Pregnancy and Work in Diagnostic Imaging Departments

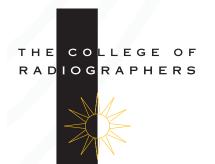
2nd Edition

Prepared by

D.H. Temperton

Published by the British Institute of Radiology in consultation with the College of Radiographers and The Royal College of Radiologists







© The British Institute of Radiology 2009

First Edition 1992

All rights reserved.

British Library Cataloguing in Publication Data
A catalogue record for this book is available from the British Library

ISBN-13 978-0-905749-67-9 Paperback ISBN-10 0-905749-67-7 Paperback

Legal Notice

All opinions expressed in the publication are those of the respective authors and not the publisher. The publisher has taken the utmost care to ensure that the information and data contained in the publication are as accurate as possible at the time of going to press. Nevertheless, the publisher cannot accept any responsibility for errors, omissions or misrepresentations howsoever caused. All liability for loss, disappointment or damage caused by reliance on the information contained in the publication or the negligence of the publisher is hereby excluded.

Published by the British Institute of Radiology, 36 Portland Place, London, W1B 1AT, UK E-mail: publications@bir.org.uk

Website: www.bir.org.uk

Typeset by the British Institute of Radiology.

Pregnancy and Work in Diagnostic Imaging Departments

2nd Edition

Prepared by D.H. Temperton

Published by the British Institute of Radiology

Published in consultation with the College of Radiographers and The Royal College of Radiologists

on	itents	Page
1.	Introduction	1
2.	Summary	1
3.	Legal requirements, dose limits and constraints	1
	3.1 Ionising radiation	1
	3.2 Non-ionising radiation	2
4.	Natural ionising radiation exposure	3
5 .	Occupational exposure	3
6.	Health effects and safety concerns for the embryo and fetus	4
	6.1 Ionising radiation	4
	6.1.1 Cancer induction	4
	6.1.2 Tissue reactions (deterministic effects)	4
	6.1.3 Heritable effects	4
	6.1.4 Ionising radiation effects summary	4
	6.2 Magnetic resonance imaging	5
	6.2.1 Static magnetic fields.	6
	6.2.2 Time-varying magnetic field gradients.	6
	6.2.3 Radiofrequency magnetic fields.	6
	6.2 4 Acoustic noise	6
	6.2.5 MRI summary	6
	6.3 Ultrasound	6
7.	Recommendations for working practices	7
	7.1 Ionising radiation	7
	7.1.1 X-ray	7
	7.1.2 Radionuclide imaging including PET	7
	7.2 Non-ionising imaging modalities	8
	7.2.1 Ultrasound	8
	7.2.2 MRI	8
8.	Conclusions	9
9.	Acknowledgements	9
10.	References	10

1. Introduction

This publication was first produced in 1992 by a working party established by The Royal College of Radiologists (RCR) and the British Institute of Radiology (BIR). Since then regulations, imaging techniques and working practices have changed. The publication has therefore been reviewed by representatives of BIR and is now republished by the BIR after consultation with both the RCR and the College of Radiographers (CoR). Although the document concentrates on the risk from ionising radiation and magnetic resonance imaging (MRI), hazards associated with ultrasound are also briefly discussed.

2. Summary

The Ionising Radiations Regulations 1999¹ require the employer to ensure that, once the employee has notified them that she is pregnant, the equivalent dose to the fetus is unlikely to exceed 1 millisievert (mSv) during the remainder of the pregnancy. At this level of exposure there is no evidence to show that there is any significant risk of radiation effects to the fetus.

Routine monitoring of staff working within imaging departments, including nuclear medicine, show that 98% of staff do not exceed the public ionising radiation dose limit of 1 mSv per year².

Strict adherence to proper working practices incorporated into local rules for all staff should ensure that all doses are as low as reasonably practicable (ALARP). Certain categories of staff, particularly those involved in interventional X-ray work, cardiac catheterisation laboratories and nuclear medicine procedures, including positron emission tomography (PET), may need to alter their working practice in order to achieve the dose constraint of 1 mSv. The employer must carry out risk assessments that consider the potential exposure of the fetus and highlight the need for specific restrictions in working practice.

