

PREGNANCY AND IONISING RADIATION

INTRODUCTION

When working with sources of ionising radiation, risks are involved. By law it is mandatory to inform and instruct all employees, and in particular female employees, who work with ionising radiation emitting sources or equipment ('*Besluit basisveiligheidsnormen stralingsbescherming*' or *Bbs*, Article 7.29.). This is achieved by this procedure, in addition to offering radiation protection courses, education and instruction, depending on the target group.

In this procedure the risks of exposure to ionising radiation during pregnancy are specified. Also, an overview is given of the current limits, conditions and recommendations for pregnant exposed employees. If more information is requested, the supervisory radiation protection officer (RPO; Dutch: 'toezichthoudend medewerker stralingsbescherming' or TMS), coordinating radiation protection expert (RPE; Dutch: 'stralingsbeschermingsdeskundige' or SBD, also 'coördinerend deskundige' or CD) or general coordinating expert (Dutch: 'algemeen coördinerend deskundige' or ACD) of the institution may be contacted at any time.

PURPOSE

The purpose of this internal procedure is formulating uniform policy for the measures that are being taken for pregnant exposed employees, working within the institutions participating in the Complex License Randwyck.

BIOLOGICAL EFFECTS OF IONISING RADIATION

When interacting with biological material, like tissue, ionising radiation causes ionisations, which may lead to damage in DNA. As a result of this damage, the following effects in cells or tissue may occur:

- the damage is repaired by the cell; no further consequences are noticeable;
- the damage is not repaired adequately, which leads to a permanent change in the DNA; this may eventually lead to cancer in the exposed person or genetic anomalies in his/her offspring; these are called *chance-related (formerly stochastic) effects*;
- the damage is so severe that cell death occurs; depending on the amount of damaged cells this may lead to loss of function of a certain organ; this effect only occurs if a certain *threshold dose* is exceeded, and is called a *tissue reaction (formerly deterministic effect)*.

The prevailing dose limits of exposed employees are focused on preventing tissue reactions; under regular work conditions these effects will not occur at all which makes only the chance-related effects relevant.

EXPOSURE OF PREGNANT EMPLOYEES: EFFECTS AND RISKS

While performing actions with sources of ionising radiation, aside from the pregnant employee performing the action, the unborn child may be exposed as well. Pregnant employees therefore deserve special attention in radiation protection care (*Bbs*, Article 7.36.). On the one hand because the rapidly-dividing tissues of unborn children are more sensitive to radiation than the tissues of the adult mother, and on the other hand because unborn children do not voluntarily choose for exposure to radiation.

Much research has been done into the possible effects of ionising radiation on the unborn child, among others in the Life Span Study (LSS) among victims of the atomic bombings of Hiroshima and Nagasaki, as well as in numerous animal and laboratory experiments. Using these studies, risk numbers have been established for irradiation of the unborn child in different development stages as well as for different dose levels.

During pregnancy the following development stages and corresponding effects are discerned:

- **preimplantation stage:** this is the period of conception until 2 weeks after; in this stage the amount of cells in the embryo still is small and non-differentiated; in this case, irradiation above a threshold dose of 100 - 200 mSv leads to an all-or-nothing effect: the embryo either dies or develops fully without further damage;
- **organogenesis:** during this stage, which runs from the 3rd to 8th week after conception, cell differentiation takes place and organs are developed; in case the threshold dose of 100 mSv applicable for this stage is exceeded, disorders or malformations may arise;
- **development of the brain:** during the 8th to 25th week after conception the brain is developing; irradiation during this period above a threshold dose of 100 - 310 mSv may lead to decrease of IQ or mental retardation; the period between the 8th and 15th week after conception is more sensitive in this regard than the period between the 16th and 25th week after conception.

The effects described above are all tissue reactions (deterministic effects): they only occur if the exposure exceeds a certain threshold dose.

With exposure to radiation during pregnancy, chance-related (stochastic) effects also need to be taken in account. These effects are not connected to a certain period during pregnancy, and there is no threshold dose. During the whole pregnancy DNA damage may arise as a result of exposure to radiation, which may lead to cancer at a young or adult age. For this effect no threshold dose can be determined; the additional chance of developing cancer as a result of radiation is estimated at 2-5 cases per 100,000 children born alive when exposed to 1 mSv. In case the damage arises in reproductive cells, this may lead to genetic effects in the offspring of the unborn child. The chance for this is estimated at 1 in 100,000 when exposed to 1 mSv. *Table 1* below summarises this information.

Table 1: Possible effects of ionising radiation on the unborn child

| Time after conception [weeks] | Effect | Threshold dose [mSv] | Risk number* [chance per mSv] |
|----------------------------------|-----------------------------------|-------------------------|-------------------------------------|
| 0 - 2 | prenatal death | 100 - 200 | $1 \cdot 10^{-3}$ |
| 3 - 8 | malformations / disorders | 100 | $5 \cdot 10^{-4}$ |
| 8 - 15 | reduction IQ / mental retardation | 100 | $4 \cdot 10^{-4}$ |
| 16 - 25 | reduction IQ / mental retardation | 100 - 310 | $1 \cdot 10^{-4}$ |
| 0 - 38 | childhood cancer | none | $2 \cdot 10^{-5} - 5 \cdot 10^{-5}$ |
| 0 - 38 | genetic effects | none | $1 \cdot 10^{-5}$ |

* this relates to an estimation of the risk number above the mentioned threshold dose

These risk numbers should always be seen in perspective of the natural incidence of disorders and genetic effects, such as:

- chance of spontaneous abortion in the preimplantation stage: naturally 50%;
- chance of mental retardation: naturally 3%.

