Diagnostic Medical Exposures

Advice on Exposure to Ionising Radiation during Pregnancy

JOINT GUIDANCE FROM

National Radiological Protection Board

College of Radiographers

Royal College of Radiologists

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Preface

The main objective of NRPB advice concerning *in utero* exposures to ionising radiations is

> 'to prevent unnecessary exposure of the fetus when medical diagnostic procedures involving ionising radiation are indicated during pregnancy'

In addition, advice is meant to help to avoid unnecessary concern or action if an exposure does occur.

NRPB issued ASP8 (Exposure to ionising radiation of pregnant women: advice on the diagnostic exposure of women who are, or who may be, pregnant)[1] in 1985. This advice suggested that there would be no risks to the conceptus following irradiation during the first 10 days of the menstrual cycle and that subsequent risks in the remainder of the first 4-week period would be likely to be so small that no special limitation on exposure was required – sometimes known as 'the 28-day rule'. In 1993, NRPB published further advice to replace ASP8 in the *Documents of the NRPB* series, in Volume 4, No. 4 – henceforth referred to as *Doc NRPB* 4(4)[2] – which drew upon data published since 1985.

The more recent data suggest that risks in the interval between 10 days and the date at which the next menstrual period is due, although still small for most diagnostic procedures, may be significant for higher dose procedures[3]. Consequently, it is considered there is a need to operate a modified policy for such higher dose procedures.

This pocket publication has been produced to present in a concise and user-friendly format the basis of the most recent NRPB advice and to provide a guide for the implementation of that advice in the everyday practice of diagnostic radiology. The opportunity has also been taken to provide the most up to date data on doses in the UK[4]. This publication is split into three parts: an introduction to the terms used in the document, a practical guide to implementation of the advice, and the scientific background to the advice.

Introduction

Scope

The advice covers the risks to the developing embryo and fetus of death, malformation, mental impairment, cancer (solid tumours and leukaemias) and heritable damage from irradiation before the mother could be aware of a pregnancy – an *unknown pregnancy**. It also considers two other issues of particular relevance: the possible risks from irradiation of the early conceptus (3–4 weeks gestational age) and from preconception gonadal irradiation. These recommendations should be read along with:

- the recommendations of a joint working party of the Royal College of Radiologists (RCR) and NRPB on patient dose reduction[5],
- the NRPB suggested national reference dose levels[6],
- the joint Institute of Physical Sciences in Medicine (now the Institute of Physics and Engineering in Medicine), the College of Radiographers (CoR) and NRPB protocol for patient dose measurements in diagnostic radiology[7],
- the advice of the Administration of Radioactive Substances Advisory Committee (ARSAC)[8].

This document also replaces the joint RCR and CoR advice of October 1986[9]. As with any use of radiation in medicine, compliance with statutory legislation is mandatory, ie with the Ionising Radiations Regulations 1985 and the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988.

Assessment of risk

Risk is assessed on the basis of dose. The doses quoted in this document are taken from the most recent UK surveys of doses for many common examinations and hence represent the latest available data on UK practice[4,8]; consequently, some of the doses in this document will not be the same as those in *Doc NRPB* 4(4)[2]. However, the information may not reflect doses in all departments for these examinations and, of course, does not provide data for all possible examinations.

It is therefore essential that all staff institute the guidance in this document on the basis of the mean doses delivered to the fetus in their departments for both radiology and nuclear medicine procedures (for this purpose, fetal dose should be assumed to be equal to uterine dose).

* For the purposes of this document, an unknown pregnancy is defined as one in which the mother is not aware of her pregnancy because a menstrual period has not been missed.

Practical Implementation

Diagnostic examination of females of reproductive age

Whenever possible, alternative investigation techniques, not involving ionising radiations, should have been considered before a decision is taken to use ionising radiations in female patients of reproductive age.

At diagnostic dose levels, the only adverse effect of radiation on the conceptus which is likely to pose a significant risk is that of cancer induction. None of the other potential hazards (death, malformation, growth retardation, severe mental retardation and heritable effects) presents a significant problem at the low exposures used in diagnostic procedures.

