STATE OF FLORIDA
DEPARTMENT OF HEALTH
BUREAU OF RADIATION CONTROL

REGULATORY GUIDE

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RADIATION DOSE TO THE EMBRYO/FETUS

A. INTRODUCTION

Section 64E-5.311, Florida Administrative Code (F.A.C.), requires that each licensee ensure that the dose to an embryo/fetus during the entire pregnancy, from occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (500 mrem or 5 mSv). Paragraph 64E-5.311(2), F.A.C., requires the licensee to make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman that would satisfy the 500 mrem limit. The dose to the embryo/fetus is to be the sum of (1) the deep-dose equivalent to the declared pregnant woman [par. 64E-5.311(3)(a) and (b), F.] the dose to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman [64E-5.311(3)(b)].

This guide provides guidance on calculating the radiation dose to the embryo/fetus. U.S. Nuclear Regulatory Commission (NRC) Regulatory Guide 8.13 (Rev. 3, 1999), "Instruction Concerning Prenatal Radiation Exposure," provides instructions concerning the risks associated with prenatal radiation exposure. The guide is available on the Internet at <http://www.nrc.gov/NRC/RG/08/index.html> or by contacting the department by phone (850/245-4545) or by mail at the following address: Florida Department of Health, Bureau of Radiation Control, Radioactive Materials Section, 4052 Bald Cypress Way, Bin C21, Tallahassee, FL 32399-1741.

B. DISCUSSION

Calculating the radiation dose to the embryo/fetus from internally deposited radionuclides requires quantitative information about maternal radionuclide intake, placental transfer and kinetics, and resulting embryo/fetus radionuclide concentrations. Intakes of radioactive material occurring prior to the pregnancy may also be important if these materials remain in the pregnant woman during all or part of the gestation period. Transfer kinetics from the mother to the embryo/fetus are modeled as a function of stage of pregnancy, route of intake by the pregnant woman, and time after intake. The stage of gestation (or fetal development) is an important parameter in estimating radionuclide concentrations in the embryo/fetus. The geometry of the embryo/fetus (i.e., size and weight) affects the radionuclide dosimetry.

It is recognized that calculation of prenatal radiation doses from internally deposited radionuclides has many associated difficulties, including a lack of quantitative information about prenatal radionuclide concentrations and transfer across the placenta. The International Commission on Radiological Protection (ICRP) in Publication 56 (Ref. 1) states that, for most radionuclides, preliminary estimates from dosimetric and biokinetic models indicate that the dose to the embryo can be approximated by the dose to the uterus. The dose to the fetus is dependent upon the activity present in both fetal and maternal tissues. ICRP Publication 56 also states that, for most radionuclides, the dose to fetal tissue will be similar to or less than the dose to the corresponding maternal tissues.

The current methods available for assessing the radiation dose to the human embryo/fetus from internally deposited radioactive materials in the pregnant woman are subject to a number of uncertainties. Revision 1 to the NRC's NUREG/CR-5631, "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses – Interim Recommendations" (Ref. 2), provides recommendations and methods for estimating the radiation doses to the embryo/fetus from internal radionuclides. In the guide, a number of radionuclides were evaluated. To expedite efforts, the initial evaluation was directed to those radionuclides that were expected to be of greatest significance for prenatal exposure in the work environment. The radionuclides that were identified and included were H-3, C-14, Co-57, Co-58, Co-60, Sr-89, Sr-90, Ru-106, I-125, I-131, I-132, I-133, I-134, I-135, Cs-134, Cs-137, U-233, U-234, U-235, U-238, Pu-238, Pu-239, and Am-241. The methods of Rev. 1 to NUREG/CR-5631 are considered interim as efforts continue to further develop the bases and calculational methods for estimating prenatal radiation doses. NUREG/CR-5631 provides details of the data and bases for the dosimetric features that were used for the radionuclides listed above.

It is expected that the embryo/fetus dose assessment methods will continue to evolve as more research is conducted in this area. As additional research is conducted, better estimates of actual embryo/fetus doses resulting from the exposure of the declared pregnant woman will be possible. For internal doses, research that categorizes the degree of placental transfer, the resulting embryo/fetus/placenta concentrations, and the potential radiation exposures of the embryo/fetus from radionuclides in their more usual chemical forms should simplify assessment of the dose to the embryo/fetus based on the maternal exposure. The ICRP is considering the formulation of dose assessment methods specific for the embryo/fetus. This regulatory guide provides acceptable methods that may be used in determining the dose to the embryo/fetus. For internal exposure, a simplified approach and a more detailed methodology are presented for conducting dose evaluations. Section 1 provides guidance on the threshold criteria for use in determining when the dose to the embryo/fetus needs to be evaluated. Section 2 presents a simplified approach for estimating the dose to the embryo/fetus from intakes by the declared pregnant woman. Section 3 provides an alternative, more detailed methodology for a limited number of radionuclides, using the gestation-time dependent dosimetric data from NUREG/CR-5631.

A graded approach for determining when to evaluate, with both a simple and more detailed dose assessment methodology, is provided. Both methods are acceptable for evaluating the dose to the embryo/fetus. It is recognized that some licensees will only need to demonstrate that the dose to the embryo/fetus is not likely to exceed the 0.05 rem (50 mrem or 0.5 mSv) monitoring threshold of 64E-5.315, while other licensees may need to determine an embryo/fetus dose for demonstrating compliance with the dose limit of 64E-5.311 and the record-keeping requirements of 64E-5.339(4).

Appendix A provides information on and a table of dose equivalent factors for use in approximating the embryo/fetus dose from radionuclides in maternal blood. Appendix B is a table of blood uptake fractions for ingested activity. Appendix C contains tables of gestation-time dependent doses to the embryo/fetus following introduction of specified radionuclides and chemical forms into maternal blood. Examples of the use of dose assessment methods are provided in Appendix D.

The total radiation dose to the embryo/fetus is the sum of the deep-dose equivalent (DDE) to the declared pregnant worker and the dose to the embryo/fetus from intakes of the declared pregnant worker. If multiple dosimetric devices are used to measure the DDE to the declared pregnant worker, the results of monitoring that are most representative of the deep dose to the embryo/fetus may be used. The licensee need not use the deep dose to the maximally exposed portion of the whole body of the mother as the deep dose to the embryo/fetus. The licensee may employ temporary or permanent shielding to reduce the deep dose to the embryo/fetus. Alternatively, deep dose to the embryo/fetus may be limited by placing more stringent restrictions on the exposure of the declared pregnant woman than on other members of the occupational work force.

As specified in 64E-5.311(1), the dose to the embryo/fetus from occupational exposure of the declared pregnant woman during the entire gestation period is not to exceed 50 mrem. In addition, the licensee is required to make efforts to avoid substantial variation in the monthly exposure throughout the period of gestation. If the dose to the embryo/fetus is found to have exceeded 50 mrem or is within 50 mrem of this dose by the time the woman declares the pregnancy to the licensee, the licensee is required to limit the additional dose to the embryo/fetus to 50 mrem during the remainder of the pregnancy.

The tables in the appendices to this guide were prepared directly from the computer outputs, which led to the values generally being expressed to three significant figures. This indicates greater accuracy than is warranted by the dosimetry model, but the results are presented in this form to avoid round off errors in calculations. In general, final results should be rounded to the nearest thousandth.

C. REGULATORY POSITION

1. Criteria for Determining Dose to the Embryo/Fetus

1.1 Monitoring

The dose equivalent to the embryo/fetus should be determined based on the monitoring of the declared pregnant woman as required by 64E-5.315. Specifically, 64E-5.315(1)(b) requires monitoring the exposure of a declared pregnant woman when the dose to the embryo/fetus is likely to exceed, in 1 year, a dose from external sources in excess of 10% of the limit of 64E-5.311 (i.e., 50 mrem). According to 64E-5.315(2)(b), the licensee must monitor the occupational intakes of radioactive material for the declared pregnant woman if her intake is likely to exceed, in 1 year, a committed effective dose equivalent in excess of 0.05 rem. Based on this 50 mrem threshold, the dose to the embryo/fetus should be determined if the intake is likely to exceed 1% of ALI (stochastic) during the entire period of gestation.

These monitoring thresholds will ensure that any potentially significant exposures to the embryo/fetus are evaluated and, as appropriate, doses are determined. The conditions specified in 64E-5.315(1) and (2) are based on a 1-year period. Prior to declaration of pregnancy, the woman may not have been subject to monitoring based on conditions specified in 64E-5.315(1)(a) and 64E-5.315(2)(a). In this case, the licensee should estimate the exposure during the period monitoring was not provided, using any combination of surveys or other available data (e.g., air monitoring, area monitoring, bioassay).

The monitoring criteria contained in 64E-5.315 do not establish required levels of detection sensitivity. For some radionuclides it may not be feasible to actually confirm by bioassay measurements an intake of 1% of their stochastic ALI. Workplace monitoring, occupancy factors, and access control should be considered as appropriate in evaluating potential exposures and monitoring requirements.

1.2 Evaluation of Dose to the Embryo/Fetus

The appropriate dose to be evaluated for the embryo/fetus is the dose equivalent for the duration of the pregnancy. An assessment of the 50-year committed dose is not appropriate. Also, it is not appropriate to use effective dose equivalent or committed effective dose equivalent. [Note: the committed dose equivalent (CDE) to the uterus may be applied to the embryo/fetus under certain conditions as a simplified approach as described in Section 2.]

1.3 External Dose to the Embryo/Fetus

According to 64E-5.311(3)(a), the DDE to the declared pregnant woman will be taken as the external dose component to the embryo/fetus. The determination of external dose should consider all occupational exposures of the declared pregnant woman since the estimated date of conception.

The DDE that should be assigned is that dose that would be most representative of the exposure of the embryo/fetus (i.e., in the mother's lower torso region). If multiple measurements have been made, assignment of the highest DDE for the declared pregnant woman to the embryo/fetus is not required unless that dose is also the most representative DDE for the region of the embryo/fetus.

1.4 Internal Dose to the Embryo/Fetus

The internal dose to the embryo/fetus should consider the exposure to the embryo/fetus from radionuclides in the declared pregnant woman and in the embryo/fetus. The dose to the embryo/fetus should include the contribution from any radionuclides in the declared pregnant woman (body burden) from occupational intakes occurring prior to conception. The intake for the declared pregnant woman should be determined using air sample data, bioassay data, or a combination of the two. Guidance on bioassay measurements used to quantify intake is being developed as "Interpretation of Bioassay Measurements." Specific guidance on workplace air sampling is found in NRC Regulatory Guide 8.25 (Rev. 1, 1992), "Air Sampling in the Workplace."

1.5 Evaluating Continuous Exposure

For continuous or near-continuous exposure to radioactive material that may be inhaled or ingested, the cumulative intake should be quantified and the dose determined at least every 30 days. If significant variation in the exposure levels may have occurred, the time interval for quantifying the intake should be reduced. More frequent evaluations should be considered as the potential dose to the embryo/fetus approaches the limit.

1.6 Existing Maternal Body Burdens

Maternal body burdens resulting from internal occupational exposures prior to conception should be included in determining the embryo/fetus dose. The contribution to the embryo/fetus dose from a maternal burden existing at the time of conception should be evaluated if the maternal burden at the time of pregnancy exceeds 1% of the radionuclide's stochastic ALI value for the appropriate mode of intake and class (for inhalation intakes). For multiple radionuclide burdens, the dose should be evaluated if the sum of the quotients of each burden divided by its stochastic ALI exceeds 0.01. Only body burdens existing at the time of conception need to be considered in evaluating this threshold; radioactive material already eliminated from the body should not be included.

This threshold of 1% ALI provides a simplified approach for determining when pre-existing body burdens should be evaluated. At this threshold, it is unlikely that any resultant dose to the embryo/fetus would be significant (i.e., greater than 10% of the 50 mrem limit). As an alternative, the dose assessment methods presented in Section 3 of this guide may be used for determining whether a pre-existing body burden represents a potentially significant dose (i.e., greater than 50 mrem).

