

ISSUE PAPER 3

DOSE LIMIT FOR THE EMBRYO/FETUS OF A DECLARED PREGNANT OCCUPATIONAL WORKER

I. Introduction

In Staff Requirements Memorandum (SRM) SECY-12-0064, "Recommendations for Policy and Technical Direction To Revise Radiation Protection Regulations and Guidance," dated December 17, 2012,¹ the Commission directed the U.S. Nuclear Regulatory Commission (NRC) staff to continue discussions with stakeholders regarding the dose limit for the embryo/fetus of a declared pregnant occupational worker.

II. Objective

Determine whether the dose limit for the embryo/fetus of a declared pregnant occupational worker should be reduced over the gestation period and develop regulatory requirements accordingly.

III. Background

Currently, the regulations at Title 10 of the *Code of Federal Regulations* (10 CFR) 20.1208(a) set the dose limit for the embryo/fetus of a declared pregnant worker at 5 millisieverts (mSv) (500 millirem (mrem)) for the entire pregnancy. The regulation at 10 CFR 20.1208(d) provides allowances for delays in the declaration of pregnancy by workers. If the dose equivalent to the embryo/fetus has exceeded 5 mSv (500 mrem), or is within 0.5 mSv (50 mrem) of this dose, at the time the woman declares the pregnancy to the licensee,

¹ SRM-SECY-12-0064 is available on the NRC's public Web site at <http://www.nrc.gov/reading-rm/doc-collections/commission/srm/2012/>.

the dose to the embryo/fetus cannot exceed 0.5 mSv (50 mrem) for the remainder of the pregnancy (10 CFR 20.1208(d)). Furthermore, licensees are to make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman to satisfy the limit in 10 CFR 20.1208(a) (10 CFR 20.1208(b)). These requirements are based on the recommendations in International Commission on Radiological Protection (ICRP) Publication 26, "Recommendations of the International Commission on Radiological Protection," issued 1977. However, ICRP Publication 103, "Recommendations of the International Commission on Radiological Protection," issued 2007, recommends that the dose to the embryo/fetus of a declared pregnant worker be the same as that for a member of the public, which is 1 mSv (100 mrem).

Before the 1991 amendments to 10 CFR Part 20, "Standards for Protection against Radiation," NRC regulations did not contain a specific dose limit for the embryo/fetus of a declared pregnant occupational worker. Instead, as a matter of policy, the NRC used a single annual limit for both sexes and relied on information in Regulatory Guide 8.13, "Instruction concerning Prenatal Radiation Exposure," issued March 1975, to maintain exposures to the embryo/fetus as low as is reasonably achievable (ALARA) (Volume 51 of the *Federal Register*, page 1092 (51 FR 1092); January 9, 1986).

In developing Regulatory Guide 8.13, the Commission considered the recommendations in National Council on Radiation Protection and Measurements (NCRP) Report No. 39, "Radiation Protection Criteria," issued in 1971. The NCRP Report No. 39 recommended that, during the entire gestation period, the maximum permissible dose equivalent to the embryo/fetus from occupational exposure of the worker should not exceed 5 mSv (500 mrem). NCRP Report No. 54, "Medical Radiation Exposure of Pregnant and Potentially Pregnant Women," issued in 1977, recommended that the total dose equivalent to the embryo/fetus from occupational exposure of the expectant mother should not exceed 5 mSv (500 mrem) and that

occupational exposure of the embryo/fetus should not exceed 0.5 mSv (50 mrem) in any month once the pregnancy is known. The ICRP Publication 26 (1977) recommended limiting the working conditions of the declared pregnant worker in such a manner that the embryo/fetus would likely receive a dose less than 5 mSv (500 mrem) for the entire gestation period (51 FR 1092; January 9, 1986).

Thousands of pregnant women are occupationally exposed to ionizing radiation each year. There are radiation-related risks throughout pregnancy that are related to the stage of pregnancy and absorbed dose. Exposure of the embryo/fetus to ionizing radiation could cause certain adverse health effects, such as cancer and developmental abnormalities. The susceptibility of the embryo/fetus to damage by radiation is well established, and data suggest that the period from 10 weeks to 17 weeks in the development of a fetus may be especially critical. In view of its greater susceptibility to health effects, limiting the dose to the embryo/fetus to not more than 5 mSv (500 mrem) during the entire pregnancy is generally considered desirable (51 FR 1092; January 9, 1986).

