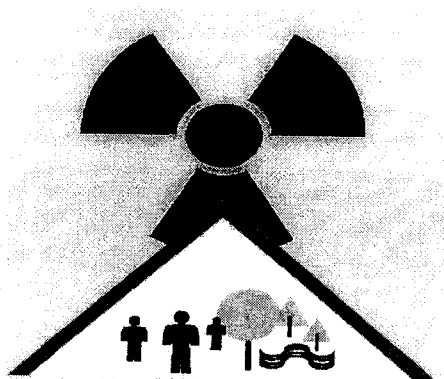


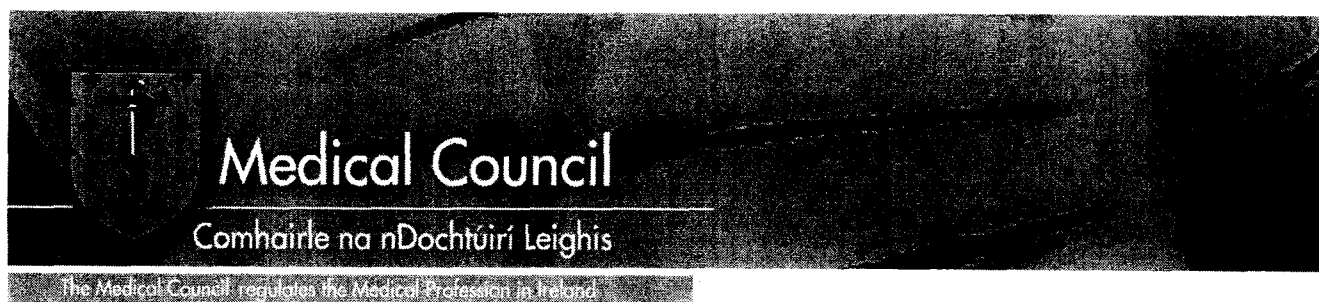
Radiation protection 100



**Guidance for protection of
unborn children and infants
irradiated due to parental
medical exposures**



European Commission



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Radiation protection 100

Guidance for protection of unborn children and infants irradiated due to parental medical exposures

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Directorate-General
Environment, Nuclear Safety
and Civil Protection

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FOREWORD

A comprehensive culture of radiation protection and safety in medicine has been progressively developing throughout the European Union with regard to the medical use of ionising radiation and has been integrated into the various branches of diagnosis and treatment.

The European Commission has contributed to this evolution with the establishment of legal requirements for the radiation protection of persons undergoing medical examinations or treatment.

The establishment of the Directive 84/466/EURATOM on health protection of individuals against the dangers of ionising radiation in relation to medical exposures, the so called "Patient Directive" (PAD84) was one of the milestones of these European initiatives.

Since 1984, the use of ionising radiation in medical practice has continued to develop, the number of installations to increase and the application to diversify. This together with the scientific and technical progress, urged the European Commission to revise Directive 84/466/EURATOM. The revised Medical Exposure Directive (MED97) 97/43/EURATOM was approved by the Council on 30 June 1997.

The protection of offspring of pregnant and breast-feeding patients needs particular consideration for several reasons. The unborn child and small children are particularly vulnerable to ionising radiation. As well as other risks, there is a risk of malformation and mental retardation for the unborn child and for both the unborn child and small children there is a risk of radiation induced cancer which may be three times as high as for the average population (ICR91). The potential benefit of the examination or the treatment involving ionising radiation will in most cases be for the mother and only indirectly for the unborn child, whereas it will incur a risk. This is contradictory to the normal situation where one person, namely the patient, incurs the risk but also derives the benefit of the examination or treatment.

It is the aim of the Commission to give some guidance to member states on the instructions and treatment needed for pregnant and breast-feeding women who can be considered as a particular subgroup of patients

For this reason the Commission consulted the group of health experts established by the Article 31 of the Euratom Treaty. This group of experts created a working party with a mandate to develop such a guidance in order to facilitate the application of the MED.

The present guidance was approved by the group of Article 31 experts during its session of 8 & 9 June 1998, taking into account comments made at the international workshop on the implementation of the MED in Madrid on 27 April 1998.

This guidance is addressed to prescribers, to practitioners responsible for diagnosis or treatment, to nurses, to medical physicists and other professional staff who are in contact with the patient, e.g. such as midwives and gynaecologists. Furthermore the report will be of interest to authorities.

Therefore this guidance has by definition a limited scope and certainly does not claim to be an exhaustive scientific report dealing with every aspect of the protection of the offspring.

The document is structured as follows:

A chapter entitled 'Biological effects of ionising radiation in unborn children and infants' gives general information on the risk of exposure to ionising radiation and how to put it into perspective. The second chapter called 'Options for the medical practitioner concerning female patients' provides guidance on how to avoid or to minimise detriment to the unborn child and to the breast-fed child. Three annexes and a schematic overview summarising different steps to be followed in the case of exposure of a female of childbearing age complete the guide. The first annex summarises a number of typical questions from mothers or mothers-to-be and gives examples of informative posters, the second gives dosimetric quantities and the third presents a number of typical absorbed doses to the unborn child. Finally, reference documents are listed.

This document will be made available in all official languages of the European Union.

Suzanne FRIGREN
Director Nuclear Safety and Civil
Protection

I. INTRODUCTION

(1) As the radiological protection of an unborn child (from conception to birth) is required by the MED, and as their protection is of particular concern, the present recommendations are made to:

- assist member states in implementing the MED by means of laws, regulations and administrative provisions
- give guidance to prescribers referring patients for procedures involving ionising radiation, to practitioners responsible for the procedures and to staff performing the procedures. This will enable these professionals to give advice to pregnant patients on radiological protection matters.

(2) Article 1 of the MED states that the directive applies to the following medical exposures:

- a) the exposure of individuals as part of their own medical diagnosis or treatment;
- b) the exposure of individuals as part of occupational health surveillance;
- c) the exposure of individuals as part of health screening programmes;
- d) the exposure of healthy individuals or patients voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;
- e) the exposure of individuals as part of medico-legal procedures.