Implementation of guidance

When a female of reproductive age presents for an examination in which the primary beam irradiates the pelvic area, or for a procedure involving radioactive isotopes, she should be asked whether she is or might be pregnant. If the patient cannot exclude the possibility of pregnancy, she should be asked whether her menstrual period is overdue. In line with accepted convention, this action should be recorded in an appropriate place, as required by local rules.

Particular problems may be experienced in obtaining this information from females under the age of 16 years; in such cases staff should refer to the guidance given by the College of Radiographers in *The implications for radiographers of the Children Act*[10].

Depending on the answers, patients can then be assigned to one of the following groups.

No possibility of pregnancy

Proceed with the examination.

Patient definitely, or probably, pregnant

If pregnancy is established, or likely, review the justification for the proposed examination, and decide on whether to defer the investigation until after delivery, bearing in mind that a procedure of clinical benefit to the mother may also be of indirect benefit to her unborn child and that delaying an essential procedure until later in pregnancy may present a greater risk to the fetus. If a procedure is undertaken, the fetal dose should be kept to the minimum consistent with the diagnostic purpose(s).

Low dose procedure, pregnancy cannot be excluded

Proceed with the examination, provided that the period is *not* overdue. If the period is overdue, follow the advice in the previous paragraph.

High dose procedures

(defined as examinations resulting in fetal doses of some tens of milligray)

In most departments, the only *routine* examinations in this category will probably be abdominal and pelvic computed tomography. However, any procedure that delivers doses to the fetus of some tens of milligray (eg some barium studies) may carry significant risks – this reinforces the importance of knowing the magnitude of doses in individual departments. The new evidence suggests that these may carry a small risk of cancer induction for the unknown fetus. One of two courses could be adopted:

- apply the rule that in females of childbearing age these examinations are booked for the first 10 days of the menstrual cycle, when conception is unlikely to have occurred (formerly known as the '10-day rule'),
- re-book patients who attend for such examinations and are identified to be in the second half of their cycle, of childbearing age and in whom pregnancy cannot be excluded. *The number of such patients is likely to be small.*

It should be emphasised that although there *may* be a small risk to the unknown fetus, this risk will increase in the months following the first missed period, and high dose examinations should only be re-booked if they can safely be postponed until after delivery, should the patient prove to be pregnant.

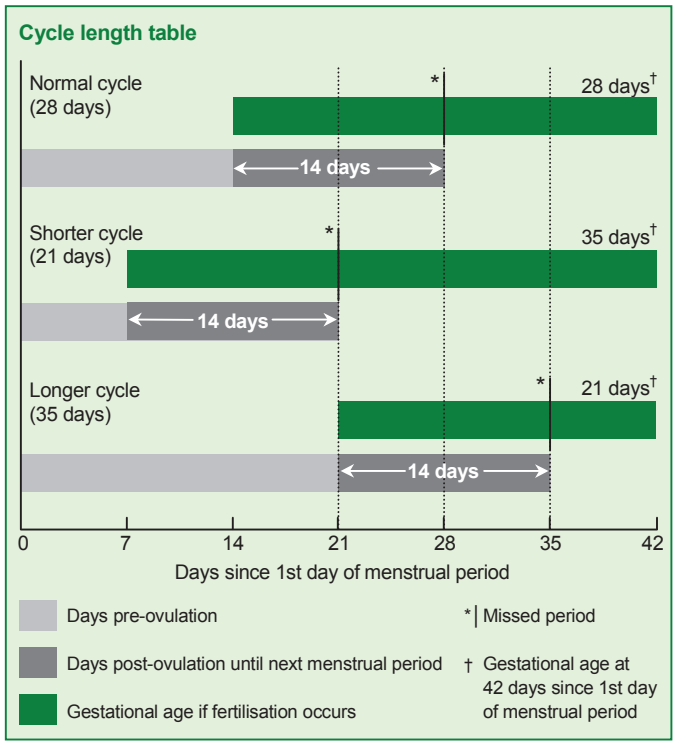
Subsequently, if it becomes obvious that a fetus has been inadvertently exposed, despite the above guidance, the small risk to the fetus of the exposure does not justify the greater risks of invasive fetal diagnostic procedures to the fetus and mother (particularly as they are unlikely to pick up any induced effect) nor does the risk justify those of a termination of the pregnancy to the mother.

