

The Declared Pregnant Woman in Nuclear Medicine

Daniel F. Kane, Ed Sims, LeRoy Stecker, Frank Bloe, Paul Early and Kathleen O'Brien

Associates in Medical Physics, Cleveland, Ohio

Recent changes in Standards for Protection Against Radiation, 10 CFR Part 20, legislated the long-suggested radiation dose limit of 5 mSv (0.5 rem) for declared pregnant women. This paper describes the current regulations regarding the declared pregnant woman, reviews associated NRC guides, offers commentary for ALARA exposures and discusses methods of compliance with this new regulatory limit.

Key Words: declared pregnant woman; occupational radiation exposure; radiation safety; nuclear regulations

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The January 1994 revision of 10 CFR Part 20, *Standards for Protection Against Radiation (1)*, commonly referred to as the New Part 20, initiated many changes in the manner in which Nuclear Regulatory Commission (NRC) licensees addressed radiation and radiation exposure. These revisions modified the perspective of radiation exposure to occupational workers and members of the public. It also legislated a new, but long-recommended dose limit for the embryo/fetus in the declared pregnant woman.

This was the first time the NRC or any regulatory agency specifically limited the absorbed dose to the unborn child. Although instructions to workers and licensees had previously been available in the form of regulatory guides (2,3), the revision of Part 20 demands a greater understanding and sensitivity to the methodology of fetal dose monitoring and record-keeping requirements.

BACKGROUND

Just slightly over a century ago, there was near universal agreement regarding the benevolence of internal and external radiation exposure. Since radiation was not detectable via the senses, it was surmised that there were no biological effects.

Potential injury to the embryo/fetus was suggested very early by Herbert Rollins, who described in 1901 the potential deleterious effects of x-ray exposure on fetal mammals (4). In 1906, Bergonie and Tribondeau described their experiences (5).

They observed that the sensitivity of cells to radiation damage was related to their reproductive activity and inversely related to the cell's degree of differentiation. In other words, they found a higher degree of sensitivity to radiation injury in cells capable of reproducing and developing into different organs, as is the case with embryonic differentiation. It was, therefore, logically postulated that embryos would be more sensitive than fetuses, fetuses more sensitive than children and children more sensitive than adults.

LINEAR NO-THRESHOLD DOSE RESPONSE MODEL

The regulatory community has long used the linear no-threshold dose response model as the basis for regulatory dose limits because of its inherent conservatism. This hypothesis is predicated on the assumption that the understood effects associated with high doses of radiation can be extrapolated linearly to zero. Just as there is a high probability of biological effect associated with high radiation exposure, there is a proportionally lower probability of effect corresponding to lower radiation exposure. The theoretical probability of injury is equal in magnitude to the amount of radiation exposure.

The stochastic and non-stochastic effects related to high levels of radiation exposure over short time periods are rather conclusively understood. Conversely, the effects of low doses of radiation over longer time periods are substantially less convincingly understood. This hypothesis may cause a high degree of anxiety in the pregnant or potentially pregnant woman by statistically implying biological effects or harm at low exposure levels. See Table 1 for definitions of relevant terms in radiation protection and biological effects.

RISK OF EMBRYONIC/FETAL INJURY

Fetal injury related to radiation exposure in-utero may be a stochastic or a non-stochastic event, depending upon a number of factors. These factors include the type of radiation, radiation dose rate, gestational age and total dose.

Embryonic death (spontaneous abortion or resorption of the zygote) is a non-stochastic effect and has been shown to occur at doses of 200 centigrays (200 rad) in mice. However, those that survive appear to be normal. This is often referred to as the all or none effect (6-8). Mettler and Moseley (6) suggest

For correspondence or reprints contact: Daniel F. Kane, Associates in Medical Physics, LLC, 1384 Old Virginia Court, Marietta, Georgia 30067.

TABLE 1
Relevant Terms in Radiation Protection and Biological Effects

Genetic effect	Inheritable changes produced by exposure to ionizing radiation, not reported or observed in atomic bomb survivors.
Non-stochastic effect	Health effects, the severity of which varies with dose and for which a threshold is believed to exist.
Stochastic effect	An effect that occurs randomly and for which the probability of the effect occurring, rather than the severity, is assumed to be a linear function of dose without threshold.
Teratogenic effect	Non-inheritable change related to radiation exposure that manifests itself through birth defects.

that there may be a threshold for this effect of 10 centigrays (10 rad) in women. Some suggest that this is the safest time to irradiate a pregnant woman due to this all or none theory. The applicability of this research is limited to the use of lower mammals and the 200-centigray (200 rad) dose administered.

