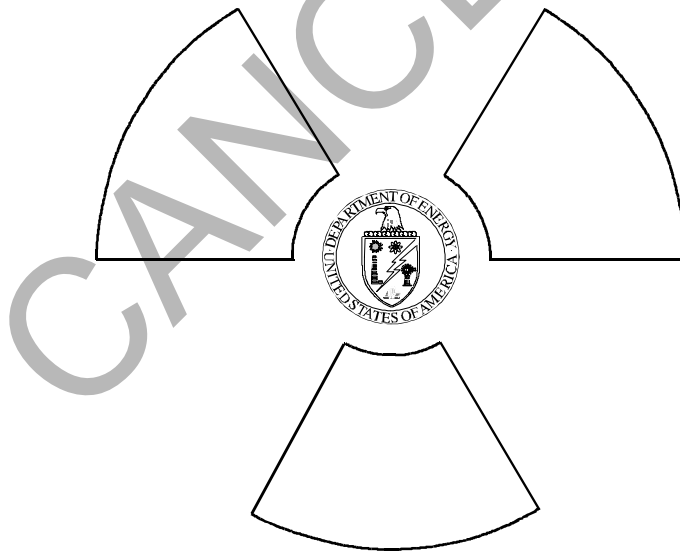


EVALUATION AND CONTROL OF RADIATION DOSE TO THE EMBRYO/FETUS GUIDE

for use with
**Title 10, Code of Federal Regulations, Part 835,
Occupational Radiation Protection**



**Assistant Secretary for Environment,
Safety and Health**

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ACRONYMS

ALI	Annual Limit on Intake
BEIR	Biological Effects of Ionizing Radiations
CFR	Code of Federal Regulations
DOE	U.S. Department of Energy
DOE G	DOE Guide
ICRP	International Commission on Radiation Protection
NCRP	National Council on Radiation Protection and Measurements
NRC	U.S. Nuclear Regulatory Commission
RPP	Radiation Protection Program
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
USLW	<i>United States Law Week</i>

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EVALUATION AND CONTROL OF RADIATION DOSE TO THE EMBRYO/FETUS

1. PURPOSE AND APPLICABILITY

This Guide provides an acceptable methodology for establishing and operating a program to control fetal exposure to ionizing radiation and evaluate the resultant dose that will comply with U.S. Department of Energy (DOE) requirements specified in Title 10 of the Code of Federal Regulations (CFR), Part 835, Occupational Radiation Protection (DOE 1998), hereinafter referred to as 10 CFR 835. In particular, this Guide provides guidance for achieving compliance with Subpart C, section 835.206 of 10 CFR 835. For completeness, this Guide also identifies recommendations contained in secondary documents (e.g., National Council on Radiation Protection and Measurements (NCRP) recommendations).

This Guide amplifies the regulatory requirements of 10 CFR 835 and provides explanations and examples of the basic requirements for control of radiation dose to the embryo/fetus as a result of the occupational radiation exposure of the declared pregnant worker. The requirements of 10 CFR 835 are enforceable under the provisions of Sections 223(c) and 234A of the Atomic Energy Act of 1954, as amended (AEC 1954).

This Guide describes measures acceptable to the DOE to control radiation dose to the embryo/fetus of a worker who has voluntarily declared her pregnancy in writing, and the training to be provided to workers and supervisors concerning the biological risks to the embryo/fetus from radiation exposure. This Guide discusses the voluntary nature of the formal declaration of pregnancy, work restrictions, and the calculation, recording, and reporting of dose equivalent to the embryo/fetus. In addition, this Guide describes a program that, when implemented, protects the rights of workers and the interests of the employer. This Guide does not address the protection of the embryo/fetus from any hazards other than ionizing radiation.

