APPENDIX E

INSTRUCTION CONCERNING PRENATAL RADIATION EXPOSURE

A. INTRODUCTION

Section 64E-5.902 of Chapter 64E-5, FAC, requires that all individuals whose work may involve exposure to radiation be instructed in the health protection problems associated with exposure to radioactive material or radiation, in precautions or procedures to minimize exposure and in the regulations that they are expected to observe. This appendix describes the instructions that should be provided concerning biological risks to the embryo/fetus exposed to radiation, a dose limit for the embryo/fetus, and suggestions for reducing radiation exposure.

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.

It is important to note that the mother assumes all risk until she specifically declares her pregnancy, in a written and signed statement, to her Principal Investigator and copies the statement to the Radiation Control Officer. Upon receipt of the statement by the Radiation Control Office, the University and Principal Investigator is responsible for assuring that the female worker's exposure will not result in 500 millirem to the fetus. After a female occupational worker voluntarily notifies her Principal Investigator and the Radiation Control Officer in writing that she is pregnant and the estimated date of conception, for the purposes of fetal/embryo dose protection, she is considered a declared pregnant worker. Section 64E-5.311, FAC, places different radiation dose limits on declared pregnant workers than on adult workers. Specifically, for a declared pregnant worker who chooses to continue working as an occupational worker, the dose limit for the embryo/fetus from conception to birth (entire gestation period) is 500 mrem. Further, efforts should be made to avoid exceeding 50 mrem per month to the pregnant worker. It is the responsibility of the pregnant worker to decide when or whether to formally declare her condition. If a woman chooses not to declare her pregnancy, she will continue to be governed by guidelines for adult occupational exposure.

Because of the sensitivity of the unborn fetus, the National Council on Radiation Protection and Measurements (NCRP) has recommended that substantial variations in the rate of exposure be avoided to the unborn fetus from occupational exposure of the expectant mother and that special precautions be taken to limit the exposure of pregnant or potentially pregnant women. If the dose to the fetus is determined to have already exceeded 500 mrem when a worker notifies her Principal Investigator and the Radiation Control Officer of her pregnancy, the worker shall not be assigned to tasks where additional occupational radiation exposure is likely during the remainder of the gestation period.

C. REGULATORY POSITION

Instructions on radiation risks should be provided to workers, including supervisors, in accordance with 64E-5.902 before they are allowed to work with radioactive materials and/or radiation producing devices or access to such areas. In providing instructions on radiation risks, employers should include specific instructions 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 the Attachments to this Appendix. Individuals should be given the opportunity to ask questions and in turn should be questioned to determine whether they understand these instructions.

ATTACHMENT 1

EFFECTS ON THE EMBRYO/FETUS OF EXPOSURE TO RADIATION AND OTHER ENVIRONMENTAL HAZARDS

For the NRC and State position to be effective, it is important that both the employee and the Principal Investigator understand the risk to the unborn fetus from radiation received as a result of the occupational exposure of the mother. This guide tries to explain the risk and to compare it with other, more familiar, risks to the unborn fetus during pregnancy. This will hopefully help pregnant employees evaluate the risk to the unborn fetus against the benefits of employment. 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.

A. RADIATION RISKS

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 millirem, the excess number of deaths (above those occurring from natural causes) was found to be 0.6 deaths per thousand children (Ref. 4).

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 rad. 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 millirem 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.

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).

B. NONRADIATION RISKS

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 fetus 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. Alcohol

It has been recognized since ancient times that alcohol consumption had an effect on the unborn fetus. Carthaginian law forbade the consumption of wine on the wedding night so that a defective fetus 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 fetus, 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).

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 that 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).

3. <u>Smoking</u>

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).

4. <u>Miscellaneous</u>

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 caused 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 in 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).

EFFECTS OF RISK FACTORS ON PREGNANCY OUTCOME

Effect	Number Occurring from Natural Causes	Risk Factor	Excess Occurrence from Risk Factor
		<u>**RADIATION RISKS**</u> **Childhood Cancer**	
Cancer death in children	1.4 per thousand (Ref. 5)	Radiation dose of 1000 millirem received before birth	0.6 per thousand (Ref. 4)
		Abnormalities	
		Radiation dose of 1000 millirad 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 millirad received 8 to 15 weeks after conception	0.5-4 per thousand (Ref. 8)
		<u>**NONRADIATION RISK**</u> **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)
Prenatal 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)

ATTACHMENT 2
PREGNANT WORKER'S GUIDE

POSSIBLE HEALTH RISKS TO THE FETUS 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 fetus. For those of you who work with radioactive materials and/or radiation producing devices or who have access to such areas, it is desirable that you understand the biological risks of radiation to your unborn fetus.