Similarly, in relation to the use of magnetic resonance imaging equipment in clinical use, the Medicines and Healthcare products Regulatory Agency (MHRA)'s Safety guidelines recommend that each site should undertake a risk assessment analysing staff movement and location in relation to the levels of the magnetic fields and the total length of time that they will be exposed³. As a precaution, pregnant staff working in magnetic resonance imaging (MRI) are advised not to remain in the scan room whilst scanning is underway because of concerns regarding acoustic noise and associated risks to the fetus. In general terms, staff can continue to work in the MR environment and can therefore continue with activities such as positioning patients, scanning, archiving and injecting contrast material, although many staff members prefer not to work in close proximity to the magnet particularly during the first trimester. Individual risk assessments are important to provide a uniformity of approach within each site.

Pregnant staff working with diagnostic ultrasound do not need to alter their working practice.

3. Legal requirements, dose limits and constraints

3.1 Ionising radiation

Statutory dose limits are incorporated into the Ionising Radiations Regulations (IRR) 1999¹. Relevant values are shown in Table 1.

The dose limit for a woman of reproductive capacity is normally irrelevant in healthcare under normal circumstances since the workload is generally spread evenly over the calendar year. These dose limits are not acceptable doses and the employer has a duty to ensure doses are as low as reasonably practicable (IRR, Reg 8). An upper limit of individual dose (or dose constraint) is used at the design or planning stage of radiation facilities to help restrict exposure. An effective dose constraint of as low as 0.3 mSv per year is often used.

In addition, the employer must undertake a risk assessment before work commences so they can decide the measures necessary to restrict doses (IRR, Reg 7). It is also a statutory requirement for employers to carry

out risk assessments which should take into account the risks to the health and safety of a new or expectant mother at work or to that of her baby or fetus from any type of hazard to which the employee or baby might be exposed⁴. The risk assessment for radiation exposure can be seen as one part of the general employer responsibility. Obviously factors other than radiation exposures need to be considered, particularly moving and handling issues such as the need to manoeuvre patients and wear lead aprons.

For women who are not pregnant, the same dose restrictions apply as for men. However, for a woman who is, or may be pregnant, additional controls are necessary to restrict the dose to the unborn child. Once an employee has notified an employer that she is pregnant, the employer must ensure that, by implementing any necessary controls on the working conditions, the equivalent dose to the fetus is unlikely to exceed 1 mSv during the remainder of the pregnancy. Any necessary restrictions in working practice should have been considered in the original risk assessment carried out for the facility or an additional evaluation will be necessary. The value of 1 mSv is consistent with international advice⁵. For employees who are breastfeeding, the employer also has a duty to ensure that significant ingestion or inhalation of radionuclides is prevented in order to minimise the dose to any infant who is being breastfed⁶. The obligations of the employer for various hazards including ionising radiation have been considered in the guidance produced by the Society of Radiographers⁷.

The dose constraint of 1 mSv should also consider the exposure to the offspring of female workers from intake of radionuclides by the mother, particularly those that are taken up preferentially by the tissues of the placenta

and fetus. Conversion coefficients are available that enable the offspring's dose (in Sv) to be calculated if the mother's intake of activity of a specific radionuclide, in Bq, is known⁸. Generally the coefficient (Sv/Bq) is highest for intakes at conception or early in pregnancy. This is the case for 99mTc. However fetal uptake of iodine increases rapidly about 11 weeks after conception when the thyroid becomes active. The coefficients for iodine are very much greater at the end of pregnancy. Generally the coefficients for calculating dose to offspring are less than the coefficients for calculating the effective dose to the female worker, so restrictions to limit the dose to the member of staff will restrict the dose to the offspring to a greater extent. This is not the case for uptake of iodine for which the offspring dose could be more than double the mother's dose9.

3.2 Non-ionising radiation

There are currently no regulations controlling the use of non-ionising radiations such as ultrasound or electromagnetic fields. A European Union Physical Agents Directive¹⁰ 2004/40/EC (EMF) which was to have been implemented in the UK in 2008 would have resulted in significant limitations in relation to the use of MRI. The implementation of this Directive has been delayed by four years to enable time to obtain and analyse new information in order to ensure a balance between the prevention of potential risks to the health of workers and access to the benefits available from the effective use of the medical technologies in question.

Various organisations have published guidance and recommendations on safe limits of exposure in

TABLE 1 IRR 99 dose limits ¹			
	Employees of 18 years of age or above	Trainees aged under 18 years	Others including public
Effective dose in a calendar year (mSv)	20	6	1
Woman of reproductive capacity at work: equivalent dose averaged throughout abdomen in any consecutive 3 monthly period (mSv)	13	13	n/a

relation to MRI both for patients and staff^{11,12,13}. The National Radiological Protection Board (NRPB)¹⁴ has recommended that the guidelines published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP) are adopted in the UK. Staff should not exceed a time weighted exposure from static magnetic fields of more than 0.2 tesla (T). Limits are also given for time varying magnetic fields. Specific limits for pregnant staff are not given.