The directive shall also apply to exposure of individuals knowingly and willingly helping (other than as part of their occupation) in the support and comfort of patients undergoing medical examination or treatment.

(3) Article 3 of the MED states that all individual medical exposures shall be justified taking into account the specific objectives of the exposure, the availability of previous diagnostic information, when appropriate, and the efficacy and availability of alternative techniques. Special attention shall be given for those exposures where there is no direct health benefit for the person undergoing the exposure.

(4) Concerning optimisation, Article 4 (1) of the MED specifies that all medical exposures for radiodiagnostic purposes shall be kept as low as reasonably achievable consistent with obtaining the required diagnostic information, and taking into account economic and social factors. For radiotherapeutic purposes, exposures of target tissue shall be individually planned; exposures of non-target tissues shall be as low as reasonably achievable, without underexposing the target tissue.

(5) If pregnancy cannot be excluded, article 10 (1) of the MED states that depending on the type of medical exposures, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure taking into account the exposure both of the expectant mother and the unborn child.

- (6) Article 10 (2) requires that in nuclear medicine for breast-feeding women, depending on the type of medical examination or treatment, special attention shall be given to the justification, particularly the urgency, and to the optimisation of the medical exposure, taking into account the exposure both for the mother and the child.
- (7) If the prescriber and the practionner justify the examination or treatment, taking into account pregnancy or breast feeding, it is the ultimate responsibility of the mother to decide if the treatment or examination should be performed after being informed on possible consequences for the unborn child or the breast-fed child.

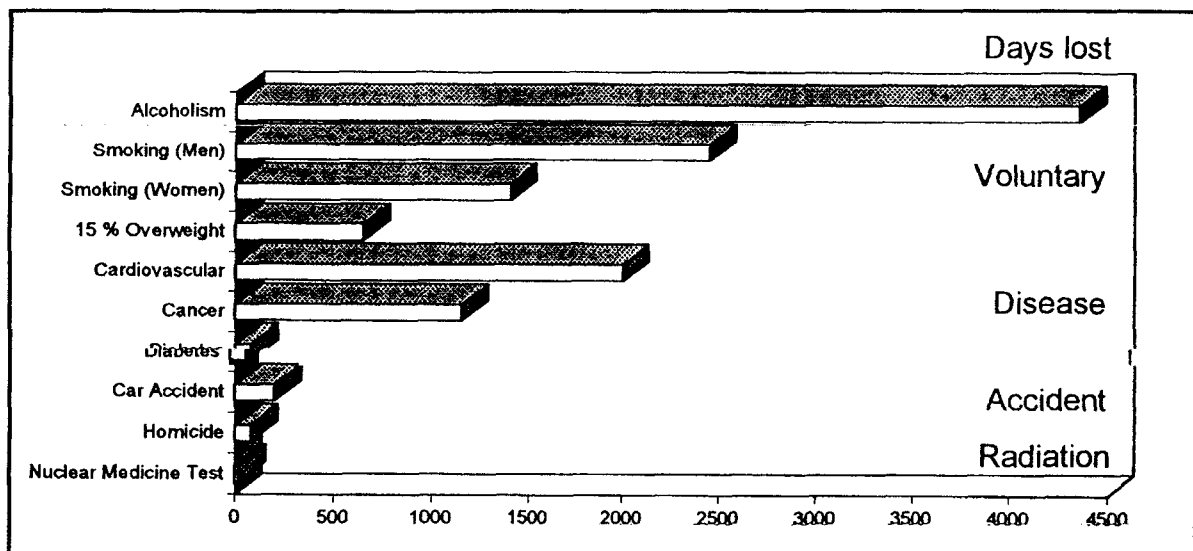
II. BIOLOGICAL EFFECT OF IONIZING RADIATION IN UNBORN CHILDREN

1. General

- (8) There are two categories of biological effects of ionising radiation: deterministic effects and stochastic effects. Deterministic effects are those caused by the decrease in or loss of organ function due to cell damage or cell killing. For these effects threshold doses exist: the function of many organs and tissues is not affected by small reductions in the number of available healthy cells. Only if the decrease is large enough will there be clinically observable pathological effects.
- (9) Stochastic effects are those that result from radiation changes in cells that retain their ability to divide. These modified cells may sometimes initiate a malignant transformation of a cell, leading to the development of a malignant clone and eventually to a clinically overt cancer. The period between the initiation and the manifestation of the disease may extend from a few years (e.g. leukaemia, thyroid cancer) to several decades (e.g. colon and liver cancer). In addition genetic effects may be initiated due to the irradiation of germ cells.
- (10) For stochastic effects no threshold dose is assumed and the probability of their occurrence is believed to be proportional to the dose (linear dose-effect relationship in the low dose, low dose-rate range). Therefore the probability of their induction should be reduced by keeping the dose as low as possible.
- (11) The probability of a fatal radiation induced cancer has been estimated (ICR91) at approximately 5 per cent per sievert effective dose¹ for the low dose, low dose rate and 1% for serious genetic diseases, for the whole population with its normal age distribution. Also curable cancers can be induced depending on the organ. For elderly people (older than about 60 years of age) the probability seems to be about 5 - 10 times lower, because their future life span may not be long enough to express the cancer and they would be unlikely to pass genetic damage to offspring. For children up to the age of 10 years, the probability of fatal cancer induction is maybe 2-3 times higher. For pregnant women the risk is the same as for the average population, however the unborn child is assumed to have the same risk as young children to develop a fatal cancer, about 15 per cent per sievert (ICR91).
- (12) When the medical profession communicates risks from exposure to ionising radiation to patients these risks should be explained and put in context so that they can be easily understood. For example, use of phrases such as "one out of 10,000 might get a radiation induced cancer" is preferable to the use of risk estimates in the form 10^{-4} . To help the patient to evaluate the figure given she should be informed about comparable risks for adults at the same time (see Fig. 1). Another possibility is to use the baseline values for serious genetic effects and for fatal childhood cancer. Congenital anomalies visible at birth are observed with as many as 6 per cent of all new-born children (UNS86), and the number of fatal childhood cancer is in the order of 1 out of 1000 in the time period from birth to the age of ten.

