

The Society & College of Radiographers

The Ionising Radiation (Medical Exposure) Regulations 2000

And

**The Ionising Radiation (Medical Exposure) (Amendment)
Regulations 2006**

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 Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000) and the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006. 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). Radiographers with the additional responsibility of Radiation Protection Supervisors (RPS) should, as good practice, be involved in IR(ME)R matters within their local department even though it is not their statutory responsibility.

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

ALARP	- as low as reasonably practicable
ARSAC	- Administration of Radioactive Substances Advisory Committee
BIR	- British Institute of Radiology
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
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
IPEM	- Institute of Physics and Engineering in Medicine
IR	- Ionising radiations
IRIC	- Incident Reporting & Investigation Centre
IR(ME)R	
2000/2006	- Ionising Radiation (Medical Exposure) Regulations 2000/ Ionising Radiation (Medical Exposure) Amendment Regulations 2006
LREC	- Local Research Ethics Committee
MPE	- Medical Physics Expert
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

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Introduction

The Ionising Radiation (Medical Exposure) Regulations 2000 (IR(ME)R 2000) is legislation aimed at the protection of the patient against the hazards associated with ionising radiation. It is made as criminal law rather than civil law. The main difference is that civil law seeks to establish fault and award compensation whereas criminal law relates to an illegal act which is punishable and compensation is a secondary issue. Legally, a signature means that the person takes responsibility for the IR(ME)R specific parts of work and it would be inappropriate for anyone to sign for something outside their control, for which they have not been trained or entitled and for that which they do not have the tools to complete. All radiographers and APs are advised to ensure that they have adequate professional indemnity insurance to cover their IR(ME)R role(s) within their workplace – SCoR offers this cover as part of individual membership and subscription

The Ionising Radiation (Medical Exposure) Regulations 2000, (IR(ME)R 2000) - came into force on 13th May 2000 in concordance with the European Directive 97/43/Euratom (The Medical Exposures Directive, 1997). The Regulations replaced the Ionising Radiation (Protection of Persons Undergoing Medical Examination or Treatment) Regulations 1988 (POPUMET) which have been repealed. The Regulations are available via: <http://www.opsi.gov.uk/si/si2000/20001059.htm> and there are separate regulations for Northern Ireland.

The following document provides guidance on IR(ME)R 2000 and notes on good practice. The guidance is not intended to be binding and cannot take the place of legal advice.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957

The 2006 Amendment to IR(ME)R 2000 moved enforcement powers within England, made amendments to certain definitions in the 2000 Regulations in order to clarify their meaning; reflect changes to terminology used in the 2000 Regulations; and make transitional provision for incomplete matters or matters not finally disposed of before the Regulations come into force on 1 November 2006. The Regulations are available via: www.opsi.gov.uk/si/si2006/20062523.htm

IR(ME)R sets down the application of this legislation, in each of the following areas:

- Responsibilities of all duty holders under IR(ME)R,
- Justification of individual medical exposures,
- Optimisation of exposures,
- Clinical audit,
- Role for expert advice,
- Equipment requirements,

- Training
- Enforcement
- Defence of due diligence
- Schedule 1 Employer's Procedures
- Schedule 2 Adequate Training

SCoR Guidance

IR(ME)R Regulations are flexible and allow a wide variety of practices to be undertaken as long as there is clear justification for the medical exposure to be undertaken.. Responsibility for compliance with IR(ME)R rests with the Employer and all entitled duty holders as defined in the Regulations. A very important document for all radiographers and assistant practitioners is the 2008 jointly authored publication entitled "A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy" written by SCoR, IPEM, RCR and HPA. This is also useful to staff working in radiological fields outside radiotherapy as it explains several elements of generic IR(ME)R information.

1) IR(ME)R – Employers Procedures

Schedule I

The term “*Employer*” in IR(ME)R means any natural or legal person who, in the course of a trade, business or other undertaking, carries out (other than as an employee), or engages others to carry out, medical exposures or practical aspects, at a given radiological installation’ (SI 2000 No 1059).

It is important to recognise that the IR(ME)R Employer relates to health and safety functions rather than employment matters.

The Employer should be considered to be the Chief Executive Officer unless an alternative individual has been formally designated but should be of sufficient seniority and normally at board level.

“Employers Procedures” as required under the Regulations and provision of these is the responsibility of the Employer. IR(ME)R includes a list of procedures required as a minimum in any radiological installation. It is imperative that roles and responsibilities are clearly set out in procedures and that everyone understands their individual role. In some cases, the Employer is the same person as the practitioner and/or the operator (e.g. dental practitioners). Such an individual is still required to establish the procedures required by this Regulation and to comply with them.

Here are the Schedule 1 procedures:

- A. correct identification of the individual to be exposed to ionising radiation
- B. entitlement to act as the IR(ME)R roles of referrer, practitioner and operator
- C. medico-legal exposures
- D. making enquiries of females of childbearing age to establish whether the individual is or may be pregnant or breastfeeding
- E. quality assurance programmes
- F. assessment of patient dose
- G. diagnostic reference levels
- H. medical research programmes
- I. information and written instructions
- J. evaluation for each medical exposure
- K. accidental or unintended doses

(SI 2000 No 1059)

Regulation 10

This regulation requires Employers to keep an up-to-date inventory of equipment. This inventory should contain the following information -

- (a) name of manufacturer,
- (b) model number,
- (c) serial number or other unique identifier,

- (d) year of manufacture, and
- (e) year of installation.

SCoR Guidance

In general terms, when producing a written procedure the following questions may help to ensure that it is written in a clear, unambiguous style:

- *What is the procedure?*
- *Who is entitled to undertake this procedure?*
- *How is it done?*
- *When is it done (e.g. Patient ID should be undertaken in advance of an exposure)*
- *Why should it be done?*
- *Any occasions when it should not be done?*
- *Should it be reviewed and if so at what intervals?*
- *Who is the person responsible for writing this procedure?*

All procedures should be subject to frequent review and in the instances of updates, older procedures should be destroyed to minimise error and confusion.

SCoR Guidance - NOTE

All radiographic staff are required to be aware of who their local IR(ME)R Employer is, to read and understand their local "Employers Procedures" and to fully understand their legal responsibilities under IR(ME)R. The following specific information about the contents of "Employers Procedures" includes guidance from the Department of Health (DH) (DH IR(ME)R guidance notes, 2007) as well as SCoR guidance but it must be stated that it is the Employers responsibility to implement IR(ME)R and the employees responsibility to adhere to IR(ME)R therefore, the specific detail of local IR(ME)R Employers Procedures may differ from that described. If the procedures are not fit for purpose or are impossible to adhere to then the operators have a duty to inform the appropriate person immediately.

Schedule 1 Employers Procedures

a) Correct Identification (ID) of the individual to be exposed to ionising radiation

It is the responsibility of the operator (individual undertaking the medical exposure) to correctly identify the individual undergoing the medical exposure. It is advised that this is done by asking the patient the following questions to which there should be an active response:

- What is your name?
- What is your date of birth?
- What is your address?

In the cases where the answers to these questions match those on the source document (i.e. request card or prescription sheet), there should be a procedure

to identify which operator has undertaken the patient ID (e.g. operator signature) and if there is more than one operator involved in the patient exposure, which requires two signatures, the procedure should state clearly which operator is responsible for the patient ID (e.g. first signature). The use of patient ID bracelets has come into question as there may be a case of mistaken identity when the ID bracelet was first put on (local procedures should be determined to avoid this happening).