Except for requirements established by regulation, contract, or administrative means, the provisions in this Guide are DOE's views on acceptable methods of program implementation and are not mandatory. Conformance with this Guide will, however, create an inference of compliance with the related regulatory requirements. Alternative methods that are demonstrated to provide an equivalent or better level of protection are acceptable. DOE encourages its contractors to go beyond the minimum regulatory requirements and to pursue excellence in their programs.

The word "shall" is used in this Guide to designate requirements from 10 CFR 835. Compliance with 10 CFR 835 is mandatory, except to the extent an exemption has been granted pursuant to 10 CFR 820, Procedural Rules for DOE Nuclear Activities (DOE 1997). The words "should" and "may" are used to represent optional program recommendations and permissible alternatives, respectively.

This Guide is applicable to all DOE activities that are subject to the requirements of 10 CFR 835.

2. DEFINITIONS

Terms defined in 10 CFR 835 are used in this Guide consistent with their regulatory definitions.

Embryo/fetus: A developing human organism from conception until birth.

Gestation period: The time from conception to birth; usually 40 weeks or approximately 9 months.

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3. DISCUSSION

DOE has codified in 10 CFR 835.206 radiation dose limits for the embryo/fetus as a result of the occupational exposure of a declared pregnant worker. These requirements are established to provide protection to the embryo/fetus in a manner that does not discriminate against the rights of the pregnant worker.

Programs established to evaluate and control radiation dose to the embryo/fetus need to balance protection of the embryo/fetus (from hazards that may arise from the mother's occupational radiation exposure) against the possibility of work discrimination against the mother. The choice of providing additional protection to the embryo/fetus is left entirely to the voluntary discretion of the mother. The Supreme Court ruled in *United Automobile Workers v. Johnson Controls, Inc.*, 499 U.S.187, 206 (USLW 1991) 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."

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4. IMPLEMENTATION GUIDANCE

Essential elements of an acceptable program to evaluate and control radiation dose to the embryo/fetus include:

- voluntary, formal declaration of pregnancy, including the estimated date of conception;
- voluntary, formal withdrawal of declaration of pregnancy;
- work restrictions for workers who have voluntarily declared their pregnancies;
- counseling of workers;
- dose calculation and monitoring methods;
- worker training;
- record-keeping; and
- reporting.

Acceptable methods for implementing these program elements are discussed in this section.

4.1. DECLARATION OF PREGNANCY/WITHDRAWAL OF DECLARATION

Due to the higher sensitivity of the embryo/fetus to ionizing radiation (relative to the sensitivity of adults), 10 CFR 835 establishes provisions for individuals to voluntarily declare their pregnancy and to accept restrictions on the dose equivalent to the embryo/fetus (i.e., 0.5 rem (0.005 Sv) gestation period dose equivalent limit, uniform exposure rate) (10 CFR 835.206). It remains the sole and fundamental responsibility of the worker to decide whether to formally declare her pregnancy and consequently become subject to the above dose limits and restrictions. It is the employers' responsibility to ensure that the worker is fully informed and provided with counseling to assist in her decision making. Deciding whether or not to accept the risk from radiation dose to the embryo/fetus is entirely the responsibility of the pregnant worker.

A pregnancy may be declared by the pregnant worker or the worker who is planning a pregnancy, and shall be formally declared in writing (10 CFR 835.2(a)). The declaration shall include the estimated date of conception ((10 CFR 835.704(d)), and should be declared as early in the pregnancy as possible. A declared pregnant worker that is planning a pregnancy should notify her supervisor as soon as possible following verification of conception. The statement should be signed by the employee and delivered to her supervisor or to a designated contact in health physics, laboratory safety, occupational health, or medical services. A sample declaration form is provided in Appendix A of this Guide.