A stochastic effect that has been significantly studied is that of childhood leukemia. The numerous studies on this hypothesis have shown varying results. In-utero exposures at Hiroshima and Nagasaki have not demonstrated a statistically increased incidence (9). Stewart and Kneale (10) in 1970 estimated that the increased incidence of childhood leukemia can be as high as 0.03 to 0.08 cases per thousand per centigray (rad) per year. This paper has been the subject of reviews and re-evaluations by many authors (11-13) and is obviously the subject of some controversy. Whether or not Stewart and Kneale demonstrated a causal effect or merely an association between intrauterine x-ray exposure and childhood leukemia is not well demonstrated and their risk estimates conflict with the estimates from atomic bomb survivors (14).

With the natural incidence of spontaneous abortion ranging from 30 to 50% of impregnations (15), coupled with a natural incidence of childhood leukemia of 4 per 10,000, an increase in these two biological effects as a result of occupational or prenatal radiation exposure would be very difficult to statistically observe in the absence of an extremely large epidemiologic study over a number of decades.

Following implantation, the embryo enters the stage of organogenesis from approximately 10 days post-conception (16) until the eighth week. This is the stage where the body organ systems are developing (16). Irradiation during this period can lead to non-stochastic endpoints, such as gross congenital malformations and growth retardation. The fetal period extends from the eighth week until birth. Non-stochastic effects of concern are growth retardation and central nervous system effects, such as microcephaly (small head size) and mental retardation (17-19). Gross abnormalities of the major organ systems do not occur at this stage.

In 1993 Kondo clearly expressed a threshold for teratogenic effects in the offspring of atomic bomb survivors (7). He stated, "The high radiosensitivity of the fetus is often taken as

evidence for the hazards of low level radiation; however, a threshold does exist for human teratogenesis, as seen in bomb survivors" (7). Kondo's work suggests a teratogenic threshold of 300-610 mSv (30-61 rem) at a 95% confidence level for mental retardation. Microcephaly was not observed below 150 cGy (150 rad).

NCRP Report 91 (20) indicates that the risk of cancer induction due to in-utero radiation exposure of the embryo/fetus is probably less than reported in previous NCRP publications. The report states, "There appears to be no greater, and probably less, risk of cancer induction than was assumed previously."

NCRP Report 91 references UNSCEAR (21) data which indicate a total risk of two incidents of any of several effects per 1000 10-mSv (1-rem) irradiations of the embryo/fetus to include mortality, induction of malformations, mental retardation, solid tumors and leukemia. The report compares this to a natural incidence of 6 per 100 for anomalies of all kinds, seriously affecting the health of newborns. Table 2 outlines a number of risks and associated potential outcomes of pregnancy.

At occupational dose limits and, in particular, at the regulatory limit for declared pregnant women, the probability of fetal injury is extremely low. As is the case with any potentially harmful agent including radiation, as the dose approaches zero the effects become so statistically insignificant that the observed effects are indistinguishable from the natural incidence of anomalies and may not be observable except with huge populations. There appears to be consensus in one area. The risk below 100 mSv (10 rem) is quite small and may not be detectable over the natural incidence of congenital malformations, childhood cancer or spontaneous abortion (6).

REGULATORY POSITION

Current NRC regulations regarding radiation exposure are described in 10 CFR 20.1208. This regulation allows for the embryo/fetus of an occupationally-exposed declared pregnant woman to receive a dose not in excess of 5 mSv (0.5 rem) during the gestational period. Additionally, if the embryo/fetus is found to have reached 4.5 mSv (0.45 rem) or exceeded 5 mSv (0.5 rem) at the time of the declaration of pregnancy, then the licensee must limit the exposure to the embryo/fetus to 0.5 mSv (0.05 rem) for the balance of the gestational period.

The basis for the 5-mSv (0.5-rem) limit for declared pregnant women dates to at least 1971 and can be found in NCRP Report 39 (22). NCRP Report 53 states that the 5-mSv (0.5-rem) limit published in 1971 and restated in 1977 was arbitrarily chosen (23). It explains that the limit was based on a woman exposed to 20-30 mSv (2-3 rem) per year with the dose received at a relatively uniform rate throughout the year. In this scenario, the embryo/fetus would not likely receive more than two twelfths of 30 mSv (3 rem) or 5 mSv (0.5 rem) during the first two months of pregnancy, when a woman may not realize that she is pregnant. This assumption was made in an era when rapid, same day, pregnancy testing was not available. This 5-mSv limit was, until recently, the nonoccupational or general public dose limit. This supported the reasonableness of

TABLE 2
Risks and Potential Outcomes of Pregnancy

General risks		
Risk factor	Outcome	Increased risk
Maternal age (20s)	Down's syndrome	1 in 2300 (6)
Maternal age (35-39)	Down's syndrome	1 in 64 (6)
Tobacco abuse (<1 pack/day)	Infant death	23 in 1000 (3)
Unknown	Spontaneous abortion	30-50% (6)
Unknown	Any malformation	40 in 1000 (25)
Unknown	Childhood cancer	1 in 1000 (25)
Unknown	Any anomaly	6 in 100 (26)
Occupational radiation risks		
Fetal exposure of 5 mSv	Serious effect	0.035 in 1000 (25)
Fetal exposure of 50 mSv	Serious effect	0.35 in 1000 (25)
Fetal exposure of 10 mSv	Childhood leukemia	1 in 3333 (6)
Fetal exposure of 10 mSv	Other childhood cancer	1 in 3571 (6)
Fetal exposure of 10 mSv	Major effect	2 in 1000 (26)

the suggested fetal dose limit by envisioning the embryo/fetus as a member of the general public within the body of an occupational worker in a restricted area.