1. Some examples of doses and eventual effects are: if 100,000 persons are exposed to 1 mSv it is assumed that 5 persons will have a fatal cancer. Equally if the exposure to those 100,000 is 5 mSv, it is assumed that 25 individuals will get a fatal cancer

Figure 1. Loss of life expectancy: Comparison of risks (based on Coh91)



2. Effects on the unborn child

- (13) A stochastic risk for radiation induced cancer is believed to be present during the entire pregnancy, with a probability of maybe 2-3 times higher than that for the whole population.
- (14) The development of the unborn child may be divided approximately into three major phases:
- the pre-implantation phase, lasting from conception to implantation.
 - the phase of major organogenesis, which extends to approximately the 8th week post-ovulatory
 - the phase of fetal development, lasting from about 9 weeks until birth, which includes the phase of major formation of the central nervous system from the 8th to 15th (25th) week (UNS93)

The type of effect on the unborn child depends on the period of the pregnancy when the irradiation is applied. Tissues with developing cells are relatively more radiosensitive.

- (15) In the early period of pregnancy when the number of cells is small the radiation effect may be in the form of a failure to implant or of the death of the unborn child. It is, however, difficult to study in man events taking place in the unborn child before implantation. Based on animal data it is anticipated that at relatively high doses this failure to implant is more likely to take place than any radiation effect in the live-born, although the stochastic risks for radiation induced effects cannot be entirely dismissed.

Taking into consideration the frequency of embryonic death and the low probability that the radiation will affect the live-born, this early period of pregnancy is generally regarded as a period with relatively low radiation risks.

- (16) In the period from the 3rd to the 8th week there is a potential for malformation of organs. The risk of malformation will depend on the period of organogenesis at the time of irradiation and is probably especially high during the most active phase of cell multiplication and differentiation of the structures being developed. As dose thresholds may apply to these effects, they appear to be deterministic in nature. Thresholds have been observed in animal experiments and on this basis the threshold in man has been estimated to be of the order of 100 mSv. In the diagnostic field the dose to the unborn child will only in very rare cases reach this level. Hence malformation of organs is very unlikely to be caused by diagnostic exposure of the mother. For comparison purposes the spontaneous incidence of such effects in live-born can be taken as a few per cent (ICR92).
- (17) Values of intelligence quotient (IQ) lower than expected have been reported in some children exposed *in utero* at Hiroshima and Nagasaki. The data are consistent with a general downward shift in the distribution of IQ with increasing dose. It is assumed that this shift is proportional to dose. A figure of about 30 IQ points per sievert relates to the dose to the unborn child in the period from 8 to 15 weeks after conception. On this basis, the change in the IQ of an individual that can be caused by a dose as large as 100 mSv will be no more than three IQ points. Small shifts in IQ cannot be identified clinically. The effects on IQ are less marked following exposure in the period from 16 to 25 weeks after conception and have not been observed for other periods. All observations on IQ relate to high doses and high dose rates. (ICR96).
- (18) A second finding is the dose-related increase in the frequency of children classified as "severely retarded". The number is small, but the data indicate an excess probability of severe mental retardation of 0.4 at 1 sievert. The effect was observed following exposures in the 8th to 15th week after conception, is less marked following exposures in the period from the 16th to 25th week and has not been observed for other periods.
- (19) For comparison purposes the normal incidence in live-born of severe mental retardation can be assumed to be around 1 in 200 (ICR92).
- (20) Particularly in the later phase of pregnancy there is a risk of growth disturbance without malformation for children irradiated *in utero*, although this may occur at all stages of pregnancy. However, with present knowledge this risk is assumed to be small but cannot be quantified.
- (21) The risk of induction of cancers either in childhood or in adult life following *in utero* irradiation throughout pregnancy is considered to be the same as for children up to the age of 10, i.e. it may be a factor of two to three times higher than that for the average population (see previous section).

3. Effects on the new-born child

- (22) A new-born child may be exposed to ionising radiation if the mother has undergone a nuclear medicine examination or treatment. This is due to the fact that the radionuclide administered to the mother will remain in her body for a certain time depending on the type of radionuclide and on biological factors. If the radionuclide at the same time emits penetrating radiation, the new-born child will be exposed to the external radiation from

the mother when close to her, i.e. during feeding or cuddling. The dose will depend on the time the child is held, the distance from the mother's body etc.

- (23) Some radiopharmaceuticals administered to a breast-feeding woman will result in transfer of radioactive substances to her milk. A new-born child will receive a dose from that radioactive milk. The level of the dose depends on various factors such as the radiopharmaceutical, the amount of milk and the time lapse between the administration of the radiopharmaceutical to the mother and the feeding of the child.
- (24) Patients with radioactive substances in their body may present a contamination problem in that they excrete radioactivity, via perspiration, saliva, breath and urine, which can be inhaled or ingested by a new-born child. Great care and attention to hygiene will in general mean that the dose to the child will be small.
- (25) The principal risk for a new-born child from ionising radiation will be induction of cancers and is considered to be of the same order as for small children i.e. a factor of two to three times higher than for the average population (see previous section).

III. OPTIONS FOR THE MEDICAL PRACTITIONER CONCERN FEMALE PATIENTS

- (26) As laid down in article 5.1 of the MED the prescriber as well as the practitioner shall be involved as specified by Member States in the justification process at the appropriate level. This is also applicable for the situation addressed in article 10 involving pregnant or breast-feeding women.
- (27) In this section general guidance is given, both for the prescriber and the practitioner, on how detriment for the unborn and breast-fed child can be avoided or minimised. For special aspects of this situation concerning justification and optimisation see e. g. MED articles 3 and 4.

A. RADIATION PROTECTION OF THE UNBORN CHILD

- (28) The recommendations in paragraphs §28-48 are intended to be applied for treatment or examination that might cause a considerable dose (above 10 mSv) to the unborn child.

