

The Society & College of Radiographers

The Ionising Radiations Regulations 1999 (IRR'99)

Guidance Booklet

Foreword

Within the UK population 15% of radiation exposures from all sources are for medical purposes (Health Protection Agency (HPA), 2008). Over a ten-year period (1991 – 2001) the use of computed tomography had doubled, accounting for 40% of the total dose to the population from medical x-rays and interestingly the use of conventional radiographic and fluoroscopic examinations had halved to 44% (Hart & Wall, 2002). Interventional and angiographic procedures together contribute to the remaining 16% (http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733842374).

Radiographic staff play a pivotal and essential role in the protection of service users, staff and members of the public from the perceived risks of ionising and non-ionising radiations and it is imperative that radiation protection practice is included in an individual's continuous professional development. The Society and College of Radiographers (SCoR), with the aid of representatives from the profession, produced this guidance booklet pertaining to the Ionising Radiations Regulations 1999 (IRR'99). Radiation protection principles and UK legislation is the responsibility of all professionals working with radiation and this booklet provides information and policy guidance from SCoR which should be of use to all radiographers, radiography students and radiography assistant practitioners (APs).

The guidance booklet has been produced with a “toolkit” approach having live hyperlinks to various websites giving direct access to specific legislation as well as published guidance relating to radiation protection matters from other organisations. It provides signposting to relevant legislation and, where appropriate, guidance on the implementation of that legislation. It is intended to be supportive to the radiographic profession by providing easily accessible information & knowledge and practical guidance – it is not a text book. Neither is it intended to be prescriptive or an attempt to interpret any legal requirements but rather to indicate where information relative to best practice can be sourced. Those practitioners who carry responsibilities for radiation protection matters are advised to ensure that they are also acquainted with the legalities of relevant legislation. Where appropriate, the SCoR clearly states specific guidance which should be regarded as an expression of professional opinion rather than as a definitive statement of a legal position.

Within this booklet, the term “*radiology*” is used to define practice within radiotherapy, diagnostic radiography, interventional radiology and nuclear medicine. The booklet has been designed to give an initial topic overview in a general format pertaining to radiology, followed by specific information relating to diagnostic imaging, radiotherapy, interventional radiology and nuclear medicine practice (if and when appropriate). In this way the live hyperlinks can be used to explore topics in greater depth and detail.

Although this guidance replaces previous SCoR guidance and publications it should be recognised that there are still some excellent “good practice” guides available from other professional bodies such as the “*Medical and Dental Guidance Notes*” (MDGN) Institute of Physics and Engineering in Medicine (IPEM) (2002).

Radiation regulations set out the legal capacity in which practices should be undertaken and frameworks under which individuals are required to act or carry out tasks. All healthcare professionals have a legal responsibility to act in the manner that is set out in local written procedures relating to the various regulations. However, it is imperative that they must also be aware of their professional responsibility in knowing whether that way of proceeding is an appropriate method to carry out the delivery of safe effective practice.

Where it is believed that this is not the case all healthcare professionals have a professional responsibility to raise this with their Employer.

The invaluable support and advice from the representatives of the SCoR Radiation Protection Reference Group, the Health Protection Agency (HPA) and those who responded via the peer review process is particularly appreciated. The booklet, which will be reviewed annually, will be available via the on-line document library of the SCoR website which will enable necessary updates to take place in a timely fashion. Any queries regarding this handbook should be directed in the first instance to Maria Murray (Professional Officer responsible for radiation protection) at MariaM@sor.org.

Glossary

ACoP (L121)	- Approved Code of Practice on IRR'99
AEC	- Automatic Exposure Control
ALARA	- As Low As Reasonably Achievable
ALARP	- As low As Reasonably Practicable
BIR	- British Institute of Radiology
BSI	- British Standards Institution
CTDi	- CT Dose index
CQC	- Care Quality Commission
DAP	- Dose Area Product
DLP	- Dose-length product
DH	- Department of Health
DHSSPS	-Department of Health, Social Services and Public Safety (Northern Ireland)
DRL	- Diagnostic Reference Levels
GA	- Generic authorisation
GB	- Great Britain (England, Scotland and Wales)
HCC	- Healthcare Commission
HIW	- Healthcare Inspectorate of Wales
HPA	- Health Protection Agency
HPC	- Health Professions Council
HSE	- Health and Safety Executive
HSC	- Health and Safety Commission
HSW	- Health & Safety at Work Act 1974
IPEM	- Institute of Physics and Engineering in Medicine
IR	- Ionising radiations
IRIC	- Incident Reporting & Investigation Centre
IRR	- Ionising Radiation Regulations 1999
ISO	- International Organisation for Standardisation
LREC	- Local Research Ethics Committee
MDA	- Medical Device Alert
NAW	- National Assembly Wales
NPSA	- National Patient Safety Agency
NRES	- National Research Ethics Service
NRLS	- National Reporting and Learning Service
PACS	- Picture Archiving-and Communications Systems
QA	- Quality assurance
QART	- Quality Assurance in Radiotherapy
RCR	- Royal College of Radiologists
RIS	- Radiology Information Systems
RMS	- Radiology Management System
RPA	- Radiation Protection Advisor
RPS	- Radiation Protection Supervisor
SI	- Statutory Instrument
UK	- United Kingdom of Great Britain and Northern Ireland

Contents

	<u>Pages</u>
Introduction	7 - 8
Section A Role of Radiation Protection Supervisor (RPS)	9
Section B Role of Radiation Protection Advisor (RPA)	9 - 10
Section C Local Rules	111
Section D Equipment	
i) Design / authorisation / installation	12 - 15
ii) Prior Risk Assessment	15
iii) QA	16 - 17
iv) Servicing & Maintenance	17 - 18
v) Malfunction (contingency planning)	18 - 19
vi) Personal Protective Equipment (PPE)	19 - 20
Section E Dose restriction	
i) dose limits	21
ii) designation of work areas	21
Section F Dose records	22 - 24
Section G Comforters and carers	25 - 26
Section H Pregnant Staff	27 - 28
Section I Incident Reporting	
i) IRR'99 Incidents and Inspections	29
ii) Employers Guidance	30
iii) Medicines & Healthcare Products Regulatory Agency	30
iv) Devolved Administrations	30
References	31 – 34
Appendices	35
Appendix I Typical staff induction checklist	36
Appendix II Radiation Health & Safety Checklist	37 - 38
Appendix III	
i) Example of ionising radiation risk assessment form (complete) – Diagnostic – example 1	39 - 40
ii) Example of ionising radiation risk assessment form (blank) – Diagnostic – example 2	41 - 45
iii) Example of ionising radiation risk assessment form (blank) – Generic – example 3	46 - 47
iv) Example of ionising radiation risk assessment form (complete)	48 - 49

	– Radiotherapy – example 4	
v)	Example of ionising radiation risk assessment form (complete)	50 - 52
	– Interventional Radiology – example 5	
vi)	Example of ionising radiation risk assessment form (complete)	53 - 56
	– Cardiac Catheter Lab – example 6	

Introduction

The Ionising Radiations Regulations 1999 (IRR'99) (www.opsi.gov.uk/si/si1999/19993232.htm) are aimed at the protection of the public and the health of those staff who work with ionising radiations (SI 1999 No. 3232). The Regulations, which replaced the Ionising Radiations Regulations 1995, came into force on 1 January 2000 in concordance with the Basic Safety Standards (96/29) 1996 Euratom Directive (http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9629_en.pdf)

The Approved Code of Practice (ACoP) and guidance (L121) provide detailed advice (i.e. a guidance document which has legal status) about the scope and duties of the requirements imposed by IRR'99 (HSE, 2000). It is aimed at Employers with duties under the Regulations but should also be useful to others such as Radiation Protection Advisers (RPA), Health and Safety Officers, Radiation Protection Supervisors (RPS) and safety representatives. Employees are legally obliged to comply with the Regulations and Local Rules and have a professional responsibility to raise with Employers, knowledge of procedures that are not fit for use.

SCoR Guidance

Although all parts of IRR'99 are important, there are a number of specific regulations within IRR'99 that SCoR believe are particularly important to the radiography profession:

Regulation 7 – Prior risk assessments (PRA) must be carried out prior to the undertaking of work with radioactive materials or introducing new techniques or working practices with ionising radiations. The RPS and the RPA should collaborate in undertaking the PRA and the results should be included in the Local Rules (see Appendix for sample PRA templates) - **see Sections A, B & D (ii)**

Regulation 8 – All necessary steps must be taken to restrict the exposure to ionising radiation to as low as reasonably practicable (ALARP) – the responsibility lies with the radiation Employer and relates to equipment engineering controls, design features, safety devices (e.g. personal protective equipment), warning signals and also relates to doses for comforters & carers – **see Sections D & G**. Regulation 8(5) relates to responsibilities when a staff member becomes pregnant - **see Section H**

Regulation 9 – Any personal protective equipment (PPE) provided by the Employer must comply with the Personal Protective Equipment (EC Directive) Regulations 1992 and that appropriate accommodation is provided for PPE when it is not being worn. The RPS has a responsibility to ensure that PPE is stored appropriately, that QA tests (e.g. leakage tests) are undertaken to ensure effectiveness and **Regulation 34(2)** states that Employees must make full use of PPE for the purpose for which it is provided – **see Section D (vi)**

Regulation 11 – Radiation dose limitations – **see Section E (i) & Schedule 4**

Regulation 12 - Contingency plans that are designed to secure restriction of exposure to ionising radiation and the health and safety of persons are in place and are effective. The responsibility lies with the RPS and RPA and details should be included in the Local Rules – **see Sections A, B & C**

Regulation 13 – Radiation Protection Adviser (RPA) – the radiation Employer must consult with an RPA – **see Section B**

Regulations 16 Designation & demarcation of areas as controlled or supervised areas – this is the responsibility of the RPA and details must be clearly documented in the Local Rules (an RPS duty) – **see Sections B & E (ii)**

Regulation 17 - Every radiation Employer shall set down in writing such Local Rules as are appropriate to the radiation risk and the nature of the operations undertaken in specific areas and that these are observed. Employees and others who may be affected by them must be made aware of the Local Rules. Also, the radiation Employer shall appoint one or more suitable RPSs for the purpose of securing compliance with IRR'99 and set down in the Local Rules the names of individuals so appointed <http://www.hse.gov.uk/pubns/irp6.pdf> - **see Sections A & C**

Regulation 20 – Designation of classified persons which is an RPA duty – **see Section B & F**

Regulation 21 – Dose assessment and recording that must be undertaken – the radiation Employers' responsibility but usually an RPS duty - **see Section A & F**

Regulation 25 – Mechanisms for the investigation and notification of overexposure - is a radiation Employers' responsibility to make an immediate investigation, and if required notify that overexposure to the Health & safety Executive (HSE) - **see Section I**

Regulation 31 – Duties of equipment manufacturers regarding consultation with the RPA and other Qualified Experts when designing new facilities (or undertaking refurbishment work) and making proper 'design assessments' and after completion undertaking critical examinations' – **see Section D (i) & (iv)**

Regulation 32 – Regarding equipment used for medical exposure highlighting issues surrounding the selection, installation and maintenance of equipment, equipment QA programmes, prevention of equipment failures and incident investigations – **see Sections D (i), (iii), (iv) & (v).**

Schedule 4 - Details relevant dose limitations for various classes of persons – **see Sections E, G & H**

Schedule 5 requires the radiation Employer to consult the appointed RPA on matters of radiological protection such as the designation and on-going monitoring of radiation work areas, the refurbishment and construction of radiation facilities, the prior inspection of plans, the use and maintenance of radiation safety features, and radiation safety management – **see Section B.**

Section A - Role of Radiation Protection Supervisor (RPS)

Radiation Employers will need to appoint, in writing, a sufficient number of RPS's within a clinical imaging / radiotherapy department to comply with Regulation 17 (4) of the IRR99 to exercise close supervision of radiation work on behalf of the Employer, to ensure adherence, among other areas, to the arrangements set out in the Local Rules. An RPS needs to understand the requirements of the Regulations, command sufficient authority from the people doing radiation work in order to supervise the radiation protection aspects of that work and to know what to do in an emergency. The number of RPSs required should be determined by the number of different locations, the range and complexity of radiation work undertaken, and factors such as shift work, and any planned/unplanned staff absence.