There may be exceptions where it may not be possible or more difficult for the patient to be directly identified, for example:

- Inpatients v outpatients
- mute or non-English speaking
- unconscious
- children
- those patients unable to identify themselves but have a carer with them

Procedures for correct ID should be in place to cover these patient examples. The use of a family member as an interpreter for non-English speaking patients is not advised. In these circumstances, formal interpreter services should be used.

Patient ID checks must be preformed prior to each medical exposure or set of medical exposures.

b) *Identify individuals “Entitled to act as referrer, or practitioner or operator”*

A note about “Entitlement”

The IR(ME)R Employer has the legal responsibility for entitling individuals to act as one or more of the three duty holder roles of referrer, practitioner and operator. Being entitled by the Employer, means that permission has been given to act, in compliance with the Regulations, according to the specific responsibilities of a duty holder role. There must be a documented entitlement process, within the Employers' procedures, that details the mechanism through which an individual becomes entitled. A specific process for checking that an individual is “adequately trained” is required before entitlement can be given to act as practitioner and / or operator. The scope of practice of an entitled individual should also be specified with procedure.

Referrers

The Referrer must be a registered healthcare professional (a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002). Decisions on who is entitled to act as a referrer should be taken at local level by agreement between the Employer and the healthcare professionals involved in medical exposures. The Employer is required to make referral criteria available to

all referrers. A comprehensive named and entitled list of all non-medical referrers should be kept in all areas within the radiology department (and kept up-to date by a person designated by the Employer) – this enables the radiographer to check that they are authorised to request. The referrer is required to provide sufficient clinical information in order that the practitioner may make a decision about justifying the medical exposure (e.g. in diagnostic radiology the use of the 2007 Royal College of Radiologists “*Making the best use of a clinical radiology service*” 6th edition publication by the referrer is usually accepted as good practice). In radiotherapy, the referral must include as a minimum details of the tumour diagnosis, histology, clinical findings and staging examinations. For referral to radiotherapy planning the Employer should define appropriate referral criteria which would normally include histology reports and some diagnostic imaging. This might be different in the case of an emergency referral such a cord compression where histology might not be appropriate. A local procedure should make allowance for emergency patients or particular national guidelines. Referral criteria also need to be in place for verification images.

SCoR Guidance

Although it is not a legal requirement within the Regulations, that medical / non-medical referrers are trained, it is normal practice that radiology departments require them to attend radiation protection/ IR(ME)R awareness training prior to being entitled to act as referrer. Guidance has been written by SCoR, and other professional bodies (RCN, 2008) to help those non-medical healthcare practitioners (including radiographers) registered with a healthcare regulatory body who wish to take on the role of IR(ME)R “Referrer” within a clinical imaging department.

The guidance is available at:

www.sor.org/auth/forms/login.php?r=documentlibrary/sor_clinical_imaging_requests_non_medically.pdf.

The guidance sets out a policy position on handling this type of request which was agreed by all the contributing organisations (including the HPA) and includes legal and professional requirements under IR(ME)R. The IR(ME)R Referrer is required to have knowledge of IR(ME)R and radiation exposure risks. Following this publication the College of Radiographers developed an “IR(ME)R awareness training study day for Nurses and Allied Health Professionals”. Similar training is generally available within local clinical imaging departments.

The Welsh Scientific Advisory Group which advises the Welsh Assembly Government has produced an excellent guidance publication on “non medical / dental referral for diagnostic investigation” - see

<http://wales.gov.uk/topics/health/professionals/committees/scientific/2007-08-guidance/good-practice/?lang=en>

Referral protocols should be in place for the different groups of medical and non-medical referrers which could contain details relating to the minimum educational

requirements. Named lists of referrers should be kept and be updated as and when appropriate.

SCoR Guidance

Electronic referrals

There may be some radiology management systems (RMS) / radiotherapy verification systems that allow electronic IR(ME)R referrals. The referrers' signature is normally their individual log on ID (name or code) and the sharing of usernames and passwords must be strictly prohibited.

The SCoR Information Management and Technology (IM&T) Group have provided the following advice by way of helping to ensure that the use of a Radiology Management System (RMS) / Radiotherapy Verification system (known as "system") can provide a safe and robust IT system to aid in electronic image requesting / radiotherapy referral:

- *There must be a facility for recording the priority of the request*
- *The system must contain features, which provide the implementation and monitoring of compliance with the IR(ME)R. The system must capture all necessary data items necessary to comply with the Regulations.*
- *The system must provide a field for authorisation of examination / treatment procedures by the IR(ME)R Practitioner/operator.*
- *The system should be able to provide appropriate information regarding LMP dates / pregnancy status.*
- *There must be a facility, supported by a drop down box (or comments box), which allows the user to indicate why a request / referral has not been justified / refused.*
- *The system administrator must be able to define the appropriate IR(ME)R roles (referrer, practitioner and operator) for all users and all examination combinations to conform to local IRMER procedures.*
- *The system needs to include an up-to-date register of referrers with their current Registration details.*
- *The RMS must implement appropriate permissions at all stages of the requesting/appointing/imaging/reporting process (diagnostic only).*
- *The RMS must be able to produce IRMER audit reports to demonstrate compliance (diagnostic only).*
- *The RMS must record the electronic 'sign off' of reports in order that an audit trail can be detailed which confirms that clinicians have received reports (diagnostic only).*

Practitioners

The Practitioner must be a registered healthcare professional (i.e. a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002). The practitioner must be entitled by the Employer and may be based on the type of medical exposure/radiotherapy treatment and on specific circumstances. It may

be appropriate to agree that certain non-medical health professionals can act as a practitioner for diagnostic/radiotherapy procedures depending upon the complexity of the examination/treatment. In clinical imaging, practitioners are normally radiologists, specialist registrars, radiographers, ARSAC certificate holders (in nuclear medicine) and dental practitioners for intra-oral or panoramic dental radiology. In radiotherapy, practitioners are normally clinical oncologists and specialist registrars / radiographers for certain procedures. The practitioner must be "adequately trained" as detailed in Schedule 2 of the Regulations to undertake the role. The primary responsibility of the practitioner is to justify medical exposures – to do this the request must be assessed using the clinical data supplied by the referrer. Justification is the process of balancing the potential benefit of the exposure against the potential detriment from the exposure to that individual in making a decision in the best interests of the individual. This requires the practitioner to have a full knowledge of the potential benefit and detriment associated with the medical exposure under consideration.

SCoR Guidance

The requirements of Schedule 2 of IR(ME)R are largely addressed by specific professional qualifications and experience. The exception to this may be where individuals undertake functions associated with role development and extension, in which case the contents of Schedule 2 must be addressed and evidence of this should be available before entitlement is extended.

The Employer should specify the scope of practice for which an individual can act as practitioner (e.g. in the case of radiographers this may mean justification for all plain film and some CT procedures or for radiotherapy planning/verification exposures). Training must be provided when equipment changes, new techniques or protocols are introduced. All training records must be written and kept up to date.

Concomitant doses in radiotherapy - Concomitant exposures are defined as all exposures within a course of radiotherapy other than the treatment exposures. These will include simulation, check simulation, computed tomography (CT) localisation and portal localisation and verification images (when these are additional to the treatment exposure).