Therefore, they are not to be applied for low dose examinations, ie. below 1 mSv, equivalent dose to the unborn child. This includes X-ray examinations where the uterus is not in the primary beam.

Further these recommendations are only applicable to women of childbearing potential, from puberty to the menopause, normally older than 12 years and less than 50 years. Women who have been sterilised, had a hysterectomy, have had oral contraceptives continuously for more than three months, are on Depo contraceptives, or within 10 days of a withdrawal bleed after oestrogen therapy, can be assumed not to be pregnant unless the woman thinks otherwise.

- (29) Having regard to the exceptions in paragraph 28, the presence of pregnancy should be evaluated when an examination or treatment involving ionising radiation is considered. The patient should be explicitly asked, orally or in writing, whether she might be pregnant or may have missed a period. The MED says in article 10.1.a: "In the case of a female of child bearing age, the prescriber and the practitioner shall inquire as specified by Member States whether she is pregnant, or breast feeding, if relevant;". These inquiries may be made on behalf of the prescriber or the practitioner by other members of the staff. The outcome of the questioning should be recorded. In addition, a notice requesting the patient to inform the staff about pregnancy should be displayed prominently (example see annex I).
- (30) If the woman answers that she has regular periods, did not miss a period and neither the woman or the prescriber or the practitioner have otherwise a reason to assume pregnancy, the examination or treatment can be performed as planned.

It must be stressed that the use of contraceptives like the contraceptive pill or coil does not necessarily guarantee non-pregnancy.

- (31) If there is any uncertainty concerning pregnancy, expressed either by the patient, the prescriber or the practitioner because of a missed period, the period is known to be

irregular or for other reasons, pregnancy should be considered. The planned exposure should be postponed until after the next period or a pregnancy test may be performed.

If there remains any doubt about pregnancy, in particular when the period is late, the woman should be treated as pregnant, according to paragraph 32. However, in the case that pregnancy is not likely (for example no sexual intercourse) or it concerns low dose to the uterus, these precautions are not necessary.

- (32) In the case the prescriber or the practitioner suspects a patient not to tell the truth about a possible pregnancy, for whatever reason, he or she should explain to the patient why there is a need to know and, at the same time, point out to her that she too has a responsibility in this procedure. If doubt remains, the practitioner should proceed with common sense.
- (33) There is no need to apply the so called ten-day-rule routinely (exposure only during the first ten days after the beginning of the last period). However, if a diagnostic examination or treatment is planned which involves a high dose to the uterus, the ten-day-rule should be applied or a pregnancy test performed.
- (34) If pregnancy is confirmed, or if the woman is to be treated as pregnant, one of the three following alternative procedures is recommended. It must be stressed, however, that these provisions are examples on what measures may be appropriate, there might be others.
 - i) **The use of other methods of diagnosis, leading to a lower dose or no dose at all to the unborn child should be carefully considered, taking into account their potential drawbacks.**
 - ii) **The examination or treatment should be postponed until after delivery, if this is considered acceptable from a clinical point of view, balancing the risk and benefit for the mother and for the unborn child.**
 - iii) **In cases when a delay of the examination or treatment is considered not to be medically acceptable, the examination should be made with special concern about the radiation dose to the unborn child. Due attention should be given to possible consequences for the mother such as reduced efficacy of the examination/treatment. The dose to the unborn child should be estimated before the examination/treatment is carried out and, if relevant, reassessed afterwards.**
- (35) In the decision-making process the possible radiation risks at high dose as described in the previous chapters, such as failure to implant or early death of the unborn child, should be given due attention. The increased risk of radiation induced malformation and of reduction in IQ must be taken into account, especially for pregnancies between week eight and fifteen.
- (36) In emergency situations, if the female's life is in danger or if she is unconscious, immediate action must be taken and it may not always be possible to follow these recommendations. In such cases it is especially important that the risk for the unborn child is estimated after the examination or treatment, to provide a sound basis for further

considerations. Recording of all technical parameters is strongly recommended to facilitate this estimation.

- (37) More detailed recommendations about how to act when the patient is pregnant or is treated as such are given below for the various types of medical procedures.

1. Diagnostic investigations

- (38) Consideration of alternative methods such as ultrasound or magnetic resonance imaging should be the first step. In certain cases sufficient diagnostic information may be achieved with lower dose from different modalities involving x-rays or nuclear medicine techniques. The choice is made by weighing the expected medical benefit of the examination for the patient against the estimated radiation dose to the unborn child for either method.

Diagnostic and interventional X-ray procedures:

- (39) For such diagnostic and interventional procedures involving the lower abdomen or pelvis action should be taken as outlined in the next paragraph, if the examination cannot be postponed until after delivery.
- (40) Reduction of the dose to the unborn child might be achieved in a number of ways. These include the following: taking a reduced number of images, selection of projections, limitation of fluoroscopic time to a minimum, shielding, and careful collimation of the radiation beam. A protocol should be available for various x-ray examinations of the abdomen to ensure that the radiation dose to the unborn child is as low as reasonably achievable, whilst taking due attention to the outcome for the patient herself. This is particularly important for certain interventional procedures and examinations using computed tomography where doses to an unborn child might be considerable.

Nuclear medicine examinations:

- (41) Irradiation of the unborn child results from placental transfer with distribution of radiopharmaceuticals in the fetal tissues, and from external irradiation from the radiopharmaceuticals present in the mother's organs (e. g. the bladder) and tissues. The chemical and biological properties of the radiopharmaceuticals are the critical factors in possible placental transfer. For dose estimations to the unborn child these factors must be taken into account. Today such data are limited -for examinations where data are lacking general precautionary measures should be taken.
- (42) Possible means for dose reduction could for example include careful selection of radiopharmaceutical and radionuclide to minimise the dose to the unborn child.
- (43) In nuclear medicine, unlike x-ray procedures, the mother may still be a source of radiation for some time after the examination or treatment has been performed. Therefore, in certain circumstances, advice should be given to avoid pregnancy for an appropriate period of time after administration of the radionuclides.
- (44) The basic safety standard (BSS96) states that the protection of the unborn child of exposed workers shall be comparable with that provided for members of the public and that it shall be most unlikely that the dose exceeds 1 mSv. This value was chosen as a dose constraint for the unborn child and can be considered a reasonable basis for

constraining medical exposures. For most diagnostic procedures it will not be necessary to advise women to avoid pregnancy for a period following the administration of radiopharmaceuticals, because the dose to the unborn child would be below the value mentioned. However, in some cases the dose to the unborn child could exceed 1 mSv. Examples for such procedures are given in Table 1 together with an indication of the period of time during which pregnancy should be avoided (from Tho98).