Regulations exist specifying limits which apply to the noise generated by MRI scanners¹⁵. The regulations also specify levels at which certain actions are required (Table 2).

The employer must make hearing protection freely available to employees when exposures exceed the lower action level. Hearing protection must be worn if the upper level is exceeded.

4. Natural ionising radiation exposure

Annual natural background levels in the UK range from 1 mSv to 100 mSv with an average value of 2.2 mSv². The variation in background doses for the fetus is much smaller with an upper limit of less than 2.5 mSv. During pregnancy the baby would typically receive a dose of about 1 mSv¹⁶. The dose constraint required by IRR99 means that the added dose received by staff at work should be no more than this, and in practice is likely to be considerably less.

5. Occupational exposure

Ionising radiation doses to staff working in hospitals depend on the type of work being undertaken and the effectiveness of working procedures that are followed to restrict exposure to a minimum. Analysis of the effective (whole body) doses recorded for more than 10,000 workers employed in diagnostic radiology (see Table 3) demonstrates that 98.8 % received doses less than or equal to 1 mSv and 1.2 % received doses in the range >1-5 mSv². The maximum dose received was less than 10 mSv.

Staff working in nuclear medicine receive higher doses with about 15% receiving doses in the range >1-5 mSv overall. Although the maximum dose received is still less than 10 mSv, nearly 30% of radiographer and nuclear medicine technicians receive doses in the range >1-5 mSv. It is likely that pregnant staff working in nuclear medicine will have to alter their working practice.

The above national data does not specifically identify doses to staff undertaking PET or PET/CT scans. A review of doses at both static centres and mobile vans in 2007 showed that out of a total of 58 staff, 18 received doses up to an including 1 mSv, 39 received between 1 and 5 mSv and 1 person received more than 5 mSv. Nearly 70% of staff exceeded 1 mSv during the year. The mean dose was 1.9 mSv. The data includes staff only working for part of the year so the mean doses for staff working a full 12 months will be higher. It can be concluded that most pregnant staff undertaking PET scanning will have to significantly alter their working practice (see section 7.1.2).

TABLE 2 Noise action values and limits for occupational exposure ¹⁵					
	Average value, dB(A)	Peak sound pressure, dB			
Lower exposure action level	80	135			
Upper exposure action level	85	137			
Exposure limit	87	140			

6. Health effects and safety concerns for the embryo and fetus

6.1 Ionising radiation

The Health Protection Agency (previously the National Radiological Protection Board), College of Radiographers and The Royal College of Radiologists have recently updated their publication "Diagnostic Medical Exposures: Advice on Exposure to Ionising Radiation during Pregnancy" published in 1998¹⁷. The discussion given below is taken from the draft of this new publication¹⁸ which gives a concise summary of the health effects to the embryo or fetus and is consistent with more recent ICRP publications^{5,19}. The nature and severity of radiation effects after prenatal exposure depends on the age of the embryo or fetus at the time of the irradiation. It is therefore important to emphasise the difference between menstrual age (the time from the last menstrual period) and gestational age (the time from fertilisation). For photons, such as X-rays and gamma rays, and electrons, the numerical value of the absorbed dose in Gy is equal to numerical value of the equivalent dose in Sv.

6.1.1 Cancer induction

The risk of excess cancer (leukemias and solid tumours) up to the age of 15 years following irradiation *in utero* after a gestational age of 3-4 weeks (menstrual 5-6 weeks) is 8 10⁻⁵ mGy⁻¹. This is equivalent to a risk of 1 cancer per 13,000 exposed in utero to 1 mGy. This is a small risk compared with the natural cumulative risk of childhood cancer (in the first 15 years) of 2 10⁻³ or about 1 in 500.

It is likely that cancer induction risk exists from the beginning of major organogenesis to term. For gestational ages up to 3-4 weeks (menstrual age 5-6 weeks) the risk of cancer induction, although not zero, is likely to be much smaller than in the later stages of pregnancy.