NCRP Report 91 (20) restated the 5-mSv (0.5-rem) total effective dose equivalent (TEDE) limit and expanded its recommendations to include that once pregnancy is known, a limit of 0.5 mSv (0.05 rem) per month should be applied to the embryo/fetus. This suggestion was designed to limit fetal exposures during any critical period of development. This recommendation was never legitimized through NRC or Agreement State regulations.

INSTRUCTIONS TO WORKERS

The 10 CFR 19.12, *Instructions to Workers* requires, in part, that all individuals working in or frequenting any portion of a restricted area be instructed in the health protection problems associated with exposure to radioactive materials or radiation. Among the topics to be discussed should be the risks of radiation exposure to the embryo/fetus (24). The instructions to workers must include the right to declare or not declare pregnancy status.

Prior to January 1994, 10 CFR Part 20 did not address a special limit of exposure for the embryo/fetus. To assist the licensees, the NRC published Regulatory Guide 8.13, *Instruction Concerning Prenatal Radiation Exposure*, in March 1975 (2) with revision in December 1987 (3). Regulatory Guide 8.13, Revision 2, describes the instructions an employer should provide the woman concerning biological risks to the embryo/fetus exposed to radiation, proposes a dose limit to the embryo/fetus, and lists suggestions for reducing radiation exposure. This revision took into consideration a proposed revision to 10 CFR Part 20, which was signed by President Reagan in January 1987 and was published in the Federal Register as "Federal Radiation Protection Guidance for Occupational Exposures" (25).

Because of the many changes related to the revision of Part 20, it again became necessary to revise Regulatory Guide 8.13.

Draft Regulatory Guide DG-8014, dated October 1994, was published and distributed to all NRC licensees for public comment (26). The draft guide serves for what will be revision 3 of Regulatory Guide 8.13. The basic components of the draft guide are to specify: (a) who should receive the instruction; (b) how the instruction is to be provided; (c) the employer's policy on declared pregnant women; and (d) the duration of lower dose limits for the embryo/fetus. The final draft is currently planned for March 1996 and will be addressed to all NRC licensees.

DECLARED PREGNANT WOMAN

A declared pregnant woman is one who has voluntarily elected to declare her pregnancy in writing to her employer. She is not under any regulatory or licensing obligation to do so. The declaration, if made, must be in writing, dated and include the estimated month of conception. The estimated date of conception is necessary to approximate the dose the embryo/fetus may have received prior to the declaration. This dose estimate can be based on previous personnel dosimetry reports, air monitoring, bioassay or area monitoring records. This document may become very important in the event of a future medical-legal action. Therefore, proper filing of the declaration is very important from both a legal as well as a regulatory perspective. The employer's acknowledgment of the pregnancy by verbal understanding or visual observation does not meet the requirements of the present regulations regarding the declaration of pregnancy. Draft Regulatory Guide DG-8014 and Appendix A of this article have suitable forms which may be used to fulfill the written notification requirement.

Just as the woman has the right to declare her pregnancy, she also has the right to revoke her declaration of pregnancy. The NRC states in *Questions and Answers Based on Revised 10 CFR Part 20* (27) that "under the regulations . . . the woman has the right to choose whether or not to declare her pregnancy, including the right to revoke the declaration. It is the woman's right to choose, not the declaration of pregnancy, that

is irrevocable." Although the NRC does not have any regulation specifying how to terminate a declaration, it is reasonable and good practice to terminate the declaration of pregnancy in writing as it was originally declared (27).

Personnel monitoring may not have been necessary for some workers because they were not likely to exceed 10% of the 50-mSv (5-rem) annual TEDE limit. But since the declaration of pregnancy, personnel monitoring would be indicated if the individual may receive 10% of the embryo/fetal dose limit or 0.5 mSv (0.05 rem).

After the declaration of pregnancy the licensee has certain obligations. The facility must ensure that the dose to the embryo/fetus during the entire pregnancy, as a result of occupational exposure, does not exceed 5 mSv (0.5 rem) (28). Until the declaration is made the woman is still considered a regular occupational worker with an annual TEDE limit of 50 mSv (5 rem). The employer has no requirements to restrict the dose to the embryo/fetus to the lower limit until the written declaration is made. Following the declaration of pregnancy, the declared pregnant woman is not eligible to participate in planned special exposures that would involve a whole-body dose and/or maternal intake that would result in exceeding the embryo/fetus dose limit (29).