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, 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 the four following sources:

	Average Annual Dose
Terrestrial: radiation from soil and rocks	28 millirem (0.28 mSv)
Cosmic: radiation from outer space	27 millirem (0.27 mSv)
Radioactivity normally found within the human body	39 millirem (0.39 mSv)
Radon	200 millirem (2.00 mSv)
	294 millirem (2.94 mSv)[1]
Dosage range (geographic and other factors)	75 to 5,000 millirem (0.75 mSv to 50.00 mSv)

The first two of these sources expose the body from the outside, and the last two exposes it from the inside. The average person is thus exposed to a total dose of about 294 millirem per year from natural background radiation.

[1] Radiation dose in this document is described in three 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 different biological effects done to the body by different types of radiation. The millirad and millirem refer to 1/1000 of a rad and rem, respectively. The Sievert (Sv) is the System Internationale unit that equivalent to 100 rem; the millisievert (mSv) refers to 1/1000 of a Sievert.

In addition to exposure from normal background radiation, radiation exposure can result from man-made materials and devices. Some consumer products such as smoke detectors, static eliminators and building materials contain radioactive material. The following lists the average annual dose from man-made radiation.

	Average Annual Dose
Fallout	< 1 millirem (< 0.01 mSv)
Nuclear Power Fuel Cycle	< 1 millirem (< 0.01 mSv)
Consumer Products	13 millirem (0.13 mSv)
Medical	54 millirem (0.54 mSv)

Medical procedures may also 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.

X-Ray Procedure	Average Dose[2]
Normal chest examination	10 millirem (0.1 mSv)
Normal dental examination	10 millirem (0.1 mSv)
Rib cage examination	140 millirem (1.4 mSv)
Gall bladder examination	170 millirem (1.7 mSv)
Barium enema examination	500 millirem (5.0 mSv)
Pelvic examination	600 millirem (6.0 mSv)

In summary, the average person is exposed to radiation daily, receiving a radiation dose of approximately 360 mrem/year (3.6 mSv/year). A dose of about 294 millirem/year (2.94 mSv/year) is from natural background radiation, while medical radiation exposure and consumer products contribute the rest (Refs 4, 19, 20).

NUCLEAR REGULATORY COMMISSION POSITION

NRC and State 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 fetus. This assumption is said to be conservative because there are no data showing ill effects from small doses; the National Academy of Sciences has expressed "uncertainty as to whether a dose of, say, 1 rad would have any effect at all." As it is known that the unborn fetus is more sensitive to radiation than adults, particularly during certain stages of development, the NRC and State has established a special dose limit for protection of the unborn fetus. However, such a limit could result in job discrimination for women of child-bearing potential. The NRC has taken the position that special protection of the unborn fetus should be voluntary and should be based on decisions made by workers and employers who are well informed about the risks involved.

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

For the NRC position to be effective, it is important that both the employee and the employer understand the risk to the unborn fetus 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 fetus during pregnancy. It is hoped this will help pregnant employees balance the risk to the unborn fetus 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 fetus As Low As Is Reasonably Achievable (ALARA).

RADIATION EXPOSURE LIMITS

Since 1906, it has been known that rapidly dividing, undifferentiated cells are more sensitive to radiation. The embryo/fetus[3] is composed of cells that meet these criteria and are more sensitive to radiation. In addition, scientific studies have shown that the embryo/fetus is more sensitive to radiation than the adult (particularly during the first 2-3 months after conception when a woman may not be aware that she is pregnant). Because of the sensitivity of the unborn fetus, the exposure to the unborn fetus of a "declared pregnant worker" shall be limited to 500 millirem (5 mSv) for the entire pregnancy (Refs 20, 25, 26); the guidance also recommends that substantial variations in the rate of exposure be avoided and efforts should be made to avoid exceeding 50 mrem per month to the pregnant worker.

ADVICE FOR EMPLOYEE

Although the risks to the unborn fetus are small under normal working conditions, it is still advisable to limit the radiation dose from occupational exposure to be ALARA, not to exceed 500 millirem (5 mSv) for the total pregnancy. The employee, Principle Investigator and Radiation Control Office should work together to decide the best method for minimizing exposure and accomplishing this goal. Some methods include reducing the time spent in radiation areas, wearing some shielding over the abdominal area, and maximizing the distance from radiation sources. The medical/health physicist will be able to estimate the probable dose to the unborn fetus during the normal nine month pregnancy period and to inform the employee of the amount. If the predicted dose exceeds 50 millirem (0.5 mSv) per month, work schedules or procedures shall be modified to limit the dose to the 500 millirem recommended limit. It is important that the employee inform her Principal Investigator and the Radiation Control Officer of her condition as soon as she realizes she is pregnant, so that the exposure to the unborn fetus can be minimized.

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[3] In conformity with 10CFR20 and 64E-5, the term "embryo/fetus" is used throughout this document to represent all stages of pregnancy. The definitions are taken from Stedman's Medical dictionary, 21st edition, The Williams and Wilkins Company, Baltimore, MD 1966 and read as follows:

Embryo: An organism in the early stages of development; in man, from conception until approximately the end of the second month. Developmental stages from this time are commonly designated as fetal.

Fetus: The unborn young of a viviparous animal after it has taken form in the uterus; in man, the product of conception from the end of the eighth week to the moment of birth.