Further information may be obtained on pages 71 – 72 “*Work with Ionising Radiation. Ionising Radiations Regulations 1999 Approved Code of Practice (ACoP) and Guidance L121*,(HSE, 2000)”– stated as L121 in this handbook and available to buy via the following link: www.hse.gov.uk/radiation/ionising/exposure.htm

The Health and Safety Executive (HSE) have also produced a very useful leaflet detailing the role of the RPS which is freely available at the following link: <http://www.hse.gov.uk/pubns/>

SCoR Guidance

The Society and College of Radiographers considers that experienced radiographers are best placed to take on the role of RPS, although all radiographers have a professional responsibility to actively contribute to radiation protection. All RPSs should receive appropriate training to undertake the role and, as it is a legal position, should have details of their RPS appointment in writing from the radiation Employer. SCoR advise that there should be at least one RPS for each area/site of work and that the RPS works closely with the Radiation Protection Advisor (RPA). The RPS must be involved in the writing of Local Rules, the undertaking of prior risk assessments, local radiation safety committee and have responsibility for undertaking regular audit to ensure compliance of Local Rules. The RPS also has a wider safety role and as such must be involved in the induction of new staff – an example of an induction checklist is given in Appendix I. In addition the RPS should work closely with the Health & Safety representative within their local department and as such carry out random checks pertaining to radiation safety (see Appendix II).

Section B - Role of Radiation Protection Advisor (RPA)

Radiation Employers need to consult a suitable RPA for advice on complying with IRR'99 (Regulation 13). Schedule 5 of IRR99 (Regulation 13(1)) specifies particular matters on which radiation Employers should seek advice from a suitable RPA (Radiation Protection News, HSE, 2008). Pages 54 – 58 of L121 give further detail on the choice and appointment of a suitable RPA and the specific matters that require consultation with an RPA. Radiation Employers need to check that the RPA selected meets the criteria of competence in a statement issued by the Health and Safety Executive regarding RPAs and has the relevant experience to provide the advice - needed further information is available from <http://www.hse.gov.uk/radiation/rpnews/statementrpa.htm> .

If an individual wishes to act as a RPA they must either:

- hold a valid certificate of competence from an organisation recognised by HSE as an Assessing Body for the certification of individual RPAs;
- or hold a National or Scottish Vocational Qualification (N/SVQ) level 4 in Radiation Protection Practice issued within the last five years.

Section C - Local Rules

Regulation 17(1) of IRR99 requires the radiation Employer to be responsible to provide written Local Rules to ensure that the risk of radiation exposure in particular radiation work areas is restricted. Local Rules are normally written by the RPS with support from the RPA and should cover normal work and also details of any contingency plans in the event of a radiation accident.

Local Rules must contain the following essential content information:

- the dose investigation level specified for the purposes of regulation 8(7)
- identification or summary of any contingency arrangements indicating the reasonably foreseeable accidents to which they relate (regulation 12(2))
- name(s) of the appointed radiation protection supervisor(s) (regulation 17(4))
- the identification and description of the area covered, with details of its designation (regulation 18(1))
- an appropriate summary of the working instructions, including the written arrangements relating to non-classified persons entering or working in controlled areas (regulation 18(2))

(L121, HSE, 2000)

Local Rules may also contain a brief summary of the following information (optional content):

- management and supervision of the work
- testing and maintenance of engineering controls and design features, safety features and warning devices
- radiation and contamination monitoring
- examination and testing of radiation monitoring equipment
- personal dosimetry
- arrangements for pregnant and breast feeding staff

The radiation Employer may also wish to include the following additional information:

- details of significant findings of any risk assessments
- a programme for reviewing whether doses are being kept as low as reasonably practicable and Local Rules remain effective
- procedures for initiating investigations
- procedures for ensuring staff have received sufficient information, instruction and training
- procedures for consultation with the appointed RPA (IPEM, 2002)

Further details are available in pages 67 – 71 of L121 (HSE, 2000) or indeed on page 11 (Table 1.3) of the “*Medical and Dental Guidance Notes*”, Institute of Physics and Engineering in Medicine (IPEM), 2002

Section D - Equipment

Regulation 32(8) of the regulations defines radiation equipment as that which delivers ionising radiation with any additional equipment which directly controls the extent of the radiation exposure (e.g. intensifying screen).

SCoR Guidance

In radiology optimum radiation protection begins with the radiography or radiotherapy equipment used and should be one of the criteria raised in the subsequent procurement process. It is essential that manufacturers are asked specific questions relating to patient and staff doses at the beginning of this process so that the information can be taken into consideration in the selection process. This is especially the case when the equipment is to be utilised in children's services in order that radiation doses to children be ALARA. Furthermore, it is equally important for equipment used for interventional radiology when new detector technology and equipment functions can significantly reduce patient and staff dose. The SCoR advise that radiographers with appropriate experience are involved in the equipment procurement process.

In 2006, the Health and Safety Executive made available the third edition of PM77 'Equipment used in connection with medical exposure' (HSE, 2006)

This guidance includes advice on:

- selection, installation, maintenance, calibration and replacement of equipment
- criteria of acceptability for both new and older equipment
- quality assurance programmes, including adoption of suspension levels
- the investigation of incidents involving a malfunction or defect in radiation equipment which results in an exposure much greater than intended.

The Welsh Scientific Advisory Committee have produced a useful publication on the procurement of equipment used for medical exposure to ionising radiation (to include diagnostic x-ray, radiotherapy and nuclear medicine) Good Practice Guidelines for Tender, Supply, Installation and Handover – March 2005 this is available for download via

<http://wales.gov.uk/docrepos/40382/cmo/professionals/policy/committees/scientific/guidance/ionising?lang=en>

i) Design / authorisation / installation of equipment

Design:

Diagnostic Radiography

The following information relating to diagnostic radiography x-ray facilities is required when designing rooms for x-ray equipment:

- required thickness of walls as well as electrical + mechanical services
- use of protective screens/shielding - taking account of x-ray attenuation etc
- entrance to the x-ray room/area
- demarcation of controlled + supervised areas

- position of the control panel for the radiographer

Further information is available from the DH website:

www.dh.gov.uk/en/Managingyourorganisation/Estatesandfacilitiesmanagement/index.htm

Radiotherapy

Information about the design of a radiotherapy department may be obtained from an NHS Estates guide entitled "*Facilities for Cancer Care Centres*" (2001).

Authorisation

Regulation 5 of the IRR'99 has placed a legal duty on radiation Employers to have written permission from HSE before carrying out specified operations. The overwhelming majority of Employers should be able to meet all the conditions in the relevant generic authorisation (GA), in which case, authorisation is automatic: the Employer does not have to apply to the HSE, and no action is required by HSE. The Employer must adhere to the conditions in generic prior authorisation summaries. Prior authorisation for the use of electrical equipment intended to produce X-rays (diagnostic & therapeutic) is available at: <http://www.hse.gov.uk/radiation/ionising/authorisation.htm> and www.hse.gov.uk/radiation/ionising/certxray.htm

Regulations 5 of IRR'99 covers the following practices:

- the use of accelerators (other than electron microscopes);
- the use of x ray machines for the following specific purposes:
- industry radiography;
- the processing of products;
- research;
- x raying of patients for medical treatment.

Radiotherapy

Details about authorisation, prior to the use of accelerators (other than electron microscopes) in radiotherapy is available at: www.hse.gov.uk/radiation/ionising/certacel.htm

Installation

General

Regulation 6 of IRR'99 requires the Employer to notify the HSE of any work relating to ionising radiation at least 28 days in advance of starting any work. A change of name of the Employer or site must also be notified to HSE.

Regulation 31(2) of IRR'99 requires that the installer must ensure that a critical examination is carried out following the installation of x-ray equipment. This is different from the physical tests usually undertaken within a department by the internal medical physics staff.

The critical examination covers verification of the correct operation of all safety features and warning devices and an assessment of the adequacy of the radiation protection for staff and visitors.

SCoR Guidance

Critical examination is required for new installations, re-installations of equipment and the replacement of parts (e.g. cathode ray tubes), where installation could have implications for the radiation protection of staff and members of the public (as well as individuals undergoing medical exposures) or affect the operation of safety features / warning devices.

The critical examination must be performed, before clinical use, in conjunction with either the installer's Radiation Protection Advisor (RPA) or the RPA of the Employer who has acquired the x-ray equipment. A written report must be sent to the department to confirm satisfactory completion of this testing.

Arrangements for the critical examination should be made when drawing up contracts with the installer.

Diagnostic Radiography

Further guidance is available in the following publications:

"Report 91, Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems", Institute of Physics and Engineering in Medicine (IPEM) 2005. This report replaces IPEM Report 77 and provides essential guidance for anyone responsible for diagnostic X-ray equipment. Available at:

www.ipem.ac.uk/ipem%5Fpublic/

The Critical Examination of X-Ray Generating Equipment in Diagnostic Radiology, Report 79, written by the Critical Examination Working Party of Institute of Physics and Engineering in Medicine in 1998 is essential guidance for all involved in the critical examination of diagnostic X-ray equipment, as required by Regulation 32 (2) of the Ionising Radiations Regulations 1998

Nuclear Medicine

A consistent approach to tendering is advocated and the British Nuclear Medicine Society have further information on this including recommendations for specific local requirements. Further guidance is available at:

www.bnmsonline.co.uk/index.php?option=com_content&task=blogcategory&id=85&Itemid=108

Radiotherapy

Radiotherapy equipment should only be installed in a room designed for the purpose and should include adequate shielding. The equipment must comply with HSG226 (HSE guidance) – see www.hse.gov.uk/radiation/rpnews/medical.htm#hsg226pm77, and BSEN60601 (electrical standards in healthcare) – see www.standardsgateway.org/UK/Standards_Catalogue/Sectors/Healthcare/relevant_standards.xalter.

The IPEM Report 93 (2006) *"Guidance for Commissioning and QA of a Networked Radiotherapy Department"* is particularly informative about the "networking equipment requirements" within a radiotherapy department.

Section 7 of the *"Medical and Dental Guidance Notes"*, Institute of Physics and Engineering in Medicine (IPEM), 2002 details considerations for practices for photons, electron beams and treatment energies over 10MeV.

Adjacent areas such as roofs, basements, ducting may be considered Controlled or Supervised Areas and appropriate systems of work for these areas should be detailed in the Local Rules.

The RPA (& the RPS if appropriate) should conduct acceptance testing data which should be then used to form a reference baseline for quality control testing.