2. Simplified Method for Determining Embryo/Fetus Dose From Maternal Intakes

The determination of the dose to the embryo/fetus from the intake of radioactive material by the pregnant woman should be based on the best available scientific data. At present, the department considers NUREG/CR-5631 to provide such data. For most radionuclides, the dose to the embryo/fetus will be similar to or less than the dose to the maternal uterus. However, the data in NUREG/CR-5631 indicate that for some radionuclides the embryo/fetus dose may be significantly different, either greater than or less than the dose to the uterus.

Based on these premises (uterus dose similar to fetal dose and the data in NUREG/CR-5631, a set of dose factors has been developed for use in calculating an embryo/fetus dose. Except for those radionuclides addressed in NUREG/CR-5631, the dose factors presented in Appendix A to this guide represent the CDE to the uterus per introduction of unit activity into the first transfer compartment (i.e., blood) of the woman.[1] For the radionuclides in NUREG/CR-5631, the dose factors in Appendix A represent the maximum dose equivalent to the embryo/fetus for the gestation period from the introduction of unit activity into the first transfer compartment of the woman at any time during the gestation period.

[1]The CDE factors for the uterus presented in Appendix A were calculated based on the modeling employed during the development of the ICRP 30 data. It is recognized that the metabolism of the pregnant woman may not be adequately represented by the standard metabolic model. However, partly because of the lack of more definitive data, this modeling has been used for determining the dose commitment factors for the uterus that may be used for evaluating compliance with the embryo/fetus dose limit.

The dose limit for the embryo/fetus is expressed as a 9-month gestation dose equivalent. Particularly for certain radionuclides with both long radiological half-lives and long-term biological retention, the CDE to the uterus may be significantly different from a 9-month gestation dose equivalent to the embryo/fetus. Several radionuclides of this type have been evaluated in NUREG/CR-5631, and data have been developed for calculating an embryo/fetus gestation dose instead of using the CDE to the uterus.

For demonstrating compliance with the dose limits of 64E-5.311, the dose factors in Appendix A may be used for approximating the embryo/fetus dose equivalent for the entire gestation period.

The steps for determining the embryo/fetus dose, using the simplified method, are as follows:

2.1 Include all the intakes by the declared pregnant woman at any time during the gestation period in the calculation of the embryo/fetus dose.

2.2 For ingested radionuclides, determine the activity uptake by the first transfer compartment (blood) by multiplying the intake (I) by the appropriate uptake factor (f_1) from Appendix B [adapted from Federal Guidance Report No. 11, Table 3 (Ref. 4)]. The uptake factor, f_1, is the fraction of an ingested compound of a radionuclide that is transferred into the first transfer compartment (i.e., blood uptake fraction).

2.3 For inhaled radionuclides, determining the fraction of initial intake that is transferred to the blood involves an evaluation of the deposition in the three compartments of the lung and the subsequent time-dependent transfer to the body fluids and to the GI tract. Unless it is known otherwise, it should be assumed that the transfer from the lung to body fluids and from lung to GI tract to body fluids follows the ICRP 30 modeling (which is the basis for this guide).

2.4 For simplicity and conservatism in the modeling, the total uptake into the blood from the maternal intake is assumed to be instantaneous. However, for radionuclides with lung clearance class of W (10- to 100-day half-life clearance) or Y (greater than 100-day half-life clearance), the actual translocation from the lung and uptake in the blood may occur over a time period that exceeds the gestation period. Clearance from the lung may take up to several years. All the initially deposited material is not immediately available for uptake by the first transfer compartment (blood). However, an incremental transfer from the lung to the blood may be assessed based on the lung model as described in ICRP Publications 30 and 19 (Refs. 3 and 5).[2]

Table 1, adapted from the data in Figure 5.2 of ICRP 30, may be used for determining the total transfer from the lung to the first transfer compartment (i.e., blood), where f_1 is the blood uptake fraction from Appendix B.[3] The lung clearance class (D, W, or Y) for a particular chemical form of a particular radionuclide may be obtained from "State of Florida Bureau of Radiation Control ALIs, DACs, and Effluent Concentrations," July 1993.

[2]As modeled in ICRP Publications 19 and 30, the clearance from the different lung compartments is assumed to follow first-order kinetics. This approach is complex, involving interlinking differential equations, and is considered outside the scope of a routine operational radiation safety program.

[3]The coefficients for the transfer fraction equations in Table 1 are applicable to particles with a 1-micrometer activity median aerodynamic diameter (AMAD). As a default, these equations may be used for all particle sizes. However, if the actual particle size distribution is known, transfer fractions for other AMAD particle sizes may be derived from data in Figure 5.2 of ICRP 30.

Table 1

Transfer Fraction of Inhaled Activity to First Transfer Compartment	
Class	Transfer Fraction (TF)
D	$0.48 + 0.15\ f_1$
W	$0.12 + 0.51\ f_1$
Y	$0.05 + 0.58\ f_1$

2.5 Based on the determination of the maternal intake, the dose to the embryo/fetus for the entire gestation period should be calculated using the following equations:

For ingestion intakes:

$$DE = \Sigma\ I_i \times f_{1,i} \times DF_I$$

(Equation 1)

For inhalation intakes:

$$DE = \Sigma\ I_i \times TF_i \times DF_I$$

(Equation 2)

where:

- DE = dose equivalent to the embryo/fetus for the entire gestation period from the acute intakes of all radionuclides during the gestation period (rem or mrem)
- I_i = intake of radionuclide i by the declared pregnant woman at any time during the gestation period (μCi)
- DF_i = dose factor for use in approximating the dose equivalent to the embryo/fetus for the entire gestation period from the introduction of unit activity (1 μCi) into the maternal blood at any time during the gestation period, from tabular data presented in Appendix A to this guide (rem/μCi or mrem/μCi in maternal blood)
- $f_{1,i}$ = the fraction of radionuclide i reaching the body fluids following ingestion (i.e., the fraction of ingested activity of radionuclide i that enters the blood), from data presented in Appendix B to this guide
- TF_i = transfer fraction of inhaled activity to the first transfer compartment (i.e., the fraction of inhaled activity of radionuclide i that enters the blood; see Table 1)

2.6 For pre-existing body burdens, the total burden determined to exist at time of pregnancy should be assumed to be available for uptake in the blood of the woman. The dose should be assigned to the embryo/fetus as if the maternal blood uptake occurs within the first month of pregnancy. The embryo/fetus dose is calculated by multiplying the maternal burden of the radionuclide by its dose factor from Appendix A using the equation:

$$DE = \Sigma\ A_i \times DF_I$$

(Equation 3)

where:

- DE = dose equivalent to the embryo/fetus
- A_i = maternal burden existing at time of pregnancy (μCi)
- DF_i = dose conversion factor (Appendix A)

This method provides a simplified and conservative approach for evaluating the significance of pre-existing conditions. If the embryo/fetus is likely to receive a dose in excess of 25% of the limit from pre-existing burdens [i.e., greater than 0.125 rem (125 mrem or 1.25 mSv)], more detailed modeling should be considered.[4]

2.7 Doses from multiple nuclides or multiple intakes should be evaluated on a frequency corresponding to the determination of the intake. Multiple dose determinations should be added to determine the total dose. Doses may need to be reevaluated if better estimates of intakes are provided by follow-up bioassay measurements.

3. Determining Gestation-Time Dependent Dose to the Embryo/Fetus Using NUREG/CR-5631 Methods

As an alternative to the simplified methods presented above, a gestation-time dependent dose to the embryo/fetus may be calculated for the radionuclides addressed in NUREG/CR-5631. The guide presents dosimetric methods for calculating the dose to the embryo/fetus following the instantaneous introduction of unit activity into the first transfer compartment (blood) of the pregnant woman at successive stages of gestation. These methods include the contribution to the embryo/fetus dose from the resultant body burdens of the declared pregnant woman and from activity in the embryo/fetus resulting from transfer across the placenta. Refer to NUREG/CR-5631 for a detailed description of the modeling.

The methods and data of NUREG/CR-5631 may be used for determining the dose to the embryo/fetus from maternal intakes at successive stages of gestation for the radionuclides H-3, C-14, Co-57, Co-58, Co-60, Sr-89, Sr-90, Ru-106, I-125, I-131, I-132, I-133, I-134, I-135, Cs-134, Cs-137, U-233, U-234, U-235, U-238, Pu-238, Pu-239, and Am-241.

The steps for determining the embryo/fetus dose using the NUREG/CR-5631 methods are as follows:

3.1 The methods presented in subsections 2.1 – 2.4 should be used for determining the uptake in the first transfer compartment (blood) of the declared pregnant woman.

3.2 Equations 1 and 2 in subsection 2.5 may be used for determining the embryo/fetus dose with the following clarifications:

[4]This approach for evaluating pre-existing body burdens does not specifically address time-dependent releases as could occur for certain radionuclides with both a long biological retention and radiological half-life. However, the assumption of blood uptake of the total burden in the first month of the gestation period provides a simple method with reasonable assurance that any actual dose to the embryo/fetus will not be significantly underestimated. More detailed evaluations may be needed for unusual circumstances in which a pre-existing body burden could present a significant source of exposure to the embryo/fetus. An evaluation of this nature should be conducted by individuals knowledgeable in the area of internal dosimetry. Such a detailed evaluation could consider the element retention functions as presented in ICRP Publications 30 and 54 (Refs. 3 and 6). Also, the modeling presented in NUREG/CR-5631 could be applied. The details of this type of an evaluation are beyond the types of analyses that are considered routinely required and, as such, are outside the scope of this guide.

3.2.1 For Equations 1 and 2, in place of the dose factor parameter, DF_i, the dose values should be taken from Appendix C for the time period representing the time of intake relative to stage of gestation. The data in Appendix C are for an absorbed dose (in rads) from the introduction of 1μCi of the radionuclide into the first transfer compartment (blood) of the woman at the beginning of the specified month of gestation. To convert from an absorbed dose (rad) to a dose equivalent (rem), the data in Appendix C should be multiplied by the appropriate quality factor from 64E-5.113(3). For H-3, C-14, Co-57, Co-58, Co-60, Sr-89, Sr-90, Ru-106, I-125, I-131, I-132, I-133, I-134, I-135, Cs-134, and Cs-137, a quality factor of 1 should be applied. For U-233, U-234, U-235, U-238, Pu-238, Pu-239, and Am-241, a quality factor of 20 should be applied, recognizing that most of the embryo/fetus dose results from alpha decay.

For some radionuclides (e.g., U-235), a blood uptake at the beginning of the gestation period results in a negligible dose contribution to the embryo/fetus. These radionuclides are identified in Appendix C by an "N" entry in the row for the 0-day of gestation at radionuclide introduction (i.e., the first row of dose factor data). For an intake within the first month of gestation, a time-weighted dose factor using the second month data (31-day row) should be used. The 31-day dose factor should be multiplied by the quotient of the days-to-date in the first gestation month at time of intake divided by 30 days. For example, assuming a maternal intake of C-14 resulting in a 1 μCi blood uptake on the 20th day of the pregnancy, the embryo/fetus dose should be determined by multiplying the cumulated dose from an intake at day 31 (i.e., Table C3, Cumulated Dose column, 1.89 x 10-4 rads) by the ratio of 20 days to 30 days (i.e., 20 ÷ by 30).

3.2.2 For using the tabular dose data in calculating the embryo/fetus dose, it may be assumed that all intakes occurring within any of the 30-day periods of gestation occur at the beginning of that period.[5] The cumulated dose column should be used in order to determine the total dose for the remainder of the gestation period.

3.2.3 For pre-existing body burdens from occupational exposure, the total burden determined to exist at time of pregnancy should be assumed to be available for uptake in the blood of the woman. The dose should be assigned to the embryo/fetus as if the maternal blood uptake occurs within the first month of pregnancy. The embryo/fetus dose is calculated by multiplying the maternal burden of the radionuclide by its dose factor (Equation 3). The dose factor to be used from the Appendix C tables is that factor corresponding to the cumulated dose for a 0-day of gestation at radionuclide introduction (i.e., right-most column, first data entry). However, for those radionuclides with an "N" for this 0-day entry, the entry for the second gestation month should be used (i.e., the right-most column, second data entry). Alternatively, time-dependent release kinetics may be used for calculating that fraction of the body burden that is translocated to the blood through the duration of the pregnancy. The time-dependent release is described in ICRP Publications 30 and 54. This approach is complex, involving interlinking differential equations, and is considered outside the scope of a routine health physics program.

