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INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

OAR 333-111-010, "Instructions to Workers," and OAR 333-111-015, "Notices, Instructions and Reports to Workers: Inspection and Investigations," requires instruction in, among other things, the health protection problems associated with exposure to radioactive materials or radiation.

OAR 333-120-170, "Dose to An Embryo/Fetus" (see below), requires licensees and registrants 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)."

In OAR 333-100-005 (30), "Declared pregnant woman" means a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception.

OAR 333-120-170 (1) reads as follows:

> The licensee or registrant shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, as defined in OAR 333-100-005 (30), does not exceed 0.5 rem (5 mSv). Records shall be kept in accordance with OAR 333-120-650.

A note follows this rule:

> *A woman is not a declared pregnant woman unless she says so in writing without being coerced. Unless a woman, who also is a radiation worker, has declared her pregnancy as required, she is to be treated as any other radiation worker.*

> Pursuant to Title VII of the Civil Rights Act of 1964, as amended, no employer may restrict a fertile female's job because of concern for the health of the fetus that a woman might conceive. The court held that sex-specific fetal-protection policies are forbidden. Additionally, a female worker legally can declare pregnancy if she does not yet have documented medical proof.

OAR 333-120-170 (1) also requires the licensee or registrant 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 OAR 333-100-005 (30) "a woman who has voluntarily informed her employer, in writing, of her pregnancy and the estimated date of conception."

Guides are issued to describe and make available to the public, information and methods acceptable to the Agency for implementing specific parts of the Agency's rules, techniques used by the agency in evaluating specific problems or postulated accidents, and guidance to applicants. Guides are not substitutes for rules, and compliance with guides is not required.

Any information collection activities mentioned in this guide are contained as requirements in OAR 333-111 or OAR 333-120, which provide the regulatory bases for this guide.

The embryo/fetus is defined in OAR 333-100-005 (42) as "The developing human organism from conception until the time of birth." The embryo is an early stage of development, before the individual limbs and organs are recognizable. In humans, this development takes about eight weeks. The organisms is considered a fetus from that stage until birth.

OAR 333-120-210 specifies the requirements for monitoring for external and internal occupational dose to a declared pregnant woman. Licensees and registrants must monitor the external occupational dose to a declared pregnant woman, using an individual monitoring device, if it is likely that the embryo/fetus will receive, from sources external to the body of the declared pregnant woman, a dose in excess of 50 millirems (0.5 millisievert) during the pregnancy.

Licensees also must monitor, but not necessarily with individual monitoring devices, the occupational intake of radioactive material by declared pregnant women likely to receive, during the pregnancy, a committed effective dose equivalent in excess of 50 millirems (0.5 millisievert).

For monitored declared pregnant women, the licensee or registrant must assess the effective dose equivalent delivered to the embryo/fetus during pregnancy. "Radiation Dose to the Embryo/Fetus"* provides guidance on calculating the radiation dose to the embryo/fetus.

OAR 333-120-650 requires that the licensee or registrant maintain records of dose to an embryo/fetus if monitoring was required, and it requires that the records of the dose to the embryo/fetus be kept with the records of the dose to the declared pregnant woman. "Guidance for Occupational Radiation Exposure Data,"* which includes recommendations concerning records of dose to the embryo/fetus, recommends that licensees and registrants be sensitive to the issue of personal privacy with regard to embryo/fetus dose. If requested by the monitored woman, a letter report may be provided to subsequent licensees or registrants to document prior embryo/fetus dose. The declaration of pregnancy also must be kept on file but may be maintained separately from the dose records [OAR 333-102-650 (5)]. The licensee or registrant must retain each required form or record until the Agency authorizes disposition of the record.

B. DISCUSSION

This guide was developed to provide guidance to licensees and registrants on instructions that must be provided concerning prenatal radiation exposure. In particular, the instructions described in this guide are intended to provide the information needed by women who become pregnant to help them make an informed decision on whether or not to formally declare their pregnancy in accordance with rules.

*Guides are available from Oregon Health Division, Radiation Protection Services, STE 705, 800 N.E. Oregon Street #21, Portland, Oregon 97232, phone (503) 731-4014; FAX (503) 731-4081.