The ICRP Publication 60, "1990 Recommendations of the International Commission on Radiological Protection," issued in 1991, clearly stated that the embryo/fetus should be regarded as a member of the public when considering the protection of female workers who are or may be pregnant. The ICRP Publication 60 (1991) and ICRP Publication 103 (2007) concluded that distinguishing between the sexes for the purposes of controlling occupational exposures is not necessary. However, under the ICRP recommendations, if a female worker has declared that she is pregnant, consideration of additional controls is necessary to protect the embryo/fetus. The ICRP stated that the methods of protection at work for women who are or may be pregnant should provide a level of protection for the embryo/fetus similar to that provided for members of the public. The recommended approach in ICRP Publication 103 (2007) is that once the pregnancy has been declared, the working conditions of the pregnant

worker should be managed to prevent the likely of an additional dose of 1 mSv (100 mrem) to the embryo/fetus for the remainder of the pregnancy.

On May 24, 2013, the NCRP published NCRP Report No. 174, "Preconception and Prenatal Radiation Exposure: Health Effects and Protective Guidance," which updates and expands on the information in NCRP Report No. 54. The document notes that scientific knowledge has increased and that public concerns have changed in the past 36 years since the publication of NCRP Report No. 54. Similar to the findings of ICRP Publication 103 (2007), the report recommends a dose limit of 1 mSv (100 mrem), including dose from the intake of radionuclides, to the embryo/fetus of a declared pregnant worker. It also recommends that the concept of ALARA should be applied to these exposures.

Although the assessment of doses to the embryo/fetus from exposures to external radiation can be related directly to exposures of the pregnant worker, assessment of doses from intakes of radionuclides are not straightforward. Doses to the embryo/fetus may result from the inhalation or ingestion of radionuclides by the mother during or before pregnancy, and additional doses to the newborn child may result from the transfer of radionuclides in breast milk. The ICRP publications provide dose coefficients for the offspring (embryo/fetus and newborn child) following radionuclide intake by the mother before or during pregnancy and during breast feeding. In a number of important cases of potential radionuclide intake, doses to the offspring may exceed doses to the mother; such cases should be taken into account when arrangements for radiation protection in the workplace are made (ICRP Publication No. 60 (1991); ICRP Publication No. 75, "General Principles for the Radiation Protection of Workers," issued in 1997; and ICRP Publication No. 96, "Protecting People against Radiation Exposure in the Event of a Radiological Attack," issued in 2005).

To provide adequate radiation protection for the embryo/fetus and to minimize the potential restriction on employment of pregnant women, the NRC recognized the importance of

female workers voluntarily informing their employers of their pregnancy and of the estimated date of conception so that arrangements can be made to restrict potential exposures. The pregnant worker has the fundamental responsibility for deciding when or whether she will formally declare her condition to her employer. This position is derived from court rulings concerning a woman's rights regarding pregnancy. Having a formal declaration of pregnancy derives from legal, not health protection, considerations.² If an occupational worker chooses not to declare her pregnancy, the licensee will not be required under the Commission's regulations to limit her dose to 5 mSv (500 mrem). In this regard, undeclared pregnant workers are protected under the NRC regulations in the same manner as all other radiation workers. The normal occupational dose limits would still be in effect, including the requirement to keep all occupational doses ALARA. Furthermore, as part of her initial employment, the female worker, like any other occupational worker, should receive instructions in radiation protection (as required by 10 CFR 19.12, "Instruction to Workers") and a copy of the current version of Regulatory Guide 8.13.³

IV. Discussion

The ICRP Publication 103 (2007) recommends that the dose to the embryo/fetus of a declared pregnant worker provide the same general level of protection as that offered for a member of the public; this dose is 1 mSv (100 mrem). The recommended approach in ICRP Publication 103 (2007) is to apply the 1 mSv (100 mrem) criterion after the declaration of pregnancy by the occupational worker.

The NRC has determined that it is appropriate and scientifically justified to explore

² See the NRC's response to public comments in the Statements of Consideration of the agency's 1991 final rule amending 10 CFR Part 20 (56 FR 23360–23373; May 21, 1991).

³ See 56 FR 23373; May 21, 1991.

whether to change the dose limit for the embryo/fetus to 1 mSv (100 mrem). In its 1991 final rule that amended 10 CFR Part 20, the NRC changed the dose limit for a member of the public from 5 mSv (500 mrem) to 1 mSv (100 mrem); however, it did not make the corresponding change to the dose limit for the embryo/fetus. Lowering the dose limit for the embryo/fetus of a declared pregnant occupational worker would align the NRC's regulatory requirements with current scientific data. The data indicate that the embryo/fetus is more sensitive to radiation than initially surmised. Exploring the option of applying the limit over the entire gestation period, or only to the portion of time following declaration, would need to be done in greater detail. The ICRP recommendations for the embryo/fetus of an occupationally exposed female reflect an approach in which the protection afforded is generally consistent with the level of protection provided for a member of the public. As such, the ICRP recommends that an embryo/fetus be limited to no more than a dose of 1 mSv (100 mrem) over the remaining pregnancy following the woman's declaration of pregnancy to the licensee. The ICRP recommendation does not include a requirement for a retrospective assessment of the dose received by the embryo/fetus before the declaration by the worker, which differs from the current requirements in 10 CFR Part 20.