Further details can be found in the “*Report 94, Acceptance Testing and Commissioning of Linear Accelerators*” Institute of Physics and Engineering in Medicine (IPEM), 2007

ii) Prior Risk Assessment (PRA)

Regulation 7 requires Employers who introduce new systems of work or new equipment using ionising radiation to undertake and record a full prior risk assessment (PRA) prior to any new work beginning. The rationale behind any PRA is to restrict exposure to ionising radiation during routine clinical practice and in the event of accidental or unintended incidents. PRA helps to designate areas surrounding sources of ionising radiation into controlled or supervised areas. Key parts of the PRA are:

- Source of radiation
- Estimated / measured doses / dose-rates
- Control of radiation exposure (i.e engineering controls)
- Systems of work that are planned / any required training
- Personal protective equipment requirements
- Potential accident situations and contingency plans

(pp 22-23 of L121, HSE 2000)

Five examples of risk assessment forms (blank & complete) are available (with kind permission of those departments represented by the radiographers on the working party for this handbook) within Appendix I, which covers practices in diagnostic radiography, radiotherapy, interventional radiology and generic practices.

Risk assessments are undertaken to identify potential hazards to staff and patients and should be performed by the RPS in consultation with the RPA. Refer to the “*5 steps to risk assessment*”, Health & Safety Executive (HSE), Chapters 1 & 19 of “*Medical and Dental Guidance Notes*”, Institute of Physics and Engineering in Medicine (IPEM), 2002 and Report 95 “*Risk Management and its Application to Medical Device Management*” (IPEM), 2008. Pages 20 – 26 of L121 (HSE, 2000) provide further guidance and good practice.

SCoR Guidance

SCoR believes that the prior risk assessment (PRA) is the most important aspect of IRR'99 as poor PRA or failure to undertake PRA normally leads to poor compliance with other areas of the regulations. PRAs are the responsibility of the Employer and should be carried out by appropriately trained staff (e.g. the RPS or other radiographers) before the actual clinical practice takes place and must be reviewed and updated when practices change or new practices are introduced and when new equipment is installed. All PRAs should be made available to all staff in the Local Rules of clinical imaging/radiotherapy departments. PRAs should be formally reviewed annually.

iii) Quality Assurance (QA)

Diagnostic Radiography

Regulation 32 (3)-(4) of IRR'99 requires that every Employer should ensure that suitable quality assurance (QA) programmes are in place for every part of the imaging system to ensure compliance with the intended purpose. Time should be allocated to appropriately trained personnel (i.e radiographers and physicists) to ensure that QA tests are undertaken at regularly scheduled intervals.

It may be that some of the complex tests allocated are carried out periodically by the medical physics dept whilst the more routine tests are part of the daily pattern of work of radiographers.

The Employer should give special attention to equipment used for medical exposure:

- a) of children (also see <http://www.pedrad.org/associations/5364/ig/index.cfm?page=391>)
- b) Involving high doses such as interventional radiology and CT and radiotherapy

SCoR Guidance

QA testing is part of the radiographer's & APs role. It is good practice that QA testing is overseen by one dedicated member of staff to facilitate efficiency and continuity. Dedicated equipment testing QA files should be kept with each piece of equipment and should contain:-

- *An equipment list,*
- *Information regarding the frequency of tests,*
- *Descriptions of the tests to be carried out (e.g. regular testing of output, AEC, collimation, fluoroscopy etc)*
- *Results sheets and quarterly QA report forms*
- *Actions that are required if the tests are "out with agreed limits"*

It is also important that regular QA meetings are held to feedback the test results. Interpretation of the results may also be used to analyse trends in order to act in the light of any adverse findings.

Further guidance is available in the following publications:

- *Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems, Report 91, Institute of Physics and Engineering in Medicine 2005*
- *Assurance of quality in the Diagnostic X-Ray Department, second edition. British Institute of Radiology (BIR) 2001*
- *Pages 125 – 127 of L121 (HSE, 2000).*

Nuclear medicine

The IPEM Report 86 (2003), *Quality Assurance in Gamma Camera Systems*, and IPEM Report 87 (2004), *Radioactive sample counting Principles and Practice* are particularly useful reports.

Radiotherapy

A quality assurance (QA) programme should be established and a definitive calibration performed before the equipment is first clinically used following the appropriate Code of Practice for Radiotherapy Dosimetry which is produced by IPEM. All dosimetry calibrations should be fully documented and undertaken by appropriately trained personnel.

SCoR Guidance

Equipment should be recalibrated by appropriately trained personnel following any servicing, maintenance or upgrade procedures that may affect outputs. As radiotherapy equipment is reliant on computer based systems, and delivery is increasingly automated, it is important that all software warnings are recorded, acted upon and reported to the appropriate person in a timely fashion. Responsibilities for QA need to be clearly defined. Examples of equipment QA checks to be carried out are:

- *Daily equipment QA performed at run up*
- *Patient information checks prior to treatment*
- *Portal imaging taken as protocol*
- *Simulator exposures as protocol*
- *Treatment verification checks*

The multidisciplinary (SCoR, RCR, IPEM, BIR, HPA & NPSA) 2008 publication entitled "Towards Safer Radiotherapy" written to improve patient safety in radiotherapy, makes 7 recommendations with regards QA systems. These relate to quality management systems, and the reporting of radiotherapy errors and near misses. This publication is available via: <http://doc-lib.sor.org/listtitles?page=2>

iv) Servicing and Maintenance

General

Regulation 32(1) of IRR'99 outlines that it is the Employer's duty to ensure that equipment is maintained so that patient dose may be minimised whilst remaining compatible with the clinical purpose.

It is the Employer's duty to ensure that the maintenance requirements in respect of mechanical and electrical safety are also addressed. An itemised list of all work done during servicing and maintenance should be recorded by the service engineer at the end of the visit and QA testing should be carried out on the equipment before it is put back into service.

Diagnostic Radiography

Further guidance is available in the following publications

- *Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems, Report 91*, Institute of Physics and Engineering in Medicine 2005
- *Equipment Used In Connection With Medical Exposure* PM77 Guidance Notes HSE 2006. Website: www.hse.gov.uk/pubns/guidance/pm77.pdf
- Safe use of work equipment. Provision and use of work equipment regulations, 1998. Approved code of Practice and Guidance HSE 1998

Nuclear Medicine

Servicing is carried out by the supplier and the regularity of such activity is dependent upon their recommendations.

Radiotherapy

Radiotherapy departments must maintain an up to date inventory of all radiotherapy equipment - including manufacturer, model and serial numbers, year of manufacture and date of installation.

Equipment should comply with BSEN 60601 – see Appendix 13 of the “*Medical and Dental Guidance Notes*”, Institute of Physics and Engineering in Medicine (IPEM), 2002 and Regulation 12 of IRR’99.

SCoR Guidance

Records of all servicing, repairs, and fault correction should be kept in a dedicated file for that piece of equipment (with QA results). The QA tests required following a repair or maintenance check may be carried out by the service engineer or by the x-ray/radiotherapy department as part of their QA programme. Good practice would be to sign the equipment over to the engineer for the service and have it handed back with a declaration that all settings are in the same configuration and the equipment is fit for purpose after the service or repair. A procedure should also be in place to ensure it is clear when a machine is in service use and not suitable for clinical use.

v) Malfunction (Contingency Planning)

Regulation 32 (5) of IRR’99 gives the Employer the responsibility of overseeing the possibility of any malfunction and to limit any consequences of such, especially where this may lead to a radiation dose being delivered greater than intended. Limitation could take the form of failsafe interlocks to prevent exposure if necessary.

Equipment may malfunction, or not perform as intended as a result of misunderstandings between service engineers and users. This can be avoided by clear hand over procedures for equipment that has undergone maintenance.

If it is suspected that an exposure greater than intended has occurred as a result of malfunction or defect in any radiation equipment an immediate investigation must be carried out and the HSE informed (Regulation 32(6&7)).

Regulation 7 of IRR’99 provides the need for an assessment of risk of accidental radiation exposure and 7(3) identifies that if such a risk is identified then the Employer must take reasonable steps to prevent accidents, the consequences of such accidents and provide Employees with information and training to restrict their exposure. Regulation 12 (1) requires the Employer to have contingency plans in place for such risks to restrict radiation exposure and the Health and Safety of anyone affected. This is more likely to occur in Radiotherapy and Nuclear Medicine if any where at all.

SCoR Guidance

It is good practice to report an error or near miss arising from equipment malfunction not only to the manufacturer but also to the Medicines & Healthcare Products Regulatory Agency (MHRA) <http://www.medical-devices.gov.uk/> to allow a national overview of trends which can be acted upon by national alert notices.

Contingency plans should be drawn up for any potential hazards with details being included in the Local Rules and rehearsals practiced at suitable intervals. Operators should utilise the necessary fault reporting procedures within the local department.

Further guidance is available in the following publications.

- *Pages 51 – 53 of L121, (HSE, 2000).*

- *Opinion on the proposal for a council directive concerning medical device. Medical Devices Directive 93/42/EEC 1992 www.medical-devices.gov.uk/*

SCoR Guidance

Nuclear Medicine

If a camera should fail a QA test, the test should be repeated at least a further two times to confirm the malfunction or to question the initial test. Injections to patients must not take place when a malfunction is suspected. If a malfunction is confirmed, alternative arrangements need to be made for those already injected with a radionuclide to be imaged either on another camera or on a different site. This will depend on the size and capacity of the department.

Should the calibrator fail a test, all injecting on patients must stop until the equipment has been corrected and checked by a physicist.

Radiotherapy

Perhaps the most important contingency would be how to end an exposure that has failed to terminate – all operators should be aware of the location of the emergency stop button and to use it when required. A lot of newer equipment comes with inbuilt safety interlocks which automatically terminate the beam in the event of a malfunction. It is important to have a procedure in place to manage the breakdown to minimise risk of an unintended exposure.

vi) Personal Protective Equipment (PPE)

Regulation 9 (1)(2) of IRR'99 states that all personal protective equipment (PPE) should be compliant with the 1992 Regulations from the EC directive and in Regulation 9(3) it is stated that it should be maintained and stored appropriately.

Regulation 8(2) itemises that PPE should be adequate and appropriate for the task and Regulation 8(4) calls for a system of work that ensures proper use. All PPE should be stored safely when not in use to minimise the possibility of damage.

Diagnostic Radiography

Each item of protection should be labelled and dated at time of issue, regular checks should be made of the condition of all PPE and records kept of these in the radiation protection file. The best method of checking would include a regular visual survey to look for damage, and an annual screening of aprons by fluoroscopy to ascertain if any cracks or folds have appeared to allow radiation through.

Further guidance is available in the following publication.

- *Pages 43-44 of L121 (HSE, 2000).*

SCoR Guidance

Lead (Pb) aprons (of sufficient lead equivalent to absorb all radiations), lead gloves, thyroid shields and lead glasses should be available in all fluoroscopy suites and theatres. The RPS may find it useful to involve the RPA in choosing the appropriate type of PPE, and the local Health and Safety team may advise on how it suits the wearer best. It is particularly recommended that lead glasses be routinely worn by interventional radiologists and cardiologists due to the potentially high eye doses and subsequent risk of the development of cataracts. It is also recommended that lead skirts are attached to the table to reduce the dose to the legs and feet and that pull

down lead equivalent visors are used to offer additional protection for the eyes and thyroid.

Dental Radiography

Dental radiographs are the most frequently carried out radiographic examination undertaken in Great Britain (NRPB, (now HPA), 2001) and accounts for 25% of all radiological examinations.

Lead aprons do not protect against internal scattered radiation, and can on occasions actually obscure part of the image.