C. REGULATORY POSITION

1. WHO SHOULD RECEIVE INSTRUCTION

Instruction concerning prenatal radiation exposure and its risks to the embryo/fetus should be provided to workers before they are allowed to work in a restricted area. Each supervisor of a female worker who will work in a restricted area should also receive the instruction.

2. HOW TO PROVIDE INSTRUCTION

The instruction should be presented both orally and in written form and should include, as a minimum, the information in the Appendix of this guide. Each worker should be given a copy of this guide. Workers should be given the opportunity to ask questions on the instructions.

3. EMPLOYER=S POLICY ON DECLARED PREGNANT WOMEN

The instruction provided should describe the employer's specific policy on declared pregnant women. In particular, the instruction should include a description of the employer's policies with respect to changes, if any, that may affect the declared pregnant woman's work situation as a result of her filing a written declaration of pregnancy consistent with Division 120 of the Oregon Administrative Rules Chapter 333.

4. DURATION OF LOWER DOSE LIMITS FOR EMBRYO/FETUS

The lower dose limit is in effect until the declared pregnant woman (1) is known to have given birth, (2) informs the licensee or registrant that she is no longer pregnant, or (3) informs the licensee that she no longer wants to be considered a declared pregnant woman.

APPENDIX

INSTRUCTIONS CONCERNING PREGNANT WOMEN

Rules require that licensees or registrants instruct individuals working with licensed radioactive materials in radiation protection as appropriate for the situation. This Appendix describes information that you should know about the radiation exposure of pregnant women. In particular, radiation protection rules allow a pregnant woman to decide whether she wants to formally declare her pregnancy to her employer, thereby taking advantage of the special dose limits provided to protect the developing embryo/fetus.

This Appendix provides information on the potential effects of declaring a pregnancy in order to help women make informed decisions on whether or not to declare pregnancy. The information is provided in the form of answers to a woman's questions.

MAKING THE DECISION TO DECLARE PREGNANCY

1. If I become pregnant, am I required to inform my employer of my pregnancy?

No. It is your choice whether to declare your pregnancy to your employer. If you choose to declare your pregnancy, a lower radiation dose limit will apply to you. If you choose not to declare your pregnancy, you will continue to be subject to the same radiation dose limits that apply to nonpregnant workers even if you are visibly pregnant.

2. If I inform my employer in writing of my pregnancy, what happens?

The amount of radiation that you will be allowed to receive will decrease because there is a lower dose limit for the embryo/fetus of female workers who have formally declared their pregnancy in writing. Ordinarily, the radiation dose limit for a worker is 5 rems (50 millisierverts) in a year. But if you declare in writing that you are pregnant, the dose to the embryo/fetus is generally limited to 0.5 rem (5 millisieverts) during the 9-month pregnancy which is one-tenth of the dose limit that an adult worker may receive in a year. In addition, licensees or registrants must make efforts to avoid substantial variation above a uniform monthly dose rate so that all the dose received does not occur during a particular time of the pregnancy. This may mean that, if you declare your pregnancy, you may not be permitted to perform some of your normal job functions and you may not be able to have emergency response responsibilities.

3. Why do the rules have a lower dose limit for a woman who has declared her pregnancy that for a normal worker?

The purpose of the lower limit is to protect her unborn child. Scientific advisory groups recommend (References 1 and 2) that the dose before birth be limited to about 0.5 rem rather than 5 rem (50 millisieverts) occupational annual dose limit because of the sensitivity of the embryo/fetus to radiation. Possible effects include deficiencies in the child's development, especially the child's neurological development, and an increase in the likelihood of cancer.

4. What effects on development can be caused by radiation exposure?

The effects of large doses of radiation on human development are quite evident and easily measurable, whereas at low doses the effects are not evident or measurable and therefore must be inferred.

For example, studies of the effects of radiation on animals and humans demonstrate clearly and conclusively that large doses of radiation, such as 100 rems (1 sievert), cause serious developmental defects in many of the body's organs when the radiation is delivered during the period of rapid organ development (References 2, 3, 4, and 5).

The developing human brain has been shown to be especially sensitive to radiation. Mental retardation has been observed in the survivors of the atomic bombings in Japan exposed *in utero* during sensitive periods. Additionally, some other groups exposed to radiation *in utero* have shown lower than average intelligence scores and poor performance in school (Reference 4).