3.3 Doses from multiple nuclides and multiple intakes should be evaluated with a frequency corresponding to the intake (i.e., at least once every 30 days). Multiple dose determinations should be added to determine the total dose. Doses may need to be reevaluated if better estimates of intakes are provided by follow-up bioassay measurements.

[5]The correlation of intake to actual stage of gestation can only be roughly estimated. For this reason, it is believed that the correlation should be limited to the best estimate of the month of gestation.

D. IMPLEMENTATION

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

Except in those cases in which an applicant proposes an acceptable alternative method of complying with specified portions of the department's regulations, the methods described in this guide will be used in the evaluation of applications for new licenses, license renewals, and license amendments and for evaluating compliance with Chapter 64E-5, F.A.C.

REFERENCES

1. International Commission on Radiological Protection, “Age-Dependent Doses to Members of the Public from Intake of Radionuclides: Part 1,” ICRP No. 56, Pergamon Press Inc., 1989.

2. M. R. Sikov et al., “Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses-Interim Recommendations,” NUREG/CR-5631, Rev. 1 (PNL-7445), U.S. Nuclear Regulatory Commission, March 1992.

3. International Commission on Radiological Protection, “Limits for Intakes of Radionuclides by Workers,” ICRP No. 30, Parts 1 through 4, including supplements, Annals of the ICRP, Vol. 2, No. 3/4, Pergamon Press Inc., 1979.

4. K. F. Eckerman, A. B. Wolbarst, and A. C. B. Richardson, “Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion,” Environmental Protection Agency, Federal Guidance Report No. 11 (EPA- 520/1- 88-020), September 1988.

5. International Commission on Radiological Protection, “The Metabolism of Compounds of Plutonium and Other Actinides,” ICRP No. 19, Pergamon Press Inc., May 1972.

6. International Commission on Radiological Protection, “Individual Monitoring for Intake of Radionuclides by Workers: Design and Interpretation," ICRP No. 54, Annals of the ICRP, Volume 19, No. 1-3, Pergamon Press Inc., 1988.

APPENDIX A

DOSE EQUIVALENT FACTORS FOR USE IN APPROXIMATING THE EMBRYO/FETUS DOSE FROM RADIONUCLIDES IN MATERNAL BLOOD

Except as noted, the dose factors (DF_i) presented in Table A-1 represent the committed dose equivalent (CDE) to the uterus per introduction of unit activity into the first transfer compartment (i.e., blood) of the woman. These entries were calculated from tabulated values of uterine CDE per unit intake and fractional absorption (f_1) from the gastrointestinal tract using ICRP-30 (Ref. A1) methodology. The DF_i dose factors were derived by dividing the CDE per unit intake by the fractional absorption factor (f_1). These dose factors are based on unit activity in the blood. The most conservative f_1 (i.e., largest fraction) for each radionuclide has been used for deriving the data in Table A-1.

For the radionuclides H-3, C-14, Co-57, Co-58, Co-60, Sr-89, Sr-90, Ru-106, I-125, I-131, I-132, I-133, I-134, I-135, Cs-134, Cs-137, U-233, U-234, U-235, U-238, Pu-238, Pu-239, and Am-241, the dose factors in Table A-1 represent the maximum dose equivalent to the embryo/fetus for the gestation period from the introduction of unit activity into the first transfer compartment of the woman at any time during the gestation period. These entries are based on the modeling of Rev. 1 to NUREG/CR-5631 (Ref. A2) and are derived from the data tables presented in Appendix C to this guide. The maximum calculated embryo/fetus dose (as presented in the Appendix C tables) from intake by the declared pregnant woman during the gestation period has been used for inclusion in Table A-1.

The dose factor data presented in NUREG/CR-5631 are for an absorbed dose expressed in units of rads. To adapt these data as presented in Appendix C to this guide for inclusion in Table A-1, appropriate quality factors have been applied to convert from rads to dose equivalent, expressed in units of rem. For beta- and gamma-emitting radionuclides, a quality factor of 1 has been applied. For U-233, U-234, U-235, U-238, Pu-238, Pu-239, and Am-241, a quality factor of 20 has been applied, recognizing that most of the embryo/fetus dose results from the alpha decay.

REFERENCES

A1. International Commission on Radiological Protection, "Limits for Intakes of Radionuclides by Workers," ICRP No. 30, Parts 1 – 4, including supplements, Annals of the ICRP, Volume 2, No. 3/4, Pergamon Press Inc., 1979.

A2. M. R. Sikov et al., "Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses-Interim Recommendations," NUREG/CR-5631, Rev. 1 (PNL-7445), U.S. Nuclear Regulatory Commission, March 1992.

Table A-1

Dose Equivalent Factors for Use in Approximating the Embryo/Fetus Dose from Radionuclides in Maternal Blood

Nuclide	DF_i (rem/μCi)	Nuclide	DF_I (rem/μCi)	Nuclide	DF_i (rem/μCi)
H-3	5.87E-05*	Cr-51	6.96E-04	Ga-68	5.66E-02
Be-7	1.67E-02	Mn-51	3.65E-04	Ga-70	8.99E-05
Be-10	1.79E-02	Mn-52	4.70E-02	Ga-72	1.53E+00
C-11	1.21E-05	Mn-52m	2.80E-04	Ga-73	9.36E-02
C-14	1.29E-03*	Mn-53	5.77E-05	Ge-66	1.42E-04
F-18	1.32E-05	Mn-54	1.86E-02	Ge-67	1.11E-05
Na-22	1.06E-02	Mn-56	2.18E-03	Ge-68	8.81E-04
Na-24	1.21E-03	Fe-52	1.30E-02	Ge-69	3.02E-04
Mg-28	3.83E-03	Fe-55	3.88E-03	Ge-71	6.99E-06
Al-26	5.33E-01	Fe-59	4.63E-02	Ge-75	1.61E-05
Si-31	3.85E-05	Fe-60	1.47E+00	Ge-77	3.40E-04
Si-32	4.33E-02	Co-55	4.01E-03	Ge-78	1.08E-04
P-32	3.03E-03	Co-56	3.43E-02	As-69	2.46E-05
P-33	4.33E-04	Co-57	2.20E-03*	As-70	2.90E-04
S-35	3.53E-04	Co-58	9.17E-03*	As-71	1.21E-03
Cl-36	2.96E-03	Co-58m	5.17E-05	As-72	2.70E-03
Cl-38	3.17E-05	Co-60	4.18E-02*	As-73	3.02E-04
Cl-39	3.89E-05	Co-6om	4.12E-07	As-74	2.90E-03
K-40	1.84E-02	Co-61	4.50E-05	As-76	1.11E-03
K-42	7.73E-04	Co-62m	5.33E-05	As-77	1.88E-04
K-43	7.10E-04	Ni-56	5.39E-02	As-78	1.85E-04
K-44	1.94E-05	Ni-57	3.60E-02	Se-70	1.61E-04
K-45	1.21E-05	Ni-59	2.71E-03	Se-73	3.66E-04
Ca-41	3.21E-05	Ni-63	6.29E-03	Se-73m	3.21E-05
Ca-45	6.61E-04	Ni-65	1.43E-03	Se-75	8.79E-03
Ca-47	5.18E-03	Ni-66	2.81E-03	Se-79	4.19E-03
Sc-43	2.48E+00	Cu-60	9.32E-05	Se-81	1.00E-06
Sc-44	4.59E+00	Cu-61	2.69E-04	Se-81m	1.46E-05
Sc-44m	2.56E+01	Cu-64	2.09E-04	Se-83	3.62E-05
Sc-46	3.15E+01	Cu-67	6.50E-04	Br-74	3.33E-05
Sc-47	1.86E+00	Zn-62	1.38E-03	Br-74m	6.18E-05
Sc-48	3.52E+01	Zn-63	5.92E-05	Br-75	6.07E-05
Sc-49	4.18E-04	Zn-65	3.49E-02	Br-76	1.20E-03
Ti-44	1.36E+00	Zn-69	3.09E-06	Br-77	3.27E-04
Ti-45	1.54E-02	Zn-69m	5.54E-04	Br-80	3.01E-06
V-47	2.29E-03	Zn-71m	5.75E-04	Br-80m	1.46E-04
V-48	4.37E-01	Zn-72	5.28E-03	Br-82	1.87E-03
V-49	8.36E-05	Ga-65	9.18E-03	Br-83	2.72E-05
Cr-48	5.77E-03	Ga-66	9.95E-01	Br-84	2.56E-05
Cr-49	3.51E-04	Ga-67	2.50E-01	Rb-79	1.15E-05

*Dose equivalent factor based on data presented in Rev. 1 to NUREG/CR-5631 (Ref. A2). All other factors represent the CDE to the uterus.

Table A-1 (contd.)

Dose Equivalent Factors for Use in Approximating the Embryo/Fetus Dose from Radionuclides in Maternal Blood

Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)
Rb-81	8.18E-05	Nb-90	2.39E-01	Rh-105	1.93E-03
Rb-81m	1.08E-05	Nb-93m	9.29E-04	Rh-106m	6.86E-03
Rb-82m	3.49E-04	Nb-94	3.04E-01	Rh-107	8.51E-05
Rb-83	7.07E-03	Nb-95	1.24E-01	Pd-100	3.94E-01
Rb-84	1.05E-02	Nb-95m	1.27E-02	Pd-101	3.33E-02
Rb-86	8.14E-03	Nb-96	2.03E-01	Pd-103	1.39E-03
Rb-87	4.22E-03	Nb-97	4.11E-03	Pd-107	7.33E-06
Rb-88	1.02E-05	Nb-98	9.66E-03	Pd-109	1.27E-03
Rb-89	1.20E-05	Mo-90	7.77E-04	Ag-102	3.76E-04
Sr-80	3.96E-04	Mo-93	4.36E-04	Ag-103	8.58E-04
Sr-81	1.22E-04	Mo-93m	4.76E-04	Ag-104	3.05E-03
Sr-82	1.25E-02	Mo-99	9.39E-04	Ag-104m	1.09E-03
Sr-83	2.31E-03	Mo-101	1.48E-05	Ag-105	1.94E-02
Sr-85	4.03E-03	Tc-93	1.33E-04	Ag-106	2.12E-04
Sr-85m	4.81E-05	Tc-93m	4.67E-05	Ag-106m	8.21E-02
Sr-87m	1.62E-04	Tc-94	4.56E-04	Ag-108m	6.59E-02
Sr-89	1.84E-02*	Tc-94m	7.08E-05	Ag-110m	1.04E-01
Sr-90	5.22E-02*	Tc-95	3.86E-04	Ag-111	1.41E-03
Sr-91	1.49E-03	Tc-95m	1.23E-03	Ag-112	2.18E-03
Sr-92	7.79E-04	Tc-96	2.62E-03	Ag-115	1.98E-04
Y-86	2.18E+01	Tc-96m	2.29E-05	Cd-104	3.30E-03
Y-86m	1.26E+00	Tc-97	4.67E-05	Cd-107	1.95E-04
Y-87	1.01E+01	Tc-97m	2.42E-04	Cd-109	2.12E-02
Y-88	3.96E+01	Tc-98	2.97E-03	Cd-113	2.77E-01
Y-90	4.66E-04	Tc-99	2.79E-04	Cd-113m	2.55E-01
Y-90m	1.21E+00	Tc-99m	3.32E-05	Cd-115	9.47E-03
Y-91	6.03E-02	Tc-101	2.96E-06	Cd-115m	1.27E-02
Y-91m	2.13E-01	Tc-104	2.07E-05	Cd-117	4.23E-03
Y-92	4.81E-01	Ru-94	2.32E-03	Cd-117m	9.62E-03
Y-93	4.18E-01	Ru-97	6.89E-03	In-109	7.95E-03
Y-94	1.10E-01	Ru-103	1.97E-02	In-110	4.01E-02
Y-95	3.56E-02	Ru-105	4.09E-03	In-110	4.50E-03
Zr-86	8.62E-01	Ru-106	7.23E-03*	In-111	3.05E-02
Zr-88	3.87E-01	Rh-99	2.19E-02	In-112	9.47E-05
Zr-89	7.31E-01	Rh-99m	3.51E-03	In-113m	1.24E-03
Zr-93	8.79E-05	Rh-100	3.86E-02	In-114m	3.05E-02
Zr-95	6.16E-01	Rh-101	3.33E-02	In-115	8.99E-01
Zr-97	5.24E-01	Rh-101m	9.40E-03	In-115m	2.16E-03
Nb-88	1.17E-03	Rh-102	1.93E-01	In-116m	4.92E-03
Nb-89	1.83E-02	Rh-102m	3.48E-02	In-117	1.22E-03
Nb-89m	1.30E-02	Rh-103m	1.18E-06	In-117m	2.61E-03

*Dose equivalent factor based on data presented in Rev. 1 to NUREG/CR-5631 (Ref. A2). All other factors represent the CDE to the uterus.

