Regulatory Guide Periodic Review

Regulatory Guide Number: **8.36, Revision 0**

Title: **Radiation Dose to the Embryo/Fetus**

Office/division/branch: **RES/DSA/RPB**
Technical Lead: **Vered Shaffer**

Recommended Staff Action: **Revise**

1. What are the known technical or regulatory issues with the current version of the Regulatory Guide (RG)?

RG 8.36 was issued in July 1992 to comply with the regulations in 10 CFR Part 20, "Standards for Protection Against Radiation," which requires that each licensee shall 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 (5 mSv). This regulatory guide supplements RG 8.13, "Instruction Concerning Prenatal Radiation Exposure," which provides instructions to occupational workers regarding prenatal radiation exposure.

Calculating the radiation dose to the embryo/fetus from internally deposited radionuclides requires quantitative information about maternal radionuclide intake, placental transfer and kinetics, and embryo/fetus radionuclide concentrations. The methodology used in RG 8.36 relies mainly on the guidance provided by the International Commission on Radiological Protection (ICRP 30), “Limits for the Intake of Radionuclides by Workers,” and NUREG/CR-5631, Revision 1, “Contributions of Maternal Radionuclide Burdens to Prenatal Radiation Dose-Interim Recommendations (1992). This guidance is outdated.

There are more up-to-date models for estimating doses to the embryo/fetus than the ones listed in this RG, such as ICRP Publication 88, “Doses to the Embryo and Fetus from Intakes of Radionuclides by the Mother,” corrected version May 2002. In addition, guidance is provided in ICRP Publication 73, “Radiological Protection and Safety in Medicine” (paragraphs 76 and 77), and in Publication 75, “General Principles for the Radiation Protection of Workers” (paragraph 124).

Also, this RG includes some technically ambiguous or inaccurate statements and the references to regulatory citations that are not consistent with current regulations.

2. What is the impact on internal and external stakeholders of not updating the RG for the known issues, in terms of anticipated numbers of licensing and inspection activities over the next several years?

There is no impact on licensing and inspection activities since this RG is consistent with current NRC regulatory requirements. However, citations to outdated references can be confusing to stakeholders.

3. What is an estimate of the level of effort needed to address identified issues in terms of full-time equivalent (FTE) and contractor resources?

An estimate of the effort needed to correct the identified issues is between 0.1 and 0.2 FTE.

4. Based on the answers to the questions above, what is the staff action for this guide (Reviewed with no issues identified, Reviewed with issues identified for future consideration, Revise, or Withdraw)?

Revise the guide.

5. Provide a conceptual plan and timeframe to address the issues identified during the review.

The staff plans to initiate a working group with representatives from the applicable NRC offices to develop a revision of this RG. The staff also will evaluate and incorporate guidance based on ICRP Publication 88, “Doses to the Embryo and Fetus from Intakes of Radionuclides by the Mother,” ICRP Publication 73, “Radiological Protection and Safety in Medicine,” and in Publication 75, “General Principles for the Radiation Protection of Workers.” This effort needs to be coordinated with other NRC offices since this RG is applicable to all NRC licensees.

The publication of the draft version of this guide for public comment is expected by the 1st quarter of CY 2018.

NOTE: This review was conducted in April 2017, and reflects the staff’s plans as of that date. These plans are tentative and subject to change.