Table 1: Nuclear medicine examinations where pregnancy within the indicated period of time may result in radiation doses to the unborn child from the time of implantation in excess of 1 mSv (Tho98)

Radiopharmaceuticals, investigations and administered activities	Avoid pregnancy (months)
59-Fe (iv): Iron metabolism 0,4 MBq	6
75-Se – Selenonorcholestrol: Adrenal imaging 8 MBq	12
131-I - MIBG: Tumour imaging 20 MBq	2
131-I – iodide: Thyroid metastases > 30 MBq	4

Note 1: The calculations are based on doses to the uterus by external radiation, and for the examinations with 59-Fe and with 131-I possible placenta transfer has also been taken into account.

Note 2: If the administered activity differs considerably from the above mentioned values, a medical physics expert should be consulted for advice.

2. Radiotherapy

- (45) In order to minimise the risk of radiation treatment of patients with unrecognised pregnancy, radiation therapy treatment should, if such a delay is justifiable, be scheduled to the first ten days after the onset of menstruation.
- (46) Before making a decision about radiation treatment of the mother to be, the dose to the unborn child should be carefully estimated. This dose will normally be high, but generally the treatment of the mother will have preference over these high doses to the unborn child. The mother to be must be involved in the discussion and decision about treatment.
- (47) The individual dose planning should be done in such a way as to minimise the dose to the unborn child without jeopardising the treatment of the mother to be, if the treatment cannot be postponed until after birth. It must be remembered that a large radiotherapy dose to the unborn child could result in severe deterministic effect or lead to a high probability of stochastic detriment.
- (48) After treatment with radiopharmaceuticals the patient should be advised to avoid pregnancy for a period of time as indicated below. This will ensure that the dose to the gametes and/or to the unborn child will probably not exceed 1 mSv. In Table 2 (Tho98)

recommendations for some common procedures are given. As the spermatozoa could be damaged in a male patient, he should be advised not to father children for four months after treatment with ¹³¹I.

Table 2: Advice for time period after treatment with radionuclides during which pregnancy should be avoided in order to ensure that the radiation dose to the unborn child is below 1 mSv (Tho98).

Nuclide & form	for treatment of	all activities up to (MBq)	avoid pregnancy (months)
¹⁹⁸ -Au colloid	Malignant disease	10,000	1
¹³¹ -I iodide *	Thyrotoxicosis	800	4
¹³¹ -I iodide *	Carcinoma thyroid	5,000	4
¹³¹ -I-MIBG *	Phaeochromocytoma	5,000	3
³² -P phosphate	Polycythemia, etc.	200	3
⁸⁹ -Sr chloride	Bone metastases	150	24
⁹⁰ -Y colloid	Arthritic joints	400	0
⁹⁰ -Y colloid	Malignancy	4,000	1
¹⁶⁹ -Er colloid	Arthritic joints	400	0

* The calculations are based on doses to the uterus by external radiation, but for the treatments with ¹³¹-I possible placenta transfer has also been taken into account.

Note: It must be stressed that the relation between activity and dose to the unborn child is not linear, therefore advice from the medical physics expert concerning the dose to be expected should be sought for activities considerably higher than those listed in Table 2.

3. Measures to be taken after examination/treatment of pregnant women

- (49) After a pregnant woman has been examined or treated with ionising radiation - either as outlined in these recommendations or when pregnancy was not known when the examination or treatment was performed - the dose to the unborn child should be evaluated by a medical physics expert or by the practitioner. If the uterus was not in the X-ray beam or the dose is estimated to be below 1 mSv, this evaluation is not necessary.
- (50) The dose and the time of pregnancy when the exposure occurred should be taken into account when discussing possible actions with the patient. The risk of everyday life compared with the risk due to the exposure should be discussed with the mother to be (see also § 12 up to § 21).

B. RADIATION PROTECTION OF THE BREAST-FED CHILD

- (51) If the planned procedure for a woman of fertile age is a nuclear medicine examination or therapy with radionuclides, the woman should be asked, orally or in writing, whether she is breast-feeding a child. A notice requesting the patient to inform the staff about breast-feeding should also be prominently displayed in the waiting area. If the answer is yes, advice about restriction of breast-feeding dependent on the diagnostic or therapeutic procedure should be given to the patient. For diagnostic procedures with some of the most common radiopharmaceuticals, Table 3 can serve as guidance. This advice will ensure that the infant will receive an effective dose below 1 mSv, which corresponds to the dose limit for the public. In the case of therapy with unsealed radionuclides breast-feeding will normally have to be stopped.
- (52) If breast-feeding is to be continued after the procedure, it is recommended to express breast milk some days before and store it to be given to the child after the administration of the radiopharmaceutical. Once the radiopharmaceutical has been administered the first breast milk should be expressed and discarded. The total time before breast feeding can be recommenced is given in Table 3. Close contact with the child should be restricted during this period.