It has been demonstrated that the use of lead protection has minimal effect on gonadal dose, and the UK Guidance Notes for Dental Practitioners (2001) state that there is no justification for the routine use of lead aprons in dental radiography. The current view of the HPA (2008) is that lead aprons give no real radiation protection benefit to the dental patient apart from those rarely used extra oral views where the main x-ray beam passes through the body. This is due to the fact that the doses arising from scatter are so low.

Likewise, operators conducting dental radiography under properly controlled conditions as laid down in dental guidance notes again should have no need of wearing lead aprons at normal radiographic workloads. They should, however, always be used when it is necessary for another person to provide assistance by supporting a patient during radiography. Protective aprons (lead equivalent of not less than 0.25mm) should be provided for any adult who is assisting with holding a patient during the examination. Thyroid collars should only be used in cases where the thyroid is in the primary beam and following advice from an RPA.

As the dose and risk to a fetus is low, there is no contra-indication to the irradiation of women who are and may be pregnant, however, the justification of the exposure should be reviewed in line with IR (ME)R 2000 procedures, and then the examination may be deferred for emotive reasons.

If the examination is undertaken, the fetal dose must be kept as low as reasonably achievable ALARA and in those cases a lead coat should be worn, mainly for the reassurance it provides for the patient.

Further guidance is available in the following publications.

- UK Guidance Notes for Dental Practitioners in the safe use of Dental Equipment. NRPB 2001 (see http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733764370)

Radiotherapy

PPE for radiotherapy staff in the form of lead (Pb) aprons are utilised in brachytherapy suites and the previously stated guidance in diagnostic radiography should be employed.

Radiotherapy treatments are with the aim of optimising exposure to the target while minimising exposure to normal tissue. The latter is achieved through the use of lead or lead equivalent materials, such as external or internal eye, shields, gum shields, post auricular shields, nasal & gonad shielding (where appropriate). Treatment fields are kept to a minimum size with shielding used to protect areas that are not to be treated (e.g. the use of diaphragms and multi leaf collimators etc).

Section E - Dose restriction

Regulation 8 of IRR'99 requires the Employer to take all necessary steps to restrict as far as is reasonably practicable the extent to which persons are exposed to ionising radiation.

In order to achieve this several control measures may be utilised:

- physical control measures (room design, Pb screens)
- systems of work (do not enter room when red light is on)
- monitoring radiation levels (environmental monitoring)
- use of PPE (only necessary if monitoring estimates indicate that PPE is required)

i) Dose Limits

Regulation 11 (1) requires the Employer to ensure that persons are not exposed to ionising radiation where relevant dose limits would be exceeded. Schedule 4 (part 1) of the regulations detail the various classes of people within a radiation environment together with their respective dose limitations.

See Schedule 4 of IRR'99 to note the effective dose limits for all class of persons to whom dose limitations apply.

- Employees (classified – 20mSv/year)
- Employees (non-classified – 6mSv/year)
- trainees under 18 years of age (6mSv/year)
- trainees under 16 years of age (1mSv/year)
- comforters & carers (5mSv/year)
- members of the public (1mSv/year)
- pregnant Employees (not to exceed 1mSv for the remaining term of pregnancy (i.e. the remaining time following notification to the RPS/RPA)
- certain organs – skin – 500mSv/year (1cm square of skin)

For further information on dose limitations to the lens of the eye, the skin and other body areas see pages 48 – 50 and 140 – 141 of L121 (HSE, 2000)

ii) Designation of work areas

Regulation 16 of IRR'99 details the requirements for the Employer to designate work areas, where ionising radiation is used, into controlled or supervised areas. Designated areas require adequate demarcation (Regulation 18), systems of work for all non-classified staff, and a monitoring system of a person's dose exposure.

Controlled area – where doses may be significant (>6mSv/year or three-tenths of any relevant dose limit) and where special procedures are carried out. Inside the treatment units in a radiotherapy department are designated as “controlled areas” with the control panel area generally not being designated as such. The treatment room is only “controlled” when the power is on – the warning lights go out when the power is off. Many RPAs also advise that x-ray rooms are controlled areas thus requiring the use of radiation warning signs and lights.

Supervised area - where doses are > 1mSv/year or an equivalent dose > one-tenth of any dose limit in Schedule 4 (usually control panels etc)

Section F - Dose Records

Persons who are likely to receive an effective dose in excess of 6mSv per year or three-tenths of any relevant dose limit must be **classified** (Regulation 20 (1) – the results of any prior risk assessment (PRA) will identify these individuals. To be designated as classified, the Employee must be over 18 years of age and fit to work with ionising radiation (as determined by a medical adviser).

It is highly unlikely that therapeutic radiographers and many diagnostic radiographers would be “classified workers” and will normally be **non-classified**.

Further information on the appropriateness of designation of classified persons may be obtained from HSE <http://www.hse.gov.uk/radiation/ionising/doses/designation.htm>

Those persons engaged in the following practices should normally be **classified**:

- therapeutic interventional radiology & cardiology procedures
- endoscopy using x-rays
- radiopharmaceutical or radionuclide preparation
- diagnostic & therapeutic radiopharmaceutical administration
- source preparation, insertion or removal in brachytherapy procedures
- intravascular or intra-operative procedures (IPEM, 2002 - p. 12 of MDGN)

Staff and patient doses in interventional radiology are among the highest received from medical exposures and consequently radiation protection has to be a priority and reliable dosimetry needs to be established. The ICRP recommendation is that two personal dosimeters should be worn (under and over the apron) for high workloads (Personal Dosimetry ICRP report 85 (2001). Periodic audit of staff eye and extremity doses is also recommended due to the potentially high doses received by the hands, feet and eyes during interventional procedures which puts them at a greater risk of experiencing deterministic injuries to the hands and eyes. The whole body doses received by operators during interventional procedures give an increased lifetime risk of fatal cancer.

Classified persons must have an assessment of their dose of ionising radiation made by an approved dosimetry service (see <http://www.hse.gov.uk/radiation/ionising/dosimetry/ads.htm>) and their dose records must be kept by their Employer for at least 50 years or until the individual reaches the age of 75 (Regulation 21 (3a). Health records for classified staff must be kept for at least 50 years, or until the individual reaches the age of 75 (Regulation 24(a). Dosimetry services are approved by HSE (Regulation 35) – see pages 91-93 of L121 (HSE, 2000).

The occupational radiation exposure records for all members of non-classified staff who are routinely monitored should be stored by the RPS and kept for at least two years as per Regulation 18(5) up to a maximum of five years which would enable any requests for an individual’s dose information from other departments, following transfer of employment, to be efficiently dealt with.

Results of periodic dose audits (e.g. for extremity dose monitoring for specific types of examinations) should be kept at least until the audit has been repeated – unless there have been significant changes in practice or areas of concern highlighted such

audits are repeated every three years. The results of such audits should be circulated to all staff members that have been involved in the audit.

Investigation reports for doses received by Employees that exceed the investigation level must be kept for at least two years (Regulation 8(7)). This should also trigger a review of working conditions in the event of recorded doses exceeding the appropriate investigation level.

Note:

The Society and College of Radiographers were notified by HSE Inspectors that during a recent HSE inspection of site radiography activities there was a discovery that a classified radiation worker had not been wearing his personal whole body dosimeter. This Employee was subsequently required to give a tape recorded statement under the Police and Criminal Evidence Act and consideration is being given to the prosecution of that individual under Section 7 of the Health and Safety at Work (HSW) Act 1974.

SCoR Guidance

It is not a legal requirement to monitor radiation doses of non-classified staff but many are subject to dosimetry as required by written arrangements in Local Rules. Employees who have been provided with a dosimeter by their Employer to ensure compliance with Regulation 18(2) (c) (ii), have a duty to look after that dosimeter and return it for processing as required (i.e. within time constraints). Provided the Employer has informed the Employee of that duty and is exercising the appropriate level of supervision, Employees who persistently fail to wear, look after or return their dosimeters promptly may be committing an offence under Section 7 of the HSW Act 1974 for which they could be prosecuted.

Personal monitoring reports should be made available to any member of staff who wishes to see their individual dose records. In cases where a radiographer may have two Employers or when a radiographer moves into new radiographic employment, there needs to be effective cooperation between those Employers such that there is a proper exchange of information regarding exposures and recorded doses.

Some Employers are keen to stop monitoring non-classified staff (including radiographers) within clinical imaging/radiotherapy departments but this issue raises some anxieties amongst many radiographers as they see their personal monitoring as a safety mechanism. SCoR are of the opinion that research is required to dispel any myths (e.g. perhaps an audit of dose measurements using personal dose meters versus environmental dose meters would give evidence that environmental monitoring is adequate for non-classified staff). SCoR advise that, in those local departments where radiographers (designated as classified or non-classified staff) wear personal dosimeters, student radiographers who attend that department for clinical placement as part of a radiography education programme, should also be subject to personal dosimetry. It is important that effective relationships are robust enough between the placement provider and the educational institution to ensure that this is acknowledged.

SCoR advise that Employers of non-classified persons working in controlled areas must be able to demonstrate either by personal dose monitoring or other suitable means that doses are properly restricted. In practice this means that if an Employer can demonstrate that suitable measurements have been undertaken (and the area

continues to be monitored) and restrictions are proved to be working, then personal dose monitoring is good practice but not essential.

Where personal dose monitoring is provided the IRR'99 regulations state that it is '...desirable, but not essential, that dose monitoring for these individuals is carried out by an approved dosimetry service...

Section G - Comforters and carers

“Comforter and carer” means an individual who (other than as part of his occupation) knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing or who has undergone any medical exposure (paragraph 127 of L121, HSE 2000)

Comforters and carers are normally adults and are often relatives or friends of patients. They must be informed of the risks of incurring exposures whilst acting in this role during an exposure. Regulation 8(3) requires the use of dose constraints to restrict exposure controlled by the concept of *as low as reasonably practicable* (ALARP) and a dose constraint of 5mSv has been advised (Schedule 4(7)). See pages 37 – 38 of L121, (HSE, 2000) for further details.

The HSE 2003 guidance entitled “*Dose constraints for comforters and carers*” available at www.hse.gov.uk/research/rrhtm/rr155.htm has been prepared by the Royal Hallamshire Hospital to enable guidance to be developed for Employers, to assist them in meeting relevant legislative requirements for the exposure of persons who offer support and care to patients undergoing procedures involving ionising radiation where this would not be considered part of their occupation.

SCoR Guidance

Diagnostic Radiography

The designation of the special category of “comforter and carer” is not normally required in the diagnostic imaging department as those helping will be exposed to well below the member of the public dose limit (>1mSv) as long as they do not undertake this role on a regular basis.

Reference should be made to the risk assessment for patient assistance during radiography procedures and also, for staff, the Local Rules for Ancillary Staff working in the Clinical Imaging Departments. For those involved in assisting patients during radiographic procedures it is important that they only remain present in the x-ray room during the exposure if this is absolutely essential – they should stand behind the control panel and lead screen whenever possible. If the patient cannot be left alone during exposure, the person who stays with them must wear the protective lead garments provided and be advised where to stand by the radiographer. In the case of a female comforter or carer, the radiographer must check that the possibility of pregnancy has been ruled out before allowing the person to stay with the patient during exposure.

If it is necessary to use manual restraint due to a lack of patient co-operation and, in such cases, when the examination must proceed, the comforter/carer must wear the protective lead (Pb) as appropriate. The comforter/carer must be positioned as far away as possible from the primary x-ray beam.