An often used solution to this perceived problem is to move the newly declared pregnant woman to a work area of lower radiation. This approach is to be discouraged. It is important to realize that any such job displacement places an additional radiation burden on fellow workers, male and female, which they may find unacceptable. Further, job displacement may increase the risk to others. Many women are not aware of their pregnancy until after the most radiosensitive period has passed. Accordingly, it is conceivable that you may be moving one known pregnant woman from an area of higher radiation at a time when risks are low, and moving another unknown pregnant woman into this area when risks are higher. However, if job displacement is the chosen program, such a program needs to be clearly understood to avoid legal complications. All occupational workers must agree at the time of employment and/or institution of the pregnancy policy program. A better program is one in which the employer devises a work schedule for all occupational workers that ensures a relatively uniform monthly exposure rate and therefore avoids substantial variations to all radiation workers. This is consistent with the prevailing ALARA program.

Most medical licensees have an ALARA license condition of 1.25 mSv (0.125 rem) per quarter or approximately 0.42 mSv (0.042 rem) per month for investigational purposes. This quarterly limit is based on the incorporation of Appendix G, "Model Program for Maintaining Occupational Radiation Exposures at Medical Institutions ALARA" found in Regulatory Guide 10.8, Revision 2. (30) into the license application. Using a nine-month regulatory limit of 5 mSv (0.5 rem); the maximum embryo/fetus dose should not exceed an average of approximately 0.55 mSv (0.055 rem) per month. While this monthly average would fall within the 5-mSv (0.5-rem) limit, it would exceed, at most medical institutions, the quarterly ALARA Level I limit of 1.25 mSv (0.125 rem) per calendar quarter. Therefore, if she is to stay under the Level 1 commitment of

the ALARA program, a declared pregnant woman should not average more than 0.4 mSv (0.040 rem) per month which corresponds to 3.6 mSv (0.36 rem) over a nine-month period.

EXTERNAL MONITORING

If the declared pregnant woman is likely to exceed 10% of the embryo/fetus dose limit, then the use of a personnel monitor is indicated as stated in 10 CFR Part 20.1502(a). The embryo/fetus dose would be the deep-dose equivalent (DDE) of the mother, which is based on the whole-body exposure at a tissue depth of one centimeter. National Voluntary Laboratory Accreditation Program (NVLAP) approved dosimetry vendors have this listed as "DDE" or "deep-dose" on their monthly film badge reports. Part 20.1201(c) mandates that the DDE and shallow-dose equivalent (SDE) must be from the part of the body receiving the highest exposure. This would seem to suggest that if one dosimeter is to be worn to monitor the declared pregnant woman, it should not be placed under a lead apron or at waist level if it has been determined that the waist is not the likely location of highest exposure. If a lead apron is not used and the waist is where the woman normally wears her badge then no change is necessary. The badge may continue to be used to monitor both the exposure of the individual and the exposure of the embryo/fetus.

In the case the badge is normally worn in another location (i.e., at the collar or on a lead apron), it should not be moved. If moved, the individual's subsequent exposures may not be comparable to previous exposures, or reflective of a change in job duties or work habits. Instead, a separate badge should be ordered for the woman to be worn at the waist level under any available shielding. When an additional badge is used, it should be ordered as a fetal dose badge. In this manner, the deep dose recorded on the fetal badge may be used as an estimate of fetal exposure.

We recommend that a running total of external exposures be initiated at the time of declaration and encompassing the entire gestation period from the estimated date of conception to delivery. The determination of external dose should consider all occupational exposures of the declared pregnant woman since the estimated date of conception. This may include exposure received during employment elsewhere.

There is an additional problem in documenting the exposure of the declared pregnant woman. Typically, TLD or film badge reports are several months in arrears and the most current exposures are not known. In this case, dosimetry history should be carefully reviewed to establish trends and a special request should be made to the dosimetry vendor to expedite processing. It may even be beneficial to order a special fetal badge with a unique control so that the fetal badge can be sent in for special handling. This may result in a faster processing turnaround.

INTERNAL DOSE

The internal dose is from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman. The radiation dose to the embryo/fetus from internally deposited radionuclides would require quantitative information about the

intake of radioactive material by the mother prior to the pregnancy and their possible retention during all or part of the gestation period, transfer kinetics from the mother to the embryo/fetus based on the stage of pregnancy, the route of intake by the pregnant woman, and the time after intake (31).

Monitoring of the intake of radioactive material is required by 10 CFR 20.1502(b) if the intake is likely to exceed 0.1 ALI (annual limit on intake) during the year for an adult worker. In the declared pregnant woman, if the committed effective dose equivalent (CEDE) is likely to exceed 0.5 mSv (0.05 rem) in one year, monitoring is required (32). Appendix B of 10 CFR Part 20 lists a stochastic ALI value of 200 μCi and a non-stochastic ALI value of 50 μCi for inhalation routes of intake for ^{131}I . The intake of the stochastic ALI will result in a CEDE of 50 mSv (5.0 rem). Based on a CEDE of 0.5 mSv (0.05 rem), the dose to the embryo/fetus must be evaluated if the intake is likely to exceed 1% of the stochastic ALI or 2 μCi of inhaled ^{131}I .

