INFO-0700 (E)

REPORT

Dose Limits for Pregnant Workers

Rationale for the Limits in the Radiation Protection Regulations

by

Radiation and Environmental
Protection Division
Atomic Energy Control Board
Ottawa, Ontario

January 1999

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

Canada

INFO-0700 (E)

DOSE LIMITS FOR PREGNANT WORKERS

RATIONALE FOR THE LIMITS IN THE RADIATION PROTECTION REGULATIONS

by

Radiation and Environmental Protection Division
Atomic Energy Control Board
Ottawa, Ontario

January 1999

Dose Limits for Pregnant Workers —
Rationale for the Limits in the Radiation Protection Regulations

Published by the Atomic Energy Control Board
AECB Catalogue number INFO-0700 (E)

This publication is distributed free of charge upon request. For additional copies, or for further information about the AECB, please write or call:

Communications Division
Atomic Energy Control Board
P.O. Box 1046, Station B
Ottawa, Ontario K1P 5S9

Telephone: (613) 995-5894 or 1-800-668-5284
Fax: (613) 992-2915
E-mail: info@atomcon.gc.ca
Web site: www.gc.ca/aecb

Table of Contents

SUMMARY

When a nuclear energy worker* (NEW) becomes pregnant, she is required by the new *Radiation Protection Regulations* to declare her pregnancy to the licensee associated with her workplace. The licensee may not be her employer (she may work for a contractor), but it is the licensee who is obliged by the regulations to inform all NEWs of the health risks due to radiation, including the particular risks to the foetus, and it is the licensee who must be notified *in writing* of the pregnancy. The licensee is required by the same regulations to ensure that the woman's dose does not exceed the more restrictive limit for pregnant NEWs, i.e., 4 mSv effective dose to the abdomen or an intake of 0.2 ALI. This combination of limits on external and internal radiation is intended to limit the effective dose to the foetus to 4 mSv during the remainder of the pregnancy following declaration. The limit is lower than the regular NEW limits of 50 mSv in a single year and 100 mSv in five years because of the greater sensitivity of the embryo and foetus to radiation.

This document discusses the AECB's rationale for proposing the 4 mSv dose limit for pregnant workers in the new *Radiation Protection Regulations*. This dose limit is higher than the limit of 2 mSv which was recommended by the ICRP in its Publication of 60 and proposed by the AECB in its Consultative Document C-122 (1991).

The reasons for proposing a dose limit of 4 mSv are based mainly on an assessment of the risks of detriment to the embryo and foetus. They can be enumerated as follows:

i) fundamentally, 4 mSv is a low dose, and measuring it with precision is difficult;

ii) the risk to the embryo and the foetus associated with a dose of 4 mSv to the mother is very small;

iii) the risk to the embryo and the foetus from a dose of 4 mSv is certainly very small when compared to the risks from other sources;

iv) during consultations leading to the adoption of the new limit, workers affected by it indicated to the AECB that the risk implications were acceptable;

v) adoption of the ICRP 60's recommended limit of 2 mSv could lead to discrimination against women, because some employers might conclude that the only effective method of compliance with the very low dose limit would be to remove a pregnant worker from work with radiation, or not hire women at all.

---

* Nuclear energy worker is defined in the Nuclear Safety and Control Act as a person who is required, in the course of the person's business or occupation in connection with a nuclear substance or nuclear facility, to perform duties in such circumstances that there is a reasonable possibility that the person may receive a dose of radiation that is greater than the prescribed limit for the general public.

HISTORICAL BACKGROUND

i) Publication C-122: *Proposed Amendments to the Atomic Energy Control Regulations for Reduced Radiation Dose Limits Based on the 1991 Recommendations of the ICRP.*

The Consultative Document C-122 was published in July 1991, announcing the AECB's intention to incorporate the ICRP 60 recommendation into the regulations. A dose limit of 2 mSv to the surface of the abdomen and an intake of 0.05 ALI were proposed for pregnant workers. The ICRP had stated that protection of the foetus should be "broadly comparable" to that of the general public. However, in ICRP 60 it was not clear whether the external dose limit was to be in addition to the internal limit. The AECB has interpreted the recommended dose limit of 2 mSv as a combination of a 1 mSv limit for external radiation and a 1 mSv limit for the effect of intakes of radioactive material by the mother during her pregnancy. A dose limit of 2 mSv during pregnancy was interpreted by the AECB as "broadly comparable" to the annual 1 mSv dose limit for the public.

ii) Public consultations on C-122

During the public consultations of C-122, the proposed 2 mSv dose limit was criticized by some interested parties as being unnecessarily low. The critics noted that doses at this level, especially those from the internal component, would be difficult to measure and compliance would be difficult to demonstrate. It was feared by workers who submitted comments that some employers might conclude that the only effective method of compliance with the dose limit of 2 mSv would be to remove a pregnant worker from work with radiation. If other work were not available, this could result in a lay-off, and eventually might lead to discrimination against the hiring of women for some types of radiation work.