The IR(ME)R practitioner responsible for the treatment exposures can justify the concomitant exposures at the outset or during the radiotherapy course, but in doing so must be aware of the likely exposures and the resulting dose so that the benefit and detriment can be assessed. This can be achieved by including likely concomitant exposures within site specific protocols with a total effective dose agreed. The IR(ME)R practitioner for the treatment exposures need not be the same practitioner for the concomitant exposures.

Therefore, the practitioner should be aware of the concomitant doses received by the patient as part of a course of radiotherapy in order to make that judgement. This could be achieved through written site specific protocols that include doses for concomitant exposures and limits to those exposures. This will be department specific according to the localisation and imaging procedures.

Operators

The operator does **not** have to be a registered healthcare professional but is required to be adequately trained for their scope of practice as detailed in Schedule 2 of the Regulations. The definition of operator is stated in IR(ME)R as '*any person who is entitled, in accordance with the Employer's procedures, to carry out practical aspects*' (SI 2000 No 1059). The Employer should specify the scope of practice and the tasks for which an individual can act as an operator and be able to demonstrate that they are adequately trained to undertake these tasks. Individual training records for operators require regular updating as individuals develop, and when equipment and techniques change or are introduced. Operators are legal duty holders who are entitled to carry out practical aspects of a medical exposure. Practical aspects include the physical conduct of the exposure and other supporting aspects that have an influence on radiation dose to the patient.

Operators may include:

- Radiographers
- Qualified Radiography Assistant Practitioners
- Dosimetrist / Physicist / Clinical Technologists
- Nurses
- Healthcare professionals (including doctors and physiotherapists who carry out a clinical evaluation on images for which they may have acted as the referring clinician and who then act on their findings. This is part of the practical aspect of the examination)

Third party service engineers would not normally be considered as operators. Where significant changes to equipment have been made, these should be checked where practicable by an operator (e.g. a medical physicist) before equipment is brought into clinical use.

SCoR Guidance

*Persons entitled to act as an Operator must have undergone training in those subjects in Schedule 2 of IR(ME)R which are relevant to their functions and area of practice. SCoR advise that, whilst possible under legislation, student radiographers and trainee assistant practitioners are **not** entitled as Operators. It is appropriate for them to operate equipment provided that they are supervised by a trained and entitled operator (Regulation 11(3) of IR(ME)R) see SCoR guidance on students and trainees being entitled as an operator at <http://doc-lib.sor.org/college-radiographers-guidance-irmer-20002006/college-radiographers-guidance>*

If an Employer entitles a student radiographer or trainee assistant practitioner as an "Operator", there must be a robust local entitlement process within the clinical department which satisfies the relevant sections of Schedule 2. As part of the entitlement process, the necessary information surrounding the individual's (student/trainee) scope of practice, the theoretical and practical training given as well as an assessment of competence must be clearly documented in the

individual's training record in line with the IR(ME)R Employer's Procedures. The Employer then assumes responsibility for ensuring that adequate and up-to-date local training of the entitled Operator is delivered and recorded, and is consistent with the tasks the individual is entitled to carry out.

c) Medico-legal exposures

This category of exposure within a clinical imaging department includes those required for legal purposes of any kind (e.g. those required in connection with legal proceedings, for insurance purposes and those required prior to emigration without a medical indication).

The referrer for a medico-legal exposure is normally a medical practitioner but, SCoR advise that a radiographer may act as practitioner for certain examinations (e.g. pre-immigration chest X-ray; pre-employment chest X-ray). It is the responsibility of the referrer to provide the previous medical history of the patient (Regulation 5 (5)) but a double of check previous medical exposures, by reference to the department records, is advisable to ensure that the individual has not already undergone the examination as part of routine clinical management to avoid unnecessary repeat exposures.

The procedure is only justified if it is not possible to use alternative techniques which have less or no ionising radiation.

d) Females of childbearing age - to establish whether the individual is or may be pregnant or breastfeeding

Clinical imaging and radiotherapy can cause damage to an unborn child (fetus), therefore it is essential that the pregnancy status is determined prior to any relevant medical exposure. Radiation risks are related to the stage of the pregnancy and the absorbed dose to the fetus.

Diagnostic Radiography

A jointly authored updated guidance booklet entitled “*Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation*” (2009) written by HPA, SCoR, and RCR about patients of childbearing age is essential reading for all diagnostic radiographers.

SCoR Guidance

*The IR(ME)R procedure should be aimed at all females of childbearing age, for X-ray examinations between the diaphragm and knees, for radionuclide imaging studies and radiotherapy treatment. The age guidance is normally set between 12 and 55 years (this is the standard usually employed although it is not legally enforceable) but a **local** procedure should be in place for dealing with the sensitive issue of potential pregnancy with younger female patients (e.g. from 9 years of age) and for female patients who are unconscious. Flow chart examples for diagnostic radiography (conscious and unconscious patients) are detailed in Appendix.*

Firstly, it is the responsibility of the referrer to investigate the pregnancy status of females who are to be referred for medical exposure using ionising radiations. The “pregnancy status” must be written on the request card etc. It is the responsibility of the operator to again check the pregnancy status before the examination / treatment. If more than one member of staff is involved in the medical exposure, the operator who initiates the exposure must be certain that the procedure for the investigation of pregnancy status has been carried out. Notices should be displayed in the clinical imaging / radiotherapy department requesting patients that they inform staff if they are or might be pregnant.

Limitations of pregnancy testing

Due to the potential for a high rate of false negatives achieved during early pregnancy, the use of pregnancy testing should not be considered as conclusive evidence that a patient is not pregnant.

Therapeutic Radiography

SCoR Guidance

See guidance for diagnostic also. Often a pregnancy status check in radiotherapy aims to cover the entire radiotherapy process in order that the patient is not repeatedly asked about their pregnancy status. However, there must be some consideration given to the timing of the declaration as there may be a significant time period between declaration and localisation/treatment that the pregnancy status may have changed. Local policies must take into account any potential for change.

There must be documented evidence that a discussion has taken place regarding pregnancy which must be available for staff to check/refer to. It is advised that all women of child bearing age should sign a pregnancy status form to confirm that they are not pregnant, before their first exposure.

The majority of patients receiving external beam radiotherapy will require localisation therefore the “Pregnancy Flow Chart” for diagnostic procedures (Appendix) may be followed if it is necessary to re-check the pregnancy status of patients.

Prior to delivery of radiotherapy, staff must be confident that a patient is not pregnant and should not assume that if a patient was not pregnant at localisation, then they will not be pregnant at treatment. A declaration either as part of the consent process or undertaken separately should be verified taking into account the date of consent/declaration. Local procedure should provide specific detail on the “pregnancy status checking” procedures. There should be a procedure if a patient informs an operator that she has become pregnant during treatment – in the first instance, no further treatment should be given until the clinical oncologist has been informed who will then decide with the patient, the efficacy of further radiotherapy (liaising with the Medical Physics Expert as necessary).

Delivering Radiotherapy to a Pregnant Patient – SCoR Guidance

A pregnant patient requiring external beam radiotherapy must be fully aware of the potential risks to the fetus and consent to treatment prior to any intervention being undertaken must be verified.

It is essential that a full risk assessment involving the clinician, therapeutic radiographers/ dosimetrists and the medical physics expert is undertaken, the aim of which is to estimate the dose to the fetus and to determine whether the dose can be reduced through modifications to the treatment plan / shielding.