Table A-1 (contd.)

Dose Equivalent Factors for Use in Approximating the Embryo/Fetus Dose from Radionuclides in Maternal Blood

Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)
In-119m	1.39E-05	Te-127m	1.82E-03	Ba-131m	1.32E-05
Sn-110	2.11E-02	Te-129	2.35E-05	Ba-133	1.27E-02
Sn-111	8.81E-04	Te-129m	3.39E-03	Ba-133m	8.77E-04
Sn-113	2.63E-02	Te-131	2.18E-04	Ba-135m	7.03E-04
Sn-117m	1.57E-02	Te-131m	6.64E-03	Ba-139	4.55E-05
Sn-119m	2.29E-03	Te-132	8.57E-03	Ba-140	1.54E-02
Sn-121	3.70E-05	Te-133	3.26E-05	Ba-141	9.47E-05
Sn-121m	5.70E-03	Te-133m	5.48E-04	Ba-142	2.74E-04
Sn-123	6.35E-03	Te-134	3.98E-04	La-131	3.77E-02
Sn-123m	2.48E-04	I-120	9.36E-05	La-132	5.07E-01
Sn-125	2.37E-02	I-120m	8.73E-05	La-135	3.43E-02
Sn-126	2.35E-01	I-121	1.79E-05	La-137	7.55E-02
Sn-127	1.14E-02	I-123	2.27E-05	La-138	2.84E+00
Sn-128	7.14E-03	I-124	2.16E-04	La-140	2.32E+00
Sb-115	2.00E-04	I-125	1.38E-03*	La-141	9.43E-03
Sb-116	1.59E-04	I-126	2.23E-04	La-142	1.91E-01
Sb-116m	1.49E-03	I-128	5.25E-06	La-143	2.85E-03
Sb-117	3.34E-04	I-129	5.11E-04	Ce-134	3.13E+00
Sb-118m	6.59E-03	I-130	2.29E-04	Ce-135	4.44E+00
Sb-119	2.08E-04	I-131	3.64E-03*	Ce-137	7.13E-02
Sb-120	3.70E-05	I-132	1.56E-04*	Ce-137m	3.31E-01
Sb-120	3.42E-02	I-132m	6.14E-05	Ce-139	1.15E+00
Sb-122	5.85E-03	I-133	9.04E-04*	Ce-141	5.56E-01
Sb-124	2.98E-02	I-134	4.83E-05*	Ce-143	1.05E+00
Sb-124m	4.88E-05	I-135	3.72E-04*	Ce-144	3.79E-01
Sb-125	8.51E-03	Cs-125	1.33E-05	Pr-136	4.12E-02
Sb-126	4.37E-02	Cs-127	5.96E-05	Pr-137	1.26E-01
Sb-126m	1.69E-04	Cs-129	2.13E-04	Pr-138m	9.61E-01
Sb-127	9.66E-03	Cs-130	6.99E-06	Pr-139	1.16E-01
Sb-128	1.33E-04	Cs-131	2.27E-04	Pr-142	1.36E-01
Sb-128	8.73E-03	Cs-132	2.10E-03	Pr-142m	1.73E-03
Sb-129	3.36E-03	Cs-134	1.11E-01*	Pr-143	4.53E-08
Sb-130	9.40E-04	Cs-134m	2.66E-05	Pr-144	8.44E-04
Sb-131	3.36E-04	Cs-135	7.07E-03	Pr-145	1.41E-02
Te-116	1.45E-03	Cs-135m	2.42E-05	Pr-147	1.95E-02
Te-121	4.87E-03	Cs-136	1.42E-02	Nd-136	3.59E-01
Te-121m	7.90E-03	Cs-137	5.94E-02*	Nd-138	8.26E-01
Te-123	3.09E-05	Cs-138	2.95E-05	Nd-139	4.11E-02
Te-123m	2.94E-03	Ba-126	1.14E-03	Nd-139m	1.74E+00
Te-125m	9.75E-04	Ba-128	1.17E-02	Nd-141	4.33E-02
Te-127	6.31E-05	Ba-131	7.40E-03	Nd-147	8.45E-01

*Dose equivalent factor based on data presented in Rev. 1 to NUREG/CR-5631 (Ref. A2). All other factors represent the CDE to the uterus.

Table A-1 (contd.)

Dose Equivalent Factors for Use in Approximating the Embryo/Fetus Dose from Radionuclides in Maternal Blood

Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)
Nd-149	1.37E-01	Gd-149	2.47E+00	Tm-166	2.37E+00
Nd-151	2.53E-02	Gd-151	4.99E-01	Tm-167	1.03E+00
Pm-141	3.63E-02	Gd-152	0.00E-01	Tm-170	5.38E-02
Pm-143	1.79E+00	Gd-153	8.92E-01	Tm-171	8.13E-03
Pm-144	8.68E+00	Gd-159	1.52E-01	Tm-172	1.89E+00
Pm-145	2.58E-01	Tb-147	6.76E-01	Tm-173	5.88E-01
Pm-146	4.34E+00	Tb-149	1.27E+00	Tm-175	2.70E-02
Pm-147	3.49E-05	Tb-150	1.01E+00	Yb-162	8.97E-02
Pm-148	2.60E+00	Tb-151	2.33E+00	Yb-166	6.08E+00
Pm-148m	1.08E+01	Tb-153	1.16E+00	Yb-167	1.23E-02
Pm-149	4.70E-02	Tb-154	5.65E+00	Yb-169	2.47E+00
Pm-150	6.86E-01	Tb-155	9.52E-01	Yb-175	2.10E-01
Pm-151	1.11E+00	Tb-156	8.65E+00	Yb-177	6.98E-02
Sm-141	4.11E-02	Tb-156m	9.32E-01	Yb-178	4.11E-02
Sm-141m	1.42E-01	Tb-156m	2.89E-01	Lu-169	3.60E+00
Sm-142	2.11E-01	Tb-157	2.39E-02	Lu-170	8.42E+00
Sm-145	5.56E-01	Tb-158	4.79E+00	Lu-171	3.72E+00
Sm-146	0.00E-01	Tb-160	6.08E+00	Lu-172	9.20E+00
Sm-147	0.00E-01	Tb-161	2.64E-01	Lu-173	1.10E+00
Sm-151	1.26E-05	Dy-155	1.08E+00	Lu-174	8.93E-01
Sm-153	3.54E-01	Dy-157	5.81E-01	Lu-174m	5.54E-01
Sm-155	5.65E-03	Dy-159	4.19E-01	Lu-176	3.45E+00
Sm-156	3.55E-01	Dy-165	1.38E-02	Lu-176m	1.53E-02
Eu-145	2.00E+00	Dy-166	3.56E-01	Lu-177	2.24E-01
Eu-146	3.38E+00	Ho-155	1.41E-01	Lu-177m	6.80E+00
Eu-147	8.51E-01	Ho-157	2.57E-02	Lu-178	8.18E-03
Eu-148	3.53E+00	Ho-159	3.47E-02	Lu-178m	5.54E-02
Eu-149	1.40E-01	Ho-161	4.70E-02	Lu-179	3.03E-02
Eu-150	2.92E-02	Ho-162	4.66E-03	Hf-170	4.74E-01
Eu-150	3.02E+00	Ho-162m	1.43E-01	Hf-172	4.63E-01
Eu-152	2.20E+00	Ho-164	3.10E-03	Hf-173	2.26E-01
Eu-152m	1.38E-01	Ho-164m	1.32E-02	Hf-175	3.70E-01
Eu-154	2.28E+00	Ho-166	1.04E-01	Hf-177m	5.22E-02
Eu-155	1.60E-01	Ho-166m	1.07E+01	Hf-178m	2.94E+00
Eu-156	1.90E+00	Ho-167	2.38E-01	Hf-179m	8.51E-01
Eu-157	2.01E-01	Er-161	6.29E-01	Hf-180m	1.71E-01
Eu-158	3.56E-02	Er-165	1.12E-01	Hf-181	4.96E-01
Gd-145	1.09E-01	Er-169	1.34E-04	Hf-182	1.16E+00
Gd-146	4.11E+00	Er-171	5.88E-01	Hf-182m	2.61E-02
Gd-147	4.91E+00	Er-172	2.59E+00	Hf-183	2.33E-02
Gd-148	0.00E-01	Tm-162	6.87E-02	Hf-184	1.94E-01

*Dose equivalent factor based on data presented in Rev. 1 to NUREG/CR-5631 (Ref. A2). All other factors represent the CDE to the uterus.

Table A-1 (contd.)

Dose Equivalent Factors for Use in Approximating the Embryo/Fetus Dose from Radionuclides in Maternal Blood

Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)
Ta-172	4.07E-02	Os-189m	5.11E-06	Hg-193m	3.23E-04
Ta-173	1.94E-01	Os-191	1.99E-02	Hg-194	1.81E-01
Ta-174	4.25E-02	Os-191m	1.12E-03	Hg-195	7.47E-05
Ta-175	4.96E-01	Os-193	8.55E-03	Hg-195m	5.48E-04
Ta-176	8.25E-01	Os-194	8.69E-02	Hg-197	2.38E-04
Ta-177	1.30E-01	Ir-182	2.23E-03	Hg-197m	2.97E-04
Ta-178	1.47E-01	Ir-184	3.24E-02	Hg-199m	7.55E-06
Ta-179	9.40E-02	Ir-185	3.85E-02	Hg-203	5.33E-03
Ta-180	1.16E+00	Ir-186	1.12E-01	Tl-194	6.44E-06
Ta-180m	3.47E-02	Ir-187	2.08E-02	Tl-194m	2.16E-05
Ta-182	2.15E+00	Ir-188	1.60E-01	Tl-195	3.49E-05
Ta-182m	2.65E-03	Ir-189	1.96E-02	Tl-197	3.85E-05
Ta-183	5.44E-01	Ir-190	2.52E-01	Tl-198	1.94E-04
Ta-184	7.40E-01	Ir-190m	1.01E-03	Tl-198m	8.36E-05
Ta-185	9.25E-03	Ir-192	1.63E-01	Tl-199	5.55E-05
Ta-186	7.03E-03	Ir-192m	8.99E-02	Tl-200	6.55E-04
W-176	6.55E-04	Ir-194	7.55E-03	Tl-201	2.48E-04
W-177	3.66E-04	Ir-194m	4.55E-01	Tl-202	1.38E-03
W-178	6.43E-04	Ir-195	1.24E-03	Tl-204	2.43E-03
W-179	8.12E-06	Ir-195m	1.03E-02	Pb-195m	1.65E-04
W-181	2.80E-04	Pt-186	2.06E-02	Pb-198	3.92E-04
W-185	3.51E-07	Pt-188	1.21E-01	Pb-199	6.51E-04
W-187	1.04E-03	Pt-189	2.08E-02	Pb-200	3.37E-03
W-188	1.68E-04	Pt-191	4.88E-02	Pb-201	1.78E-03
Re-177	1.49E-05	Pt-193	1.07E-04	Pb-202	6.77E-02
Re-178	8.37E-06	Pt-193m	2.71E-03	Pb-202m	1.91E-03
Re-181	4.61E-04	Pt-195m	1.58E-02	Pb-203	2.02E-03
Re-182	4.56E-04	Pt-197	2.64E-03	Pb-205	3.63E-04
Re-182	1.92E-03	Pt-197m	1.12E-03	Pb-209	9.93E-06
Re-184	1.64E-03	Pt-199	5.40E-04	Pb-210	2.31E+00
Re-184m	1.31E-03	Pt-200	2.04E-02	Pb-211	3.63E-04
Re-186	4.53E-04	Au-193	1.63E-03	Pb-212	3.29E-02
Re-186m	9.43E-04	Au-194	1.10E-02	Pb-214	5.64E-04
Re-187	1.82E-06	Au-195	2.35E-03	Bi-200	1.66E-03
Re-188	3.73E-04	Au-198	5.66E-03	Bi-201	4.07E-03
Re-188m	8.19E-06	Au-198m	1.05E-02	Bi-202	4.83E-03
Re-189	2.46E-04	Au-199	1.68E-03	Bi-203	2.54E-02
Os-180	1.78E-03	Au-200	1.01E-04	Bi-205	4.82E-02
Os-181	1.75E-02	Au-200m	1.61E-02	Bi-206	9.03E-02
Os-182	1.07E-01	Au-201	1.15E-05	Bi-207	4.88E-02
Os-185	1.33E-01	Hg-193	4.88E-05	Bi-210	1.46E-03