iii) Public meetings and the technical presentations on the risk to the embryo and foetus from prenatal exposure

The AECB felt that it was necessary to give those radiation workers who were most likely to be affected an opportunity to present their views directly to AECB staff. Therefore, a series of eight public meetings was held in seven cities across Canada, and at a mine site, to obtain further comments. The main objective of these meetings, attended by a total of 338 people, was to discuss the proposed limit of 2 mSv with the female workers and to include them in the decision making process. During the meetings, an AECB consultant (Dr. D. Myers) presented the risks to the embryo and foetus from 2 mSv as well as the risk from natural causes. A report entitled *Comments on ICRP 60 Rationale for Dose Limits for the Pregnant Worker* (INFO-0421) was used for this purpose. It indicated that a dose of 2 mSv to the embryo and foetus would carry a risk of 1:10 000 for childhood cancer. For fatal cancer in later life, 2 mSv to the embryo and foetus carries a risk of 3:10 000. These risks were compared to the risks which the foetus faces from natural causes, which are much higher. Table 1 shows the comparison of the risks from 10 mSv, 4 mSv and 2 mSv with the natural occurrence of fatal and non-fatal cancers. Table 2

contains a list of a number of natural risks to a foetus. Because choosing a dose limit is mainly a risk-based decision, it is important to note that the quantitative risk estimates for very small doses have many uncertainties. Therefore, the numbers presented in Table 1 should not be interpreted as exact figures but as approximate values.

Women who work in the uranium mining industry receive some exposure from inhaled radon progeny. Calculations based on the latest ICRP lung model (LUDEP) show that since most of the inhaled radioactive material is deposited in the mother's lung, the dose to the foetus is about 1/1000 of the lung dose. Therefore, the normal occupational limit for radon progeny affords adequate protection for the foetus.

The meeting participants were presented with data from the National Dose Registry (NDR) for doses received by pregnant workers. Since 1986, 300 to 400 pregnant workers have been monitored for external radiation doses each year. The maximum dose to any individual, recorded for the remainder of the pregnancy following declaration, varied from 1.3 mSv to 2 mSv. The dose limit at the time was 10 mSv to the abdomen of the worker.

The NDR data for the category of nuclear medicine technologist (not those who are pregnant) indicate that 50% of these workers receive less than 2 mSv per year, and only 5% receive more than 5 mSv per year. These doses are well below the occupational limits and should not be a source of concern to the majority of workers in this field. Female workers in other sectors of the nuclear industry may receive higher average doses but it is expected that in most of these cases the licensee would be able to transfer them to jobs with lower doses if they became pregnant.

The NDR data cited above do not include any contribution from internal contamination. Information that is available at present suggests that this does not make a major contribution to total dose in most cases.

The participants at the meetings were of the general opinion that slightly higher risks, i.e., about double that from 2 mSv, would be acceptable when compared to the risks to the foetus from natural causes. Following the technical presentations, a majority of the workers* who would be most affected by the proposed limit suggested a dose limit of 4 or 5 mSv during pregnancy; a value between the previous limit of 10 mSv and the ICRP's recommendation of 2 mSv. (* One group of workers did not support the higher limit. This group was subject to general labour code regulations in their province which were seen as more advantageous to workers who became pregnant.)

OTHER INFORMATION ON RISK TO THE EMBRYO AND FOETUS

Table 3 summarizes additional information obtained from other publications on the effects of radiation exposure to the embryo and foetus.

BEIR V, 1990: For childhood cancer, the risk estimate quoted in ICRP 60 is 2.8×10^{-5} per mSv (or 1:10 000 for 4 mSv). The same data were analyzed earlier by Gilman et al. (1989) showing a risk estimate of 13×10^{-5} per mSv (or 5:10 000 for 4 mSv).

UNSCEAR 1994: UNSCEAR concluded that studies of uterine exposure gave a wide range of risk estimates from relatively high to essentially undetectable risk, including (possibly) none at all. It was stated in the report that there was no biological reason to assume that the embryo or foetus is radiation resistant, but the exact quantification of effects was subject to much uncertainty. Based on the more recent analysis of the Oxford survey of childhood cancer, risk for mortality of all childhood cancers is about 5×10^{-5} per mSv. This value corresponds to a mortality risk of 2:10 000 for 4 mSv prenatal exposure.

NCRP 1994: A Commentary by the NCRP entitled *Considerations Regarding the Unintended Radiation Exposure of the Embryo, Foetus or Nursing Child*, May 1994, which is the most recent NCRP publication on the subject, includes a section on radiation risks which reviews information from other NCRP publications. For childhood cancer induction following prenatal exposure, the Commentary concludes that the risk is numerically about the same as for the irradiation of young children, i.e., 10×10^{-5} per mSv (or 4:10 000 for 4 mSv). For heritable effects, i.e., effects in the foetal genetic material that will be expressed in foetus' descendants, the risk is given as 10^{-5} per mSv. This figure is derived from animal experiments and no human study has shown such risks.