The current regulations at 10 CFR Part 20 (as established by 10 CFR 20.1208, "Dose Equivalent to an Embryo/Fetus") provide for a limit of 5 mSv (500 mrem) during the pregnancy. The dose limit becomes effective upon a formal declaration from the worker to the licensee, and an assessment of any exposure before the declaration must be done to determine the allowable exposure for the remainder of the pregnancy (10 CFR 20.1208(d)).

The current limit in 10 CFR 20.1208 reflects an alignment with the previous dose limit for members of the public (5 mSv (500 mrem)). The 1991 amendments changed the public dose limit to 1 mSv (100 mrem). However, a corresponding change in the dose limit for the embryo/fetus of a declared pregnant woman was not made. The NRC believes that additional interactions with stakeholders and interested parties are necessary to understand the implications of aligning its requirements with ICRP Publication 103 (2007) in this area.

During the earlier stakeholder interactions in 2010, stakeholder views regarding a potential lowering of the dose limit for the embryo/fetus of the declared pregnant woman were mixed. Many licensees indicated that they had no problems complying with the present requirements. Furthermore, they indicated that their response to a declaration of pregnancy has been to accommodate the individual in such a way that there was essentially no exposure to the embryo/fetus for the duration of the pregnancy. Therefore, a revision to 1 mSv (100 mrem), as recommended by ICRP and NCRP, may not cause significant concerns. However, some nuclear pharmacy licensees indicated that their routine annual occupational exposures are close to several millisieverts (several hundred millirem), and a reduction to the 1-mSv (100 mrem) dose limit could pose a potential impact, depending on when an individual chooses to declare her pregnancy. (For example, the nuclear pharmacy may be required to change her work schedule or work assignment to comply with the 1 mSv (100 mrem) dose limit.) In addition, some stakeholders from the medical community raised concerns that the change in dose limit could require a reconfiguration or modification of their facilities. Nevertheless, these stakeholders noted that their facilities are typically designed using conservative assumptions. In addition, some stakeholders have stated that the 1 mSv (100 mrem) dose limit should be applied to the entire gestation period (similar to the current requirements that apply to the entire gestation period) to ensure adequate protection.

A second issue raised was the potential for varying degrees of protection for the embryo/fetus when the dose limit requirements are only applied after a formal declaration. For example, if an individual chooses to declare relatively late in the pregnancy, the ICRP recommendation could actually mean that the embryo/fetus could have accumulated a greater dose than that allowed under the current NRC regulation. Conversely, a declaration early in the pregnancy would be more restrictive. A stakeholder also noted that the current requirements restrict the additional dose that can be received after declaration if the retrospective assessment indicates that the exposure before declaration already exceeded the 5 mSv (500 mrem) limit. In this situation, a change to the 1 mSv (100 mrem) limit applied after declaration would apparently not pose a substantial impact and, in fact, would be less restrictive. Several stakeholders indicated that a more restrictive limit could result in an increase in occupational workers choosing not to declare their pregnancy to ensure their continued employment.

A third issue raised concerned the limits of detection for routine dosimetry monitoring. For many dosimetry systems (using thermoluminescent dosimeters), the minimum detectable exposure is in the range of 0.1 mSv (10 mrem). If an individual declares early in the pregnancy, the actual monitoring of that individual with sufficient precision to ensure compliance would be challenging. The NRC staff will explore this issue as it moves forward to develop the details of the draft technical basis and potential impacts. Moreover, some stakeholders indicated that changing the dose limits may create an opportunity for lawsuits since it may imply that the current requirements are unsafe.

A fourth issue concerns the amount of dose received by the embryo/fetus at the time of declaration. Regardless of whether a requirement exists for a retrospective assessment of dose, or only for the application of a dose limit to the embryo/fetus, after the declaration of pregnancy, the total dose to an embryo/fetus depends on the dose received before declaration of pregnancy. Under 10 CFR 20.1208, if the dose already received exceeds 5 mSv (500 mrem)

or if it is within 0.5 mSv (50 mrem) of the 5 mSv (500 mrem) dose limit at the time of declaration, the allowable exposure is restricted to an additional 0.5 mSv (50 mrem). However, under the ICRP recommendations, the embryo/fetus would be allowed an additional dose up to 1 mSv (100 mrem) under the same circumstances. Therefore, under this scenario, the current NRC requirement would be more restrictive. If the accumulated dose to an embryo/fetus is 4.0 mSv (400 mrem) or less before declaration of pregnancy, the current NRC requirement allows for a dose up to 5 mSv (500 mrem). However, the ICRP recommendations would limit any additional dose to 1 mSv (100 mrem) regardless of the previously accumulated dose. Under this second scenario, the ICRP recommendation is the more restrictive requirement.