*Dose equivalent factor based on data presented in Rev. 1 to NUREG/CR-5631 (Ref. A2). All other factors represent the CDE to the uterus.

Table A-1 (contd.)

Dose Equivalent Factors for Use in Approximating the Embryo/Fetus Dose from Radionuclides in Maternal Blood

Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)	Nuclide	DF_i (rem/μCi)
Bi-210m	8.66E-02	U-233	5.84E-01*	Am-245	2.68E-04
Bi-212	1.70E-03	U-234	5.84E-01*	Am-246m	1.51E-02
Bi-213	4.36E-04	U-235	5.34E-01*	Am-246	2.03E-02
Bi-214	3.52E-04	U-236	1.81E-01	Cm-238	1.31E-01
Po-203	1.07E-03	U-237	5.42E-03	Cm-240	3.50E-02
Po-205	1.64E-03	U-238	5.10E-01*	Cm-241	8.69E-01
Po-207	4.03E-03	U-239	5.52E-05	Cm-242	3.30E-02
Po-210	3.05E+00	U-240	4.17E-03	Cm-243	3.74E-01
At-207	8.32E-04	Np-232	8.69E-03	Cm-244	3.19E-02
At-211	3.92E-02	Np-233	2.85E-03	Cm-245	3.11E-01
Fr-222	2.13E-03	Np-234	1.45E+00	Cm-246	1.27E-01
Fr-223	8.58E-03	Np-235	2.99E-03	Cm-247	9.51E-01
Ra-223	7.84E-01	Np-236	4.29E-01	Cm-248	3.49E+01
Ra-224	3.85E-01	Np-236	5.25E-02	Cm-249	1.07E-03
Ra-225	6.23E-01	Np-237	3.59E-01	Cm-250	2.76E+02
Ra-226	1.69E+00	Np-238	6.07E-01	Bk-245	4.11E-01
Ra-227	6.10E-05	Np-239	2.55E-01	Bk-246	1.04E+00
Ra-228	2.90E+00	Np-240	7.07E-02	Bk-247	2.83E-01
Ac-224	9.47E-02	Pu-234	1.24E-01	Bk-249	8.40E-04
Ac-225	3.68E-01	Pu-235	1.72E-03	Bk-250	1.54E-01
Ac-226	1.66E-01	Pu-236	6.81E-02	Cf-244	9.25E-05
Ac-227	2.60E-01	Pu-237	1.07E-01	Cf-246	2.88E-02
Ac-228	3.12E-01	Pu-238	1.11E+00*	Cf-248	4.18E-02
Th-226	3.02E-03	Pu-239	1.04E+00*	Cf-249	9.80E-01
Th-227	3.52E+00	Pu-240	2.80E-02	Cf-250	3.30E-01
Th-228	4.40E+01	Pu-241	2.96E-04	Cf-251	4.26E-01
Th-229	8.51E+01	Pu-242	2.81E-02	Cf-252	1.15E+01
Th-230	1.26E+01	Pu-243	9.62E-03	Cf-253	8.55E-04
Th-231	8.97E-02	Pu-244	1.07E+00	Cf-254	3.70E+02
Th-232	2.26E+01	Pu-245	2.22E-01	Es-250	4.77E-02
Th-234	2.33E-01	Pu-246	1.34E+00	Es-251	1.24E-01
Pa-227	2.42E-03	Am-237	2.60E-02	Es-253	3.58E-02
Pa-228	9.58E-01	Am-238	7.81E-02	Es-254m	5.22E-01
Pa-230	1.04E+00	Am-239	1.63E-01	Es-254	1.33E+00
Pa-231	2.25E-01	Am-240	1.16E+00	Fm-252	2.61E-02
Pa-232	8.95E-01	Am-241	2.22E-01*	Fm-253	1.38E-01
Pa-233	3.81E-01	Am-242m	3.64E-02	Fm-254	6.11E-03
Pa-234	6.77E-01	Am-242	1.32E-02	Fm-255	2.85E-02
U-230	6.13E-01	Am-243	4.74E-01	Fm-257	2.60E-01
U-231	2.63E-03	Am-244m	1.05E-05	Md-257	3.69E-02
U-232	6.02E-01	Am-244	3.92E-01	Md-258	5.96E-02

*Dose equivalent factor based on data presented in Rev. 1 to NUREG/CR-5631 (Ref. A2). All other factors represent the CDE to the uterus.

APPENDIX B

BLOOD UPTAKE FRACTIONS FOR INGESTED ACTIVITY

Element	f_1	Element	f_1	Element	f_1
Actinium (Ac)	1E-3	Germanium (Ge)	1E0	Radium (Ra)	2E-1
Aluminum (Al)	1E-2	Gold (Au)	1E-1	Rhenium (Re)	8E-1
Americium (Am)	1E-3	Hafnium (Hf)	2E-3	Rhodium (Rh)	5E-2
Antimony (Sb)	1E-1	Holmium (Ho)	3E-4	Rubidium (Rb)	1E0
Arsenic (As)	5E-1	Hydrogen (H)	1E0	Ruthenium (Ru)	5E-2
Astatine (At)	1E0	Indium (In)	2E-2	Samarium (Sm)	3E-4
Barium (Ba)	1E-1	Iodine (I)	1E0	Scandium (Sc)	1E-4
Berkelium (Bk)	1E-3	Iridium (Ir)	1E-2	Selenium (Se)	8E-1
Beryllium (Be)	5E-3	Iron (Fe)	1E-1	Silicon (Si)	1E-2
Bismuth (Bi)	5E-2	Lanthanum (La)	1E-3	Silver (Ag)	5E-2
Bromine (Br)	1E0	Lead (Pb)	2E-1	Sodium (Na)	1E0
Cadmium (Cd)	5E-2	Lutetium (Lu)	3E-4	Strontium (Sr)	3E-1
Calcium (Ca)	3E-1	Magnesium (Mg)	5E-1	Sulfur (S)	8E-1
Californium (Cf)	1E-3	Manganese (Mn)	1E-1	Tantalum (Ta)	1E-3
Carbon (C)	1E0	Mendelevium (Md)	1E-3	Technetium (Tc)	8E-1
Cerium (Ce)	3E-4	Mercury (Hg)	1E0	Tellurium (Te)	2E-1
Cesium (Cs)	1E0	Molybdenum (Mo)	8E-1	Terbium (Tb)	3E-4
Chlorine (Cl)	1E0	Neodymium (Nd)	3E-4	Thallium (Tl)	1E0
Chromium (Cr)	1E-1	Neptunium (Np)	1E-3	Thorium (Th)	2E-4
Cobalt (Co)	3E-1	Nickel (Ni)	5E-2	Thulium (Tm)	3E-4
Copper (Cu)	5E-1	Niobium (Nb)	1E-2	Tin (Sn)	2E-2
Curium (Cm)	1E-3	Osmium (Os)	1E-2	Titanium (Ti)	1E-2
Dysprosium (Dy)	3E-4	Palladium (Pd)	5E-3	Tungsten (W)	3E-1
Einsteinium (Es)	1E-3	Phosphorus (P)	8E-1	Uranium (U)	5E-2
Erbium (Er)	3E-4	Platinum (Pt)	1E-2	Vanadium (V)	1E-2
Europium (Eu)	1E-3	Plutonium (Pu)	1E-3	Ytterbium (Yb)	3E-4
Fermium (Fm)	1E-3	Polonium (Po)	1E-1	Yttrium (Y)	1E-4
Fluorine (F)	1E0	Potassium (K)	1E0	Zinc (Zn)	5E-1
Francium (Fr)	1E0	Praseodymium (Pr)	3E-4	Zirconium (Zr)	2E-3
Gadolinium (Gd)	3E-4	Promethium (Pm)	3E-4		
Gallium (Ga)	1E-3	Protactinium (Pa)	1E-3		

APPENDIX C

RADIATION ABSORBED DOSE TO THE EMBRYO/FETUS FOLLOWING INTRODUCTION OF SPECIFIED RADIONUCLIDES AND CHEMICAL FORMS INTO THE MATERNAL TRANSFER COMPARTMENT (BLOOD)

The entries for selected radionuclides and chemical forms in the tables in this appendix have been calculated from the modeling presented in Rev. 1 to NUREG/CR-5631 (Ref. C1). It has been assumed that 1 Ci of activity is introduced into the maternal transfer compartment (blood). Pregnancy is assumed to begin at the time of fertilization, roughly 2 weeks after menses, and gestation is considered to consist of nine 30-day months.

Radiation dose rates were calculated from the initial fraction that was present after a single administration at the start of each of these months or on the assumed final day (day 270) of gestation. Monthly doses were determined by integrating under the curve relating the fraction of the activity in the embryo/fetus at the start of each month after administration and the fraction at the beginning of the subsequent month of gestation. Monthly doses are shown for the inclusive periods, expressed in days. Doses to the embryo/fetus from radionuclides in maternal organs were calculated; when appropriate, these are included to provide total radiation absorbed doses. The tabulated values of cumulated doses were determined as the sum of the monthly doses.

As noted in Rev. 1 to NUREG/CR-5631, ICRP Publication 30 (Ref. C2) employs a metabolic model in which a fraction of activity in the first transfer compartment (blood) often is assumed to go immediately to excretion. Because of the minuscule mass of the embryo/fetus immediately following fertilization, for some materials the biokinetic model thus predicts that there would be negligible initial activity in the embryo after administration at that time, and that there would be minimal activity at later times. As a consequence, the dose rate and doses also would be negligible, which is indicated by N in the table. For these nuclides, an approximation of the cumulative dose for an intake occurring during the first 30 days should be made based on a time-weighted average of the 31-day intake data. The cumulative dose from an intake in the first 30 days of pregnancy may be estimated by multiplying the 31-day cumulated dose value by the ratio of the days-to-date in the first month to a 30-day period. For example, assuming a maternal intake of C-14 resulting in a 1 μCi blood uptake on the 20th day of the pregnancy, the gestation dose should be determined by multiplying the cumulative dose from an intake at day 31 (i.e., Table C3, Cumulated Dose column, 1.89E-04 rads) by the ratio of 20 days to 30 days (i.e., 20 divided by 30).

REFERENCES

C1. M. R. Sikov et al., “Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Dose--Interim Recommendations,” NUREG/CR-5631, Revision 1 (PNL-7445), U.S. Nuclear Regulatory Commission, March 1992.