The sensitivity of the brain undoubtedly reflects its structural complexity and its long developmental period (and hence long sensitive period). The most sensitive period is during about the 8^{th} to 15^{th} weeks of gestation followed by a substantially less sensitive period for the 2 months after the 15^{th} week (Reference 4). There is no known effect on the child's developing brain during the first two months of pregnancy or the last three months of pregnancy (Reference 4).

No developmental effects caused by radiation have been observed in human groups at doses at or below the 5 rem (50 millisieverts) occupational dose limit. Scientists are uncertain whether there are developmental effects at doses below 5 rems (50 millisieverts). It may be that the effects are present but are too mild to measure because of the normal variability from one person to the next and because the tools to measure the effects are not sensitive enough. Or, it may be that there is some threshold dose below which there are no developmental effects whatsoever.

In view of the possibility of developmental effects, even if very mild, at doses below 5 rems (50 millisieverts), scientific advisory groups consider it prudent to limit the dose to the embryo/fetus to 0.5 rem (5 millisieverts) (References 1 and 2). At doses greater than 5 rems (50 millisieverts), such a might be received during and accident or during emergency response activities, the possibility of developmental effects increases.

5. How much will the likelihood of cancer be increased?

Radiation exposure has been found to increase the likelihood of cancer in many studies of adult human and animal groups. At doses below the occupational dose limit, an increase in cancer incidence has not been proven, but is presumed to exist even if it is to small to be measured. The question here is whether the embryo/fetus is more sensitive to radiation than an adult.

While the evidence for increased sensitivity of the embryo/fetus to cancer induction from radiation exposure is inconclusive, it is prudent to assume that there is some increased sensitivity. Scientific advisory groups assume that radiation exposure before birth may be 2 or 3 times more likely to cause cancer over a person's lifetime than the same amount of radiation received as an adult (Reference 1). If this is true, there would be 1 radiation-induced cancer death in 200 people exposed *in utero* at the occupational dose limit of 5 rems (50 millisieverts) (Reference 1). Scientific advisory groups have considered this risk to be too high and have thus recommended that the radiation dose to the embryo/fetus

be limited to a maximum of 0.5 rem (5 millisieverts). At that dose, there would be 1 radiation-induced cancer death per 2000 people. This would be in addition to the 400 cancer deaths from all causes that one would normally expect in a group of 2000 people.

6. How does the risk to the embryo/fetus from occupational radiation exposure compare to other avoidable risks?

The risk to the embryo/fetus from 0.5 rem or even 5 rems of radiation exposure is relatively small compared to some other avoidable risks.

Of particular concern is excessive consumption of alcohol during pregnancy. The U.S. Public Health Service has concluded that heavy alcohol consumption during pregnancy (three drinks per day and above) is the leading known cause of mental retardation (Reference 6). Children whose mothers drank heavily during pregnancy may exhibit developmental problems such as hyperactivity, distractibility, short attention spans, language difficulties, and delayed maturation, even when their intelligence is normal.

In studies tracking the development of children born to light or moderate drinkers, researchers have also correlated their mothers' drinking patterns during pregnancy with low birth weight, decreased attention spans, delayed reaction times, and lower IQ scores at age 4 years. Youngsters whose mothers averaged three drinks per day during pregnancy were likely to have IQ's averaging 5 points lower than normal.

Cigarette smoking may also harm the unborn (Reference 6). There is a direct correlation between the amount of smoking during pregnancy and the frequency of spontaneous abortion and fetal death. Children of mothers who smoke while pregnant are more likely to have impaired intellectual and physical growth. Maternal smoking has also been associated with such behavioral problems in offspring as lack of self-control, irritability, hyperactivity, and disinterest. Long-term studies indicate that these children perform less well than matched youngsters of nonsmokers on tests of cognitive, psychomotor, language, and general academic functioning.

Alcohol and smoking are only examples of other risks in pregnancy. Many other toxic agents and drugs also present risk. In addition, many factors that cannot be controlled present risk. There is an increased risk in pregnancy with increasing maternal age. Maternal disease may be an important risk factor. Malnutrition, toxemia, and congenital rubella may be associated with birth defects. Maternal diabetes and high blood pressure have been associated with problems in the newborn. In addition, many birth defects and developmental problems occur without an obvious cause and without any obvious risk factors. For example, viruses that we may not even be aware of can cause defects, and defects can arise from spontaneous random errors in cell reproduction. But these are things that we can't do anything about.