Scientific Basis for Advice

The following text explains the biological and epidemiological basis for the advice, along with specific advice for each type of health effect [more detailed information is given in *Doc NRPB* 4(4)[2]].

Timescales – menstrual cycle and gestational age

Confusion can arise in the relationship of gestational age (to which the effects of exposure are related) to the number of days since the beginning of the menstrual cycle (on which decision-making for exposure depends). Such problems are compounded when the menstrual cycle varies from 28 days; particularly in those females with shorter cycles who have the potential for fertilisation soon after the menstrual period. In this section, it will be assumed that conception occurs on the 14th day of a 28-day cycle, with gestational age being counted from this day. Assumed gestational age will be used in the text with days since the start of the last menstrual cycle *in italics*.



For shorter cycles, the number of days by which the cycle is shorter than 28 is the number of days by which the presumed gestational age needs to be *increased*.

For longer cycles, the number of days longer is equal to the number by which gestational age must be *decreased*.

However, the greater gestational age for shorter cycles does not significantly affect the implementation of this guidance. The effects of cycle length are shown in the figure.

Health effects to embryo or fetus

Deterministic effects of radiations

Deterministic effects of ionisingradiation are those which result from damage to a number of cells in tissues, for which there is a dose threshold for an observed clinical effect (but not of course for cell damage). The principal deterministic effects of external radiation on the developing embryo and fetus are death, malformation, growth retardation and abnormal brain development leading to severe mental retardation (SMR).

Table 1 provides a summary of the acute radiation dose thresholds below which it is judged that these effects will not occur in the human embryo and fetus. Data on Japanese atomic bomb survivors exposed *in utero* at gestational ages of 8–15 weeks – *70–119 days (10–17 weeks)*

TABLE 1 Estimates of threshold doses for deterministic effects following fetal irradiation with x-rays or gamma rays

	MINIMAL DOSE (mGy) FOR:		
AGE (WEEKS)	DEATH	GROSS MALFORMATIONS	MENTAL RETARDATION (JAPANESE DATA)
0–1	No threshold at day 1 100 thereafter	No threshold at day 1?	–
2–5	250–500	200	No effects observed to about 8 weeks
5–7	500	500	
7–21	>500	Very few observed	Weeks 8–15: no threshold? Weeks 16–25: threshold dose Weeks 25–term: no effects observed
To term	>1000	Very few observed	

Notes

Based on data from human epidemiological studies and animal experiments.

? Indicates considerable uncertainty.

last menstrual cycle – suggest the possibility of a non-threshold type response for the induction of SMR, interpreted as representing a loss of 30 IQ points per gray of x-rays or gamma rays.

Table 2 provides mean and maximum fetal doses estimated from the most recent surveys of diagnostic radiology practice. Doses for the same type of procedure vary widely between patients and hospitals. Based on mean doses the common procedures giving the greatest fetal exposure are barium enemas (6.8 mGy), pelvic and abdominal CT (25 and 8 mGy, respectively) and nuclear medicine procedures. For all other procedures listed in the table, apart from three fairly uncommon nuclear medicine procedures, the mean doses to the fetus are substantially lower. Fetal dosimetry from internal emitters is more complex than that for external sources, and the figures shown in the table for nuclear medicine procedures are based on estimates of the dose to the uterus from surrounding maternal organs, with no allowance for placental transfer of radionuclides to the fetus.

It is important whenever possible to estimate the typical fetal dose delivered rather than use a published mean fetal dose for a procedure. The actual dose given in a procedure may be greater than the mean by up to a factor of ten, depending on the patient size and technique. Only in the case of x-ray examinations of areas of the body remote from the lower abdomen, can it be assumed that the likely maximum dose from the procedure would be less than a few milligray (Table 2). In the case of nuclear medicine procedures, although differences also exist between the mean and maximum doses, fewer common procedures are likely to involve fetal doses of more than a few milligray.

In practical terms, the threshold doses for the induction of death and gross malformation (Table 1) following fetal irradiation all lie well above the mean doses of Table 2 and are only approached by the maximum dose (about 80 mGy) noted in the case of pelvic CT procedures. For the induction of mental retardation in offspring, even an assumed no-threshold response in the 8–15 week period of gestation – *70–119 days (10–17 weeks) last menstrual cycle* – would not have important implications, since for a maximum fetal dose of about 100 mGy the predicted three point IQ loss would be undetectable on an individual basis. In general, therefore, fetal doses are unlikely to cause deterministic effects in an individual pregnancy.