V. Proposals

The NRC staff believes that additional interactions with stakeholders and other interested parties are necessary to understand the implications of various proposals related to the dose limit for the embryo/fetus of the declared pregnant occupational worker. As discussed above, the NRC staff is already aware of certain situations among certain licensees (e.g., nuclear pharmacists for which a change could present a potential impact). Nevertheless, the staff believes that it is appropriate and scientifically justified to explore, in detail, a change in the dose limit for the embryo/fetus to 1 mSv (100 mrem).

The NRC has determined that it is appropriate and scientifically justified to explore whether to change the dose limit for the embryo/fetus to 1 mSv (100 mrem). In its 1991 final rule that amended 10 CFR Part 20, the NRC changed the dose limit for a member of the public from 5 mSv (500 mrem) to 1 mSv (100 mrem); however, it did not make the corresponding change to the dose limit for the embryo/fetus. Lowering the dose limit for the embryo/fetus of a declared pregnant occupational worker would align the NRC's regulatory requirements with current scientific data. In addition, scientific data indicate that the embryo/fetus is more

sensitive to radiation than initially surmised. Therefore, more examination is necessary before the NRC can align its current regulations with scientific data and with international and national radiation protection recommendations. Therefore, the NRC staff is proposing the following two potential options in addressing the dose limit to the embryo/fetus of the declared pregnant occupational worker:

- (1) The first option is to maintain the current dose limit. Currently, 10 CFR 20.1208 specifies the dose limit to the embryo/fetus of a declared pregnant worker as 5 mSv (500 mrem) for the entire pregnancy. In addition, it provides that, if the dose to the embryo/fetus exceeds 5 mSv (500 mrem) or is within 0.5 mSv (50 mrem) of this dose by the time the woman declares the pregnancy and if the licensee limits any additional dose to the embryo/fetus to less than 0.5 mSv (50 mrem) during the remainder of the pregnancy, the licensee has complied with the NRC's regulations. Maintaining the limits "as is" include the arguments that the current rule is well established and understood and that some stakeholders do not consider the risk difference between 5 mSv (500 mrem) and an additional 1 mSv (100 mrem) after the declaration of pregnancy significant.
- (2) The second option is to change the requirements and to establish the dose limit as 1 mSv (100 mrem) from the declaration of pregnancy and for the remainder of the pregnancy. Limiting the dose to 1 mSv (100 mrem) would align the NRC's regulatory requirements with the recommendations in ICRP Publication 103 (2007). In addition, it is supported by scientific data that show that following the ICRP recommendations would result, in most cases, in fewer doses to the embryo/fetus than the current NRC regulatory requirements would. In addition, this option also simplifies the requirement because a retrospective dose assessment to the embryo/fetus before a declaration would not be necessary.

The susceptibility of the embryo/fetus to damage by radiation is well established. Since the Law of Bergonié and Tribondeau was published in 1906,⁴ the sensitivity of cells to radiation damage is known to be related to their reproductive activity and to be inversely related to their degree of differentiation. Based on this principle, minors are more radiosensitive than adults, and the embryo/fetus is even more radiosensitive. This principle has long been a factor in the development of the radiation exposure standards, especially those in Subpart C, "Occupational Dose Limits," of 10 CFR Part 20, which establishes different limits for minors, adults, and the

⁴ *Comptes Rendus des Seances de l'Academie des Sciences*, 143:983–985, 1906.

embryo/fetus.⁵

Scientific research and data indicate that the embryo/fetus is several times more sensitive to radiation exposure than members of the general population. Therefore, it is scientifically justified to consider whether the embryo/fetus should be afforded additional protection from radiation exposure beyond that currently provided to the general population. The costs associated with a reduction in the dose limit to the embryo/fetus could potentially include changes in programs, procedures, monitoring, and recordkeeping. The NRC staff recognizes that licensees may need to modify their radiation protection programs, even if exposures to the embryo/fetus are already below the new dose limits in ICRP Publication 103 (2007), to further ensure that the limit will not be exceeded.

The NRC staff believes that additional input from the public, the regulated community, and other stakeholders is necessary to understand the implications of potential options on this issue.

⁵ See NRC Regulatory Guide 8.13.