TABLE 1: Estimates of the effects of low doses of radiation on the human embryo and foetus

Health detriment	Risk for the foetus following **10 mSv** exposure over the 8 months of pregnancy (per 10 000)	Risk for the foetus following **4 mSv** exposure over the 8 months of pregnancy (per 10 000)	Risk for the foetus following **2 mSv** exposure over the 8 months of pregnancy (per 10 000)	Spontaneous incidence per 10 000 live births
Childhood cancers	5*	2	1	200
Life-time cancers	15	6	3	2 500

Source: Modified from Myers D.K. Comments on ICRP 60 Rationale for Dose Limits for the Pregnant Worker (INFO-0421), June 1992

*** This risk estimate is derived from a risk coefficient = 5 x 10^{-2} per Sv (95% C1, 0.8 x 10^{-2} - 9.5 x 10^{-2} per Sv) from Mole R.H. (1990).**

TABLE 2: Comparison of risks to the foetus during pregnancy

Risk Factor	Pregnancy Outcome (Effect)	Risk of Occurrence (% of foetus exposed to risk factor that develop the effect)
Maternal German Measles	Defects of heart, lens of the eye, skeletal muscle, inner ear, teeth	67%
Maternal cigarette smoking	Low birth weight	20%
Maternal alcohol consumption:		
2 drinks/day	Low birth weight	10%
2 - 4 drinks/day	Signs of foetal alcohol syndrome (growth	10%
> 4 drink/day	deficiency, brain	20%
chronically alcoholic	dysfunction, characteristic facial signs)	50%
Maternal age:		
20 years	Down's syndrome (mental and	0.04%
35 - 39 yrs.	physical growth retardation)	1.5%
Living at high altitude:		
5000 ft.	Low birth weight	10%
Unknown	Developmental anomaly	2-4%
Unknown	Intrauterine growth retardation	2-3%
Genetic	ABO haemolytic disease	1%
Unknown	Chromosomal abnormalities (natural incidence)	0.5%
Unknown	Major malformation rate at delivery	2.75%
Unknown	Malformations and genetic diseases at 1-2 yrs. of age	6-10%
Unknown	Spontaneous abortion during pregnancy	30-50%
Embryo or foetal irradiation:	Childhood leukaemia deaths	0.03%
10 mSv	before age 12	
	Deaths from other childhood cancers before age 10	0.03%

Source: Medical Effects of Ionizing Radiation, Mettler, F.A. and Moseley, R.D.; Grune and Stratton Inc. 1985.

TABLE 3: Risk of childhood cancer per 10 000 exposed from 4 mSv of radiation dose to embryo and foetus, from other publications

Health detriment	Gilman et al. (1989)	BEIR V (1990)	UNSCEAR (1994)	NCRP (1994)
Childhood cancers	5*	1**	2†	4‡

The risk estimates in the table are derived from the following risk coefficients:

* Risk estimate = 13×10^{-2} per Sv (95% CI, 8.4×10^{-2} - 19.2×10^{-2} per Sv)

** Risk estimate = 2.8×10^{-2} per Sv (upper bound risk estimate)

† Risk estimate = 5×10^{-2} per Sv (95% CI, 0.8×10^{-2} - 9.5×10^{-2} per Sv) (from Mole R.H. et al. 1990)

‡ Risk estimate = 10×10^{-2} per Sv

REFERENCES

1. Consideration regarding the unintended radiation exposure of the embryo foetus or nursing child (1994). NCRP Commentary No. 9, National Council on Radiation Protection and Measurements, Bethesda, Maryland.

2. Gilman E.A., Kneale, G.W., Knox, E.G. et al. (1989) Recent estimates of the risk of childhood cancer following the irradiation of the foetus in: Low Dose Radiation Biological Basis of Assessment (K.F. Baverstock and J.W. Stather eds), Taylor and Francis, London.

3. Health Effects of Exposure to Low Levels of Ionizing Radiation (1990). Committee on the Biological Effects of Ionizing Radiations. National Research Council, National Academy Press, Washington D.C.

4. International Commission on Radiological Protection, ICRP Publication 60 (1991), Pergamon Press.

5. Mettler, F.A. and Moseley, R.D.: Medical Effects of Ionizing Radiation, Grune & Stratton Inc., 1985.

6. Mole, R.H. Fetal dosimetry by UNSCEAR and risk coefficients for childhood cancer following diagnostic radiology in pregnancy (1990). J. Radiol. Prot. 10, pp. 199-203.

7. Mole, R.H. Childhood cancer after prenatal exposure to diagnostic x-ray examinations in Britain (1990). Brit. J. Cancer 62, pp. 152-168.

8. Sources and Effects of Ionizing radiation. United Nations Scientific Committee on the Effects of Atomic Radiation. 1994 Report to the General Assembly.