Advice

Radiation doses resulting from most diagnostic procedures in an individual pregnancy present no substantial risk of causing fetal death or malformation or impairment of mental development.

TABLE 2 Fetal doses following common diagnostic procedures; taken from UK surveys of diagnostic radiology and nuclear medicine[4,8]

	FETAL DOSE (mGy)	
EXAMINATION/PROCEDURE	**MEAN**	**MAXIMUM**
Conventional x-ray		
Abdomen	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
Computed tomography		
Abdomen	8.0	49
Chest	0.06	0.96
Head	<0.005	<0.005
Lumbar spine	2.4	8.6
Pelvis	25	79
Pelvimetry	0.2	0.4
Nuclear medicine		
^{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}Seleno-cholesterol	–	14.0
^{67}Ga tumours and abscesses	–	12.0
^{131}I thyroid metastases	–	22.0

Note Fetal doses cited are those assumed from estimates of uterine dose.

Stochastic effects of radiations

Stochastic effects of radiation are those which have their origins in the probability of induction of damage to single cells in tissues, for which there is believed to be no dose threshold. Such effects are the induction of cancer and hereditary disease. However, consideration of the risks of such effects must be judged relative to their natural incidence.

Cancer induction

After a gestational age of 3–4 weeks – *35–42 days (5–6 weeks) last menstrual period* – NRPB considers that the number of excess cancer cases (leukaemias and solid tumours) up to age 15 years following irradiation *in utero* should be taken as 1 in 17 000 per mGy ($6\,10^{-5}$ mGy^{-1}) for x-rays and gamma rays. Since approximately 50% of all childhood cancers are fatal, the excess risk of cancer death is taken as 1 in 33 000 per mGy ($3\,10^{-5}$ mGy^{-1}). These data are summarised in Table 3.

TABLE 3 Risk of cancer up to age 15 years per mGy following fetal exposure for x-ray and gamma rays

CANCER TYPE	FATAL	NON-FATAL	TOTAL
Leukaemia	1 in 80 000	1 in 80 000	1 in 40 000
Others	1 in 57 000	1 in 57 000	1 in 29 000
Total	1 in 33 000	1 in 33 000	1 in 17 000

Note Risks are rounded to the nearest 1000.

For UK national rates, the baseline risk of cancer in the first 15 years of life is about 1 in 650 ($1.5\,10^{-3}$). About half of these cancers are fatal. However, since this natural risk will rise with age, reaching 20%–25% over a lifetime, such risk comparison is deemed inappropriate for judging the acceptability, or otherwise, of lifetime risks. Nevertheless, it may be noted that, even if the lifetime risk of fatal cancer induced in the fetus is as much as four times greater than that to age 15 years, judgements based on comparing induced risks with natural risks to 15 years will be conservative; while a fetal dose of about 25 mGy will double the natural risk of fatal cancer to age 15 years, it will only result in an excess lifetime fatal cancer risk of less than 0.5%.

Table 4 illustrates the frequency of excess fatal cancer to age 15 years resulting from typical fetal medical exposures; these data and the derived risk of 1 in 33 000 per mGy ($3.0\,10^{-5}$ mGy^{-1}) are chosen for risk estimation because of the relative lack of epidemiological evidence for cancer incidence and for lifetime cancer risk following

fetal irradiation. These fetal risks are given as the probability of excess disease per procedure on the basis of the mean doses of Table 2 and range from 1 in 30 000 per procedure ($3.3\ 10^{-5}$) for pelvic x-rays up to 1 in 1300 per procedure ($7.5\ 10^{-4}$) for pelvic CT. The majority of radiological and nuclear medicine procedures carry risks of less than around 1 in 5000, but the risk of fatal childhood cancer of around 1 in 1300 indicated for pelvic CT procedures (with a mean fetal dose of 25 mGy) should be regarded as significant since, although small, it is similar in magnitude to the natural cumulative risk of fatal childhood cancer in England and Wales to age 15 years, about 1 in 1300 ($7.7\ 10^{-4}$). However, any procedure that delivers doses to the fetus of some tens of milligray (some barium studies) may carry such significant risks – this reinforces the importance of knowing the magnitude of doses in individual departments. In the case of unknown pregnancy where gestational age may be up to 3–4 weeks – *35–42 days (5–6 weeks) last menstrual cycle* – the cancer risk, although not zero, is judged to be lower than in the subsequent phases of fetal growth.