Undifferentiated Cells: Those cells in early development which have not progressed to a mature and specialized state, such as muscle or nerve cells.

INTERNAL HAZARDS

This guidance has been directed primarily toward a discussion of radiation doses received from external sources. Workers must also be aware of the risk of radioactive material entering the body in working places where unsealed radioactive material is used. Nuclear medicine clinics, research laboratories, and certain manufacturers use radioactive material in bulk form, often as a liquid or a gas. General precautions[4] 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.

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 Principal Investigator is required to have demonstrated that he/she will have safe procedures and practices before the Radiation Control Office will authorize their approval to use radioactive material under one of the University's radioactive material licenses. Workers are urged to follow established procedures and consult the Radiation Control Office or medical/health physicist whenever problems or questions arise.

RADIONUCLIDE CHARACTERISTICS

Biological data has been collected for a set of radionuclides which are expected to be of greatest significance for prenatal exposure in the work environment. These materials are: tritium, as gas and water; tritium and carbon in three typical organic forms--glucose, amino acid, and thymidine; and iodine.

<u>TRITIUM</u>

Trace amounts of inorganic tritium in gaseous form or when incorporated into water are readily absorbed from the lung or gastrointestinal (GI) tract. In air most tritium will form water, as will some small amount of that which is absorbed, so that little tritium actually enters the body as a gas. Physiologic studies demonstrate that water crosses the placenta in both directions. The percentage water content of the embryo and fetal tissues generally is measurable greater than that of the corresponding tissues in adults, so that their relative tritium concentrations may be slightly greater. For practical purposes, it may be assumed that the concentration of tritium in the conceptus is the same as that of the pregnant woman, and that it would be readily excreted in parallel with its loss from her body.

[4] Specific precautions are made on a case-by-case basis for specific radionuclide of interest.

Tritium in the form of tritiated water is assumed to be uniformly distributed throughout the maternal and embryo/fetal soft tissues. It is assumed that tritiated water has a biological half-life of 10 days (Ref. 23).

ORGANICALLY BOUND TRITIUM AND CARBON

1. Glucose

Glucose is actively transported from maternal to fetal blood across the placental layers and uterine blood. Fetal brain, liver, kidney and skeletal muscle are the major organs that utilize glucose, and the overall glucose utilization rate is higher in the fetus than in the pregnant female.

Glycolysis of tritium-labeled glucose produces tritiated water, which then can exchange and distribute throughout the intracellular and extracellular water pools in both maternal and fetal compartments. A limited fraction of the tritiated water may subsequently become incorporated into lipid via lipogenesis, but this is sufficiently small that it can be ignored for dosimetry purposes. Catabolism of ^{14}C-labeled glucose results in $^{14}CO_2$ production in the fetus, but this does not accumulate in the fetus, rather it is randomly excreted to the mother via the placenta, and then exhaled. There are essentially no available concentration data for ^{3}H-glucose or ^{14}C-glucose applicable to radiation dosimetry (Ref. 23).

2. Amino Acids

In general, the concentrations of free amino acids in fetal tissues are similar to those in maternal tissues. Significant amounts of labeled amino acids are incorporated in protein during organogenesis or the growth phases of gestation. Concentration concurrently would be reduced through dilution by further incorporation of amino acids during progressive growth, so that consistently major deviations from maternal concentration would not be expected (Ref. 23).

3. Thymidine

Biological behavior of radiolabeled thymidine under conditions of accidental or environmental exposure is not clear. There does not appear to be any major differences between the metabolic behavior of ^{3}H- or ^{14}C-labeled thymidine and both precursors are incorporated into the DNA of proliferating cells. Only a fraction (10%) of that which enters the adult is incorporated; most of the remainder is catabolized rapidly and excreted. There is long-term retention of incorporated thymidine; it remains in the DNA until the cell divides, where it is partitioned between the daughter cells, and some may be re-utilized when the cell dies. The processes by which thymidine crosses the placenta have not been established (Ref. 23).

IODINE

The fetal thyroid begins to concentrate iodine at about 90 days of age and continues to accumulate iodine throughout gestation. Inorganic iodine in the blood readily crosses the placenta and is accessible to the embryo or fetus. Depending on which iodine radionuclides are involved, their decay schemes and half-lives, and whether exposure is chronic or acute, the thyroid concentration in the last months of pregnancy has been estimated to be as much as three to ninefold greater in the human fetus than in the adult.

The thyroid begins to secrete iodine shortly after it starts to concentrate iodine, and this secretion continues throughout gestation resulting in an organic iodine concentration of about 75% that in maternal blood. The concentrations of individual species of organic iodine (in particular triiodothyronine (T_3) and thyroxine (T_4) in fetal and maternal blood are not well correlated, which suggests that there is little, if any, placental transfer of organic iodine. Concentrations of T_3 and T_4 change abruptly at birth, and within about a week, reach values comparable to adults (Ref. 23, 24).

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