6.1.2 Tissue reactions (deterministic effects)

External irradiation of the embryo or fetus with large doses can cause death, malformation and severe mental retardation. These tissue reactions (previously called deterministic effects) have a dose threshold below which the effect or reaction will not occur. This is because a sufficient number of cells in the relevant tissue need to be damaged for a clinically observable effect. At doses below the threshold for a particular effect, there is no risk of the effect occurring.

In its most recent review in 2007, the International Commission on Radiological Protection (ICRP)⁵ concluded that no tissue reactions (or deterministic effects) of practical significance are expected to occur in the embryo or fetus below doses of 100 mGy. As the fetal exposures likely to be received by female workers generally (and specifically workers in clinical imaging departments) are likely to be significantly less than 100 mGy, tissue reactions will not occur.

6.1.3 Heritable effects

This risk of heritable effects resulting from prenatal irradiation at all stages of pregnancy is taken as being the same as the risk from irradiation after birth, namely $0.5 \cdot 10^{-5} \, \text{mGy}^{-1}$ (or 1 in 200,000 per mGy)¹⁸. This risk is significantly smaller than the 2.4 10^{-5} quoted in the previous guidance¹⁷. The natural frequency of congenital defects is estimated to be in the range of 1-3% (or even higher if minor abnormalities are included). The risk of inducing heritable effects following a fetal dose of 1 mGy (1 in 200,000) is therefore very small compared with natural risk (more than 1 in 100) and over ten times smaller than the risk of inducing childhood cancer.

6.1.4 Ionising radiation effects summary

For the fetal exposures likely to be received by female workers, the most significant hazard is the induction of subsequent excess childhood cancer. However the risk

TABLE 3. Annual whole body occupational doses						
Occupational group	Number of wor	ers in dose range (mSv)		Average annual dose (mSv)		
	0-1	>1-5	>5-10			
Diagnostic radiology						
Radiographers	4581	30	1	4612	0.06	
Diagnostic radiologists	456	11	0	467	0.15	
Interventional radiologists	63	4	0	67	0.35	
Cardiologists	544	29	0	573	0.20	
Other clinicians	1178	19	0	1197	0.08	
Nurses	2120	21	0	2141	0.07	
Scientist & technicians	590	2	0	592	0.03	
Other staff	804	5	0	809	0.08	
Total	10336	121	1	10458	0.08	
Percentage	98.8	1.2	< 0.01	-	-	
Nuclear medicine	Nuclear medicine					
Pharmacists	82	13	1	96	0.42	
Radiographers & nuclear medicine technicians	181	81	0	262	0.71	
Scientists	83	5	0	88	0.25	
Clinicians	62	6	0	68	0.28	
Nurses	49	15	0	64	0.70	
Other staff	220	3	0	223	0.03	
Total	677	123	1	801	0.40	
Percentage	84.5	15.4	0.1	-	-	

(Adapted from HPA-RPD-001. Ionising Radiation Exposure of the UK population: 2005 Review.)

of excess childhood cancer following a fetal dose of about 1 mGy (approximating the dose constraint required by IRR99) is small - only about 4% of the natural risk of childhood cancer.

6.2 Magnetic resonance imaging

Detailed advice and information concerning the protection of patients and volunteers undergoing MRI procedures (as opposed to staff assisting with these procedures) has been published by the Health Protection Agency²⁰ which includes epidemiological studies on reproductive and development outcomes and the effects of acoustic noise on the fetus. The results of a postal survey which examined the reproductive health of women employed at clinical MRI facilities in the USA^{21,22} concluded that the relative risk of various reproductive outcomes (delayed conception in planned pregnancies, miscarriages, delivery before 39 weeks, low birth weight and sex ratios of babies) were all close to one and none of the differences was significantly significant.

The following summary is extracted from the 2007 MHRA Report "The safety of magnetic resonance imaging equipment in clinical use"³. During MRI imaging and spectroscopy, individuals being scanned and those in the immediate vicinity of the scanner can be simultaneously exposed to the 3 types of magnetic fields described below.

6.2.1 Static magnetic fields

The relevant potential hazards associated with strong static fields are biological effects such as the creation of electrical potentials and the resulting currents generated by body movements and the potential hazard of ferromagnetic materials being strongly attracted towards the magnet and therefore being a projectile hazard.

The National Radiological Radiological Board, NRPB¹¹, concluded that prolonged exposure of animals and cells to static fields of about 1 tesla (T) had no effect on preor post-natal development and did not result in damage to chromosomes in germ cells or in somatic cells. Thus the development of genetic (including heritable) effects is unlikely.