Table 3: Recommendations for interrupting breast-feeding after administration of radiopharmaceuticals in routine use (Mou97)

Pharmaceutical	Recommendation	Category
^{51}Cr -EDTA $^{99}\text{Tc}^{\text{m}}$ -DISIDA $^{99}\text{Tc}^{\text{m}}$ -DMSA $^{99}\text{Tc}^{\text{m}}$ -DTPA $^{99}\text{Tc}^{\text{m}}$ -diphosphonates $^{99}\text{Tc}^{\text{m}}$ -glucoheptonate $^{99}\text{Tc}^{\text{m}}$ -gluconate $^{99}\text{Tc}^{\text{m}}$ -HMPAO $^{99}\text{Tc}^{\text{m}}$ -MAG3 (100 MBq) $^{99}\text{Tc}^{\text{m}}$ -MIBI $^{99}\text{Tc}^{\text{m}}$ -sulphur colloid ^{111}In -leucocytes (20 MBq) ^{201}Tl -chloride (80 MBq)	Interruption not essential (up to the activity given; if the activity is omitted, it is much greater than the maximum normally used)	I
$^{99}\text{Tc}^{\text{m}}$ -MAA (13 h; 100 MBq) $^{99}\text{Tc}^{\text{m}}$ -pertechnetate (47 h; 800 MBq; 25 h; 80 MBq)	Interruption for a definite period (period: corresponding maximum administered activity)	II
$^{99}\text{Tc}^{\text{m}}$ -erythrocytes $^{99}\text{Tc}^{\text{m}}$ -technegas $^{99}\text{Tc}^{\text{m}}$ -MAG3 (>100 MBq) $^{99}\text{Tc}^{\text{m}}$ -microspheres $^{99}\text{Tc}^{\text{m}}$ -pyrophosphate ^{123}I -iodide ^{123}I -MIBG ^{123}I -hippuran	Interruption with measurement	III
Sodium ^{32}P -phosphate ^{67}Ga -citrate ^{123}I -HSA ^{131}I -iodide	Cessation	IV

Note: ^{123}I should be free from ^{124}I and ^{125}I

C. RADIATION PROTECTION OF THE INFANT AGAINST EXTERNAL RADIATION FROM THE PARENTS

- (53) The dose from external radiation originating from diagnostic nuclear medicine examinations of the mother will generally be low. However, even the small doses that might be received can be avoided by minimising prolonged close contact between the patient and the nursed child during the first few hours after administration of radiopharmaceuticals. Care in this respect should also be observed if the child is bottle-fed. The mother should be informed about the possible radiation risks to the child.
- (54) For patients undergoing radiotherapy with radiopharmaceuticals it is normally necessary to restrict close contact to infants during the first two weeks after administration. The practitioner, after consultation with the medical physics expert, should give appropriate advice to the patient or his legal guardian. More detailed recommendations for I-131 treatment are given in the guidance on radiation protection following Iodine-131 therapy (Iod98).

Annex I: Typical questions (from the mother or mother-to-be) and answers

Annex II: Definition of dosimetric quantities

Annex III: Typical fetal doses from medical procedures

ANNEX I

TYPICAL QUESTIONS (FROM THE MOTHER OR MOTHER-TO-BE) AND RELATED ANSWERS

Pregnancy

Q. *What will happen if I do not have the scan?*

A. It is important for you, and also for the baby that the mother is well. To ensure this is the case your consultant has asked us to do the investigation.

Q. *Will it harm my baby?*

A. The radiation dose you and your baby will receive is very small. In fact, the variation of the dose from natural radiation within a whole country is even greater than that. (Pregnant technicians are allowed to work in this department, and those living in certain parts of the country receive greater doses than that naturally.)

Q. *I was told that the X-ray examination could give a high dose to my child. What is the risk involved compared to the normal incidence of abnormalities?*

A. The naturally occurring incidence of abnormalities is 3 – 6 %. Under the most unfavourable circumstances the dose to your unborn child would add to this risk x % (x = dose to the fetus in mSv according to Table 3 annex III times 0,04²), which is much lower/a factor of hundred lower/less than half compared to the natural incidence.

Breast-feeding

Q. *Why do I have to discontinue breast-feeding?*

A. Some of the radioactive substances which we have given you will come out in your milk. We want to ensure that your child will receive a radiation dose from your milk less than he/she would receive naturally during the course of a year.

Q. *What do I do with the expressed milk during the interruption period?*

A. The milk which you expressed before the test can be given to the baby in a bottle. All milk expressed during the interruption period should be thrown away down the sink.

Q. *Is it still safe to continue breast-feeding after the recommended time has elapsed?*

A. Yes. The times we have given you are based on information which has been gathered from all over the world.

Q. *Is it still ok to hold/cuddle my baby?*

A. Cuddling your baby is most important, but you should try to avoid doing so for long periods (greater than 1 hour at a time). However by tomorrow (for technetium diagnostic tests) you need take no special precautions. *Depending on the procedure and the radiopharmaceutical.*

Two examples of informative posters to be exposed in hospitals and waiting rooms:

² The highest quoted risk figure is that for severe mental retardation during the most unfavourable period of pregnancy

Patients, Staff and Relatives



**Please inform the
staff if you think that
you may be pregnant**

PATIENTS



**Please inform the
staff if you are
breastfeeding.**

ANNEX II DOSIMETRIC QUANTITIES

The basic physical quantity used in radiological protection is the **absorbed dose**, D_T , averaged over an organ or defined tissue, T, where D_T is the energy deposited in the organ divided by the mass of that organ. The unit of absorbed dose is called the gray (Gy).

Some radiations are more effective than others in causing stochastic effects. To allow for this, a further quantity has been introduced. This is the **equivalent dose**, H_T , which is the average absorbed dose in an organ or tissue multiplied by a dimensionless radiation weighting factor, w_R . For almost all the radiation used in medicine, the radiation weighting factor is unity, so the absorbed dose and the equivalent dose are numerically equal. The exceptions are alpha particles, for which the radiation weighting factor is 20, and neutrons, for which the radiation weighting factor is between 5 and 20, depending on the energy of the neutrons. To avoid confusion with the absorbed dose, the unit of equivalent dose is called the sievert (Sv).

In this document all doses are given as equivalent doses.

Radiation exposure of the different organs and tissues in the body results in different probabilities of harm and different severities. The combination of probability and severity of harm is called here '**detriment**', meaning health detriment. To reflect the combined detriment from stochastic effects in all the organs and tissues of the body, the equivalent dose in each organ and tissue is multiplied by a **tissue weighting factor**, w_T , and the results are summed over the whole body to give the **effective dose**, E . It is given by the expression

$$E = \sum_T w_T \cdot H_T.$$

The unit of effective dose is called the sievert (Sv).