C2. International Commission on Radiological Protection, “Limits for Intakes of Radionuclides by Workers,” ICRP No. 30, Parts 1 through 4, including supplements, Annals of the ICRP, Volume 2, No. 3/4, Pergamon Press Inc., 1979.

APPENDIX D

EXAMPLES OF EMBRYO/FETUS DOSE CALCULATIONS

The purpose of this appendix is to present examples of the methods of the guide for calculating the dose equivalent to the embryo/fetus. The examples have been developed to demonstrate the calculational methods; the methods for evaluating and determining maternal exposures, body burdens, and intakes are not included. These examples are not intended to describe all the measures that would be required for determining the maternal exposure. Instead, the examples are presented to concisely demonstrate the calculational methods once data on maternal exposure have been obtained. It is important to keep in mind that an evaluation is no better than the quality of the data. In applying the methods of this guide, a primary concern has to be the reliability of the maternal exposure data. The calculation of the embryo/fetus dose consists of a two-step process. First, the content of a radionuclide in maternal blood has to be determined. This is accomplished by multiplying the intake by the appropriate transfer fraction. The second step involves the determination of the embryo/fetus dose based on the maternal radionuclide blood content.

Six example calculations are provided. Cases 1 and 2 address ingestion intakes by the declared pregnant woman. Cases 3 and 4 address inhalation intakes. Case 5 evaluates a pre-existing body burden and determines the embryo/fetus dose equivalent based on the maternal burden existing at time of pregnancy. Case 6 presents an example of summing external and internal doses and instituting worker controls to ensure the dose limit is not exceeded.

The two methods in the guide for calculating the embryo/fetus dose equivalent are presented: the Simplified Method as presented in Section 2 of this guide, and the NUREG/CR-5631 Gestation-Time Dependent Method as presented in Section 3.

* *

CASE 1

EMBRYO/FETUS DOSE FOLLOWING ACUTE INGESTION INTAKE BY DECLARED PREGNANT WOMAN

1.1 Exposure Scenario

A declared pregnant woman unknowingly ingests a substance that contains trace amounts of Co-58. The licensee determines that the woman ingested 22 µCi of Co-58 over a 4-day period.* The intake is confined to a short time period (relative to the effective biological retention half-life of Co-58) within the first month of the pregnancy. Because the intake is assumed to have occurred within a single 30-day gestation period interval (i.e., a 30-day period as used for calculating intakes and doses), the ingestion may be treated as a single, acute intake.

1.2 Determining Blood Uptake

The calculation of the dose to the embryo/fetus is based on the amount of the intake that is available for uptake within the first transfer compartment (i.e., blood). Applying the guidance in subsection 2.2, the blood uptake for an ingestion intake may be calculated by multiplying the intake by the gut-to-blood transfer factor (f_1):

$$\text{Blood Uptake} = f_1 \times \text{Ingestion Intake}$$

For cobalt, the f_1 value from Appendix B is 0.3. For this example, the predetermined ingestion intake is 22 µCi. Inserting these values into the above equation results in the following calculation of the maternal blood content:

Blood Uptake = 0.3 x 22 µCi = 6.6 µCi

1.3 Calculating the Embryo/Fetus Dose Equivalent

The calculation of the embryo/fetus dose equivalent is based on the activity uptake into the first transfer compartment (i.e., maternal blood). First, the dose will be calculated using the Simplified Method as presented in Section 2. Next, the gestation-time dependent method for calculating the dose equivalent will be presented.

1.3.1 Simplified Method

Section 2 presents the Simplified Method for calculating the embryo/fetus dose equivalent. From Appendix A, the Co-58 dose equivalent factor is 9.17E-03 rem/µCi (in blood). The dose equivalent is calculated using Equation 1 from subsection 2.5. Substituting the values for intake, the gut-to-blood transfer factor (f_1) and dose factor into this equation yields the following dose equivalent calculation:

Dose Equivalent = Intake x f_1 x Dose Factor

= 22 µCi x 0.3 x 9.17E-03 rem/µCi

= 0.0605 rem

1.3.2 Method Using NUREG/CR-5631

Section 3 presents the method for calculating the embryo/fetus dose using the gestation-time dependent methodology of NUREG/CR-5631. Table C5 of Appendix C presents the gestation-time dependent dose factors for Co-58. From this table, the column under the heading "Cumulated Dose" presents the dose to the embryo/fetus for the remainder of the gestation period resulting from the introduction of unit activity (i.e., 1 µCi) into the blood of the woman at the beginning of the specified monthly gestation period interval. The cumulated dose factor for a Co-58 intake during the first month of gestation is 8.79E-03 rad per microcurie in maternal blood. Paragraph 3.2.1 states that it should be assumed that all intakes occurring within any of the 30-day time periods of gestation occur at the beginning of that period. As discussed in the regulatory position in paragraph 3.2.1, a radiation quality factor of 1.0 should be used for Co-58 in converting from an absorbed dose in rads to an equivalent dose expressed as rems. Applying the method specified in subsection 3.2, the dose equivalent to the embryo/fetus is calculated as follows:

Dose Equivalent = Intake x f_1 x Dose Factor x 1.0 rem/rad

= 22 µCi x 0.3 x 8.79E-03 rad/µCi x 1.0 rem/rad

= 0.0580 rem

[*] Acceptable methods for determining intake using bioassay measurements are presented in U. S. NRC Regulatory Guide 8.9 (Revision 1, 7/93) “Acceptable Concepts, Models, Equations, and Assumptions for a Bioassay Program.”

CASE 2

EMBRYO/FETUS DOSE FOLLOWING CHRONIC INGESTION INTAKE BY DECLARED PREGNANT WOMAN

2.1 Exposure Scenario

Over an extended period of time, a declared pregnant woman unknowingly consumes water that contains low levels of tritium contamination. The licensee discovers the tritium-contaminated water in the third month of the woman's pregnancy. A thorough evaluation of the situation and associated personnel exposures is conducted, including bioassay measurements and contaminated water sample analysis. It is determined that the source did not exist prior to the woman's pregnancy. In keeping with the regulatory positions specified in subsections 2.7 and 3.3, multiple intakes should be evaluated on at least a 30-day frequency. The licensee determines that the declared pregnant woman ingested the following amounts of tritium over the 3-month period:

Stage of Gestation at Time of Intake (days)	Intake (µCi)
0 – 30	156
31 – 60	248
61 – 90	185

2.2 Determining Blood Uptake

The amount of tritium that is available for uptake by the blood is calculated by multiplying the intake by the f_1 value for the radionuclide. For tritium, the value of f_1 is 1.0 (refer to the hydrogen entry in Appendix B). Therefore, the amount of tritium that is absorbed into the blood (as evaluated for calculating the embryo/fetus dose) is the same as the intake quantities presented above.

2.3 Calculating Embryo/Fetus Dose Equivalent

2.3.1 Simplified Method

Equation 1 from subsection 2.5 may be used for calculating the dose equivalent for the entire gestation period from each monthly intake. The tritium dose factor from Appendix A is 5.87E-05 rem per microcurie in maternal blood. The dose contribution to the embryo/fetus for each monthly intake may be calculated as follows:

Dose Equivalent = Intake x f_1 x Dose Factor

First-month intake:	156 µCi x 1.0 x 5.87E-05 rem/µCi	= 0.009 rem
Second-month intake:	248 µCi x 1.0 x 5.87E-05 rem/µCi	= 0.015 rem
Third-month intake:	185 µCi x 1.0 x 5.87E-05 rem/µCi	= 0.011 rem
TOTAL		= 0.035 rem

2.3.2 Method Using Revision 1 to NUREG/CR-5631

Using the methods of NUREG/CR-5631, the dose to the embryo/ fetus is calculated in a manner similar to that of the Simplified Method, as presented above. However, as discussed in subsection 3.2.1, the dose factor should be taken from Appendix C for the time period representing the time of intake relative to stage of gestation. Table C1 in Appendix C presents the H-3 dose factors. The first column of Table C1 presents the gestation time (e.g., 0, 30, 60 days), and the last column presents the cumulated dose to the embryo/fetus for the remainder of the gestation period following the introduction of unit activity into maternal blood at the specified gestation time. As specified paragraph 3.2.2, an intake at any time within a specific monthly gestation period (i.e., a 30-day period) may be assumed to have occurred at the beginning of the monthly period for the purpose of determining the appropriate dose factor to be used. For example, for intakes occurring during the first month of pregnancy, the dose factor under the "Cumulated Dose" column corresponding to 0 days of gestation (as designated in the left-most column of the table) should be used. Cumulated dose factors taken from Table C1 for intakes in the respective months of gestation are presented below:

Stage of Gestation at Time of Intake	Cumulated Dose Factor for Remainder of Gestation Period (rad/µCi, blood)
1st Month (0 - 30 days)	9.03E-06
2nd Month (31 - 60 days)	1.77E-05
3rd Month (61 - 90 days)	4.02E-05

Using these gestation-time dependent dose factors, the dose equivalent to the embryo/fetus is calculated using the regulatory position specified in subsection 3.2. The radiation quality factor for H-3 is 1.0. The dose to the embryo/fetus for the remainder of the gestation period resulting from intakes occurring within each month is calculated as follows:

Dose Equivalent = Intake x f_1 x DF_i

First-month intake:	156 µCi x 1.0 x 9.03E-06 rad/µCi x 1.0 rem/rad	= 0.001 rem
Second-month intake:	248 µCi x 1.0 x 1.77E-05 rad/µCi x 1.0 rem/rad	= 0.004 rem
Third-month intake:	185 µCi x 1.0 x 4.02E-05 rad/µCi x 1.0 rem/rad	= 0.007 rem
TOTAL		= 0.013 rem*

* The difference between the sum of the monthly doses and the total (i.e., 0.012 rem versus 0.013 rem) is caused by rounding. In keeping with the recommendation contained in the Discussion section of this guide, final results should be rounded to the nearest thousandth of a rem.

CASE 3

EMBRYO/FETUS DOSE FOLLOWING ACUTE INHALATION INTAKE BY DECLARED PREGNANT WOMAN

3.1 Exposure Scenario

During the performance of a medical administration, a woman worker accidentally receives a single, acute inhalation intake of 100 µCi of I-131. At the time of the exposure, the woman was in the third month of pregnancy but had not declared her pregnancy to her employer (the licensee). Shortly thereafter, she declares her pregnancy in writing.