Prior to the pregnant patient starting treatment phantom measurements must be undertaken with and without shielding. The treatment plan should be reviewed to determine whether any modifications would reduce the dose to the fetus.

Shielding to the abdomen to minimise the dose further might be required, the design of which will be specific to the individual patient. It is essential that the shielding is safe and robust. During treatment, dosimetric measurements could be obtained to confirm the dose to the fetus (vaginal vault) and other areas as required. There must be a record of the shielding configuration and dosimetry results.

SCoR Guidance (not relating to IR(ME)R) - Fertility following examinations

Nuclear Medicine

Male patients should not father a child for up to 6 months after their radioiodine therapy date and this advice must be included in the radioiodine therapy information leaflet that is given to all patients.

Therapeutic Radiography

The issue of fertility should be discussed between the clinician and patient before radiotherapy procedures are begun; patients may, if there is a risk of infertility, wish to have eggs or sperm banked before commencing treatment.

e) Quality assurance programmes

IR(ME)R defines quality assurance as, ‘any planned and systematic action necessary to provide adequate confidence that a structure, system, component or procedure will perform satisfactorily and safely complying with agreed standards and includes quality control’ (SI 2000 No 1059). Regulation 4(3) (b) states that quality assurance programmes are required for standard operating procedures – this is not about equipment which is dealt with under IRR 1999. All procedures should be regularly reviewed to ensure that they are effective and appropriate and to identify any necessary amendments. To ensure that the QA programme is being followed, a system of regular audits is essential, and to undertake this, an IR(ME)R implementation group may be set up within clinical imaging departments with the remit to review IR(ME)R procedures, to audit implementation and to report any failure. This implementation group must undertake a rolling programme of audit of implementation of the IR (ME) R procedures.

SCoR Guidance

Therapeutic Radiography

The requirements for QA in radiotherapy departments are likely to be fully met by an ISO9001 quality system but such a system is not an essential requirement. Compliance with IR(ME)R is a statutory requirement and it is the responsibility of the Employer to ensure that there is a set of written procedures in place to which the duty holders must then adhere. A quality management system (e.g. QART) can help compliance with IR(ME)R, but it must be clear which parts of the documents are intended to form part of the IR(ME)R procedures. For further details see pages 33-35 of the 2008 jointly authored publication entitled “A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy” written by RCR, SCoR, IPEM, and HPA.

f) Assessment of patient dose

For each medical exposure the dose of ionising radiation to the individual undergoing the exposure is to be kept as low as reasonably practicable (ALARP) and consistent with the intended diagnostic or therapeutic purpose. All relevant dose information for each patient exposure should be recorded.

SCoR Guidance

Diagnostic radiography

In plain film radiography the following information should be recorded by the operator on the request card to aid in exposure audits and the ongoing monitoring of exposure factors:

- i. kV and mAs
- ii. Total examination dose-area product (DAP) if a DAP meter is fitted on the set
- iii. If a DAP meter is not fitted and automatic exposure control (AEC) is used, giving a record of kVp and mAs for each exposure
- iv. If a DAP meter is not fitted and automatic exposure control (AEC) is not used, record “std” to indicate that standard factors taken from the exposure chart were used or record kVp and mAs if non-standard exposure factors were used

For examinations involving fluoroscopy the operator should record DAP and screening time. If a DAP meter is not fitted to the equipment the operator must record screening time

For CT scanning, information required to be recorded should include the number of slices, slice widths, kVp, and mAs. Alternatively the scanner may provide information on dose-length product (DLP) and CT Dose Index (CTDI).

For radionuclide imaging studies, the operator administering the dose must record the administered activity on the request form and sign it.

Patient dose information and typical effective doses, equivalent periods of natural background radiation and lifetime fatal cancer risks from diagnostic medical exposures is available via the HPA website at:

[www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733826941
?p=1158934607708](http://www.hpa.org.uk/webw/HPAweb&HPAwebStandard/HPAweb_C/1195733826941?p=1158934607708)

Therapeutic radiography

For treatment purposes, tumour dose, beam energy, beam number & projections must be recorded – the use of in-vivo dosimetry is another method for the assessment of patient dose and procedures relating to this should also be included. Further information is available from the jointly authored guidance entitled “Implementing In-vivo dosimetry” written by SCoR, RCR, BIR, & IPEM & available via: www.sor.org/members/document-library/sor_invivo_joint.pdf

For planning & verification purposes using simulator, kVp and mAs should be recorded; in using CT simulator (see diagnostic advice above).

g) Diagnostic Reference Levels

Regulation 4(3)(c) of the Regulations requires that Employers establish Diagnostic Reference Levels (DRLs) and undertake appropriate reviews if they are consistently exceeded. The DH produced guidance in 2007 – available at: www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074067

Further information may be obtained from “Report 88 - Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-Ray Examinations” (2004) written by a Joint Working Party IPEM, BIR, RCR, NRPB and CoR. This report shows how diagnostic reference levels may be used as a practical tool by departments to develop quality assurance and clinical audit programmes in order to comply with the legislation.

DRLs are used for the following purposes:

- i) To determine whether the doses to patients are kept as low as reasonably practicable (ALARP)
- ii) To provide a feedback mechanism for generic justification protocols to ensure that the exposure of patients to radiation are compatible with the assumptions made by the practitioner responsible for the generic justification
- iii) To provide a feedback mechanism for practitioners conducting high dose interventional procedures to indicate whether there may be a risk of exceeding the threshold dose for deterministic effects

DRLs are set for a sufficient number of common diagnostic radiological procedures so that relevant DRLs are available for examinations for every piece of diagnostic X-ray equipment. Local DRLs should be established with the support of the Medical Physics Expert (MPE). In the absence of adequate audit data, national or European DRLs should be used.

Regulation 4(6) requires ongoing review of local DRLs and the evaluation of the reasons why DRLs may have been exceeded. Corrective action might include setting new values for DRLs

SCoR Guidance

Therapeutic Radiography

IR(ME)R does not require DRLs to be set for radiotherapy planning but the principle of ALARP must still be applied and the implementation of DRLs is good practice which radiotherapy departments should be moving towards.. An estimate of time and exposure rate is sufficiently accurate when concomitant exposures are compared with subsequent therapeutic exposures. A chart of typical screening times and exposures for a selection of techniques should be available as reference to the operators. CT and simulator exposures should be recorded in the patient's record, so that any concomitant exposures may be estimated.

Interventional Radiology

IR(ME)R requires DRLs to be set for all radio-diagnostic examinations, however, interventional work tends to be mostly of a therapeutic nature and therefore does not require DRLs. For the diagnostic procedures in interventional radiology there are a broad range of doses produced due to patient size, the complexity of examinations and the variations in the technique by the operator and consequently it is difficult to establish local DRLs for common interventional procedures. Work is in progress to establish National Diagnostic Levels for the most common interventional procedures.

h) Medical research programmes

Procedures must be in place for the use of ionising radiation for clinical research purposes to ensure that the use of ionising radiations in research are properly justified, that doses for research exposures are kept as low as reasonably practicable and to inform research subjects appropriately of the relevant risk from the radiation exposure.

The procedures should provide that:

- the individuals concerned participate voluntarily in the research programme
- the individuals concerned are informed in advance about the risks of the exposure
- the dose constraint set down in the Employer's procedures for individuals for whom no direct medical benefit is expected from the exposure is adhered to
- individual target levels of doses are planned by the practitioner for patients who voluntarily undergo an experimental diagnostic or therapeutic practice from which the patients are expected to receive a diagnostic or therapeutic benefit (NRES, 2008).