Records of doses received by comforters and carers

Records (name, exposure factors, DAP readings) must be kept for all staff or relatives who assist during exposures and these should be audited by the RPS to ensure that the same person is not routinely asked to assist.

Therapeutic Radiography

External Beam Radiotherapy

No person other than the patient must be in the treatment room during mega-voltage or kilo-voltage treatment. Advice within the Medical and Dental Guidance Notes (IPEM, 2002) states that in exceptional circumstances a person other than the patient may be present in the treatment room during kilo-voltage treatment. In such cases adherence to the guidance for comforters and carers in diagnostic radiography is advised.

SCoR Guidance

Before any intervention takes place which requires a person remaining in the room with a patient, the RPA, the Medical Physics Expert and the RPS should undertake a detailed PRA. There should be a written system of work formulated. The results of the PRA must be fully explained to the individual as part of a formal process of knowingly and willingly obtaining consent to act as the comforter/carer. It is advised that the comforter/carer sign a disclaimer given the extreme doses that could be received as a result of his/her failure to comply with the issued precautions.

CT and Simulation

Adherence to the guidance for comforters and carers in diagnostic radiography is advised.

Nuclear Medicine

Due to the increased risk of exposure the role of comforters and carers should not involve a female who is or is suspected of being pregnant. Information for comforters and carers should be included in the patient information leaflets. This should include avoiding direct continuous contact with a patient particularly in bed at night or, in the case of a child, for example, on the lap watching television. The exact length of time to avoid continuous contact with a patient who has undergone a nuclear medicine procedure will depend on the isotope being administered.

This information should be written in conjunction with the RPS and RPA and made available by the radiographer or technologist.

Interventional Radiology

The guidance for comforters and carers for diagnostic radiography also applies to interventional radiography – the high doses associated with interventional examinations indicate that such individuals should only be present if absolutely necessary and in such instances they should stand as far away from the patient and equipment as possible throughout the procedure which, in most cases, means that their role of comforter or carer is not feasible.

Section H - Pregnant Staff

Regulation 8(5) places duties on Employers to protect Employees including those of child bearing age, those who are pregnant and those who have returned to work who may still be breastfeeding. It is the responsibility of the Employee to notify the Employer (e.g. the radiography manager) of a confirmed pregnancy and this should be done in writing as soon as possible (Regulation 14(c)). Upon notification to the Employer of a pregnancy the dose to the fetus should not exceed 1mSv during the remainder of the pregnancy (Regulation 8(5)) and to ensure this the pregnant Employee should be monitored monthly. Further useful information is available on pages 40 and 60 of L121 (HSE, 2000).

SCoR Guidance

In certain circumstances, the pregnant Employee could also wear a direct reading device (either an electronic dose-meter or pocket ionisation chamber) to allow an immediate indication of dose received – this way there is a rapid indication that the dose received will not exceed 1mSv

Under Regulation 7 there must be a prior risk assessment (PRA) undertaken for any “risky” procedures involving Employees who are pregnant or breastfeeding – risky procedures (notwithstanding those not relating to radiation dose) may be defined as high dose fluoroscopy theatre work and unsealed radio-nuclides. If the conclusions of that PRA indicates that some sort of action is required (e.g. that the risk of the Employee receiving more than 1mSv for the rest of the pregnancy cannot be avoided) then the Employer must take action by, for example, offering the Employee alternative work within the dept.

Further information on pregnancy issues for staff

- *The Health and Safety Executive have produced a useful guidance booklet for pregnant Employees entitled “Working safely with ionising radiation: Guidelines for expectant or breastfeeding mothers” - <http://www.hse.gov.uk/pubns/indg334.pdf>*
- *A useful SCoR publication is “Health and Safety and Pregnancy – Guidance for health and safety representatives and members” (2007) – pages 12-15.*
- *The publication entitled “Pregnancy and work in Diagnostic Imaging” from the British Institute of Radiology (to which SCoR had input) is available at http://www.sor.org/members/document-library/archive/sor_pregnancy_at_work_2nd_edition_final2.pdf*
- *There is a very useful PowerPoint presentation relating to ionising radiation and pregnancy (for staff and patients) on the ICRP website – available at: www.icrp.org/docs/ICRP_84_Pregnancy_s.pps*

Several radiographers have reported fertility difficulties to SCoR and have suggested that working with ionising radiation may be a causal factor. SCoR understands the anxieties surrounding this topic but are not in a position to support this hypothesis as there is presently no evidence to support this theory.

For those concerned about this topic, further reading is advised.

- Roman E, Doyle P, Ansell P, Bull D, Beral V (1996) Health of children born to medical radiographers. *Occup Environ Med* **53**: 73–79 available for free download at www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=8777454&query_hl=3&itool=pubmed_docsum .
- And research analyses for nuclear industry workers at:
 - Maconochie N, Doyle P, Roman E, Davies G, Smith PG, Beral V. Nuclear industry family study: methods and description of a United Kingdom study linking occupational information held by Employers to reproduction and child health. *Occupational & Environmental Health* (1999) Dec;56(12):798-808. Available for free download at www.ncbi.nlm.nih.gov/entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=10691340&query_hl=9&itool=pubmed_docsum
 - Draper GJ, Little MP, Sorahan T, Kinlen LJ, Bunch KJ, Conquest AJ, Kendall GM, Kneale GW, Lancashire RJ, Muirhead CR, O'Connor CM, Vincent TJ., Cancer in the offspring of radiation workers: a record linkage study. *British Journal of Cancer* (1997) Nov 8;315(7117):1181 Available for free download at www.ncbi.nlm.nih.gov/entrez/query.fcgi?itool=abstractplus&db=pubmed&cmd=Retrieve&dopt=abstractplus&list_uids=9393219.
 - Bunch KJ, Muirhead CR, Draper GJ, Hunter N, Kendall GM, O'Hagan JA, Phillipson MA, Vincent TJ, Zhang W. Cancer in the offspring of female radiation workers: a record linkage study. *British Journal of Cancer* (2009), Volume 100, Issue 1, pages 213-218. Available free of charge for download at <http://www.nature.com/bjc/journal/v100/n1/index.html#Epidemiology>

Section I - Incident Reporting

a) IRR99 Incidents and Inspections

Regulation 25 requires the Employer to make an immediate investigation in the event that an overexposure to persons (staff, comforters or carers, and members of the public) has been suspected. The investigative reports should be made available to the local radiation safety committee and be kept for at least two years. In the event of a confirmed overexposure, a notification of the radiation incident must be made to the relevant Inspector of the Health & Safety Executive (HSE) (see <http://www.hse.gov.uk/radiation/ionising/>) and reports should be made via this e-mail link notification.for.ionising.radiation@hse.gsi.gov.uk

In addition, concerning radiation equipment, Regulation 32(6) states: *“Where a radiation Employer suspects or has been informed that an incident may have occurred in which a person while undergoing a medical exposure was, as the result of a malfunction of, or defect in, radiation equipment under the control of that Employer, exposed to ionising radiation to an extent much greater than that intended, he shall make an immediate investigation of the suspected incident”*

Such incidents are normally of a complex nature and the RPA must be involved before a report is notified to HSE.

Confirmed over-exposures due to equipment malfunction or defect must be immediately reported to the relevant Inspector at HSE – over-exposures due to human error should not be reported to HSE but rather to another appropriate authority (see IR(ME)R). An IRR’99 investigation under Regulation 32(6) is not formally required if the malfunction or defect results in exposures less than intended but it is good practice for the Employer to investigate such circumstances also.

Following an investigation into the suspected over-exposure incident due to equipment malfunction or defect the Employer must keep the immediate report for a period of at least two years from the date it was made. Records of detailed investigations must be kept for a period of at least 50 years (Regulation 32(7a,b)).

Further information is available from sections 40 - 66 of the HSE guidance for notification of incidents involving radiation equipment entitled “Guidance Note PM77 (Third edition) *Equipment used in connection with medical exposure* (HSE, 2006)”.

This Guidance Note contains advice on compliance with IRR’99, for Employers who have control of equipment used in connection with medical exposure to ionising radiation. The Guidance Note supplements the advice in L121 (HSE, 2000).

Health & Safety Executive (HSE) Inspections

A HSE Inspector will check:

- That the Employer has established a suitable QA programme
- That clearly established QA tests exist
- That action levels are clearly defined
- That staff responsibilities are clearly defined
- That records of procedures, results and any actions taken are kept

| The standard used by the HSE Inspectors is IPEM Report 91 [Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems](#).

b) Employers Guidance - Joint HSE and DH guidance.

[The regulatory requirements for medical exposure to ionising radiation: an Employers overview](#): (ISBN 0 7176 2134 0 Reference HSG223 HSE Books). This guidance is particularly useful for Trust / Health Board Chief Executives as it provides an explanation of the responsibilities of Employers under ionising radiation protection regulations on how to manage the use of radiation in the workplace.

c) Medicines & Healthcare products Regulatory Agency

It is good practice to ensure that comprehensive and effective systems are in place for the reporting of medical device related adverse incidents to the Medicines & Healthcare products Regulatory Agency (MHRA), and that these systems are regularly reviewed and maintained. This would include instances where a near miss arises from equipment malfunction. In addition, the adverse incident reporting process for medical devices should be followed, managed by the [Medicines and Healthcare products Regulatory Agency](#).

The following are examples of recent MHRA Medical Device Alerts:

i) Medical Device Alert (MDA/2009/014) – regarding the report of an x-ray tube head falling onto an x-ray table. See <http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON038838>

ii) Medical Device Alert (MDA/2008/001) – regarding the under-reporting of adverse incidents involving medical devices. See <http://www.mhra.gov.uk/Publications/Safetywarnings/MedicalDeviceAlerts/CON2033513>

d) Devolved Administrations

In **Scotland**, the Incident Reporting & Investigation Centre (IRIC) co-ordinates the investigation of adverse incidents on behalf of the Scottish Government Health Directorates (SGHD.) IRIC maintains close links with MHRA and SGHD. See <http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/>

Adverse incidents may be reported via <http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/how-to-report-adverse-incident/>

In **Northern Ireland**, guidance for reporting adverse incidents is contained in the Northern Ireland Adverse Incident Centre (NIAIC) - <http://www.dhsspsni.gov.uk/index/hea/niaic.htm>

Reporting Adverse Incidents information is available at: http://www.dhsspsni.gov.uk/index/hea/niaic/niaic_reporting_incidents.htm

In **Wales**, guidance for reporting adverse incidents is contained in Welsh Health Circular 1997 (28). This is only downloadable from an NHS Wales intranet site - <http://howis.wales.nhs.uk/doclib/whc199728-e.pdf>

REFERENCES

A short guide to the Personal Protective Equipment at Work Regulations 1992, The Health and Safety Executive, <http://www.hse.gov.uk/pubns/indg174.pdf> (sourced 13th March, 2009)

Acceptance Testing and Commissioning of Linear Accelerators, Report 94, (2007) Institute of Physics and Engineering in Medicine (IPEM), York, England - http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

Assurance of quality in the Diagnostic X-Ray Department, (2001) second edition. British Institute of Radiology (BIR)

Dose constraints for comforters and carers, Research Report 155, (2003) The Health and Safety Executive (written by the Royal Hallamshire Hospital), www.hse.gov.uk/research/rrhtm/rr155.htm

Equipment used in connection with medical exposure, PM77 (2006), The Health and Safety Executive - www.hse.gov.uk/pubns/guidance/pm77.pdf (sourced on 23rd February 2009)