6.2.2 Time-varying magnetic field gradients

The main safety concerns associated with time-varying magnetic field gradients are biological effects (such as peripheral nerve and muscle stimulation) and the acoustic noise generated when the field gradients are switched on and off. Electric fields and circulating currents can be induced in a body exposed to time varying electromagnetic fields. These can then interfere with the normal function of nerve cells and muscles.

NRPB concluded in 1991 that there was some equivocal data suggesting that developing chicken embryos were sensitive to prolonged exposure to weak extra-low frequency magnetic fields¹¹. They suggested that it would be prudent to avoid exposure of pregnant women during the first trimester. However ICNIRP concluded that "There is no clear evidence that exposure to static or low frequency magnetic fields can adversely affect pregnancy outcome"¹².

6.2.3 Radiofrequency magnetic fields

The main safety concerns for patients associated with radiofrequency fields are thermal heating leading to heat stress induced burns and contact burns. Heat stress is a particular concern for pregnant patients. Both NRPB¹¹ and ICNIRP¹² have concluded that generally no adverse effects are expected for rises in body temperature less than 1 °C. However the rise in body temperature for people with less heat tolerance should be restricted to 0.5 °C. NRPB also suggested that adverse effects on embryo or fetal development will be avoided if temperatures in tissues do not exceed 38 °C.

Contact burns are the most common adverse incident associated with the use of MRI but these should not be relevant to staff, nor specifically to pregnant staff.

6.2.4 Acoustic noise

A hazard associated with the switching of the gradient fields is the production of acoustic noise. This sound, generated within the aperture, can reach hazardous levels and has resulted in temporary hearing loss to staff, carers and patients when ear protection has not been worn. Despite concerns since the early 1990s regarding possible effects of excessive noise on fetal health, reviews of the evidence are inconclusive^{23,24}.

6.2.5 MRI summary

There is currently no convincing evidence for any deleterious effects on the developing fetus from the static and time varying magnetic field encountered by workers in MR imaging environments.

6.3 Ultrasound

There is no evidence to suggest that occupational exposure to diagnostic ultrasound could cause any effects on the fetus *in utero*. There can be no significant absorption of ultrasound in the abdomen unless the transducer is deliberately coupled to the surface of the pregnant abdomen.

7. Recommendations for working practices

7.1 Ionising radiation

The first responsibility in relation to protecting the fetus rests with the pregnant member of staff. Even if she would prefer to keep her condition confidential, she needs to declare her pregnancy to her employer so that the employer can consider actions to achieve the 1 mSv dose constraint. This restriction does not mean that it is necessary for the pregnant women to stop working with radiation or radioactive materials completely. Until the employer has received written notification, they are not obliged to take any action other than those they would do for all their employees. Once notified, the employer must ensure that a risk assessment has been undertaken, review the doses that employees carrying out similar duties normally receive and, if appropriate, alter these duties to ensure that the 1 mSv dose constraint is achieved.

Some pregnant workers will naturally remain concerned even though the dose to their baby will be significantly below the dose constraint of 1 mSv. They may request to alter their duties so there will be no or reduced occupational exposure even though they realise the risks are small. Although under no legal obligation, the employer may be able to agree to this request if the department is sufficiently large and flexible to enable other employees to take over the worker's duties. Such action will avoid the potential difficulty that may arise if the employee subsequently has a baby with a congenital abnormality (which will occur in 3% of births quite naturally – see section 6.1.3). It may however mean that another member of staff could receive additional radiation exposure because of the pregnant coworker.

7.1.1 X-ray

For exposure to external radiation, a restriction of 1 mSv dose to the fetus can be taken as broadly equivalent to a dose to the surface of the abdomen of a pregnant woman of about 2 mSv in many working situations such as exposure to diagnostic X-rays²⁵. Indeed the dose recorded by a personal dosemeter worn by diagnostic radiology workers under a lead apron may overestimate the fetal

dose by a factor of 10 or more²⁶.

If the previous personal whole body dosemeter results recorded for a pregnant member of staff are such that the cumulative readings are likely be to more than 2 mSv during the declared term of the pregnancy, it is recommended that, as a precautionary measure, their duties are altered to ensure that the dose constraint of 1 mSv to the fetus is achieved.