It is important to note that *intake* is not the equivalent of *uptake*. Previously, the monitoring of uptake was required. Intake is derived from the calculated uptake value divided by the intake retention factor (IRF). IRF values for many isotopes and chemical forms can be found in NUREG 4884. Using the IRF values, an uptake of 6.65 μCi (24.6 kBq) equals an intake of 50 μCi (1.85 MBq) of ^{131}I .

Regulatory Guide 8.36, *Radiation Dose to the Embryo/Fetus*, was developed with the revision of Part 20 to provide guidance on calculating the radiation dose to the embryo/fetus (31). The International Commission on Radiation Protection (ICRP) Publication 56 (33), states that estimates from models indicate that the dose to the embryo can be approximated by the dose to the uterus. It 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.

To calculate the dose from internally deposited radionuclides, assistance can be found from multiple sources. Some include:

1. Appendix F of *Principles and Practice of Nuclear Medicine* (34);
2. NUREG/CR-5631, revision 1, *Contribution of Maternal Radionuclide Burdens to Prenatal Radiation Doses—Interim Recommendations* (35);
3. Regulatory Guide 8.36, *Radiation Dose to the Embryo/Fetus* (31); and
4. the International Commission on Radiation Protection (ICRP) Publication 30, *Limits for Intakes of Radionuclides by Workers* (36).

In addition to these and other sources, a medical physics consultant in cooperation with the RSO can be used to estimate the body burden.

FETAL DOSE IN EXCESS OF 5 mSv (0.5 rem)

If the TEDE of the declared pregnant woman is found to have exceeded 5 mSv (0.5 rem), the employer is required to assure that the embryo/fetus dose does not exceed 0.5 mSv

(0.05 rem) for the remainder of the pregnancy. As an example, if a woman declares her pregnancy in the fifth month and the employer determines that she has a cumulative DDE of 6 mSv (0.6 rem), then the employer is obligated to limit her dose for the remaining four months to 0.5 mSv (0.05 rem).

It is conceivable that a declared pregnant woman's exposure may exceed the 5-mSv (0.5-rem) limit for the embryo/fetus. This qualifies as a reportable event to the NRC, applicable state agency or both. An investigation as to the cause of the exposure should be immediately undertaken. A written report to the governing agency is required to be submitted within 30 days of learning of such an occurrence. The required content of the report is described in 10 CFR 20.2203(b).

RECORD KEEPING

The 10 CFR 20.2106 requires licensees to maintain records of the radiation exposures of all individuals for whom personnel monitoring is required. Regulatory Guide 8.7, *Instructions for Recording and Reporting Occupational Radiation Exposure Data*, revision 1 (37), describes an acceptable program for the preparation, retention and reporting of records of occupational exposures. This regulatory guide includes copies of NRC Forms 4 and 5 and detailed instructions on completing them. The employer is required to maintain each required form or record until the NRC terminates that specific license. The guide also recommends that the employer be sensitive to the issue of personal privacy with respect to the embryo/fetus dose. If requested by the monitored woman, a letter report may be provided to subsequent employers to document prior embryo/fetus dose.

When monitoring is required under 10 CFR 20.1502, then the monitoring results, as required under 10 CFR 20.2106, must be recorded on NRC Form 5 or equivalent. The equivalent for external exposure reporting are the report forms from NVLAP accredited dosimetry vendors. A worksheet that can be used to summarize the occupational dose to the declared pregnant worker (embryo/fetus) is shown in Appendix A. Data should be recorded from the monthly film badge reports as soon as they are received.

DECLARED PREGNANT WORKER POLICY

The obligatory requirements of the employer following the woman's declaration of pregnancy could prompt the employer to institute restrictive fetal-protection policies in the workplace. Earlier, fetal-protection policies were common in many nonradiation industries. On March 20, 1991 the U.S. Supreme Court ruled, in a major sex-discrimination case (38), that employers may not bar women of childbearing age from certain jobs because of potential risk to their fetus. This decision effectively reversed a September 1989 ruling by a federal court of appeals that upheld Johnson Control's policy of barring women of childbearing age from jobs where the lead concentration in their blood could be above safe levels, unless the employee demonstrated that she was infertile.

The policy was challenged by the employees and by the United Auto Workers (UAW) on the basis that it deprived

women of job opportunities that were available to men. The Court held that Title VII of the Civil Rights Act of 1964, as amended, forbids sex-specific fetal-protection policies. In the majority opinion, Justice Harry Blackmun commented, "Women as capable of doing their jobs as their male counterparts may not be forced to choose between having a child and having a job. Congress made clear that the decision to become pregnant or to work while being pregnant or capable of becoming pregnant was reserved for each individual woman to make for herself" (38,39).