Guidance Notes for Dental Practitioners on the Safe Use of X-ray equipment (2001) available for download at http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1195733764370 (sourced 16th March, 2009)

Guidance for Commissioning and QA of a Networked Radiotherapy Department, Report 93, (2006), The Institute of Physics and Engineering in Medicine (IPEM), York, England - http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

Health and Safety at Work etc. Act (1974). London: HMSO, http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1974/cukpga_19740037_en_1 (sourced 16th March, 2009)

Health and Safety and Pregnancy – Guidance for health and safety representatives and members (2007) The Society of Radiographers, London, England, www.sor.org/members/document-library/sor_health_safety_pregnancy.pdf

International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources (1996) International Atomic Energy Agency (IAEA), Vienna http://www-pub.iaea.org/MTCD/publications/PDF/SS-115-Web/Pub996_web-1a.pdf (sourced 13th March 2009)

Medical and Dental Guidance Notes, (2002) The Institute of Physics and Engineering in Medicine (IPEM), York, England - http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

National Health Service Reform and Health Care Professions Act (2002), OPSI http://www.opsi.gov.uk/acts/acts2002/ukpga_20020017_en_1 (sourced 13th March 2009)

Patient dose database (diagnostic) Health Protection Agency (2008)
http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733826941?p=1158934607708 (sourced 23rd February 2009; last updated 4th September 2008)

Radiation Protection News, Health and Safety Executive
<http://www.hse.gov.uk/radiation/rpnews/rpa.htm> (sourced 23rd February 2009, last updated 24th July 2008)

Radiation Protection Supervisors, Ionising Radiation Protection Series No. 6, HSE Information Sheet (free leaflet), Health & Safety Executive
<http://www.hse.gov.uk/pubns/> (sourced 23rd February 2009, last updated 24th July 2008)

Radiation Protection-European Guidelines on Radiation Protection in Dental Radiology (2004), Office for Official Publications of the European Communities, Luxembourg
http://ec.europa.eu/energy/nuclear/radioprotection/publication/doc/136_en.pdf
(sourced 16th March, 2009)

Radiation exposure of the UK population from Medical and Dental Examinations, (2002) Hart, D; Wall, BF; National Radiological Radiation protection Board (NRPB), England

Recommended Standards for the Routine Performance Testing of Diagnostic X-Ray Imaging Systems, Report 91, (2005) The Institute of Physics and Engineering in Medicine (IPEM), York, England,
http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts, (2006), Northern Ireland Adverse Incident Centre (NIAIC)
http://www.dhsspsni.gov.uk/index/hea/niaic/niaic_reporting_incidents.htm (sourced 10th March 2009)

Risk Management and its Application to Medical Device Management, Report 95, (2008) The Institute of Physics and Engineering in Medicine (IPEM), York, England -
http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

Safe use of work equipment. Provision and use of work equipment regulations, (1998). Approved code of Practice and Guidance, The Health & Safety Executive
http://www.hsebooks.com/Books/product/product.asp?catalog_name=HSEBooks&product_id=5000&MSCSProfile=3C79F0C7EA3162B289A6F3317CC124D86FABF8251554A41AA6D4685D7499F7DC7FF270BBDFD946835C28A51F41CCD0A4F0B4A18D786AFD2D713723256C684D834BB641DEB2F8DF078092AF26CC41CD01521BF8CE6929304D143F4AC6E1770CE60912CC87B0E4D44C0F85B9DEBF14878202930188402490D712F062D8F4CEECE7D6ED2A84646B2CB (sourced 16th march, 2009)

The Critical Examination of X-Ray Generating Equipment in Diagnostic Radiology, Report 79, (1998), The Institute of Physics and Engineering in Medicine, York, England - http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

The design of radiotherapy treatment room facilities, Report 75, The Institute of Physics and Engineering in Medicine, York, England - http://www.ipem.ac.uk/ipem_public/default.asp?id=366 (sourced 23rd February, 2009)

The Ionising Radiations Regulations 1999, Statutory Instrument 1999 No. 3232, www.opsi.gov.uk/si/si1999/19993232.htm (sourced 30th March 2009)

The Health and Social Care Act (2008) Statutory Instrument 2008 No. 3168 (C.143) http://www.opsi.gov.uk/si/si2008/uksi_20083168_en_1 (sourced 10th March)

The Justification of Practices Involving Ionising Radiation Regulations (2004), Statutory Instrument 2004 No 1769 - www.opsi.gov.uk/si/si2004/20041769.htm (sourced 23rd February 2009)

The Management of Health and Safety at Work Regulations (1999) Statutory Instrument 1999 No. 3242 - <http://www.opsi.gov.uk/si/si1999/19993242.htm> (sourced 23rd February 2009)

The regulatory requirements for medical exposure to ionising radiation (2001) Health & Safety Executive, http://www.hsebooks.com/Books/product/product.asp?catalog_name=HSEBooks&product_id=3770&MSCSProfile=3C79F0C7EA3162B289A6F3317CC124D89E116F6BC5EBE46E5129DDC6CD8B384EC2988532BEC9BED7D0B851D43474B5BF47D8B12E73DB57AC77FA4BB3227F5EEC58C1BB757CC2E3CCA3D91BB51460680095D147D8DE7E291063B6AAAB2977539D13E1F19A3AE78DA430903C2FEB72A36620755DF76DD99EA637C98A5A6CD36DE70697177273888726 (sourced 10th March 2009)

The procurement of equipment used for medical exposure to ionising radiation (to include diagnostic x-ray, radiotherapy and nuclear medicine) Good Practice Guidelines for Tender, Supply, Installation and Handover (2005) Welsh Scientific Advisory Committee <http://new.wales.gov.uk/docrepos/40382/cmo/professionals/policy/committees/scientific/guidance/ionising?lang=cy>

Work with Ionising Radiation. Ionising Radiations Regulations (1999) Approved Code of Practice (ACoP) and Guidance L121, Health and Safety Executive http://www.hsebooks.com/Books/product/product.asp?catalog_name=HSEBooks&product_id=3419&MSCSProfile=3C79F0C7EA3162B289A6F3317CC124D806D9EAB4AD93995013D055CF63414CB5E71AB0F841604246F0BC6510959D057ABAA5CA8E82EAE5805D8C4FDAEA7D289817F935101A7BB10B194AC24C7E948B9CD145F5A41EC62968BA58A88AC671B3765C5F7C40229C15643723A060B1EC83E05D56F4EB2AC57A64843DF551CB2B372A98FB29B5EA10F207 (sourced 10th March 2009)

Working safely with ionising radiation: Guidelines for expectant or breastfeeding mothers, The Health & Safety Executive - <http://www.hse.gov.uk/pubns/indg334.pdf>
(sourced 23rd February 2009)

APPENDICES

- Appendix I Typical staff induction checklist
- Appendix II Radiation Health & Safety Checklist
- Appendix III
- i) Example of ionising radiation risk assessment form (complete)
 - Diagnostic – example 1

 - ii) Example of ionising radiation risk assessment form (blank)
 - Diagnostic – example 2

 - iii) Example of ionising radiation risk assessment form (blank)
 - Generic – example 3

 - iv) Example of ionising radiation risk assessment form (complete)
 - Radiotherapy – example 4

 - v) Example of ionising radiation risk assessment form (complete)
 - Interventional Radiology – example 5

 - vi) Example of ionising radiation risk assessment form (complete)
 - Cardiac Catheter Lab – example 6

Appendix I

Typical staff induction checklist

General

- Read local rules
- Read IRMER Employers Procedures

Examination rooms / treatment / simulator units

- Read Work Instruction Files (standard operating procedures) relevant to unit and activities associated with unit
- Switching on and off procedures
- Machine QA
- Contingency procedures
- Use of equipment
- Techniques relevant to unit
- Use of radiology information system / record and verify system
- Staff organisation
- Consent process
- The request card / treatment prescription
- QA procedures

Patient care

- Review clinics
- Patient information
- Departmental skin care
- Support services, nursing, dietician, Macmillan staff
- Post treatment follow up clinics

Additional

- Appointment booking system
- Hospital transport
- Telephone procedure/ bleep system
- Doctors clinics
- Private patient procedures

Radiation protection

- Staff monitoring procedures
- Departmental contingency plans
- IR(ME)R procedures
- Incident reporting procedures and documentation

Health and safety

- Departmental procedures
- COSHH
Emergency / crash procedure

Appendix II Radiation Health & Safety Checklist

Radiations Regulations:

Is a copy of the Ionising Radiation Regulations 1999 available to staff for reference?

Is a copy of the Ionising Radiation (Medical Exposure) Regulations 2000 available to staff for reference?

Are the Local Rules available to staff for reference?

Are the Local Rules adequate ie do they indicate as a minimum:

- i) Details of Radiation Protection Supervisor?
- ii) Details of Radiation Protection Advisor?
- iii) Details of Prior Risk Assessments?
- iv) Details of Contingency Plans?
- v) Details of the procedure for declaration of pregnancy for female staff and the subsequent risks?
- vi) Details of Controlled Areas in department?
- vii) Details of Supervised Areas in department?
- viii) Details of the procedure for incident reporting of an unintended radiation dose to patients / public / learners / other staff?

Departmental Environment:

Are there sufficient radiation warning lights and hazard signs?

Are the radiation warning lights working effectively?

Are all entrances visible from the control panel?

Is there a suitable range of personal protective equipment for radiation use available?

Is the personal protective equipment stored correctly?

Is the personal protective equipment checked regularly (e.g. QA leakage tests)?

Are there adequate warning notices to pregnant patients?

Staff Personal Dosimetry:

Are staff aware of their classification as radiation workers?

Is there a process for the retrieval of staff dose records from a previous employer?

Is there a procedure for personal dosimetry of staff within dept?

Is there a robust collection process of personal dosimeters?

- i) Do all staff comply with this process?

Is there a process for the recording of accurate and appropriate dose records of staff?

Is there a process in place for informing staff of their personal dose record?

Training:

Is there a robust checking procedure to ensure that staff are adequately trained?

Is there a robust training system of radiation protection procedures in place for new radiation staff?

Is this training recorded, continually updated and kept for reference?

Other:

Are non-radiation workers allowed access to radiation areas (e.g. general public, domestic / ancillary staff, learners)?

If so:

- i) Is there a robust training system of radiation protection procedures in place for new radiation staff?
- ii) Is this training recorded, continually updated and kept for reference?
- iii) Is there a process in place for personal dosimetry?
- iv) Is there a process for the recording of accurate and appropriate dose records?

Is there a robust investigative procedure in place following the reporting of an unintended radiation dose to patients / public / learners / other staff?

If so, are staff aware of this investigative procedure?

