available at idph.state.ia.us).
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 Ionizing 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, 1998.¹

¹ 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.

FORM LETTER FOR DECLARING PREGNANCY

This form letter is provided for your convenience. To make your written declaration of pregnancy, you may fill in the blanks in this form letter, you may use a form letter the licensee has provided to you, or you may write your own letter.

DECLARATION OF PREGNANCY

To: _____

In accordance with the IDPH rules 641-40.22, "Dose to an Embryo/Fetus," I am declaring that I am pregnant. I believe I became pregnant in _____ (only the month and year need be provided).

I understand the radiation dose to my embryo/fetus during my entire pregnancy will not be allowed to exceed 500 millirem (5 millisievert) (unless that dose has already been exceeded between the time of conception and submitting this letter). I also understand that meeting the lower dose limit may require a change in job or job responsibilities during my pregnancy.

(Your signature)

(Your name printed)

(Date)