The *Standards for Protection Against Radiation*, as well as common sense, requires that a policy be established with respect to the declared pregnant worker. It is very important that the policy clearly allows for the voluntary declaration of pregnancy, limits the fetal dose to 5 mSv (0.5 rem) and provides for appropriate training of all involved individuals. A suggested policy is given in Appendix A.

TYPICAL EXPOSURES

In a recent paper by Bloe and Williams (40), who reviewed the client dosimetry results of a national medical physics consulting practice involving 846 nuclear medicine technologists, an annual mean dose of 1.78 mSv (0.178 rem) was observed. Technologists employed exclusively in PET imaging ($n = 6$) and nuclear pharmacists ($n = 103$) over the same period had averaged slightly higher annualized exposures of 4.12 mSv (0.412 rem) and 1.81 mSv (0.181 rem), respectively.

These observations illustrate two relevant facts. First, it is unlikely that a pregnant woman, who is a nuclear medicine technologist, will exceed the regulatory limit of 5 mSv (0.5 rem). Second, because of the low probability of such an event, there is little reason for the pregnant nuclear medicine technologist to elect to not declare her pregnancy or to substantially alter her job duties.

HOT LAB

Owens and Hung (41) described a range of technologist exposures from 3 mSv (0.3 rem) to 0.72 mSv (0.072 rem) annually. While the unique nature of the facility observed in this article may not be directly comparable to the typical nuclear medicine facility, their work does suggest that technologist job responsibilities can have a great effect on the DDE received. They observed that individuals in areas dedicated to radionuclide injection and radiopharmaceutical preparation received the highest annual DDE with 3.0 and 2.88 mSv (0.3 and 0.288 rem), respectively. Nuclear cardiology personnel followed with annualized exposures of 1.44 mSv (0.144 rem) and general nuclear medicine technologists had the lowest annual DDE of 0.72 mSv (0.072 rem). Again, this study exhibits the expectation that the 5.0-mSv dose limit is not exceeded.

LEAD APRONS

In keeping with the ALARA principle, it seems logical that a lead apron should be worn by a pregnant woman. Published data indicate that a lead apron will lower the exposure by one

half when working in the nuclear medicine department (42). Conversely, it can be argued that the likely exposure and attendant radiation risk is so low that a lead apron could serve to increase the possibility of physical disability related to the additional weight of the apron coupled with the altered center of gravity that occurs in the gravid state. The use of lead aprons becomes a personal decision. It has been our experience that most technologists decline the option of wearing lead aprons and, when worn, they are worn inconsistently. Most commercially available aprons theoretically provide minimal protection against the gamma energies of radionuclides employed in nuclear medicine. To be effective, a wrap-around lead apron is recommended to control the exposures received from behind and from the side.

EXPOSURE FROM PATIENTS

Nuclear medicine technologists can receive the majority of their whole-body exposure from patients who have received radioactive material. It is helpful to think of the nuclear medicine patient as an unshielded source. While most technologists would not carry an unshielded syringe containing a bone radiopharmaceutical in their pocket, many do not think twice about being near a patient during the course of an exam. It bears mentioning that 0.1 milligrays (0.010 rad) per hour can be realized from the surface of a patient containing 740 MBq (20 mCi) of ^{99m}Tc .

It is also important to remember that the inverse square law applies to point sources. It can not be applied to a source the size of patients for a quick determination of dose as a function of distance. However, the use of distance still remains beneficial in dose reduction. Maximal distance consistent with good patient care is highly encouraged and will result in dose reduction.

RADIONUCLIDE THERAPY

The administration of volatile radiopharmaceuticals in therapeutic quantities is relatively contraindicated in the declared pregnant worker. This recommendation applies especially to the administration of ^{131}I -sodium iodide due to its volatility and, therefore, the increased probability of a radionuclide intake. Such an intake creates internal dosimetry problems that greatly complicate dosimetry calculations in the pregnant worker. The embryo/fetus exposure can be elevated because of a maternal intake due to intimate distance, extended retention time and particle decay.

The administration of volatile radiopharmaceuticals such as ^{131}I -sodium iodide should be approached with extraordinary caution and with appropriate controls (aggressive bioassay program, fume hoods, remote measurement/administration, etc.). Just as a running total for external monitoring is indicated, a running ALI total is valuable in instances where bioassays are indicated to demonstrate that the maternal intake does not lead to a CEDE in excess of 0.5 mSv (0.05 rem).

CONCLUSION

Radiation and pregnancy are two issues fraught with emotion and opinion. It is not unusual to find numerous dissenting

opinions even among the most educated and well-intentioned physicists, physicians and technologists. The reality is that no one has objectively demonstrated the numerical risk of low-level occupational radiation exposure either to the fetus or to the mother.

Many estimates of this risk are available from a variety of peer-reviewed sources. It is important to remember that risk estimates are just that—estimates. They are extrapolations based on the clearly defined effects observed at high-dose levels and/or rates. Estimates and extrapolations are not the equivalent of direct measurement or observation and the limitations of the estimation should be given an appropriate level of credibility.