Appendix III (i)

Ionising radiation risk assessment form – Diagnostic – example 1 (complete)

Room:	1	Assessed by:	
Assessment Date:		Review Date:	

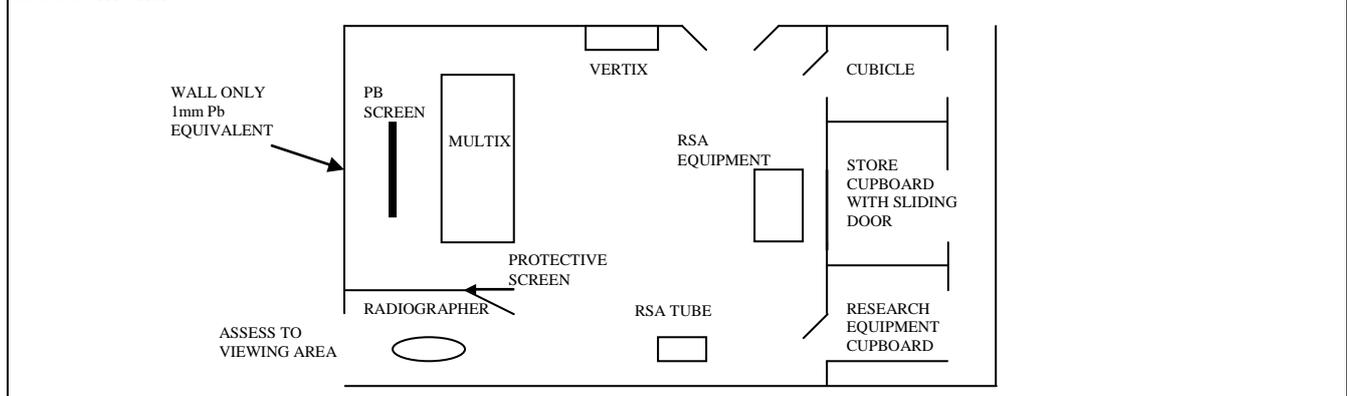
Description of work performed:	General Radiography including inpatients, outpatients, adults and children. RSA Photogrammetry of hips and knees
Persons present in the room during exposure:	Patient Radiographer Health Care Assistant Comforter & Carer when required

Current Control: What is currently in place to reduce the risk?	Local Rules Controlled areas and warning signs/lights Standard Operating Procedures/Protocols RSA equipment 'locked' when not in use, key must be signed out and in.
Best Control: What more could be done to reduce the risk?	Replace equipment with DR to reduce dose. Lead protection of viewing area/room 1 wall only 1 mm, Local Rules must be enforced. Mobile lead screen in place.

Predicted Frequency	5	Significance of Outcome	2	Rating	High
Scope to improve:					
High		Medium		Low	✓

If the risk for an investigation performed in the room is deemed to be High, Electronic Personal Dosemeter (EPD) measurement for staff is recommended.

Include a sketch of the room and equipment below, include the positions of staff if in the room during exposure and any other room or equipment details (protective screens etc.) relevant to this assessment.



<p>Equipment Details</p> <p>Make:</p> <p>Model:</p> <p>Date of manufacture (approx):</p> <p>DAP meter:</p> <p>Type of DAP meter (cGycm²):</p> <p>Dose saving features:</p>	<p>Siemens</p> <p>2 Polydoros LX, Multix & Vertix, 2 Ceiling suspended 3D Tubes</p> <p>1995</p> <p>Yes</p> <p>Yes</p> <p>Filtration & collimation</p> <p>Standard Resolution CR plates in use</p>
--	--

<p>Personal Protective Equipment</p> <p>Lead Rubber Aprons:</p> <p>Thyroid Shields:</p> <p>Leaded Glasses:</p> <p>Gonad Shields:</p> <p>Lead Rubber Gloves:</p> <p>Screens:</p> <p>Other:</p>	<p>2</p> <p>1</p> <p>Not required</p> <p>Kings Lynn selection</p> <p>1 pair</p> <p>Not required</p> <p>Octostop filters used</p>
---	--

<p>ALARP Assessment</p> <p>Are Local Rules on display?</p> <p>Who is the Operator?</p> <p>Is there evidence of training?</p> <p>Are the names of people present during exposure recorded?</p> <p>Are radiation warning lights functioning?</p> <p>Are regular QA checks performed?</p> <p>Fluoroscopy:</p> <p>Use of low does screening modes:</p> <p>Use of pulsed fluoroscopy:</p> <p>Restriction of field size:</p>	<p>Yes</p> <p>Radiographer</p> <p>Yes – Training File & Induction</p> <p>Yes in Comforter & Carer Log</p> <p>Yes</p> <p>Yes</p> <p>N/a</p> <p>N/a</p> <p>N/a</p>
---	--

<p>Action to be Taken:</p> <p>Does this RA satisfy ALARP?</p> <p>Other comments/suggestions:</p>	<p>Yes</p> <p>Consider replacing equipment with DR technology. Viewing area/Room 1 wall only 1 mm lead protection, if the tube has to be directed at this wall, the mobile lead screen must be used as additional protection.</p>
---	---

Ionising radiation risk assessment form – Diagnostic – example 2 (blank)

This form should be completed before the x-ray room, equipment or new technique is put into use

Room or equipment identification:	Installation date:
-----------------------------------	--------------------

Description of equipment, expected use (or description of modified technique) and location:

Name of person undertaking assessment:
--

Date Assessment completed:	Date room/equipment/technique will be brought into use:
----------------------------	---

Manager's signature:

Potential Hazard:	Exposure to X-rays	Risk Measure: Radiation Dose ¹
-------------------	--------------------	---

1. CHECKLIST

Advice of RPA

Comment/Action required

Action Y/N

Advice of RPA	Comment/Action required	Action Y/N
Has advice of RPA been sought and received	Yes/No	
What dose constraint was used in the planning stage for areas outside the new facility?	---	1 mSv per year/ 0.3 mSv per year/ Other
Is advice implemented	Yes/No	
Does RPA final report require further action	Yes/No	

Staff dose

What staff groups will be involved	-----	Which staff groups?
Will procedures in the room involve staff remaining close to the patient whilst x-rays are being generated	Yes/No	

¹ Radiation dose which could potentially be received can be taken as an indication of the risk. The employer must keep radiation doses as low as reasonably practicable and certainly less than any dose limits. The annual effective dose limit is 1 mSv for members of the public and 20 mSv for staff working with radiation. For the population as a whole an effective dose of 1 mSv carries a risk of excess fatal cancer of 1 in 20,000. This risk is similar to the risk from smoking 75 cigarettes, travelling 2,500 miles by car, or working in a typical factory for 2 years.

Is it likely that staff doses will increase (or be significant)		Consider: is the room replacing a similar existing room and if so is the radiographic workload likely to increase and by what proportion	
• Whole Body (Film dose greater than 1 mSv)	Yes/No		
• Hand doses (Equivalent dose to skin greater than 50 mSv)	Yes/No		
• Eye (Equivalent dose to lens greater than 15 mSv) /Thyroid doses	Yes/No		

Staff doses contd

Comments/Action Needed

Action Y/N

Has personal monitoring been arranged for the necessary staff groups	Yes/Not necessary Yes/Not necessary Yes/Not necessary		
• Film badges for whole body			
• TLDs for hands			
• TLDS for eye or thyroid			
If the whole body dose is likely to exceed 2 mSv per year, has special consideration been given to restricting access to pregnant staff	Yes /NA		
Are any staff likely to need to be designated as classified workers (i.e. their dose is likely to be more than 3/10ths of a dose limit) and, if so, has this been arranged	Yes/No		

Protective Devices

Are sufficient lead aprons and storage racks available	Yes/No		
Is there a need for further devices, if so what. (e.g. lead gloves, thyroid shields, leaded spectacles, mobile screens, ceiling suspended screens, lead drapes for image intensifier)	Yes/No		

Area designation

Are controlled/supervised areas agreed with RPA	Yes/No		
Will workload per week be less than Mobiles (at any particular location): 20 radiographs Dental 100 intra orals 50 OPGs	Yes/No	If workload is exceeded controlled area might need to be extended beyond normal default distance. More details given in the Local Rules	

Warning Signs/lights

Are correct warning lights and signs provided at all entrances to controlled area (not required for mobile x-ray equipment which is used in several locations)	Yes/No		
--	--------	--	--

Local Rules

Have Local Rules been prepared for this room/equipment which contain:	Yes/No		
• a description of any controlled areas (and supervised areas if these exist)	Yes/No		
• special working procedures by which non-classified staff can enter the controlled areas	Yes/No		
• the name of the Radiation Protection Supervisor	Yes/No		
• a contingency plan for potential accidents	Yes/No		
Are these Local Rules readily available to all staff	Yes/No		
Have all staff (radiographic and other) who will enter read the Local Rules	Yes/No		

Training

Comments/Action Needed

Action Y/N

Has the manufacturer or supplier provided the necessary documentation and training about the safe use and maintenance of the equipment	Yes/No		
Is any extra training needed for staff (radiographic and other)	Yes/No		
Has training been implemented	Yes/No		
Are female staff aware of the importance on notifying the Employer, in writing, if they become pregnant	Yes/No		

Commissioning tests

Did the critical examination/commissioning tests of this equipment indicate any radiation protection concern for staff or patient	Yes/No		
Have the recommendations of the critical examinations/ commissioning tests been implemented	Yes/No		

Quality Control

Has a planned preventative maintenance programme been arranged for the radiation equipment including any interlocks and warning devices?	Yes/No		
Has a quality assurance programme been agreed and documented for this room, including patient dosimetry measurements.	Yes/No		
Are baseline measurements performed and satisfactory	Yes/No		

Accidents

Have appropriate steps been taken to prevent accident situations and to limit the consequences of potential accidents:?	Yes/No	e.g. back –up timers on AECs, shrouded footswitches (or switches to prevent x-ray production), prevention of multiple exposures on one cassette....	
---	--------	---	--

Young people

Are any additional procedures necessary for young people who may be present in the controlled areas	Yes/No		
---	--------	--	--

2. ACTION TO BE TAKEN TO REDUCE RISK

Nature of Hazard	Agreed Action (Eliminate / substitute / engineering control / Procedural control/ PPE)	Person Responsible	Priority	Action Date	Completion Date

--	--	--	--	--	--

3. OTHER COMMENTS/ RECORD OF REVIEWS

Staff involved :
Others involved :
ALARP assessment :

Action to be taken:		
Residual risk		
Comments:		
<table border="1"> <tr> <td>Date for next review:</td> <td></td> </tr> </table>	Date for next review:	
Date for next review:		

Reason for assessment :	Prior:	√	Review:	
Comments: Risk assessment prior to clinical use				

Appendix III (iv)

Risk Assessment Form (Radiotherapy) example 4 (complete)

Assessed by:		Signed:	
---------------------	--	----------------	--

Designation of Assessor :	Head of Radiotherapy physics
----------------------------------	------------------------------

Description of area / equipment assessed :	New Gulmay D3300 x-ray unit installed into the Orthovoltage treatment room. X-ray energy range 60KV-250KV (capacity for 300KV if room shielding requirements sufficient)
---	--

Description of risks (Rate Severity & Frequency as High Medium or low)			
Risk No	sev	Freq	
01	L	L	Excess radiation doses to members of radiotherapy staff
02	L	L	Excess radiation doses to other members of staff
03	L	L	Excess radiation doses to carers/ supporters
04	L	L	Excess radiation doses to members of the public
05	M	L	Excess radiation doses to patients
06	M	L	Human errors – failure to follow procedures (risk to all groups)
07	L	L	Electrical failures leading to injury (risk to all groups)
08	L	L	Mechanical failures leading to injury (risk to all groups)
09	L	L	Radiation dose to pregnant member of staff