These issues are addressed in the guidance entitled “*Approval for research involving ionising radiation, Version 2*” (2008) the National Research Ethics Service [NRES]) www.nres.npsa.nhs.uk/rec-community/guidance#ionisingrad

i) Information and written instructions

Regulation 7(5) requires the Employer’s procedures to include the giving of instructions and information in cases where radioactive medicinal products are administered to a patient. The instructions and information are written to aid the consent process and should specify how doses resulting from the patient’s exposure can be restricted so as to protect persons in contact with the patient, set out the risks associated with ionising radiation and be given to the patient prior to leaving the place where the medical exposure was carried out.

j) Procedures for the carrying out and recording of an evaluation for each medical exposure

Regulation 7(8) requires the Employer to ensure that a clinical evaluation of the outcome of each medical exposure is recorded and to set out in procedure, how and when this is to be done. The outcome of all exposures must be recorded and is within the optimisation requirements primarily designed to prevent unnecessary exposures being undertaken. If an exposure is not to be evaluated then it cannot be justified and therefore should not be undertaken.

SCoR Guidance

Diagnostic radiography

If the practitioner or operator knows that no clinical evaluation will be recorded, then the exposure cannot be justified and the request must not be authorised.

The evaluation of a medical exposure is via the imaging report whether as an initial report or a final report – procedures should be in place to ensure a report is produced and recorded for each medical exposure. This normally involves radiologists and radiographers (or other clinicians) recording the image report within notes or on a PACs system in a timely fashion to allow further patient management to occur.

The National Diagnostic Imaging Board (England) produced a best practice guidance entitled “Radiology Reporting Times” (2008) in which states that the Standard for turn around times in image reporting are:

Urgent Cases	-	Immediate (within 30 minutes)
Inpatients and A&E cases	-	Same working day
All other cases	-	by next working day

SCoR Guidance

Therapeutic radiography

Radiotherapy includes a range of medical exposures and the purposes of clinical evaluation for each of these are quite different. All radiation treatment doses, simulation, and verification doses should be recorded in the individual patient record by adequately trained operators (oncologists and radiographers). Planning exposures (simulator or CT simulator) are evaluated by their actual use in the treatment pathway. Verification and portal imaging exposures are evaluated for correctness in beam placement.

Accumulative effect of the treatment exposures is evaluated during the course at clinic review or post treatment at follow up.

k) Procedures to ensure the probability and magnitude of Accidental or unintended doses are reduced so far as possible.

Regulation 4(5) requires the Employer to carry out investigations of incidents and appropriate reviews. All departments should have procedures in place to deal with this locally (e.g. independent dose checks, reporting or errors procedures).

SCoR Guidance

Patients who undergo an examination/treatment that was not intended, due to mistaken identity or other procedural failure, and were consequently exposed to radiation, should be considered as having received an unintended dose of radiation, in which case an Incident/ Near Miss Report Form 1 should be completed. See further information in Section 5 of this booklet.

Radiotherapy

Misidentification of a patient or dataset used for treatment delivery should be reported to the appropriate authority. The importance of reporting and learning from errors and near misses is discussed in the guidance document “*Towards Safer Radiotherapy*” written by SCoR, RCR, IPEM, BIR, HPA & NPSA (2008). . The publication is available via: <http://doc-lib.sor.org/listtitles?page=2>

2) Adequate training – Schedule 2

The Employer has a responsibility to ensure that all entitled practitioners and operators are adequately trained to perform the tasks in their defined scope of practice (Regulation 4((4)a and (4)b)) and consequently, practitioners and operators shall not carry out a medical exposure or any practical aspect without having been adequately trained. (Regulation 11(1))

Practitioners and operators shall have successfully completed training, including theoretical knowledge and practical experience as detailed in Schedule 2 which is divided into 2 sections

- subjects that are relevant to the individuals' functions as practitioner or operator
- subjects that are relevant to specific areas of their scope of practice:
diagnostic radiology, radiotherapy and nuclear medicine

(SI 2000 No 1059)

a) *Training Records for Practitioners and Operators*

IR(ME)R Regulation 11(4) states:

'The Employer shall keep and have available for inspection by the appropriate authority an up-to-date record of all practitioners and operators engaged by him to carry out medical exposures or any practical aspect of such exposures or, where the Employer is concurrently practitioner or operator, of his own training, showing the date or dates on which training qualifying as adequate training was completed and the nature of the training' (SI 2000 No 1059)

SCoR Guidance

Adequate training to achieve and maintain professional registration for non-medical staff is determined by the relevant regulatory body as defined in the National Health Service Reform and Healthcare Professions Act 2002. The Society & College of Radiographers recognises that the pre-registration radiography education programmes it approves, and which are approved by the Health Professions Council (HPC) to give eligibility for registration as a radiographer, address the requirements of Schedule 2 of IR(ME)R. Hence, these may be used as the benchmark by which the Employer defines 'adequate training'

For all practitioners and operators, this initial training & education should only be considered as a starting point rather than an endpoint in demonstrating adequate training within a local department. Responsibility for ensuring that adequate and up-to-date local training is delivered and recorded rests with the Employer and must be consistent with the scope of practice and tasks the individual is entitled to carry out. Training records need to reflect continuous development and local department-specific training, as well as that achieved through additional external qualifications and courses.

Training records for radiographers could include:

- *Professional Registration Details – for radiographers their HPC number and period of registration*
- *Details of academic qualifications – DCR/BSc/MSc/Post-graduate certificates etc.*
- *Individual training profiles for each radiographer outlining which particular x-ray/radiotherapy equipment and techniques that they have been trained to use and who they were trained or declared as competent by.*
- *A competency matrix of all radiographers may be useful to see a complete overview of all radiographers' training*
- *Radiographers must also keep their own training file/portfolio containing evidence of ongoing continuing professional development (CPD).*
- *Evidence of CPD may include certificates of attendance, reflective reports, learning of new techniques etc.*

b) Agency Staff

Regulation 11(5) states: '*Where the Employer enters into a contract with another to engage a practitioner or operator otherwise employed by that other, the latter shall be responsible for keeping the records and shall supply such records to the Employer forthwith upon request*' (SI 2000 No 1059).

It is essential that companies supplying radiography agency staff provide their HPC registration and relevant training details to allow Employers to entitle them as an IR(ME)R duty holder.

c) Induction of new staff

It is always important for Employers to provide induction for new staff within clinical imaging/radiotherapy departments to aid the entitlement process and to ensure that new staff are adequately trained.

SCoR Guidance

All new staff should complete an induction programme that should include training on local equipment and tasks related to their specific role and that which provides an opportunity for staff sign-off as competence is reached. Before moving onto a new post in another department, it is advisable for staff to obtain copies of their own training record from their Employer. This should provide, for the new Employer, a foundation to establish what an individual is trained to do and what additional training might be required to allow the new Employer to entitle them forthwith.

The following points should typically be included in an induction checklist even though many of them go beyond IR(ME)R matters. It is equally important that the checklist meets the needs and expectations of the RPS, as they have a wider safety role:

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*

3) Role of the Medical Physics Expert (MPE)

Regulation 9 requires the Employer to have a medical physics expert (MPE) involved in every medical exposure. The MPE should be:

- a) closely involved in every radiotherapeutic practice other than standardised therapeutic nuclear medicine practices;
- b) available in standardised therapeutic nuclear medicine practices and in diagnostic nuclear medicine practices;
- c) involved as appropriate for consultation on optimisation, including patient dosimetry and quality assurance, and to give advice on matters relating to radiation protection concerning medical exposure, as required, in all other radiological practice

(SI 2000 No 1059)

IPEM (2002) have usefully described the MPE role (in Appendix 5 of MDGN-IPEM, 2002) for the various radiology modalities and radiotherapy.