Although the vast majority of staff working within diagnostic radiology departments should be able to continue working without exceeding the dose constraint, Table 3 showed that certain occupational groups (e.g. interventional radiologists and cardiologists) receive higher average doses and have a higher percentage of staff in the >1-5 mSv group than the majority of staff working with diagnostic X-rays. Vascular surgeons may also undertake a large interventional workload and are likely to receive higher doses. Staff in these occupational groups may have to alter their duties.

As with general ALARP principles, pregnant staff should remain behind any protective screen whenever possible. If they need to be outside the main protective screen, they should spend as little time as possible close to the X-ray tube or patient, stand well back during image acquisitions and make full use of additional screens such as lead drapes.

7.1.2 Radionuclide imaging including PET

For work with ^{99m}Tc or ¹³¹I, it has been shown that a limit of 1.3 mSv to the maternal abdomen surface will restrict the fetal dose to 1 mSv²⁷. For practical purposes and as a conservative measure it is recommended that the abdominal limit is set at 1 mSv when working with ^{99m}Tc or ¹³¹I. A 1 mSv limit should definitely be applied for staff working with higher energy radionuclides such as those used in PET imaging. Table 3 showed that 30% of radiographers and clinical technologists working in nuclear medicine receive doses in the range >1-5 mSv from external doses. This figures rises to about 70% for staff carrying out PET scanning (section 5). These staff will have to alter their working practice if they become pregnant. For example although they may continue to enter the scan room to check patients and table position,

they will typically need to stop injecting patients, escorting them to the toilet and unpacking radiopharmaceuticals. Radiopharmacists may also have to reduce their workload to achieve the dose constraint of 1 mSv.

The dose to imaging staff from a particular examination varies between departments so it is necessary for each department to individually review any controls that are required. However achieving the 1 mSv dose constraint could typically mean restricting the daily workload to less than six ^{99m}Tc studies or one ¹³¹I study for the declared term of the pregnancy of seven months²⁷. Published doses to staff assisting with PET ¹⁸FDG scans arising from unpacking the FDG, dispensing, scanning and providing patient care varies but, on average, are typically around 5 µSv per patient²⁸, which is higher than for normal nuclear medicine examinations. The exact dose will depend on local practice such as administered activity, lead glass thickness available, time spent near the patient, etc.

With good controls on contamination, it is likely that the fetal dose from internal contamination of the mother will be small compared with fetal dose from external irradiation. Airborne contamination levels resulting from ^{99m}Tc nebulisers used for nuclear medicine lung ventilation studies would normally result in maternal doses less than 0.3 mSv per year²⁹ and usually much less than this³⁰. Fetal dose will be smaller still (see section 3.1). The airborne activity measured with Technegas generators is lower than with nebulisers so the dose from inhaled activity would be even lower and is negligible compared with the dose from external radiation³¹.

However, Harding and Mountford³² advised that it is probably wise for staff who are known to be pregnant to avoid dealing with radioactive spills, using aerosols or unshielded krypton generators and imaging very ill patients.

7.2 Non-ionising imaging modalities

7.2.1 Ultrasound

Pregnant staff working with diagnostic ultrasound do not need to alter their working practice.

7.2.2 MRI

The 2007 MHRA Report³ concluded the following in relation to pregnant staff:

"Each site should undertake a risk assessment analysing staff movement and location in relation to the levels of magnetic fields and the total length of time they will be exposed."

Current guidelines for occupational exposure to all workers can also be applied to pregnant workers. Application of the time weighted occupational exposure limit of 0.2 T will ensure that pregnant staff are not exposed to fields as high as 1 T at which some effects have been seen (section 6.2.1). Commercially available clinical systems in the UK range from 0.2 T to 3 T with a few research facilities operating above 3 T. Most sites will be able to operate well within the 0.2 T constraint. However it worth emphasising that, with open magnets, there can be field strengths of 2 T outside the scanning aperture.

It is also expected that the level of time-varying electromagnetic fields and radiofrequency will be relatively low except in the immediate vicinity of the scanning aperture. Although there are hazards for the patients, it is not expected that generally these will cause a problem for staff or pregnant staff. However particular care is needed for staff involved with interventional procedures and possibly for staff having to remain very close to the scanning aperture. The magnetic fringe field plots showing at least the 0.5 and 3 mT contours around each scanner should be on display in MRI departments. These should be clearly explained to staff.

For the above reasons the MHRA recommends that

"It is advisable that pregnant staff do not remain in the scan room whilst scanning is underway because of concerns of acoustic noise and risks to the fetus".