Comparison with other risks

Table 2 below shows a comparison between effects caused by ionising radiation and disorders caused by other factors, both for tissue reactions and for chance-related effects.

Table 2: Comparison between effects caused by ionising radiation and disorders caused by other factors

| Cause | Tissue reaction | Incidence [%] |
|----------------------------|--------------------------------|---------------|
| tobacco consumption mother | low birth weight | 20 |
| alcohol consumption mother | | |
| 2 glasses per day | low birth weight | 10 |
| 2 - 4 glasses per day | growth disorder / brain damage | 10 |
| >4 glasses per day | growth disorder / brain damage | 20 |
| age mother | | |
| 20 years old | Down syndrome | 0.04 |
| 35 - 39 years old | Down syndrome | 1.5 |
| various unknown causes | spontaneous abortion | 30 - 50 |
| irradiation embryo: 1 mSv | none | - |
| irradiation embryo: 50 mSv | prenatal death | 5 |
| Cause | Chance-related effect | Incidence [%] |
| various causes | death by childhood cancer | 0.075 (UK) |
| irradiation fetus (1 mSv) | death by childhood cancer | 0.002 - 0.005 |

DOSE LIMITS

To protect the pregnant employee and her unborn child as well as possible a dose limit has been set for the pregnancy period. The *Bbs* states in *Article 7.36*:

'The employer ensures that the work conditions of the pregnant employee are such that the equivalent dose as a result of the work are as low as reasonably possible for the unborn child, and that it is unlikely that the dose will exceed 1 millisievert from the moment of notification to the employer of the pregnancy until the end of the pregnancy.'

This dose constraint prevents tissue reactions (with threshold dose) from occurring, and limits the risk of chance-related effects like cancer.

To be able to protect unborn children as well as possible, it is important to report a pregnancy to both the administrative manager and the RPO/RPE as early as possible, so that necessary and/or desired dose-limiting measures may be taken in consultation.

After being notified of the pregnancy, the supervisor, in agreement with the RPO/RPE, will determine using the risk analysis which potential exposure is applicable for the pregnant employee when performing the work activities within her (current) range of tasks. If this potential exposure may lead to a dose higher than 1 mSv, it needs to be determined, based on the exposure during each work activity, which work activities may or may not be performed by the employee during the pregnancy.

In coordination with the supervisor and on the recommendation of the RPO/RPE, further agreements may be subsequently made about additional monitoring and possible additional measures.

BREASTFEEDING

During the period of breastfeeding, extra attention needs to be given to preventing contamination of the mother's body with radioactive substances, as these may be transferred to the child through breastfeeding. Article 7.36. of the Bbs states:

'The employer ensures that an employee, if she has reported to him that she is breastfeeding, performs no work activities during this period involving a relevant risk of contamination of the body, based on the risk inventory and evaluation, as stated in Article 5 of the Working Conditions Act.'

RESPONSIBILITIES

Employer and Experts

As stated earlier in this procedure, the employer is responsible (Bbs, Articles 7.29. and 7.36.) for informing women about the risks of radiation for the unborn child as a result of handling sources of ionising radiation. Also, the employer is obliged to ensure that the equivalent dose for the unborn child is as low as reasonably possible, but certainly will not exceed 1 mSv.

The employer places the responsibility of the practical execution of this obligation with the RPO/RPE, who take care of informing the employees and give tailored advice in securing the compliance to the dose limits.

Pregnant Employees

A pregnant employee is obliged to report a pregnancy to the employer as early as possible, so that, if necessary, appropriate measures can be taken to meet the limits set for the unborn child. In addition, the employee needs to report her intention to breastfeed in good time, so that this may also be taken into account when planning the work activities.

LIST OF ABBREVIATIONS

| Dutch | | English | |
|-------|---|---------|------------------------------|
| ACD | algemeen coördinerend deskundige | - | general coordinating expert |
| Bbs | Besluit basisveiligheidsnormen stralingsbescherming | - | - |
| CD | coördinerend deskundige | - | coordinating expert |
| SBD | stralingsbeschermingsdeskundige | RPE | radiation protection expert |
| TMS | toezichthoudend medewerker stralingsbescherming | RPO | radiation protection officer |

REFERENCES

- Besluit basisveiligheidsnormen stralingsbescherming: <https://wetten.overheid.nl/BWBR0040179/2018-07-01>
- ICRP, International Commission on Radiological Protection; Pregnancy and Medical Radiation. ICRP Publication 84.
- Eggels-Hofman C.J.J. and Kicken P.J.H.: 'Stralingsbescherming voor zwangere vrouwen in een medische omgeving'.
- Leijen C.: 'Radiologisch werk tijdens en na de zwangerschap'.