SCoR Guidance

The RPA and RPS roles have no statutory responsibility in the IR(ME)R whereas the MPE does, but in reality, the RPA and the MPE may be one and the same person. It must be clear, though, that an RPA may be an independent clinical scientist who advises a department on IRR'99 but the MPE must be fully involved (i.e. normally employed) in the department. The definition of an MPE is: 'a person who holds a science degree or its equivalent and who is experienced in the application of physics to the diagnostic and therapeutic uses of ionising radiation' (SI 2000 No 1059).

Although the IR(ME)R MPE within departments is usually registered as a Clinical Scientist by the Health Professions Council (HPC) under the Health Professions Order 2001, SCoR believe that an appropriately trained radiographer with the relevant qualification (i.e. a science degree) may also be able to undertake this role.

4) Equipment

Regulation 10 requires the Employer to keep and have ready for inspection an updated inventory of all equipment which includes information about:

- Name of manufacturer
- Model number
- Serial number
- Year of manufacture
- Year of installation

Regulation 4(2) requires the Employer to ensure that written protocols (or standard operating procedures) are in place for every type of standard radiological practice and each equipment (SI 2000 No 1059). The Healthcare Commission and the Medicines & Healthcare Products Regulator Agency (MHRA) have co-produced a useful poster highlighting the importance of maintaining equipment protocols – available at:

<http://www.mhra.gov.uk/Publications/Postersandleaflets/CON038792>

It is advisable that protocols are:

- reviewed regularly (usually every 2 years as a minimum and after notable change in process has taken place)
- amended (if required) by only key staff with that responsibility
- discarded if out-of-date
- updated if and when equipment manufacturers change hardware or software.

5) Incident Reporting

a) Mandatory Reporting under IR(ME)R

Regulation 4 requires the Employer to provide a framework of procedures for medical exposures and to carry out investigations of incidents and appropriate reviews.

Regulation 4(5) requires Employers to “make an *immediate preliminary investigation*” of *incidents* and then “*forthwith notify the appropriate authority*” unless the Employer is certain that no exposure *much greater than intended* has occurred.

A detailed investigation and dose assessment is required and it is presumed that notification to the appropriate authority will take place, unless there is early confirmation that there is no need. (SI 2000 No 1059)

SCoR guidance

It is imperative that there are no undue delays in notifying the IR(ME)R appropriate authority (the IR(ME)R Inspector) of a reportable incident following the local preliminary investigation. This is obviously important in learning from errors but also in protecting the patient / public.

Notifiable IR(ME)R Incidents

Notifiable incidents under IR(ME)R are those where a dose “*much greater than intended*” has been delivered to an individual and should be reported to the appropriate authority. Under-doses are not notifiable but must still be locally investigated.

“*Much greater than intended*”

The current guidance as to what constitutes an exposure “***much greater than intended***” under IR(ME)R is available from the Department of Health (2007) – available at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957 (based on Appendix 2 of the “Guidance Note PM77 (Third edition) *Equipment used in connection with medical exposure* (HSE, 2006)” The HSE (2006) guidance details the doses which are likely to be “*much greater than intended*” for particular types of medical exposure.

Further guidance is awaited from the DH (by end of 2009) – SCoR has made a contribution to this forthcoming guidance.

Examples of incidents that require investigation:

- 1) Patient ID error
- 2) Wrong imaged anatomy / Geographical miss of the target volume
- 3) Human error resulting in incorrect exposure or repeated exposure

- 4) Repeat of treatment planning x-ray procedures due to equipment failure or incorrect imaging protocols applied.
- 5) Incorrect treatment dose given (greater or lower than intended)

The detailed local preliminary investigation of incidents required by the Regulations should be aimed at:

- *finding out what happened*
- *where the failure actually lay (i.e. what was the initiating error)*
- *what action is required to minimise the chance of a similar failure?*
- *what actual dose was given to the patient in the incident and how did this compare to the intended dose?*
- *If the error was due to equipment malfunction, it is also reportable to the Health & Safety Executive (HSE)*

(DH, 2007)

Initial incident reports following a medical over-exposure due to human error must be kept for at least two years, detailed reports must be kept for 50 years (Regulation 4(5)).

The dose received by the patient due to any over-exposure incident must be recorded in the patient's notes. It is good practice that the patient is also informed of the incident unless there is good reason for the patient not to be (which should be documented in the patients notes) – how the patient is informed is down to local procedure but the IR(ME)R practitioner and referrer should be involved.

IR(ME)R Inspectorate information

There are 4 separate IR(ME)R Inspectorates (the “*appropriate authority*” for the four UK home countries (contact details below). IR(ME)R inspections are undertaken either on:

- a **pro-active basis** (where inspections provide assurance of regulation compliance and guidance is given)
- or on a **re-active basis** (where evidence is gathered following an incident being reported - sometimes this may involve interviewing witnesses / duty-holders under caution).

i) IR(ME)R Incident notification to CQC (England only)

In England, the Healthcare Commission (HCC) was the independent inspection body for both the NHS and independent healthcare. From 1st April 2009, the HCC became the Care Quality Commission (CQC), the new independent regulator of all health and adult social care in England (a merger between the Mental Health Act Commission and the Commission for Social Care and Inspection).

The IRMER email address changed to IRMER@cqc.org.uk and this email should be used for any correspondence to the IRMER team.

For the foreseeable future, the IRMER incident webform will still be located on the Healthcare Commission website. A link to the webform that is on the Healthcare Commissions website is also to be provided from the new Care Quality Commissions website - www.cqc.org.uk. In due course it is planned to relocate the webform to the CQC website for the radiology / radiotherapy community to access the incident reporting form to submit IRMER notifications.

Further information about the use of ionising radiation and the CQC is available from the following link:

<http://www.cqc.org.uk/guidanceforprofessionals/healthcare/allhealthcarestaff/managingrisk/useofionisingradiation.cfm> where there is information about how to report an IR(ME)R incident, their inspection programmes and the key findings of previous inspections.

Note

Information about reporting incidents is available on the CQC website at:

<http://www.cqc.org.uk/guidanceforprofessionals/healthcare/allhealthcarestaff/managingrisk/useofionisingradiation/reportingincidents.cfm>. A link is there to the HSE for incidents that involve a medical exposure to a patient through equipment failure.

Notifications can be made directly to CQC by using their web-based notification form – available from:

<https://admin.webforms.cqc.org.uk/popup/survey.php?sid=944966036>

An example of the normal sequence of events when a radiation incident (IR(ME)R) notification has been made to CQC (England)

- completion of web form (normally done by a departmental head or RPA)
- upon receipt CQC attach a number automatically to the case
- CQC phones the person who completed the form – because CQC need to know how the “internal report” is proceeding (i.e. more background information and if the dept had instigated its own internal inspection etc) and that when is the “internal” report going to be sent to CQC
- The decisions about whether an inspection is required or not is done with a group at CQC (e.g. physicists and others) – including the CQC Lead IR(ME)R Inspector.
- The decision is conveyed back to the hospital (dept) – a written letter which, as the Employer, must go to the CEO (and copied to the person who originally completed the web-form)
- If there is to be no inspection – the letter normally states something like “the dept must abide by the recommendations within the internal report, continue to monitor protocols etc”
- Then the case is closed.