Current control measures in place to reduce risk	Effectiveness of Controls / Further actions required :
<p>Risk 01 RPS for Radiotherapy. Local Rules. Contingency plans: (part of Local Rules). Audio Visual warnings of radiation present in the room. Door interlock, last man out button. Whole body monitoring of staff undertaken. Shielded Treatment Room. Critical examination to be done by manufacturer after installation, this to include dose survey.</p>	<p>Updated Local Rules to be issued re staff and register signed RPS to action</p> <p>Critical exam, manufacturers have ap trust RPA to do this, RPA to action.</p>
<p>Risk 02 Controlled Area defined: Warning signs in place to restrict access to Controlled Area.</p>	<p>As above.</p>
<p>Risk 03 No carers/ supporters allowed in treatment room with patient during treatment exposure.</p>	<p>As above.</p>
<p>Risk 04 No casual access allowed. Warning signs and door interlock.</p>	<p>As above.</p>
<p>Risk 05 IRMER procedures. Designated MPE in Radiotherapy. Treatment prescribed by IRMER Practitioner Oncologist. Treatment calculations done and checked by therapeutic radiographers (registered healthcare professionals) acting as operators. Clinical scientists (registered healthcare professionals) to calibrate machine and produce data for calculations. Radiotherapy Physics to set up QA checks to ensure accurate doses are delivered.</p>	<p>Ensure IRMER procedures and work instructions are up to date. Ensure all staff aware of any changes procedures / working practice. Treatment Superintendent Radiographer Head of RT Physics/MPE to Action</p>
<p>Risk 06 Staff training. Clinical audit of IRMER procedures. Manufactures to provide 2 days of training.</p>	<p>Staff training and competencies to be completed. Treatment Superintendent Radiographer Head of RT Physics to Action.</p>
<p>Risk 07 Electrical safety checks to be done. PPM to be done, servicing in the first 12 months to be carried out by Manufacturers, afterwards by Radiotherapy physics technician who will receive training.</p>	<p>Radiotherapy physics technician to carry out electrical safety checks. Head of RT Physics to Action.</p>
<p>Risk 08 Routine QA to be set up.</p>	<p>Ceiling struts to be load tested. Head of RT Medical Physics to Action. Routine QA to check applicator mount physical integrity of unit. Head of RT to action.</p>
<p>Risk 09 As risk 01. Individual risk assessment done when member of staff becomes pregnant.</p>	<p>As risk 01</p>

Radiation Risk Assessment for Interventional Fluoroscopy Examinations (example 5) (complete)

Type of Procedure:

Interventional examinations using fluoroscopic exposures e.g. angiography, angioplasty, nephrostomy, PTCs, stent insertions (ureteric, oesophageal, arterial, venous), varicele embolisations etc.

Location: Interventional X-ray room in the x-ray department

Workload: e.g. 5 sessions per week, 4 cases per session from the above procedures.

Staff Groups (and Others) Involved

Radiographers and Radiologists; Outside Specialists (Service engineers, medical physicists etc)

Radiology Sister

Radiography helpers

Ancillary staff (porters; cleaners; hospital maintenance staff etc.)

Patient escorts (either members of the public or other hospital staff)

Identified Radiation Risks

Risk of exposure to 50-120kV x-rays, either from the primary beam or from secondary radiation from the patient and c-arm tube head.

Control Measures for Routine Work

Designation of Area

The whole of the examination room is designated as a controlled area.

Dose to individuals in adjacent areas will not exceed 0.3mSv per year.

Structural Protection

All walls, floors and doors are designed so that the controlled area does not extend beyond the room.

Separate control room built using adequate attenuation materials.

Engineering Controls and Warning Devices

Warning lights indicating mains on and expose conditions on patient entrances.

Warning signs demarcating controlled area and restricting access at all entrances. Digital locks on patient corridor access into the suite.

Provision of PPE

Protective aprons and thyroid shields used by radiographic staff and anyone else required to remain within the controlled area during exposure (this will introduce a manual handling risk: see manual handling risk assessment).

Lead glasses should be used by the Radiologists.

Lead rubber table side drapes should be used for all interventional work.

Systems of Work (documented in Local Rules)

Radiographers and Radiologists; Outside Specialists (Service engineers, medical physicists etc)

Staff who are required to remain out in the room must wear protective lead aprons and thyroid shields and stand as far away as practicable from the c-arm and patient.

Lead glasses should be used by the Radiologists.

Lead rubber table side drapes should be used for all interventional work.

Radiography Helpers and Ancillary Staff (porters; cleaners; hospital maintenance staff etc.)

When the 'mains on' indication is on the above may only enter with the permission from radiographic staff.

Should not remain within the room during the exposure.

Patient Escorts

May only enter with the permission from radiographic staff.

Must remain in the control room during exposure with the exception of special circumstances, when instructions from radiographic staff must be followed.

Projected Dose

If control measures are followed, all staff and members of the public are likely to receive an annual dose in the 'low' category (effective dose < 2mSv/year). No staff should require designation as classified due to this work.

Training Requirements**Radiographers and Radiologists; Outside Specialists (Service engineers, medical physicists etc)**

Professional training in radiation protection.

Read Local Rules.

Radiology Sister

In-house tutorial on radiation protection.

Read relevant section of Local Rules.

Radiography Helpers

In-house tutorial on radiation protection.

Read relevant section of Local Rules.

Ancillary Staff (porters; cleaners; hospital maintenance staff etc.)

Read relevant section of Local Rules.

Audit Methods

Routine whole body personal monitoring for radiographers, radiologists, x-ray nurses and radiography helpers.

An appropriate investigation level as required under IRR99 Reg 8(7) is 2mSv in any calendar year.

Maintenance and Testing of Engineering Controls

Warning lights and safety features tested during routine service (3/4 monthly).

Additional Precautions for Pregnant/Breastfeeding Women or Young/Inexperienced Employees**Pregnant/Breastfeeding Women**

No special measures required.

Young/Inexperienced Employees

Should always work under supervision until assessed as adequately trained.

Possible Accident situations and Required Contingency Arrangements**Hazard**

X-ray production fails to terminate at end of set time; Non-release of footswitch.

Contingency Arrangement

Unit must be disconnected from mains supply, using the emergency stop button.

Hazard

Unprotected personnel inadvertently in controlled area during exposure.

Contingency Arrangement

Exposure halted if possible (with due regard to examination requirements). Person to be removed or provided with protection as appropriate.

Review Arrangements

This risk assessment is subject to annual review by the RPS, and must be included in the report to the Radiation Protection Committee.

Prepared by: _____

Signature: _____ **Date:** _____

Agreed by RPA: _____

Signature: _____ **Date:** _____

Cardiac Catheterisation Laboratory Radiation Risk Assessment for Cardiac Examinations (Example 6) (complete)

Work Practice

Type of procedure: Patient examinations involving Cardiac Angiography and Pacemaker insertions
Location: Cardiac catheterisation laboratory within the Cardiology Department.
Workload: **5 angio sessions per week, 5 patients per session as typical.**
1 pacing session per week –typically 2 patients per session.
1 angioplasty session per week, 3 patients per session.

Staff groups (and others) involved.

Radiographers
Cardiology Nurses
Cardiologists
Cardiac technicians
Outside specialists (service engineers, medical physicists etc)
Ancillary staff (Porters, Cleaners, maintenance staff etc)
Patient escorts (either members of the public or other visiting hospital staff)

Identified radiation risks

Risk of exposure to 50 - 120 kV X-rays from secondary radiation from the patient and tube head and from the primary beam for operators.

Control measures for routine work

Designation of area

The catheter laboratory (procedure room, control room and equipment room) is designated as a controlled area and is designated permanently as a controlled area. The area is defined by the structures of the room including doors/chicanes and entrances.

Structural protection

Walls, floors, doors etc designed so that controlled area does not extend beyond the laboratory unit and so that staff working in adjacent areas receive less than 0.3mSv p.a.
Control room protected by a screen.
Ceiling suspended protective shield in the procedure room for operators
Mobile screens provided for nursing staff.
Table side drapes to protect legs of those stood close to table

Engineering controls and warning devices

Warning lights at all entrances to the controlled area indicating “controlled area” when mains on and “X-rays on” during expose condition. Also X-rays on warning light to be provided at entrance from control desk through to X-ray room.
Warning signs demarcating controlled area and restricting access at all entrances to controlled area

Provision of PPE

Protective aprons and thyroid collars available –checked prior to first use then checked yearly and documented.

Systems of work

Radiographers, Nurses, Cardiologists

Only essential staff remain in the procedure room during exposure/examination.
Other staff stay in the protected control room .
All staff remaining in the procedure room to wear protective apron (with thyroid and eye protection if appropriate).
Staff stand as far away from X-ray tube and patient as practicable and on the intensifier side (rather than tube side) of the patient where appropriate.
Clinician at table performing the procedure uses ceiling mounted protective shield and table side protection where possible.
Others in room e.g. assisting nurses to make use of mobile protective screens when possible.
Only one patient examined at any time.
One operator uses pump injections for the procedure—Cardiologists stand behind mobile screen during acquisition , Radiographer screen ,injects and acquires for the coronary series.

Outside specialists (service engineers, medical physicists etc)

Only essential staff remain in the procedure room during exposure.
Other staff stay in the protected control room.
All staff remaining in the procedure room to wear protective apron (with thyroid and eye protection if appropriate).
Operators at table use ceiling mounted protective shield where possible.
Staff stand as far away from X-ray tube and patient table as practicable.

Ancillary staff (Porters, Cleaners, Hospital maintenance staff etc),

May only enter the laboratory with the permission from a member of the radiographic staff.
Do not remain within the procedure room during exposure.

Patient escorts

May only enter with the permission from radiographic staff.
Do not remain within the procedure room during exposure.

Projected dose

If control measures are followed all members of staff likely to receive annual effective doses < 1mSv per year (low dose category) and extremity dose < member of the public dose limit.

Staff working in the adjacent areas likely to receive annual effective doses < 0.3 mSv per year.

No staff should require designation as classified due to this work.

Training requirements

Radiographers, Cardiologists , Outside specialists (service engineers, medical physicists etc)

Professional training in radiation protection/updates.
Read Local Rules

Nurses,

Radiation protection tutorial from RPS
Read Local Rules

Ancillary staff (Porters, Cleaners, maintenance staff etc),

Read relevant section of Local Rules
To be instructed in precautions by appropriate line manager
Regular staff to have interview with RPS to ensure Local Rules understood.

Audit methods

Routine whole body personal monitoring for cardiologists, radiographers, cardiac technicians and cardiology nurses

Visiting cardiologists with workload <50 cases per year asked to bring the personal monitors from their main radiation Employer. Workload to be audited to ensure all clinicians with workload > 50 per year are monitored separately.

An appropriate investigation level as required under IRR99 Reg 8(7) is 2 mSv in any calendar year.

Periodic extremity and eye dose monitoring when appropriate. Initially cardiologists and scrub nurses to be provided with eye badges for first 6 months and results reviewed.

Maintenance and testing of Engineering Controls

Warning lights and safety features tested during routine service (three monthly) and documented .

Any engineering controls that require maintenance should be maintained in efficient working order and good repair.

Any problems noted in routine use should be reported to the RPS. A fault log should be maintained in the laboratory.

Extra precautions for pregnant women and inexperienced Employees

Pregnant women

RPS perform individual risk assessment.

Inexperienced Employees

Should always work under supervision until assessed as adequately trained.

Possible accident situations and required contingency arrangements

Hazard

X-ray production fails to terminate at end of set time/release of footswitch..

Contingency arrangement

Unit must be disconnected from mains supply.

Hazard

Unprotected personnel inadvertently in room during exposure

Contingency arrangement

Exposure halted if possible (with due regard to examination requirements). Person to be removed or provided with protection as appropriate.

Review Arrangements

Risk assessment to be reviewed by RPS annually, and findings included in report to the Radiation Protection Committee.

Agreed by Radiation Protection Supervisor:

Name:

Signature _____

Date: _____

Agreed by Radiation Protection Adviser:

Name: _____

Signature _____

Date: _____