TABLE 4 Risk of hereditary disease and cancer following typical fetal diagnostic medical exposure to radiation

EXAMINATION/ PROCEDURE	MEAN FETAL DOSE[b] (mGy)	PROBABILITY OF DISEASE PER MEAN EXPOSURE[a]	
		HEREDITARY DISEASE[c]	FATAL CANCER TO AGE 15 YEARS[d]
Conventional x-ray			
Abdomen	1.4	1 in 30 000	1 in 24 000
Barium enema	6.8	1 in 6 000	1 in 5 000
Barium meal	1.1	1 in 38 000	1 in 30 000
Intravenous urography	1.7	1 in 24 000	1 in 20 000
Lumbar spine	1.7	1 in 24 000	1 in 20 000
Pelvis	1.1	1 in 38 000	1 in 30 000
Computed tomography			
Abdomen	8.0	1 in 5 000	1 in 4 000
Lumbar spine	2.4	1 in 24 000	1 in 14 000
Pelvis	25	1 in 1 700	1 in 1 300
Nuclear medicine			
^{99m}Tc bone scan	3.3	1 in 13 000	1 in 10 000

Notes

(a) Risks are rounded to the nearest 1000 except for doses > 10 mGy which are rounded to the nearest 100.

(b) Data of Table 2.

(c) Using a risk coefficient of 1 in 42 000 per mGy ($2.4\ 10^{-5}$ mGy^{-1}).

(d) Using a risk coefficient of 1 in 33 000 per mGy ($3.0\ 10^{-5}$ mGy^{-1}).

Advice

For the majority of diagnostic procedures, giving fetal doses up to a few milligray, the associated risks in childhood are judged to be acceptable when compared with the natural risk. Consequently, exposure of the fetus in these circumstances is not considered to justify the greater risks of invasive fetal diagnostic procedures to both the fetus and mother (particularly as they are unlikely to pick up any induced effect) nor to justify the risks of a termination of the pregnancy to the mother.

Known pregnancy

Following exposure of pregnant women to a higher dose procedure (exposing the fetus to some tens of milligray, eg pelvic CT or some barium studies) there may be more than a doubling of the natural cancer risk in the unborn child. This level of excess risk is about 1 in 1000 for the individual fetus and is unlikely to be a reason for termination of the pregnancy or for the use of invasive fetal diagnostic procedures.

Unknown pregnancy

For most diagnostic radiation exposures of the unknown conceptus the risks of cancer will be small. Those few procedures yielding doses of some tens of milligray should be avoided, if possible, even in unknown pregnancy. One way of avoiding such risks would be to restrict the use of high dose diagnostic procedures to the early part of the menstrual cycle when pregnancy is unlikely, ie a limited return to the '10-day rule'. Any procedure that delivers doses to the fetus of some tens of milligray (eg some barium studies, pelvic and abdominal CT and more complex radiological procedures) may carry significant risks – this reinforces the importance of knowing the magnitude of doses in individual departments. Alternatively, such procedures could be routinely booked, accepting that re-booking may be necessary for those small number of patients where pregnancy cannot be excluded. This assumes that the examination can be safely postponed until after delivery, if the patient proves to be pregnant. In adopting this strategy, it should be remembered that delaying an essential procedure until later in pregnancy may present a greater risk to the fetus than it would during the period of unknown pregnancy.

Heritable effects

The risk of heritable effects from fetal irradiation is judged to be the same as that applying after birth, ie 1 in 42 000 per mGy ($2.4\ 10^{-5}$ mGy^{-1}) for x-rays and gamma rays.