This is consistent with advice issued by the American College of Radiology³³. They recommended that pregnant staff should not be within the MR scanner bore nor remain within the scanner room during actual data acquisition.

Staff can continue to work in the rest of the MR environment and can therefore continue with activities such as positioning patients, scanning, archiving and injecting contrast material. Entering the MR scan room in response to an emergency is also acceptable.

Hearing protection, such as earplugs, can be provided for staff to reduce noise levels by 10-30 dB. For pregnant staff, although this protection will be effective for the mother's ears it obviously won't help in reducing the noise level to the fetus. However any effects from noise on reproductive outcomes is probably indirect due to its role as a stressor to the mother so the provision of hearing protection may reduce the fetal risk²³.

The application of risk assessments should result in a practical limitation of exposure to static and time varying fields where this can be accomplished without a negative impact on patient care.

8. Conclusions

Routine monitoring of all categories of staff working with radiographic procedures including nuclear medicine show that 98% of staff receive less than the public ionising radiation dose limit of 1 mSv per year. Only a small number of pregnant staff will need to alter their duties to ensure that the dose to the fetus during the declared term of pregnancy will remain less than the legal dose constraint of 1 mSv.

However some pregnant staff may be particularly concerned about any additional dose and may request to alter their duties. Although under no legal obligation to do so, the employer may be able to agree to this request if the imaging department is sufficiently large and flexible to enable other employees to take over the worker's duties.

Pregnant staff working in magnetic resonance imaging (MRI) are advised not to remain in the scan room whilst scanning is underway because of concerns of acoustic noise and risks to the fetus. This will obviously prevent participation in interventional procedures but activities such as positioning patients, scanning, archiving and injecting contrast material can continue, provided a

suitable risk assessment is carried out. It has become common practice for many pregnant members of staff not to enter the magnet room during their first trimester. Whilst this is not based on any scientific evidence of risk or any legal obligation, employers try to consider the anxieties of such staff. By considering the risk assessment, employers can provide a suitable system of work for pregnant staff to continue working within the MR environment with minimal change to their normal practice.

It is possible that when the amended version of the European Union Physics Agents Directive 2004/40/EC (EMF) is implemented in the UK, probably sometime in 2012, there may be implications for workers and hence pregnant workers operating in the environment of clinical MR systems. Within the legal framework for the management of worker safety in MRI that will then exist, significant changes to current advice and guidance may be required including additional measures for the management of pregnant workers.

Pregnant staff working with diagnostic ultrasound do not need to alter their working practice.

9. Acknowledgements

The author would like to thank Andy Jones for his contribution to the MRI sections and Maria Murray (CoR) and Jo McHugo (RCR) for their contributions to the document as a whole. He would also like to thank Jonathan Eatough, Jerry Williams, Claire Cousins, Andy Rogers, Peter Mountford, Hazel Starritt and Steve Chandler for their helpful comments on various drafts. Thanks also to Stan Batchelor, Debbie Peet, Andy Rogers, Karen Goldstone, John Biggart and Michelle Poulson who all provided data on the whole body doses to staff working in PET centres.

10. REFERENCES

- I Ionising Radiations Regulations. (1999) SI 1999/3232. http://www.opsi.gov.uk/si/si1999/uksi_19993232 en.pdf
- 2 Health Protection Agency. (2005) Ionising Radiation Exposure of the UK Population 2005 Review. HPA-RPD-001. http://www.hpa.org.uk/ web/HPAwebFile/HPAweb_C/1194947389360
- 3 Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. DB2007(03) (2007). http://www.mhra.gov.uk/Publications/ Safetyguidance/DeviceBulletins/CON2033018
- 4 Management of Health and Safety at Work Regulations (1999) SI 1999/3242. http://www.opsi. gov.uk/si/si1999/19993242.htm
- 5 ICRP Publication 103. (2007) The 2007 Recommendations of the International Commission on Radiological Protection. Annals of the ICRP, 37, 2-4.
- 6 ICRP Publication 95. (2004) Doses to infants from ingestion of radionuclides in Mothers' Milk. Annals of ICRP, 34 (3-4).
- 7 The Society of Radiographers. (2007) Health and Safety and Pregnancy, SoR, London.
- 8 ICRP Publication 88. (2002) Doses To The Embryo And Foetus From Intakes Of Radionuclides By The Mother, Annals of ICRP, 21(1-3).
- Phipps AW et al. (2001) Doses to the embryo/ foetus and neonate from intakes of radionuclides by the mother. Part 1: Doses received in utero and from activity present at birth. Health & Safety Executive Report 397/2001 http://www.hse.gov.uk/research/crr htm/2001/crr01397.htm
- Directive 2004/40/EC of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks from physical agents (electromagnetic fields). (2004).
- National Radiological Protection Board. (1991)
 Principles for the Protection of Patients and
 Volunteers During Clinical Magnetic Resonance
 Diagnostic Procedures. Docs of NRPB 2 (1).
- 12 International Commission on Non-Ionizing Radiation. (2004) Medical Magnetic Resonance (MR) Procedures: Protection of Patients. Health Physics August 2004, 87(2), 494-522.
- 13 International Commission on Non-Ionizing