There may be an increased risk related to our chosen occupation and even if this risk is extremely small, it still may be present. Despite the best efforts of numerous scientists, over the past fifty years, the risk remains uncertain and poorly defined. What is clear is the great difficulty the nuclear medicine community has in demonstrating a genuine risk to the worker or embryo/fetus at or below regulatory dose levels.

Managers of occupational workers, especially declared pregnant workers, are charged to be sensitive to this risk and control it to the extent necessary and reasonable under the circumstances. Ultimately, it is the responsibility of the pregnant and occupationally exposed woman to assess her risk tolerance in light of the normal risks of day-to-day life and to assure that she continues to take every reasonable precaution to avoid excessive radiation exposure. Continued careful attention to the traditional concepts of time, distance and shielding remain the basis for the prevention of excessive fetal exposure and the mitigation of risk, if any.

APPENDIX A

Sample Policy Considerations for the Declared Pregnant Worker

I. GENERAL

It is the licensee's responsibility to ensure that the dose to the embryo/fetus from the occupational exposure of a declared pregnant worker, does not exceed 5 mSv (0.5 rem) over the entire pregnancy. The licensee must also make an effort to avoid substantial variations in a uniform monthly exposure.

The declaration of pregnancy must be in writing and is voluntary. That is, the pregnant worker need not declare her pregnancy if she so chooses. Further, the licensee is not required to restrict the dose to the embryo/fetus to 5 mSv (0.5 rem) until a written declaration of pregnancy is made. It should also be noted that the declaration can be revoked at any time. The revoking of the declaration of pregnancy must also be in writing.

The written declaration of pregnancy must include an estimated date of conception. The estimated date of conception will be necessary in the determination of the accumulated dose the embryo/fetus may have received prior to the declaration of pregnancy. An example form that is used to document the

DECLARATION OF PREGNANCY	
I, _____, do hereby make this voluntary declaration of pregnancy. My estimated date of conception was _____, 199__.	
It has been explained to me that I am making this voluntary declaration of pregnancy.	
I understand that this means the licensee must take measures to ensure that the total dose to the embryo/fetus during the entire pregnancy from occupational exposure does not exceed 0.5 rem (5 mSv). If, as of this date, the total dose to the embryo/fetus is 0.45 rem (4.5 mSv) or greater, the total dose to the embryo/fetus during the remainder of the pregnancy shall not exceed 0.05 rem (0.5 mSv).	
It has been explained to me that these measures may include the reassignment of duties to those that will result in lower occupational exposure or the placement of certain restrictions on the duties I may perform.	
It has also been explained to me that I may revoke the declaration of pregnancy at any time and that the revoking of the declaration must be in writing.	
_____	_____
Employee	Date
_____	_____
Radiation Safety Officer	Date

FIGURE 1. Sample declaration of pregnancy form.

declaration of pregnancy (Fig. 1) is included with these policy considerations. The accumulated dose the embryo/fetus may have received prior to the declaration of pregnancy will have to be subtracted from 5 mSv (0.5 rem) to determine the dose the embryo/fetus will be allowed to receive during the remainder of the pregnancy. If the dose is determined to be 4.5 mSv (0.45 rem) or greater by the time the declaration is made, it is the licensee's responsibility to ensure that the embryo/fetus receives only 0.5 mSv (0.05 rem) during the remainder of the pregnancy. An example form that is used to document the occupational exposure to the embryo/fetus (Fig. 2) is included.

The 5-mSv (0.5-rem) dose limit shall be the sum of the deep-dose equivalent to the declared pregnant worker from external sources of radiation and the dose from radionuclides in the embryo/fetus and/or pregnant worker. Only radionuclides that have been ingested or inhaled due to occupational exposure need to be considered. Radionuclides that may have been administered to the worker for diagnostic or therapeutic procedures should not be considered.

Several methods that can be used to determine the dose to the embryo/fetus from radionuclides in the embryo/fetus and/or declared pregnant worker are presented in NRC Regulatory Guide 8.36, *Radiation Dose to the Embryo/Fetus* (31).

The internal dose will only need to be determined if the intake is likely to result in a committed effective dose equivalent (CEDE) of 0.5 mSv (0.05 rem), which represents 1% of the stochastic annual limit on intake (ALI). The calculations to determine dose to the embryo/fetus from internal radionuclides

Date: _____

OCCUPATIONAL EXPOSURE TO EMBRYO/FETUS

Employee name: _____

Birth date: _____

Social Security #: _____

Estimated date of conception: _____

External dose since date of conception: _____ rem(1)

Internal dose since date of conception: _____ rem(2)

Total dose since date of conception:(1)+(2) _____ rem(3)

Dose, 1st month post-declaration: _____ rem

Dose, 2nd month post-declaration: _____ rem

Dose, 3rd month post-declaration: _____ rem

Dose, 4th month post-declaration: _____ rem

Dose, 5th month post-declaration: _____ rem

Dose, 6th month post-declaration: _____ rem

Dose, 7th month post-declaration: _____ rem

Dose, 8th month post-declaration: _____ rem

TOTAL _____ rem(4)

Total dose to the embryo/fetus:((3)+(4)) _____ rem

(1) Record measurement that is most representative of the exposure to the embryo/fetus.