Other points of note –

- 9 out of 10 cases will not have an inspection

- There is to be an annual inspection form (which is risk based)
- If there are a few notifications from the one dept HC may obviously decide to inspect (even if they are seen to be fairly minor incidents).

The IR(ME)R Inspector (England) within CQC (previously HCC) had written the first report entitled: “*Ionising Radiation (Medical Exposure) Regulations 2000. A report on regulation activity from 1 November 2006 to 31 December 2007*”

The report highlights the nature of incidents where patients have been exposed to ionising radiation to a degree ‘*much greater than intended*’. The total number of notifications HC received during the 14 -month period from 1 November 2006 to 31 December 2007 was 329 – available at: http://www.cqc.org.uk/publications.cfm?fde_id=817

The CQC also publish individual reports from proactive visits on their website – see

<http://www.cqc.org.uk/guidanceforprofessionals/healthcare/allhealthcarestaff/managingrisk/useofionisingradiation/o/inspectionreports.cfm>

Review of the annual reports and site inspection reports is an excellent tool in improving radiation protection in clinical departments.

The IR(ME)R Inspectorate for England has a detailed annual inspection programme and also writes quarterly IR(ME)R reports for the radiology and oncology community and he is particularly keen to hear feedback from radiographers as to the usefulness of these reports.

To view the inspection programme and the reports follow

<http://www.cqc.org.uk/guidanceforprofessionals/healthcare/allhealthcarestaff/managingrisk/useofionisingradiation/ourinspectionprogrammes.cfm>

ii) Other IR(ME)R Inspectorate details

Responsibility for the protection of patients undergoing medical exposure to ionising radiation has been devolved to the home countries. All notifications of incidents where patients have been exposed to ionising radiation to a degree ‘***much greater than intended***’ (IR(ME)R,2000) should be sent to the relevant IR(ME)R Inspectorates.

Wales

The enforcing authority for Wales for the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) is the Welsh Ministers. The Minister for Finance and Public Service Delivery and the Minister for Health and Social Services has agreed to the transfer of the IR(ME)R enforcement programme from Health

Protection Division (HPD) of the National Assembly Wales (NAW) to Healthcare Inspectorate Wales (HIW) and agreed to transfer the IR(ME)R budget to HIW. For further information see

http://wales.gov.uk/publications/accessinfo/drnewhomepage/healthdrs/Healthdrs_2009/transfioniisngradregstohiw/?lang=en

Dr Owen Crawley, the Welsh Chief Scientific Adviser in NAW still retains the current warrant but warrants are also issued to inspectors in HIW who will be taking on the responsibilities for reactive inspections in the near future.

HIW has the responsibility of being the “appropriate authority” for IR(ME)R inspectorate arrangements on a pro-active arrangement which are organised on a “risk” basis and which are formally reported back to the community and the public. Self-assessment tools that relate to the generic healthcare standards for Wales also include IR(ME)R information and are completed by local departments. See HIW IR(ME)R page at:

<http://www.hiw.org.uk/page.cfm?orgid=477&pid=35707>

The Welsh Chief Scientific Adviser retains professional oversight of IR(ME)R and NAW retains policy oversight and a meeting takes place annually with HIW to discuss IR(ME)R issues. Regular seminars are organised via the Chief Scientific Adviser’s office to disseminate information and learning – the latest had the theme of “patient safety in radiotherapy”. See

<http://wales.gov.uk/topics/health/professionals/scientific/ionising-radiation-regulations/2234682/?lang=en>

Note

Incidents in Wales, which result in a patient receiving a radiation dose “*much greater than intended*”, must be reported to:

Dr Crawley
Chief Scientific Adviser
Department of Public Health and Health Professionals
Welsh Assembly Government
Cathays Park
Cardiff
CF10 3NQ

E-mail: CMO.webmaster@Wales.gsi.gov.uk

Information about what should be supplied to the inspectors following a detailed investigation of an IR(ME)R incident is available on the Welsh Government website at: <http://wales.gov.uk/dphhp/publication/professionals/scientific/ionising-radiation-regulations/ionising-radiation-regulations?lang=en>

Scotland

The enforcing authority for Wales for the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) is the Scottish Ministers. Dr Arthur M Johnston is the Warranted Inspector appointed by the Scottish Ministers and his contact details are:

St Andrew's House
Regent Road
Edinburgh
EH1 3DG
Tel 0131 244 2779
Fax 0131 244 1030
<http://www.scotland.gov.uk/Topics/Health>

Northern Ireland

Incidents in Northern Ireland which have gone through a local preliminary investigation and which results in a patient receiving a radiation dose "*much greater than intended*", must be reported to:

Deputy Chief Medical Officer
DHSSPS
Castle Buildings
Stormont
Belfast
Tel: 028 9052 0710
<http://www.dhsspsni.gov.uk/index/hss.htm>

The enforcement powers and responsibility for inspections under IR(ME)R will lie with the Regulation and Quality Improvement Authority (RQIA) from the end of summer 2009 – see <http://www.rqia.org.uk/home/index.cfm> .

b) Voluntary reporting

It is mandatory to report those incidents described under IR(ME)R to the appropriate authority. As discussed, the CQC and HIW share information via their respective websites on those incidents reported, and on their findings at pro-active inspections within the radiology community. The findings and the reports provide valuable tools for improving radiation protection in radiology on a national scale. Much more could be learned if information about lower level incidents (i.e. those that are not notifiable) was to be shared.

Towards Safer Radiotherapy (2008) has a dedicated chapter to ‘Learning from errors’ (Chapter 6) in radiotherapy. Much of the ethos of this document is transferable across the different modalities in radiology. This discusses the value of local and national learning from errors and near misses. It also proposes a voluntary national UK radiotherapy reporting, analysis and learning system, with the provision of feedback to the radiotherapy community.

i) **National Patient Safety Agency**

The National Patient Safety Agency (NPSA) has an established system of voluntary reporting of patient safety incidents and near misses called the National Reporting and Learning Service (NRLS). The NPSA have engaged expertise from the HPA to undertake analysis of radiotherapy incidents. The first analysis was reported on the NPSA website in its quarterly report in May 2008.
<http://www.npsa.nhs.uk/nrls/patient-safety-incident-data/quarterly-data-reports/>

The HPA now have a data sharing agreement with the NPSA to provide the expertise to undertake the analysis of data collected on radiation incidents on a regular basis. It is envisaged that these reports will be routinely published on the NPSA website as part of their quarterly reports. This will enable the national sharing of any lessons learnt from incidents and near misses.