- Radiation. (1998) Guidelines for limiting exposure to time varying electric, magnetic and electromagnetic fields (up to 300 GHz). Health Physics, 74(4), 494-522.
- National Radiological Protection Board. (2004)
 Review of the Scientific Evidence for Limiting
 Exposure to Electromagnetic Fields (0–300 GHz).
 Docs of NRPB 15(3). http://www.hpa.org.uk/web/
 HPAwebFile/HPAweb_C/1194947383619
- The Control of Noise at Work Regulations. (2005) Statutory Instruments SI 2005/1643 http://www.opsi.gov.uk/si/si2005/uksi_20051643_en.pdf
- 16 Health and Safety Executive (HSE). Working safely with ionising radiation: Guidelines for expectant or breast feeding mothers. INDG334. www.hse.gov.uk/pubns/indg334.pdf
- Joint guidance from NRPB, CoR, RCR (1998).
 Diagnostic Medical Exposures. Advice on Exposure to Ionising Radiation during Pregnancy.
 http://www.hpa.org.uk/web/HPAwebfile/HPAweb_C/1194947359535
- Health Protection Agency, The Royal College of Radiologists, College of Radiographers. (2009)
 Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation. Doc HPA, RCE-9. http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1238230 848780?p=1199451989432.
- 19 ICRP Publication 90. (2003) Biological Effects after prenatal irradiation (Embryo and foetus). Annals of the ICRP, 33(1-2).
- 20 Health Protection Agency. (2008) Protection of Patients and Volunteers undergoing MRI procedures. RCE-7. http://www.hpa.org.uk/web/HPAwebFile/HPAweb C/1222673275524
- 21 Kanal E et al. (1993) Survey of reproductive health among female MR workers. Radiology, 187, 395-9.
- Evans JA et al. (1993) Infertility and pregnancy outcome among magnetic resonance workers. J Occup Medic, 35, 1191-5.
- 23 Health and Safety Executive. (1994) Noise and the Foetus: a critical review of the literature. Report 63/1994. HSE Books http://www.hse.gov.uk/research/crr_pdf/1994/crr94063.pdf
- 24 American Academy of Pediatrics. (1997) Committee on Environmental Health. Noise: a hazard for the fetus and newborn. Pediatrics,

- 100(4), 724-727.
- 25 Work with Ionising Radiation. Ionising Radiations Regulations Approved Code of Practice and Guidance. (2000) Health and Safety Executive L121
- 26 ICRP Publication 84. (2000) Pregnancy and Medical Radiation. Annals of ICRP, 30,(1).
- 27 Mountford PJ. (1997) Risk Assessment of the Nuclear Medicine Patient. Br J Radiol, 70, 671-84.
- 28 Benetar NA et al. (2000) Radiation dose rates from patients undergoing PET: implications for technologists and waiting areas. European Journal of Nuclear Medicine, 27, 538-9.
- 29 Mackie A et al. (1994) Airborne radioactive contaminations following aerosol ventilation studies. Nucl Med Commun, 15, 161-7.
- 30 Greaves CD, et al. (1995) Air contamination following aerosol ventilation in the gamma camera room. Nucl Med Commun, 16, 901-4.
- 31 Lloyd JJ et al. (1994) Contamination levels and doses to staff arising from the use of Technegas. Nucl Med Commun, 15, 435-440.
- Harding LK & Mountford PJ. (1993). Pregnant employees in a nuclear medicine department. Nucl Med Commun, 14, 345-346.
- 33 American College of Radiology. (2007) ACR Guidance Document for Safe MR Practices: 2007 AJR, 188, 1-27. http://www.acr.org/ SecondaryMainMenuCategories/quality_safety/ MRSafety/safe_mr07.aspx