3.2 Determining Blood Uptake

The calculation of the dose to the embryo/fetus is based on the amount of the intake that is available for uptake within the first transfer compartment (i.e., blood). Also, the transfer to the blood is a function of the lung clearance class. The lung clearance class for all chemical compounds of iodine is Class D, denoting a 0- to 10-day lung clearance half-life. (State of Florida Bureau of Radiation Control "ALIs, DACs, and Effluent Concentrations," July 1993 provides the lung clearance classes for the different chemical compounds of the specified radionuclides.) Applying the guidance of the regulatory positions specified in subsections 2.3 and 2.4, the transfer fraction of inhaled activity to the blood for a Class D radionuclide may be calculated as follows:

$$TF_i \text{ (Class D)} = 0.48 + 0.15 \times f_i$$

TF_i = transfer fraction of inhaled activity to the first transfer compartment

$f_{1,i}$ = gut-to-blood transfer factor for radionuclide i (from Appendix B)

0.48 = fraction of inhalation intake that is cleared directly from the lung to the blood for Class D compounds

0.15 = fraction of inhaled radionuclide that is cleared from the lung to the GI tract for Class D compounds

For iodine, the f_1 value from Appendix B is 1.0. Inserting these values into the above equation results in the following calculation of the transfer fraction:

$$TF_i = 0.48 + 0.15 \times 1.0$$
$$= 0.63$$

The resultant blood uptake may be calculated by multiplying the transfer fraction by the total intake:

$$\text{Blood Uptake} = TF_i \times \text{Inhalation Intake}$$
$$= 0.63 \times 100 \text{ µCi}$$
$$= 63 \text{ µCi}$$

3.3 Calculating Embryo/Fetus Dose Equivalent

3.3.1 Simplified Method

For this example, the predetermined inhalation intake is 100 µCi. From Appendix A, the dose factor for I-131 is 3.64E-03 rem/µCi (in blood). The dose equivalent to the embryo/fetus may be calculated using Equation 2 from subsection 2.5:

$$\begin{aligned} \text{Dose Equivalent} &= I_i \times TF_i \times DF_i \\ &= 100\ \mu\text{Ci} \times 0.63 \times 3.64\text{E-}03\ \text{rem}/\mu\text{Ci} \\ &= 0.229\ \text{rem} \end{aligned}$$

3.3.2 Method Using NUREG/CR-5631

Section 3 presents the method for calculating the embryo/fetus dose using the methodology of NUREG/CR-5631. The inhalation intake is determined to have occurred during the third month of the gestation period. Table C13 of Appendix C presents the gestation-time dependent dose factors for I-131. In this table, the left-most column specifies the beginning time for each monthly gestation period (e.g., 0 for 0 - 30 days, 31 for 31 - 60 days). The right-most column presents the corresponding cumulated dose to the embryo/fetus for the remainder of the gestation period for unit activity introduced into the maternal blood. From this table, the cumulated dose factor for an I-131 intake during the third month of gestation is 9.94E-05 rad/µCi uptake into blood. As discussed in subsection 3.2.1, a radiation quality factor of 1.0 should be used for I-131. Applying the methods of the regulatory position specified in subsection 3.2, the dose equivalent to the embryo/fetus may be calculated. The value for the transfer fraction (TF_i) is the same as calculated above (i.e., 0.63). Using these parameter values along with Equation 2, the embryo/fetus dose is calculated as follows:

$$\begin{aligned} \text{Dose Equivalent} &= I_i \times TF_i \times DF_i \times 1.0\ \text{rem/rad} \\ &= 100\ \mu\text{Ci} \times 0.63 \times 9.94\text{E-}05\ \text{rad}/\mu\text{Ci} \times 1.0\ \text{rem/rad} \\ &= 0.006\ \text{rem} \end{aligned}$$

This example illustrates the difference that can occur by using the gestation-time dependent dose factors for the calculation of the embryo/fetus dose equivalent. The Simplified Method, as presented above, for this example yields an embryo/fetus dose of 0.229 rem; using the gestation-time dependent dose factors results in a calculated embryo/fetus dose equivalent of 0.006 rem –a factor of almost 40 less. This difference reflects the fact that during early embryonic development there is no preferential uptake of iodine by the embryo; the thyroid has not yet developed. It is not until approximately the beginning of the fourth month of the gestation period that the fetal thyroid develops to a point that thyroid iodine uptake is thought to occur. Therefore, any maternal intakes during the second and third trimesters will result in a significantly larger dose to the embryo/fetus than will result from the same intake during the first trimester.

CASE 4

EMBRYO/FETUS DOSE FOR CHRONIC INHALATION INTAKE BY DECLARED PREGNANT WOMAN

4.1 Exposure Scenario

During the third through fifth month of her pregnancy, a declared pregnant woman is exposed to airborne levels of U-238. Extensive air sampling and follow-up bioassay measurements are conducted to closely monitor the woman's intake. From these measurements, it is determined that the U-238 consists of a mixture of 30% Class D and 70% Class Y compounds. In keeping with subsections 2.7 and 3.3 of the guide, intakes over an extended time should be evaluated on at least a 30-day frequency. The licensee determines that the woman inhaled the following amounts of U-238 over the 3-month period:

Stage of Gestation at Time of Intake (days)	Class D Intake (µCi)	Class Y Intake (µCi)
61 – 90	0.038	0.089
91 – 120	0.061	0.14
121 – 150	0.15	0.35

4.2 Determining Blood Uptake

The calculation of the dose to the embryo/fetus is based on the amount of intake that is available for uptake within the first transfer compartment (i.e., blood). Also, the transfer to the blood is a function of the lung clearance class. Applying the guidance in subsections 2.3 and 2.4, the transfer fraction (TF_i) of inhaled activity to the first transfer compartment for a Class D compound may be calculated as follows:

$$TF_i \text{ (Class D)} = 0.48 + 0.15 \times f_i$$

TF_i = transfer fraction of inhaled activity to the first transfer compartment

$f_{1,i}$ = gut-to-blood transfer factor for radionuclide i (from Appendix B)

0.48 = fraction of inhalation intake that is cleared directly from the lung to the blood for Class D compounds

0.15 = fraction of inhaled radionuclide that is cleared from the lung to the GI tract for Class D compounds

The resultant total blood uptake is calculated by multiplying the TF_i value by the inhalation intake:

$$\text{Blood Uptake} = TF_i \times \text{Inhalation Intake}$$

For a Class Y compound, the transfer fraction is calculated as follows:

$$TF_i \text{ (Class Y)} = 0.05 + 0.58 \times f_i$$

0.05 = fraction of inhalation intake that is cleared directly from the lung to the blood for Class Y compounds

0.15 = fraction of inhaled radionuclide that is cleared from the lung to the GI tract for Class Y compounds

The total blood uptake can be calculated in the same manner as discussed above for the Class D compound.

For uranium, the f_1 value from Appendix B to the guide is 0.05. Applying the above equations, the amounts of U-238 transferred to the blood as a function of gestation period are presented in the following table:

Stage of Gestation at Time of Intake (days)	Transfer Fraction and Blood Uptake (Class D)		Transfer Fraction and Blood Uptake (Class Y)	
	Transfer Fraction (TF_i)	Blood Uptake (µCi)	Transfer Fraction (TF_i)	Blood Uptake (µCi)
61 – 90	0.49	0.0186	0.079	0.00703
91 – 120	0.49	0.0299	0.079	0.0111
121 – 150	0.49	0.0735	0.079	0.0276

4.3 Calculating Embryo/Fetus Dose Equivalent

4.3.1 Simplified Method

The dose to the embryo/fetus is calculated by using Equation 2 from subsection 2.5 of the guide. From Appendix A, the dose factor for U-238 is 5.10E-01 rem/µCi (in blood). Applying this dose factor along with the monthly transfer fractions (as calculated above) results in the following dose calculations:

Class D Inhalation Intake Dose Equivalent = Intake x TF_i x DF_i

Third-month intake: 0.038 µCi x 0.49 x 5.10E-01 rem/µCi = 0.009 rem

Fourth-month intake: 0.061 µCi x 0.49 x 5.10E-01 rem/µCi = 0.015 rem

Fifth-month intake: 0.15 µCi x 0.49 x 5.10E-05 rem/µCi = 0.037 rem

TOTAL = 0.061 rem

Class Y Inhalation Intake Dose Equivalent = Intake x TF_1 x DF_i

Third-month intake: 0.089 µCi x 0.079 x 5.10E-01 rem/µCi = 0.004 rem

Fourth-month intake: 0.14 µCi x 0.079 x 5.10E-01 rem/µCi = 0.006 rem

Fifth-month intake: 0.35 µCi x 0.079 x 5.10E-01 rem/µCi = 0.014 rem

TOTAL = 0.024 rem

The dose to the embryo/fetus resulting from each single-month intake should be determined by adding the Class D component with the Class Y component. The total gestation period dose is the sum of the cumulated dose resulting from each monthly intake.

Gestation Month	Class D Dose (rem)	Class Y Dose (rem)	Total Dose (rem)
3rd (61 - 90 days)	0.009	0.004	0.013
4th (91 - 120 days)	0.015	0.006	0.021
5th (121 - 150 days)	0.037	0.014	0.051
TOTAL	0.085 rem		

4.3.2 Method Using Revision 1 to NUREG/CR-5631

Using the methods of NUREG/CR-5631, the dose to the embryo/fetus is calculated in a manner similar to the Simplified Method above. However, as discussed in subsection 3.2, the dose factor should be taken from Appendix C for the period representing the time of intake relative to stage of gestation. Table C23 of Appendix C presents the gestation time dependent dose factors for U-238. In this table, the left-most column specifies the beginning time for each monthly gestation period (e.g., 0 for 0 - 30 days, 31 for 31 - 60 days). The right-most column presents the corresponding cumulated dose to the embryo/fetus for the remainder of the gestation period per unit activity introduced into the maternal blood. From Table C23, the U-238 cumulated dose factors for intakes in the respective month of gestation are presented below:

Stage of Gestation at Time of Intake	Cumulated Dose Factor for Remainder of Gestation Period (rad/µCi, blood)
3rd Month (61 - 90 days)	4.75E-03
4th Month (91 - 120 days)	7.98E-03
5th Month (121 - 150 days)	1.31E-02

Using these gestation-time dependent dose factors, the dose equivalent to the embryo/fetus is calculated using the regulatory position specified in subsection 3.2 of the guide. A radiation quality factor of 20 should be used for U-238 as specified in the regulatory position in subsection 3.2.1. The dose equivalent is calculated on a monthly basis as follows:

Class D Inhalation Intake Dose Equivalent = Intake x TF_1 x DF_i x 20 rem/rad

Third-month intake: 0.038 µCi x 0.49 x 4.75E-03 rad/µCi x 20 rem/rad = 0.002 rem

Fourth-month intake: 0.061 µCi x 0.49 x 7.98E-03 rad/µCi x 20 rem/rad = 0.005 rem

Fifth-month intake: 0.15 µCi x 0.49 x 1.31E-02 rad/µCi x 20 rem/rad = 0.019 rem

TOTAL = 0.026 rem

Class Y Inhalation Intake Dose Equivalent = Intake x TF_1 x DF_i x 20 rem/rad

Third-month intake: 0.089 µCi x 0.079 x 4.75E-03 rad/µCi x 20 rem/rad = 0.001 rem

Fourth-month intake: 0.14 µCi x 0.079 x 7.98E-03 rad/µCi x 20 rem/rad = 0.002 rem

Fifth-month intake: 0.35 µCi x 0.079 x 1.31E-02 rad/µCi x 20 rem/rad = 0.007 rem

TOTAL = 0.010 rem

The dose to the embryo/fetus resulting from each single-month intake should be determined by adding the Class D component with the Class Y component. The total gestation period dose is the sum of the cumulated dose resulting from each monthly intake.

Gestation Month	Class D Dose (rem)	Class Y Dose (rem)	Total Dose (rem)
3rd (61 - 90 days)	0.002	0.001	0.003
4th (91 - 120 days)	0.005	0.002	0.007
5th (121 - 150 days)	0.019	0.007	0.026
TOTAL	0.036 rem		

* *

CASE 5

PRE-EXISTING MATERNAL BODY BURDEN AT TIME OF PREGNANCY

5.1 Exposure Scenario

A declared pregnant woman is determined to have an existing body burden of Cs-137 at the time of pregnancy. The burden is a result of an acute inhalation intake that occurred around 2 months prior to the pregnancy. Extrapolating from bioassay measurements, the body burden at the time of pregnancy is estimated to be 2.8 µCi.

5.2 Evaluating the 1% ALI Threshold

The regulatory position specified in subsection 1.6 states that if a body burden existing at time of pregnancy exceeds 1% of the stochastic ALI for the appropriate mode of intake (ingestion or inhalation), the dose to the embryo/fetus from this burden should be evaluated. From State of Florida "ALIs, DACs, and Effluent Concentrations," July 1993,, the inhalation stochastic ALI value for Cs-137 is 200 µCi (Column 2 entry under Table 1 of the appendix). Since the existing burden of 2.8 µCi is larger than 1% of this ALI value, the dose to the embryo/fetus should be evaluated.

5.3 Determining Blood Uptake

Subsection 2.6 states that the total burden determined to exist at the time of pregnancy should be assumed to be available for uptake in the blood of the woman. Therefore, for this example, blood uptake should be assumed to be the same as the existing body burden of 2.8 µCi.