The links between the quantities are illustrated in Fig. 1.

Absorbed doses in organs and effective doses cannot be measured directly. They are derived from other, measurable quantities. These include simple quantities such as absorbed dose in a tissue equivalent material at the surface of a body or in a phantom.

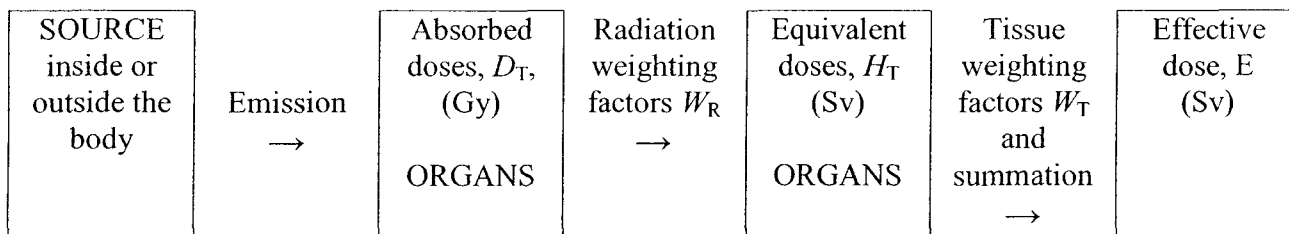


Fig. 1 The relationship between absorbed dose, D_T , equivalent dose, H_T , and effective dose, E .

ANNEX III TYPICAL FETAL DOSE FROM MEDICAL EXPOSURES

The following table shows examples of absorbed doses to the unborn child from common diagnostic procedures taken from NRPB surveys of diagnostic radiology and nuclear medicine procedures (NRP98). The doses can vary considerably depending on the physiology and pathology of the patient, the technique and procedure used. Thus, the figures are only given a rough indication of the absorbed doses.

Table: *In utero* doses following common diagnostic procedures; taken from NRPB surveys of diagnostic radiology and nuclear medicine (NRP98)

Examination	Fetal equivalent dose (mSv)	
	Mean	Maximum
<i>Conventional X-rays</i>		
Abdomen (AP only)	1.4	4.2
Barium enema	6.8	24
Barium meal	1.1	5.8
Chest	< 0.01	< 0.01
Intravenous urography	1.7	10
Lumbar spine	1.7	10
Pelvis	1.1	4
Skull	< 0.01	< 0.01
Thoracic spine	< 0.01	< 0.01
<i>Computed tomography</i>		
Abdomen	8	49
Chest	0.06	0.96
Head	< 0.005	< 0.005
Pelvis	25	79
Pelvimetry	0.2	0.4
<i>Nuclear medicine</i>		
^{99m} Tc bone scan (phosphate)	3.3	4.6
^{99m} Tc lung perfusion (MAA)	0.2	0.4
^{99m} Tc lung ventilation (aerosol)	0.3	1.2
^{99m} Tc kidney scan (DTPA)	1.5	4.0
^{99m} Tc thyroid scan (pertechnetate)	0.7	1.6
^{99m} Tc dynamic cardiac scan (RBC)	3.4	3.7
⁵¹ Cr glomerular filtration (EDTA)	< 0.01	0.01
²⁰¹ Tl myocardial perfusion (thallium)	3.7	4.0
^{99m} Tc brain scan (pertechnetate)	4.3	6.5
⁷⁵ Se Seleno-cholesterol	-	14.0
⁶⁷ Ga tumours and abscesses	-	12.0
¹³¹ I thyroid metastases	-	22.0

Calculation of doses from X-ray examinations

The assistance of a medical physics expert will be needed for the calculation of doses to the unborn child from X-ray examinations. However, the figures below can be used for an estimation of the dose if the tube voltage (kV) and the current-time product (mAs) are known.

Conventional X-rays

The figures represent a rough estimation and are applicable for a focus-film-distance of approximately 1 m and for AP/PA projections of colon, pelvis, lumbar spine etc., where the unborn child is in the primary beam.

Tube voltage (kV)	Current-time product (mAs)	Equivalent dose to the unborn child (mSv)
70	1	0.04
90	1	0.1
110	1	0.2

The absorbed dose will increase proportionally with the current-time product.

If the current-time product is not known due to the use of an automatic exposure control it can be estimated from an exposure table, if the sensitivity of the film-screen system is known.

The figures are also valid for fluoroscopy with the elapsed time being converted from minutes to seconds.