10 CFR 835 also allows an individual who has declared her pregnancy to withdraw her declaration and to return to the general employee occupational dose limit (5 rem total effective dose equivalent in a year). The employer is considered to be notified of the withdrawal of the declaration of pregnancy at the time that the individual submits a signed and dated statement to her supervisor or to the designated contact, indicating that she is withdrawing her formal declaration of pregnancy. A sample form is provided in Appendix C of this Guide. No additional explanation or justification should be requested by the employer. The worker shall be allowed to withdraw her declaration of pregnancy at any time (10 CFR 835.2(a), Declared pregnant worker), thus terminating any work restrictions. Once such notification has been made, it is the employer's responsibility to remove any imposed work or area restrictions as discussed in Section 4.2 of this Guide, Work Restrictions Following Declaration of Pregnancy.

The rights (e.g., right to work) and privacy of the worker should be maintained before, during, and following any declaration of pregnancy. All aspects of the worker's withdrawal of the declaration of pregnancy should also be maintained confidential. The rights and privacy of workers who have chosen not to declare their pregnancy should also be respected. Because 10 CFR 835.901 requires that radiation safety training include discussions of the risks of exposure to radiation and radioactive materials during pregnancy, and include an individual's rights and responsibilities as related to the facility's radiation protection program, there is no need to remind an undeclared pregnant worker of the opportunity for a pregnant employee to avail herself of the special limits for protection of the embryo/fetus. Such reminders would be inappropriate in light of the *United Auto Workers v. Johnson Controls, Inc.* case previously cited. DOE G 441.1-12, RADIATION SAFETY TRAINING GUIDE (DOE 1999a) provides guidance on initial and biennial training, as well as recommendations for annual refresher training.

4.2. WORK RESTRICTIONS FOLLOWING DECLARATIONS OF PREGNANCY

Following the submittal of a declaration of pregnancy, the radiation dose equivalent received by the embryo/fetus prior to the declaration (i.e., from the estimated date of conception to the date of declaration) should be calculated as soon as practicable. Section 4.4 of this Guide provides an acceptable methodology. Once this dose equivalent has been calculated, the dose equivalent allowed for the remaining gestation period should be determined. An evaluation of the dose equivalent that the embryo/fetus is likely to receive while the declared pregnant worker is performing her current job duties should be performed to determine if work restrictions are necessary. The evaluation should take into consideration the 0.5 rem dose equivalent limit, the dose equivalent remaining for the gestation period, and the requirement not to vary substantially above a uniform exposure rate that would satisfy the 0.5 rem limit during the gestation period. If the nature of the declared pregnant worker's duties make it likely that either the 0.5 rem limit will be exceeded or that substantial variation will occur, then work restrictions shall be established (10 CFR 835.206(a) and (b)). If it is determined that the dose equivalent to the embryo/fetus has already exceeded 0.5 rem, the declared pregnant worker shall not be assigned to tasks where additional occupational exposure is likely during the remainder of the gestation period (10 CFR 835.206(c)), unless she voluntarily revokes her pregnancy declaration.

A uniform exposure rate in rem/week may be calculated by subtracting the dose equivalent received by the embryo/fetus prior to the declaration of the pregnancy from the 0.5 rem limit and then dividing this difference by the approximate number of weeks remaining in the gestation period. For example, for a pregnancy that was declared at 10 weeks into the gestation period with a calculated dose equivalent of 200 mrem to the embryo/fetus prior to the declaration of the pregnancy, a uniform exposure rate for the remainder of the pregnancy would be $(500 \text{ mrem} - 200 \text{ mrem}) / 30 \text{ week}$ or approximately 10 mrem/week. 10 CFR 835 allows flexibility for a facility-specific determination of what constitutes a "substantial variation." The value selected will vary depending on site-specific factors such as nature of work performed, radiological conditions in the areas to be entered, and the sensitivity and accuracy of the individual monitoring methods used. DOE recommends a value equal to the calculated uniform dose equivalent rate per week +100%. In the example cited above, this would be any dose rate greater than 20 mrem/week. Each facility should determine and document the methods used to identify a "substantial variation."