In summary, you are advised to keep radiation exposure of your unborn child below 0.5 rem, but you should also remember that alcohol consumption, cigarette smoking, and the use of other drugs can do a great deal of harm.

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 to occupational radiation at all, but your employer may not have such a position or may not be willing to provide you with a job involving no radiation exposure. Even if you receive no occupational exposure at all, you will receive a

dose typically about 0.3 rem (3 millisieverts) from unavoidable natural background radiation (Reference 7).

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

Only your employer can tell you what effect a declaration of pregnancy will have on your job status. As part of your radiation safety training, your employer should tell you its policies with respect to the job status of declared pregnant women. In addition, we recommend that, before you declare your pregnancy, you talk to your employer and ask what a declaration of pregnancy would mean specifically for you and your job status. However, if you do not declare your pregnancy, the lower exposure limit of 0.5 rem (5 millisieverts) does not apply.

It is most likely that your employer will tell you that you can continue to perform your job with no changes and still meet the Agency's limit for exposure to declared pregnant women. A large majority of licensee or registrant employees (greater than 90%) receive, in 9 months, occupational radiation doses that are below the 0.5 (5 millisieverts) limit for a declared pregnant woman.

If the dose you currently receive is above the 0.5 rem (5 millisieverts) dose allowed for a declared pregnant woman, it is quite likely that your employer can and will make a reasonable accommodation that will allow you to continue performing your current job, for example, by having another qualified employee perform a small part of the job that accounts for much of the radiation exposure.

On the other hand, it is possible, although not common, that your employer will conclude that there is no reasonable accommodation that can be made without undue hardship that would allow you to do your job and remain within the dose limits for a declared pregnant woman. In these few instances, your employer may conclude that you can no longer be permitted to do your current job, that you must be removed from your job, and that there is no other job available for someone with your training and job skills.

If your employer concludes that you must be removed from your current job in order to comply with the lower dose limits for declared pregnant women, you may be concerned about what will happen to you and your job. The answer to that depends on your particular situation. That is why you should talk to your employer about your particular situation. In addition, telephone numbers that may be useful for obtaining information are listed in response to question 20 in this guide.

HOW TO DECLARE YOUR PREGNANCY

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

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

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

No. No proof is necessary.

11. Can I tell my employer orally rather than in writing that I am pregnant?

No, the declaration must be in writing. As far as the rules are concerned, an oral declaration or statement is the same as not telling your employer that you are pregnant.

12. If I have not declared by pregnancy in writing, but my employer notices 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 choice of whether to declare your pregnancy and thereby work under the lower dose limits is your choice, not your employer's. Your employer may not remove you from a specific job because you appear pregnant.

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

No. The lower limits apply only if you declare that you are already pregnant.

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

If you have declared your pregnancy in writing, you should promptly inform your employer that you are no longer pregnant. The rules do not require that the revocation of a declaration be in writing, but we recommend that you revoke the declaration in writing to avoid confusion. Also, your employer may insist upon a written revocation for its own protection. If you have not declared your pregnancy, there is no need to inform your employer of your new, nonpregnant status

If you have a miscarriage and become pregnant again before you have revoked your original declaration of pregnancy, you should submit a new declaration of pregnancy because the date of conception has changed.

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

The dose to the embryo/fetus must be limited until (1) your employer knows that you have given birth, (2) your inform your employer that you are no longer pregnant, or (3) you inform your employer that you no longer wish to be considered pregnant.

16. If I have declared my pregnancy it 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 limits no longer apply.

17. What if I work under contract at a facility where there are licensed radioactive materials or registered devices, and my employer is not the licensee?

The rules state that you should formally declare your pregnancy to your employer in writing. You can ask your employer to give a copy of your declaration to the licensee or registrant, or you may give a copy of your written declaration directly to the licensee or registrant.

18. Can I tell my employer I am pregnant when I know I am not in order to work under the lower dose limits?

The purpose of the Agency rules is to allow a pregnant woman to choose a heightened level of protection from radiation exposure for the embryo/fetus during her pregnancy. That purpose would not be served by intentionally declaring yourself to be a pregnant woman when you know you are not pregnant. There are no Agency rule requirements specifically addressing the actions your employer might take if you provide a false declaration. However, nothing in Agency rules would prevent your employer from taking action against you for deliberately lying.