CT-scanning

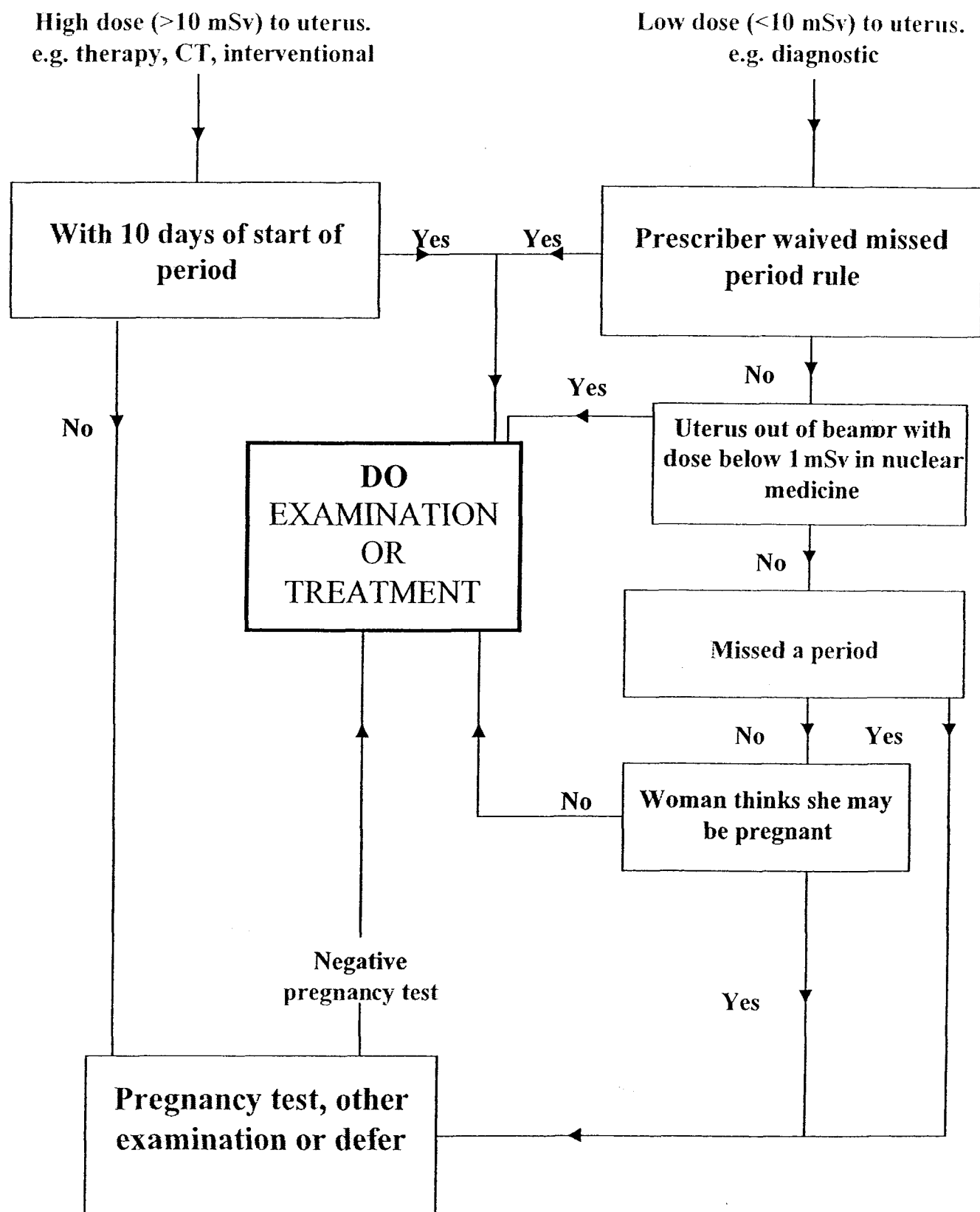
The figures are representing a rough estimate and apply for CT-examinations with non-overlapping consecutive scans where the unborn child is in the primary beam. The absorbed dose is an average value for different makes and types scanners. Most examinations are performed with a tube voltage in the indicated range.

Tube voltage (kV)	Current-time product (mAs)	Absorbed dose to the unborn child for one scan (360°) (mSv)
120-130	1	0.1

The absorbed dose will increase proportionally to the current-time product at a certain tube voltage; the mAs-values used are typically in the range 100 to 300 which will give a dose to the unborn child of the order of one to several tens of mSv.

Female Patients of Reproductive Capacity

Schematic overview



REFERENCES

- BIR73 BIR Diagnostic Radiology in early pregnancy and grounds for recommending abortion. Statement of Radiation Protection committee, BIR London, 1973.
- BSS96 *Council directive 96/29/EURATOM of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionizing radiation.* Official Journal of the European Communities L 159, 1-28, 1996.
- Coh91 Cohen B L; *Catalog of risks extended and updated.* Health Phys. 61: 317-335, 1991.
- ICR91 International Commission on Radiological Protection
1990 Recommendations of the International Commission on Radiological Protection, ICRP Publication 60. Oxford: Pergamon Press, 1991.
- ICR92 International Commission on Radiological Protection.
Radiological Protection in Biomedical Research, ICRP Publication 62. Oxford: Pergamon Press, 1992.
- ICR96 International Commission on Radiological Protection.
Radiological Protection and Safety in Medicine, ICRP Publication 73. Oxford: Pergamon Press, 1996.
- Iod98 European Commission; Radiation Protection following I-131 therapy (exposures due to out-patients or discharged in-patients).
Radiation Protection 97, 1998 – OPOCE Luxembourg
- MED97 *Council directive 97/43/EURATOM of 30 June 1997 on health protection of individuals against the dangers of ionizing radiation in relation to medical exposure, and repealing Directive 84/466/EURATOM.* Official Journal of the European Communities L 180, 22-27, 1997.
- Mou97 Mountford, PJ; *Risk assessment of the nuclear medicine patient.* Br J Radiol 70 (1997), 671-684.
- NRP98 National Radiological Protection Board. *In utero advice document.*
- PAD84 *Council directive 84/466/EURATOM of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment.* Official Journal of the European Communities L 265, 1-3, 1984.
- Tho98 Thomson WH; *Private communication*, 1998
- UNS86 United Nations. *Ionising radiation: Genetic and Somatic Effects of Ionizing Radiation.* United Nations Scientific Committee on the Effects of Atomic Radiation, 1986. Report to the General Assembly, with annexes. United Nations sales publication E.86.IX.9. United Nations, New York, 1986.
- UNS93 United Nations. *Sources and Effects of Ionizing Radiation.* United Nations Scientific Committee on the Effects of Atomic Radiation, 1993. Report to the General Assembly, with annexes. United Nations sales publication E.94.IX.2. United Nations, New York, 1993.

ABSTRACT

The Medical Exposure Directive (97/43/EURATOM) requires special attention for the protection of offspring of pregnant and breastfeeding patients exposed to ionising radiation for medical purposes. The prescriber of the exposure and the practitioner are obliged to ask the woman in childbearing age if she might be pregnant or missed a period. This guide includes a schematic overview of the procedure to be followed in such situation. It also gives information on the risk of exposure of unborn children and infants and also provides ways to avoid or to minimise possible detriment to them. Three practical annexes allow the practitioner to better respond to frequent questions from pregnant and breastfeeding women based on knowledge about dosimetric quantities and typical doses to the unborn child from common examinations and treatments. A number of reference documents are included.