Additional work or area restrictions for the declared pregnant worker, based on limiting the total dose (internal and external) may be established as necessary to ensure compliance with the total dose equivalent and "substantial variation" criteria. Procedures should provide for coordination between radiation protection and line management, occupational health or medical services. Examples of typical restrictions include reducing the time allowed in radiological areas (including prohibiting access to certain areas), restricting the time spent in certain areas within a radiological area, restricting performance of certain tasks, and requiring use of supplemental controls, such as shielding, ventilation, and personal protective equipment. To determine whether restrictions should apply, each facility should evaluate the worker's dose history and radiological conditions in those areas to which the declared pregnant worker may have access. Also, employers should provide declared pregnant workers the option of a mutually agreeable work assignment that does not involve additional occupational dose. The training for workers should identify such restrictions and options (see DOE G 441.1-12).

Due to difficulties in evaluating fetal dose resulting from radioactive material intakes, restrictions should be imposed to minimize a declared pregnant worker's radioactive material intakes. Consideration should be given to restricting declared pregnant workers from entering areas where they may receive an intake of radionuclides. ALARA (total dose) aspects should also be considered in implementing these restrictions. If it is not practical to restrict the declared pregnant worker from entry into areas where intakes are likely to occur, enhanced use of engineering controls (primary) and administrative controls (secondary) should be considered.

Any additional workplace restrictions for the declared pregnant worker shall (10 CFR 835.206) remain in place until the baby is born, the declaration of pregnancy has been withdrawn (see the sample declaration in Appendix B), or it is determined that such restrictions are not required to ensure compliance with 10 CFR 835.206.

Radiological work restrictions apply only to declared pregnant workers. If the worker does not declare her pregnancy, she cannot be restricted in her work or in the dose that she receives unless these restrictions apply to all employees of similar position, i.e. general employees or radiological workers as specified in 10 CFR 835.

4.3. COUNSELING

An employee with expertise in health physics, laboratory safety, occupational health, or medical services should be designated as a contact for female workers to obtain counseling or additional information on the subject of the risks to the embryo/fetus from exposure to ionizing radiation. Individuals who provide this counseling should receive training in risk communication and be knowledgeable of the risks of fetal radiation exposure. NRC Regulatory Guide 8.13, *Instruction Concerning Prenatal Radiation Exposure* (NRC 1987) and NCRP Report No. 16, *Limitation of Exposure to Ionizing Radiation* (NCRP 1993) provides information on the risks of radiation dose to the embryo/fetus.

Counseling of any worker on the risks of exposure to radiation to the embryo/fetus should be documented regardless of the worker's decision to declare or not to declare the pregnancy.

4.4. DOSE DETERMINATION AND MONITORING METHODS

4.4.1 Dose Determination

The dose equivalent to the embryo/fetus should be determined as soon as practicable after a worker submits a declaration of pregnancy, at sufficient intervals after declaration to ensure the limit is not exceeded and that substantial variations do not occur, and at the end of the gestation period. It may be necessary to include the dose for the entire reporting period during which conception occurred, unless more detailed records are available to determine the fraction of the dose received since the time of conception. If enough information is available to assume that the previous dose was received in a linear fashion, the fraction of the dose may be used that corresponds to the fraction of the reporting period during which the worker was pregnant. This method is appropriate for the majority of workers who work on a variety of tasks during a reporting period, none of which results in a significant dose. At the conclusion of a declared pregnancy the dose received by the embryo/fetus prior to the declaration of pregnancy plus the dose received during the remainder of the pregnancy should be calculated as the sum of:

- the dose equivalent to the embryo/fetus from external sources of radiation;
- the dose equivalent to the embryo/fetus from intakes of radionuclides in the embryo/fetus; and
- the dose equivalent to the embryo/fetus resulting from intakes of radionuclides in the declared pregnant worker.