(2) Consult Regulatory Guide 8.36 for guidance.

(3) If total dose is already 0.45 rem or greater, the dose to the embryo/fetus must be restricted to 0.05 rem for the remainder of the pregnancy.

FIGURE 2. Sample occupational exposure to embryo/fetus form.

require quantitative information about maternal radionuclide intake, gestational age, placental transfer and kinetics, and resulting radionuclide concentration. If the dose to the embryo/fetus from internal radionuclides is a concern, consideration should be given to contacting a medical physicist for assistance. It is the responsibility of the radiation safety officer to implement this policy and to assure compliance with the policy.

II. PERSONNEL MONITORING

Monitoring may not have been required for a worker prior to her pregnancy because she was not likely to exceed 10% of the 50-mSv (5-rem) per year threshold of 5 mSv (500 millirem) or 10% of the ALI. However, following declaration of pregnancy, monitoring will be required for a worker if she is likely to exceed 10% of the declared pregnant worker limit of 5 mSv (0.5 rem) per year or 1% of the ALI. In this case, the licensee must estimate the exposure received during the period monitoring was not required by using air monitoring, area monitoring or bioassay records.

The declared pregnant worker who is likely to receive a deep-dose equivalent (DDE) in excess of 0.5 mSv (50 millirem) in a year must wear a personnel monitoring device at waist level under a lead apron, if used, to record the most representative exposure to the embryo/fetus.

This may result in a policy change for the woman who currently wears a personnel monitoring device at waist level. If a lead apron is used, an additional badge to be worn under the

apron must be issued. The badge that is currently in use is to remain in use outside the lead apron.

For the worker who wears a single personnel monitoring device at the collar, a second personnel monitoring device is to be issued. This monitor is to be worn at waist level under a lead apron, if one is worn. In this way, the most representative exposure to the embryo/fetus can be recorded while maintaining consistency with previous maternal exposure records.

III. JOB RESPONSIBILITIES

Once the declaration of pregnancy has been made in writing, a review of the individual's exposure history must be made. If it is determined to be unlikely that the embryo/fetus will receive in excess of 5 mSv (500 millirem) during the entire gestation period, reassignment or restrictions may not be necessary. However, if it is determined that the dose to the embryo/fetus is likely to exceed 5 mSv (500 millirem), in lieu of a leave of absence until delivery, consideration may be given to reassignment of the declared pregnant worker to an area of little or no radiation exposure or to placing certain duty restrictions on the individual to limit the exposure to the embryo/fetus.

It is important to realize that any job displacement will result in additional radiation exposures to fellow workers; this is a burden that some may find unacceptable. To avoid legal and human resource complications, such a program needs to be clearly understood and agreed upon by all nuclear medicine employees at the time of employment.

Duties that may be considered for restriction because they represent a higher probability for the embryo/fetus to exceed 5 mSv (500 millirem) are as follows:

1. *Nuclear Medicine.* If possible, the declared pregnant nuclear medicine technologist should be restricted from involvement in ^{131}I therapies for the treatment of hyperthyroidism or thyroid carcinoma.
2. *Laboratory.* If possible, the declared pregnant laboratory technologist should be restricted from procedures involving the iodination of proteins.
3. *Nursing.* If possible, the declared pregnant nurse should be restricted from caring for patients that are undergoing ^{131}I treatment for thyroid carcinoma or treatment with brachytherapy sources.
4. *Radiation Therapy.* If possible, the declared pregnant therapy technologist should be restricted from handling brachytherapy sources.

IV. EDUCATION

Educational material should be made available for the pregnant worker to review. Examples of suggested publications are NCRP Report No. 53, *Review of NCRP Radiation Dose Limit for Embryo and Fetus in Occupationally Exposed Women* and NCRP Report No. 54, *Medical Radiation Exposure of Pregnant and Potentially Pregnant Women*.

The pregnant worker should already have reviewed NRC Regulatory Guide 8.13, *Instruction Concerning Prenatal Radiation Exposure (2)* and the facility's policy for a pregnant woman during her initial training. Upon declaration, both Regulatory Guide 8.13 and the facility's pregnancy policy should again be presented to the pregnant worker for review. Consideration should be given to documenting the employee's review of Regulatory Guide 8.13 and the facility's policy for the pregnant woman both during initial training and upon declaration of pregnancy.

V. RECORDS

All records of exposure to the embryo/fetus and the written declaration of pregnancy should be maintained on file until the NRC terminates the license.

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Please see end of second continuing education article, by Thomas, for CE tests questions, answer sheet and answers to the March 1996 CE tests.