The natural frequency of heritable disease manifesting at birth in human populations has been estimated to be in the range 1%–3%, rising perhaps to 5%–6%, if minor and somewhat uncertain congenital abnormalities ascertained in some studies are included. Thus, the increased heritable risk of about 1 in 1000 (10^{-3}) for the offspring of an individual fetus associated with high dose diagnostic procedures is small compared with the natural risk of heritable disease. It should also be noted that the heritable risk coefficient of 1 in 42 000 per mGy ($2.4\ 10^{-5}$ mGy^{-1}) used in these calculations may tend to overestimate the frequency of induced heritable disease and that the risk of heritable effects encompasses a diversity of disorders of widely differing severity; therefore, this risk coefficient cannot be directly compared with that applying in the case of fatal cancer.

Table 4 illustrates the risk of new germ line mutations underlying heritable disease resulting from typical fetal diagnostic medical exposures; these are given as the probability of induced hereditary disease per procedure on the basis of the mean doses of Table 2. The calculated risks range from about 1 in 38 000 per procedure ($2.6\ 10^{-5}$) for pelvic x-ray exposures up to about 1 in 1700 per procedure ($6\ 10^{-4}$) for pelvic CT. It may be seen that the majority of procedures carry risks of less than 1 in 10 000 (10^{-4}); for a few procedures these risks could rise to around 1 in 1000 (10^{-3}).

Advice

For radiation-induced hereditary disease expressing itself in the descendants of the unborn child, the risk for any individual pregnancy following fetal irradiation from medical diagnostic procedures is judged to be small relative to the natural risk of heritable disease; thus, it does not justify the greater risks of invasive fetal diagnostic procedures to the fetus and mother (particularly as they are unlikely to pick up any induced effect) nor does it justify those of a termination of the pregnancy to the mother.

Preconception gonadal exposure

Heritable effects

When considering possible, gonadal exposure of the patient, dose minimisation through correct alignment, collimation and the use of gonadal shields whenever practical will minimise possible heritable

effects. This advice applies to both female and male patients before and within the reproductive period of their lives. The risk of new mutations expressing as heritable disease in the descendants of patients is judged to be small compared with the risk of those arising naturally.

Cancer in offspring

The special issue of cancer risk to offspring following parental gonadal irradiation prior to conception is not judged to provide grounds for restriction on post-exposure reproduction in patients or to provide any reason for termination of resulting pregnancies or employment of invasive fetal diagnostic procedures. There are no human data to suggest preconception effects of radiation in men or women. Restriction in the use of beneficial medical diagnostic procedures, on the basis of such possible risks from preconception exposures, is considered to be inappropriate.

Advice

The heritable and cancer risks to subsequent offspring following gonadal exposure of putative parents are small compared with natural risks. Such exposures do not provide justification for restricting post-exposure reproduction or termination of a pregnancy nor do they justify the employment of invasive fetal diagnostic procedures. Nevertheless, gonadal dose minimisation is recommended as a matter of simple prudence.

References

1 NRPB. Exposure to ionising radiation of pregnant women: advice on the diagnostic exposure of women who are, or may be, pregnant. Chilton, ASP8 (1985).

2 NRPB. Statement by NRPB. Diagnostic medical exposures: advice on exposure to ionising radiation during pregnancy. *Doc NRPB,* 4, No. 4, 1–3 (1993).

3 NRPB. Diagnostic medical exposures: exposure to ionising radiation of pregnant women. *Doc. NRPB,* 4, No. 4, 5–14 (1993).

4 Hart, D, *et al.* Doses to patients from medical x-ray examinations in the UK – 1995 review. Chilton, NRPB-R289 (1996).

5 NRPB/RCR. Patient dose reduction in diagnostic radiology. *Doc NRPB,* 1, No. 3, 1–46 (1990).

6 NRPB. Medical exposure: guidance on the 1990 recommendations of ICRP. *Doc NRPB,* 4, No. 2, 43–74 (1993).

7 Dosimetry Working Party of the Institute of Physical Sciences in Medicine. National protocol for patient dose measurements in diagnostic radiology. Chilton, NRPB (1992).

8 ARSAC. Notes for guidance on the administration of radioactive substances to persons for purpose of diagnosis, treatment or research. London, Administration of Radioactive Substances Advisory Committee (1993).

9 RCR/CoR. Guidelines for implementation of ASP8. Exposure to ionising radiation of pregnant women: advice on the diagnostic exposure of women who are, or who may be, pregnant. London, Royal College of Radiologists and College of Radiographers (1986).

10 CoR. The implications for radiographers of the Children Act. London, College of Radiographers (1995).

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