A sample dose record form is provided in Appendix C of this Guide. Detailed dose equivalent calculations should be attached to the record form. The dose to the embryo/fetus from radiation external to the mother should be taken as the deep dose equivalent to the mother's abdomen or torso.

If an intake of radioactive material occurs, or occurred between conception and the declaration of pregnancy, the dose equivalent to the embryo/fetus should be determined as follows. The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and in the mother that are relatively uniformly distributed, such as ^{137}Cs and compounds of ^3H and ^{14}C that are not organically bound, may be considered to be the same as the dose equivalent to the mother because, under these circumstances, the same energy would be deposited per gram of tissue in both the mother and the fetus. For other exposure conditions, refer to NUREG/CR-5631, Rev. 1, *Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses* (Sikov et al. 1992). The information given in this report or in NRC Regulatory Guide 8.36, *Radiation Dose to the Embryo/Fetus* (NRC 1992), should be used to estimate the internal dose. If other methods are used, the basis for their use in demonstrating an equivalent or better level of protection should be documented.

4.4.2 Monitoring Methods

Guidance on internal and external dose monitoring methods is provided in DOE G 441.1-3, INTERNAL DOSIMETRY PROGRAM GUIDE (DOE 1999b) and DOE G 441.1-4, EXTERNAL DOSIMETRY PROGRAM GUIDE (DOE 1999c), respectively.

4.5. TRAINING

It is important that all individuals who enter a controlled area understand the risk to the embryo/fetus from ionizing radiation received as a result of the mother's occupational exposure. It is also important that procedures regarding fetal exposure be well understood by workers and their supervisors.

Note that the radiation safety training requirements in 10 CFR 835.901 (which include the risk of prenatal exposure to ionizing radiation) pertain to workers who are allowed unescorted access to, and/or receive occupational radiation dose in, controlled areas. Under certain conditions, it is possible that a pregnant worker outside of the controlled area could receive a dose exceeding the 0.05 rem monitoring threshold, but not be subject to the 10 CFR 835.901 training requirements. If such conditions exist, measures should be implemented to ensure that affected workers are aware of the risks of fetal radiation exposure and their rights to declare their pregnancy. This information should be disseminated through radiation safety training or equivalent measures.

Additional guidance on radiation safety training programs can be found in DOE G 441.1-12 and NRC Regulatory Guide 8.13.

4.6 RECORD-KEEPING AND REPORTING

Record-keeping and reporting guidance may be found in DOE G 441.1-11, OCCUPATIONAL RADIATION PROTECTION RECORD-KEEPING AND REPORTING GUIDE (DOE 1999d).

5. REFERENCES

AEC (Atomic Energy Commission) 1954. Atomic Energy Act of 1954, as amended. Public Law 83-703 (68 Stat. 919), Title 42 U.S.C. sec. 2011.

DOE (U.S. Department of Energy) 1997. Procedural Rules for DOE Nuclear Activities. 10 CFR 820, 58 FR 43680, *Federal Register* Vol. 58, No. 157, dated 10-8-97. Washington, D.C.

DOE 1998. Occupational Radiation Protection. 10 CFR 835. 63 FR 59662. *Federal Register* Vol. 63, No. 213, dated 11-4-98. Washington, D.C.

DOE 1999a. DOE G 441.1-12. RADIATION SAFETY TRAINING GUIDE, dDated 3-17-99. Washington, D.C.

DOE 1999b. DOE G 441.1-3. INTERNAL DOSIMETRY PROGRAM GUIDE, dated 3-17-99. Washington, D.C.

DOE 1999c. DOE G 441.1-4. EXTERNAL DOSIMETRY PROGRAM GUIDE, dated 3-17-99. Washington, D.C.

DOE 1999d. DOE G 441.1-11. OCCUPATIONAL RADIATION PROTECTION RECORD-KEEPING AND REPORTING GUIDE, under development at time of publication. Washington, D.C.