5.4 Calculating the Embryo/Fetus Dose Equivalent

5.4.1 Simplified Method

With the assumption that the blood uptake equates to the body burden existing at the time of pregnancy, the dose to the embryo/fetus is calculated simply by multiplying the burden by the radionuclide dose factor. From Appendix A to the guide, the dose factor for Cs-137 is 5.94E-02 rem/µCi (in blood); therefore, the dose is calculated as follows:

Dose Equivalent = A_i (pre-existing burden) x DF_i

= 2.8 µCi x 5.94E-02 rem/µCi

= 0.166 rem

5.4.2 Method Using NUREG/CR-5631

Similar to the calculation above, the dose to the embryo/fetus is calculated by multiplying the body burden existing at time of pregnancy by the appropriate gestation-time dependent dose factor. Table C19 of Appendix C presents the gestation-time dependent dose factors for Cs-137. In this table, the left-most column specifies the beginning time for each monthly gestation period (e.g., 0 for 0 - 30 days, 31 for 31 - 60 days). The right-most column presents the corresponding cumulated dose to the embryo/fetus for the remainder of the gestation period for unit activity introduced into the maternal blood. As stated in subsection 3.2.3, the uptake in the blood for burdens existing at time of pregnancy should be assumed to occur during the first month of pregnancy.* From this table, the cumulated dose factor for a Cs-137 intake during the first month of gestation is 5.83E-02 rad/µCi uptake into blood. As discussed in subsection 3.2.1 of the guide, a radiation quality factor of 1.0 should be used for Cs-137. The dose equivalent to the embryo/fetus is calculated as follows:

Dose Equivalent = A_i (pre-existing burden) x DF_i x 1.0 rem/rad

= 2.8 µCi x 5.83E-02 rad/µCi x 1.0 rem/rad

= 0.163 rem

* Paragraph 3.2.3 of the guide allows the use of time-dependent release kinetics for estimating the uptake in the maternal blood. This in-depth evaluation may be warranted for unusual exposure situations; however, for this example, the simplifying assumption of total uptake during the first month will be used. Also, note that for certain radionuclides a blood uptake at the beginning of the gestation period results in a negligible dose contribution to the embryo/fetus. For these radionuclides, per guidance in paragraph 3.2.3 and Appendix C, the cumulated dose value for the second month of the gestation period (i.e., the 31-day gestation time) should be used.

CASE 6

MATERNAL CHRONIC EXTERNAL EXPOSURE AND INHALATION INTAKE

6.1 Exposure Scenario

During the processing of byproduct material specimens, a woman receives periodic exposure to airborne levels of Cs-137 and Ce-144. The lung clearance class for all compounds of cesium is Class D; and for cerium the chemical compound is determined to be an oxide, thereby representing a "Y" lung clearance class. The woman becomes pregnant. However, she does not inform her employer (the licensee) until the third month of the gestation period. At this time, she becomes a declared pregnant woman and the more restrictive dose limits of section 64E-5.311, F.A.C., for the embryo/fetus become applicable. Once declared, past exposures incurred during the gestation period and any burdens existing at time of pregnancy should be evaluated.

The licensee evaluates the dosimetry records for the declared pregnant woman, including air sample data and bioassay measurements. It is determined that at the time of pregnancy the woman had an existing body burden of 1.14 µCi of Cs-137 and 0.12 µCi of Ce-144. Intakes during the first, second, and third months of the gestation period are determined and are presented in the following table:

Stage of Gestation at Time of Intake (days)	Total Intake (µCi)	
	Cs-137 (Class D)	Ce-144 (Class Y)
Pre-Existing	1.14	0.12
0 - 30	0.48	0.078
31 - 60	0.76	0.14
61 - 90	0.23	0.093

The declared pregnant woman's external exposure is evaluated and is determined to be 0.285 rem from the time of pregnancy to the time of declaration. After declaration, the licensee imposes radiological controls to ensure that additional exposures are kept to a minimum, pending a thorough evaluation of the woman's exposures and the resultant embryo/fetus dose equivalent.

6.2 Evaluating Embryo/Fetus Dose Equivalent from Pre-Existing Body Burden

6.2.1 Evaluating the 1% ALI Threshold

Subsection 1.6 states that if a body burden existing at time of pregnancy exceeds 1% of the stochastic ALI for the appropriate mode of intake (ingestion or inhalation), the dose to the embryo/fetus from this burden should be evaluated. From State of Florida Bureau of Radiation Control "ALIs, DACs, and Effluent Concentrations," July 1993, the inhalation stochastic ALI value for Cs-137 is 200 µCi, and for Class Y Ce-144 is 10 µCi (Column 2 entry under Table 1 of the appendix). Since the sum of the existing burdens of 1.14 µCi of Cs-137 and 0.12 µCi of Ce-144 divided by their respective ALI values is larger than 0.01 (i.e., $(\text{burden}_i \div \text{ALI}_i) > 0.01$), the dose to the embryo/fetus resulting from the maternal pre-existing burden should be evaluated.

6.2.2 Determining Blood Uptake

Subsection 2.6 states that the total burden determined to exist at the time of pregnancy should be assumed to be available for uptake in the blood of the woman. Therefore, for this example, blood uptake should be assumed to be the same as the existing body burdens of 1.14 µCi of Cs-137 and 0.12 µCi of Ce-144.

6.2.3 Calculating the Embryo/Fetus Dose Equivalent from Pre-Existing Burden

Only the Simplified Method will be used in this example for calculating the embryo/fetus doses. For Cs-137, the approach for using the gestation-time dependent method (NUREG/CR-5631 method) would be similar to the calculations presented in Case 5, paragraph 5.4.2. For Ce-144, gestation-time dependent dose factors have not been developed.

With the assumption that the blood uptake equates to the body burden existing at the time of pregnancy, the dose to the embryo/fetus is calculated simply by multiplying the burden by the radionuclide dose factor. From Appendix A, the dose factor for Cs-137 is 5.94E-02 rem/µCi (in blood) and for Ce-144 is 3.79E-01 rem/µCi (in blood). The dose is calculated as follows:

$$\begin{aligned}\text{Dose Equivalent} &= A_i \text{ (pre-existing burden)} \times DF_i \\ &= (1.14\ \mu Ci_{Cs\text{-}137} \times 5.94E\text{-}02\ \text{rem}/\mu Ci) + (0.12\ \mu Ci_{Ce\text{-}144} \times 3.79E\text{-}01\ \text{rem}/\mu Ci) \\ &= 0.068 + 0.045\ \text{rem} \\ &= 0.11\ \text{rem}\end{aligned}$$

6.3 Calculating the Embryo/Fetus Dose Equivalent from Intakes During Pregnancy

6.3.1 Evaluating 1% ALI Threshold

Based on the requirements of paragraph 64E-5.315(2)(b), F.A.C., and subsection 1.1 of this guide, the dose to the embryo/fetus is to be evaluated if intakes during the year by the declared pregnant woman are likely to exceed 1% of the stochastic ALIs. Without having to consider other intakes by the woman during the year, the 1% threshold is exceeded based on the intakes by the declared pregnant woman during the first 3 months of the pregnancy. Therefore, an evaluation of the embryo/fetus dose is required.

With multiple intakes occurring during a single monthly period, the intakes may be modeled as cumulative intakes within each specified gestational monthly period.

6.3.2 Determining Blood Uptake

The calculation of the dose to the embryo/fetus is based on the amount of the intake that is available for uptake within the first transfer compartment (i.e., blood). Also, the transfer to the blood is a function of the lung clearance class. Applying the guidance of the regulatory positions specified in subsections 2.3 and 2.4, the transfer fraction (TF_i) of inhaled activity to the first transfer compartment for a Class D compound may be calculated as follows:

$$TF_i \text{ (Class D)} = 0.48 + 0.15 \times f_i$$

TF_i = transfer fraction of inhaled activity to the first transfer compartment

$f_{1,i}$ = gut-to-blood transfer factor for radionuclide i (from Appendix B)

0.48 = fraction of inhalation intake that is cleared directly from the lung to the blood for Class D compounds

0.15 = fraction of inhaled radionuclide that is cleared from the lung to the GI tract for Class D compounds

The resultant total blood uptake is calculated by multiplying the TF_i value by the inhalation intake:

$$\text{Blood Uptake} = TF_i \times \text{Inhalation Intake}$$

For a Class Y compound, the transfer fraction is calculated as follows:

$$TF_i \text{ (Class Y)} = 0.05 + 0.58 \times f_i$$

0.05 = fraction of inhalation intake that is cleared directly from the lung to the blood for Class Y compounds

0.58 = fraction of inhaled radionuclide that is cleared from the lung to the GI tract for Class Y compounds

The total blood uptake can be calculated in the same manner as discussed above for the Class D compound.

For cesium, the f_1 value from Appendix B is 1.0; for cerium, the value is 3E-04. Applying the above equations, the amounts of Cs-137 and Ce-144 that are transferred to the blood as a function of gestation period are presented in the following table:

Stage of Gestation at Time of Intake (days)	Transfer Fraction and Blood Uptake of Cs-137 (Class D)		Transfer Fraction and Blood Uptake of Ce-144 (Class Y)	
	Transfer Fraction (TF_i)	Blood Uptake (µCi)	Transfer Fraction (TF_i)	Blood Uptake (µCi)
0 - 30	0.63	0.30	0.050	0.0039
31 - 60	0.63	0.48	0.050	0.0070
61 - 90	0.63	0.14	0.050	0.0046

6.3.3 Calculating Embryo/Fetus Dose Equivalent from Maternal Intakes

Only the Simplified Method will be used in this example for calculating the embryo/fetus doses. For Cs-137, the approach of the gestation time dependent method (the method in NUREG/CR-5631) would be similar to the calculations presented in Example 4, paragraph 4.3.2, of Appendix D. For Ce-144, gestation-time dependent dose factors have not been developed.

The dose to the embryo/fetus is calculated by using Equation 2 from subsection 2.5. From Appendix A, the dose factor for Cs-137 is 5.94E-02 rem/μCi (in blood) and for Ce-144 is 3.79E-01 rem/μCi (in blood). Applying these dose factors along with the monthly transfer fractions (as calculated above) results in the following dose calculations:

Class D Inhalation Intake – Cs-137 Dose Equivalent = Intake x TF_1 x DF_i

First-month intake: 0.48 μCi x 0.63 x 5.94E-02 rem/μCi = 0.018 rem

Second-month intake: 0.76 μCi x 0.63 x 5.94E-02 rem/μCi = 0.028 rem

Third-month intake: 0.23 μCi x 0.63 x 5.94E-02 rem/μCi = 0.009 rem

TOTAL = 0.055 rem

Class Y Inhalation Intake – Ce-144 Dose Equivalent = Intake x TF_1 x DF_i

First-month intake: 0.078 μCi x 0.050 x 3.79E-01 rem/μCi = 0.001 rem

Second-month intake: 0.14 μCi x 0.050 x 3.79E-01 rem/μCi = 0.003 rem

Third-month intake: 0.093 μCi x 0.050 x 3.79E-01 rem/μCi = 0.002 rem

TOTAL = 0.006 rem

6.4 Summing Internal and External Doses

The doses to the embryo/fetus for the existing maternal burden, the maternal inhalation intakes, and the deep-dose equivalent to the declared pregnant woman are summarized in the following table:

Exposure Pathway and Stage of Gestation	Embryo/Fetus Dose Equivalent (rem)		
	Cs-137	Ce-144	Total
Pre-Existing Body Burden	0.068	0.045	0.113
Inhalation Intakes (0 – 30 days)	0.018	0.001	0.019
Inhalation Intakes (31 – 60 days)	0.028	0.003	0.031
Inhalation Intakes (61 – 90 days)	0.009	0.002	0.011
Deep-Dose Equivalent (0 – 90 days)	0.285		
Total	0.459		

The sum of the deep-dose equivalent to the declared pregnant woman and the embryo/fetus dose resulting from the inhalation intakes of the declared pregnant woman represents the total dose equivalent to the embryo/fetus (i.e., 0.285 rem deep-dose equivalent, plus 0.17 rem dose equivalent from internal exposures). This total of 0.459 rem is within 0.05 rem of the 0.5 rem limit for the embryo/fetus. Therefore, the dose limit for the embryo/fetus for the remainder of the gestation period is an additional dose of 0.05 rem from the date of the declared pregnancy [refer to subsection 64E-5.311(4), F.A.C.].