STEPS TO LOWER RADIATION DOSE

19. What steps can I take to lower my radiation dose?

Your employer should already have explained that to you as part of the instructions that licensees and registrants must give to all workers. However, you should ask your supervisor or the radiation safety officer whether any additional steps can be taken.

The general principles for maintaining exposure to radiation as low as reasonably achievable are summarized below. You should already be applying these principles to your job, but now is a good time to review them.

External Radiation Exposure: External radiation is radiation you receive from radiation sources or radioactive materials that are outside your body. The basic principles for reducing external radiation exposure are time, distance, and shielding. Decrease your time near the radiation sources, increase your distance from radiation sources, and increase the shielding between yourself and the radiation source. You should work quickly and efficiently in a radiation area so that you are not exposed to the radiation any longer than necessary. As the distance is increased from the source of radiation, the dose decreases. When possible, you should work behind shielding. The shielding will absorb some of the radiation, thus reducing the amount that reaches you.

Internal Radiation Exposure: Internal radiation is radiation you receive from radioactive materials that have gotten into your body, generally entering with the air you breathe, the food you eat, or the water you drink. Your employer will have specific procedures to minimize internal radiation exposure. Those procedures probably incorporate the following general precautions that should be taken when you are working with radioactive materials that are not encapsulated:

1. Wear lab coats or other protective clothing if there is a possibility of spills.

2. Use gloves while handling unencapsulated radioactive materials.

3. Wash hands after working with unencapsulated radioactive materials.

4. Do not eat, drink, smoke, or apply cosmetics in areas with unencapsulated radioactive materials.

5. Do not pipette radioactive solutions by mouth.

These basic principles should be incorporated into the specific methods and procedures for doing your individual work. Your employer should have trained you in those specific rules and procedures.

If you become pregnant, it is a good time to review the training materials on the methods and procedures that you were provided in your training. You can also talk to your supervisor about getting refresher training on how to keep radiation doses as low as reasonably achievable.

ADDITIONAL INFORMATION

20. Where can I get additional information?

You can find additional information on the risks of radiation in the Agency Guide "Instruction Concerning Risks from Occupational Radiation Exposure." You can also telephone the Agency at (503) 731-4014.

If you believe you have been discriminated against, you should contact the U.S. Equal Employment Opportunity Commission (EEOC), 1801 L Street NW., Washington, DC 20507, or an EEOC Field Office by calling (800) 669-4000 or (800) 669-EEOC. For individuals with hearing impairments, the EEOC's TDD number is (800) 800-3302.

REFERENCES

1. National Council on Radiological Protection and Measurements, *Limitation of Exposure to Ionizing Radiation*, Report No. 116, Bethesda, MD, 1993. [The National Council on Radiological Protection and Measurements (NCRP) is a nonprofit corporation chartered by Congress in 1964 to collect information and make recommendations on protection against radiation. This publication, on pages 37-39, summarizes the conclusions of the NCRP with respect to protection of the human embryo/fetus against radiation. This publications should be available through most good public library systems and most good university libraries. Your employer may also have a copy.]

2. ICRP Publication 60 - - 1990 *Recommendations of the International Commission on Radiological Protection, Ann.* ICRP 21:No. 1-3, Pergamon Press, 1991. [This publication, on pages 146-149, summarizes the conclusions of the ICRP on the effects of radiation on the human embryo/fetus.]

3. *Health Effects of Exposure to Low Levels of Ionizing Radiation (BEIR V),* Committee on the Biological Effects of Ionizing Radiations, National Research Council, National Academy Press, Washington, DC, 1990.

4. United Nations Scientific Committee on the Effects of Atomic Radiation, *Sources and Effects of Ionizing Radiation*, United Nations, New York, 1993.

5. National Council on Radiation Protection and Measurements, *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus, or Nursing Child*, NCRP Commentary No. 9, National Council on Radiation Protection and Measurements, Bethesda, MD, 1994.

6. *Alcohol, Tobacco, and Other Drugs May Harm the Unborn*, U.S. Department of Health and Human Services, Public Health Service, Alcohol drug Abuse, and Mental Health Administration, DHHS Publications No. (ADM) 92-1711, Rockville, Maryland, 1990.

7. National Council on Radiological Protection and Measurements, *Exposure of the Population in the United States and Canada from Natural Background Radiation*, Report No. 94, Bethesda, MD, 1987.