NCRP (National Council on Radiation Protection and Measurements) 1993. *Limitation of Exposure to Ionizing Radiation*. NCRP Report No. 116. Washington, D.C.

NRC (U.S. Nuclear Regulatory Commission) 1987. *Instruction Concerning Prenatal Radiation Exposure*. Regulatory Guide 8.13. Washington, D.C.

NRC 1992. *Radiation Dose to the Embryo/Fetus*. Regulatory Guide 8.36. Washington, D.C.

Sikov et al. 1992. Sikov, M. R., R. J. Traub, T. E. Hui, H. K. Meznarich, and K. D. Thrall. 1992. *Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses*. NUREG/CR-5631, Rev. 1. Washington, D.C.

USLW 1991. *United Automobile Workers v. Johnson Controls, Inc.* 499 U.S. 187, 206 (1991).

Appendix A

DECLARATION OF PREGNANCY FORM

DECLARATION OF PREGNANCY

In accordance with Section 206 of 10 CFR 835, I am voluntarily declaring that I am pregnant, for the purposes of lowering the dose received by my embryo/fetus. I realize that work restrictions may be imposed to ensure that the embryo/fetus does not receive a dose in excess of that given in 10 CFR 835 (500 mrem, or 0.005 Sv, during the entire gestation period). I also realize that supplemental dosimetry may be supplied to me, along with periodic reports of the dose received by my embryo/fetus.

Estimated Date of Conception _____

_____	_____
Printed name of worker	ID# (SSN)
_____	_____
Signature of worker	Date
_____	_____
Printed name of supervisor	Title
_____	_____
Signature of supervisor	Date
_____	_____
Printed name of Health Physics or Medical Representative	Title
_____	_____
Signature of Health Physics or Medical Representative	Date

Submission of this form will in no way affect the benefits, seniority, or potential for promotion of the person signing this form. This declaration may be withdrawn at any time by signing and submitting the form "Withdrawal of Pregnancy Declaration."

Appendix B

WITHDRAWAL OF PREGNANCY DECLARATION FORM

WITHDRAWAL OF PREGNANCY DECLARATION

I am withdrawing my previous declaration of pregnancy. I understand that, as a result of signing and submitting this form, any work restrictions that have been imposed as a result of the previously submitted "Declaration of Pregnancy" will be lifted.

Date of Pregnancy Declaration _____

Printed Name of worker

ID# (SSN)

Signature of worker

Date

Printed name of supervisor

Title

Signature of supervisor

Date

Printed name of Health Physics
or Medical Representative

Title

Signature of Health Physics
or Medical Representative

Date

Appendix C

EMBRYO/FETAL DOSE EQUIVALENT RECORD

EMBRYO/FETAL DOSE EQUIVALENT RECORD		
Date of Declaration of Pregnancy	_____	
Estimated Date of Conception	_____	
Estimated External Dose (prior to declaration of pregnancy)		_____
External Dose for remaining period of pregnancy		_____
Estimated Internal Dose (prior to declaration of pregnancy)		
From radionuclides in the embryo/fetus	_____	
From radionuclides in the mother	_____	
Subtotal		_____

Internal Dose for remaining period of pregnancy		
From radionuclides in the embryo/fetus	_____	
From radionuclides in the mother	_____	
Subtotal		_____
Total Dose during gestation period		_____

**UNITED STATES
DEPARTMENT OF ENERGY**
Office of Worker Protection Programs and Hazards Management (EH-52/270CC)
19901 Germantown Road, Germantown, MD 20874-1290

Request for Changes to
**EVALUATION AND CONTROL OF RADIATION
DOSE TO THE EMBRYO/FETUS**
(Use Multiple Pages as Necessary)

Page No. _____ Section No. _____ Paragraph No. _____	_____ Facility Requesting Change _____ Contact Person _____ Telephone Number - Fax Number
--	--

Description of Change Request:

Suggested Specific Word Changes:

EH-52 Technical Staff Contact:
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