The NPSA also issue “Safer Practice Notices” periodically – an example of such a Safer Practice Notice relating to a reported failure to act on radiological imaging reports is available for download at <http://www.npsa.nhs.uk/nrls/alerts-and-directives/notices/radiological/>

ii) In England - the Cancer Standards also have a requirement for systems to be in place for handling incidents etc. Further information is available at http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4002999

iii) For further guidance, the staff of the HPA, Radiation Protection Division, Medical Exposures Department is able to give advice on all radiographic safety matters and have particular support for radiotherapy services – see
<http://www.hpa.org.uk/webw/HPAweb&Page&HPAwebAutoListName/Page/122236714369?p=1222236714369>

REFERENCES

A Guide to Understanding the Implications of the Ionising Radiation (Medical Exposure) Regulations in Radiotherapy (2008), SCoR, IPEM, RCR and HPA, The Royal College of Radiologists, England

Approval for research involving ionising radiation, Version 2 (2008) the National Research Ethics Service [NRES] www.nres.npsa.nhs.uk/rec-community/guidance#ionisinggrad (sourced 13th March, 2009)

Clinical Imaging Requests from Non-Medically Qualified Professionals, (2008) The Royal College of Nursing in conjunction with SCoR, GCC, CSP, NHS Alliance, RCR, GOC, HPA www.sor.org/auth/forms/login.php?r=documentlibrary/sor_clinical_imaging_requests_non_medically.pdf

Code of Conduct and Ethics, (2008) The College of Radiographers, London

Guidance on the establishment and use of diagnostic reference levels (DRLs), (2007) Department of Health www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074067 (sourced 10th March 2009)

Guidance on the Establishment and Use of Diagnostic Reference Levels for Medical X-Ray Examinations Report 88 (2004) written by a Joint Working Party: IPEM, BIR, RCR, NRPB and CoR, 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)

Implementing In-vivo dosimetry (2008) SCoR, RCR, BIR, & IPEM, The Royal College of Radiologists, London www.sor.org/members/document-library/sor_invivo_joint.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)

Ionising Radiation (Medical Exposure) Regulations 2000 (SI 2000 No 1059), London, HMSO, <http://www.opsi.gov.uk/si/si2000/20001059.htm> (sourced 10th March 2009)

Ionising Radiation (Medical Exposure) Regulations (Northern Ireland) 2000 <http://www.opsi.gov.uk/sr/sr2000/20000194.htm> (sourced 26th May 2009)

Ionising Radiation (Medical Exposure)(Amendment) Regulations (2006), (SI 2006/2523) London, HMSO, www.opsi.gov.uk/si/si2006/20062523.htm (sourced 10th March 2009)

Making the Best Use of a Radiology Department 6th edition, (2007) The Royal College of Radiologists, England

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/11957338_26941?p=1158934607708 (sourced 23rd February 2009; last updated 4th September 2008)

Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation (2009), Health Protection Agency (HPA), The Royal College of Radiologists and the College of Radiographers; Health Protection Agency, England

http://www.hpa.org.uk/servlet/Satellite?c=HPAweb_C&childpagename=HPAweb%2FHPAwebStandard&cid=1238230848780&p=1199451989432&pagename=HPAwebWrapper (sourced 7th July 2009)

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

The Drugs Act (2005) Statutory Instrument 2005 No. 3053(C. 128) - www.opsi.gov.uk/si/si2005/20053053.htm(sourced 23rd February 2009)

The European Directive 97/43/ Euratom, The Medical Exposures Directive (1997)
http://ec.europa.eu/energy/nuclear/radioprotection/doc/legislation/9743_en.pdf
(sourced 7th July 2009)

The Ionising Radiation (Medical Exposure) Regulations 2000 (together with notes on good practice) (2007), Department of Health, England
www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4007957 (sourced 10th 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 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)

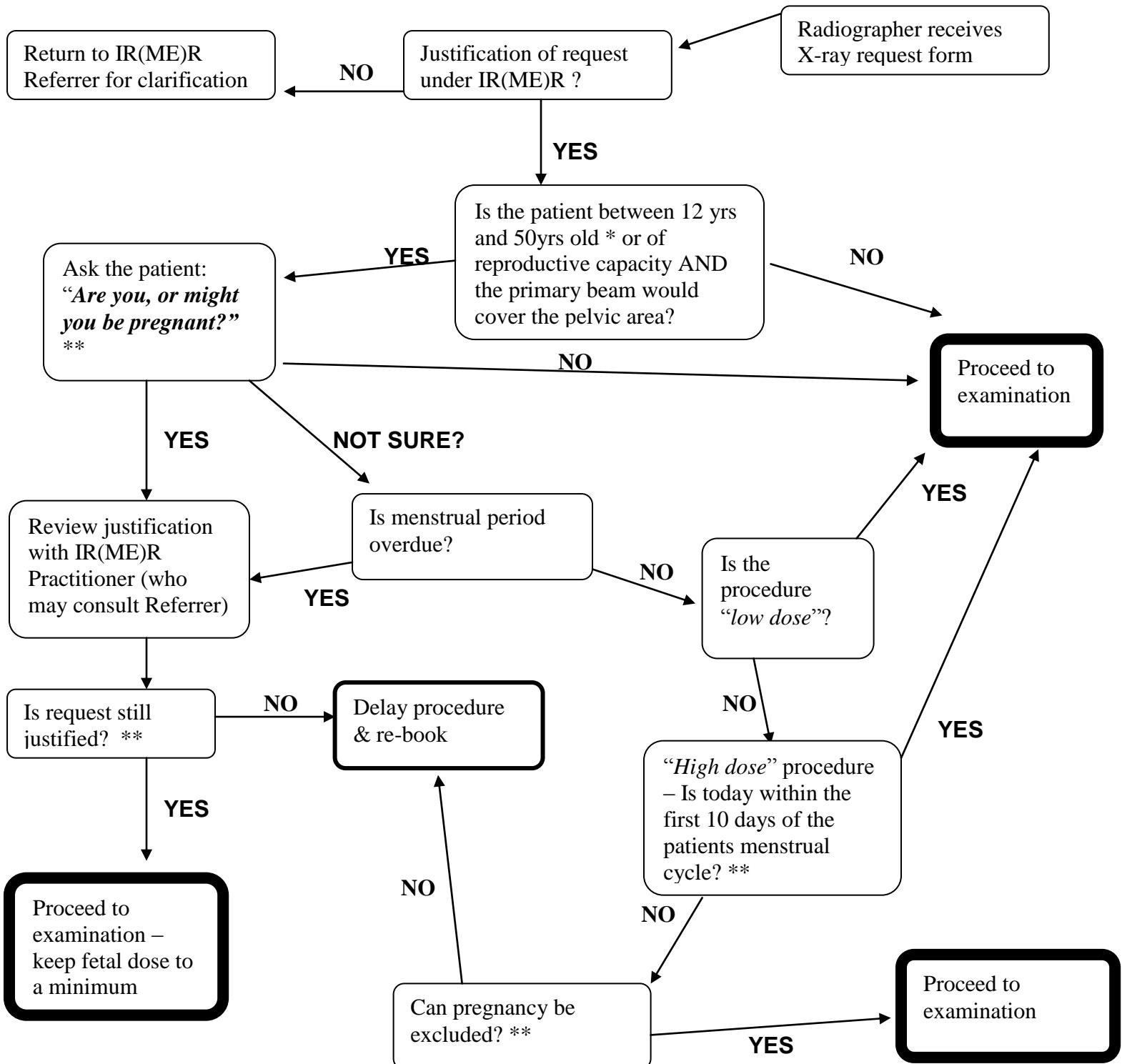
Towards Safer Radiotherapy, (2008) SCoR, RCR, IPEM, BIR & NPSA; The Royal College of Radiologists, London - <http://doc-lib.sor.org/listtitles?page=2>

Appendix

IR(ME)R Pregnancy status for **diagnostic radiography** – flow chart examples

- i) Conscious patient
- ii) Unconscious patient

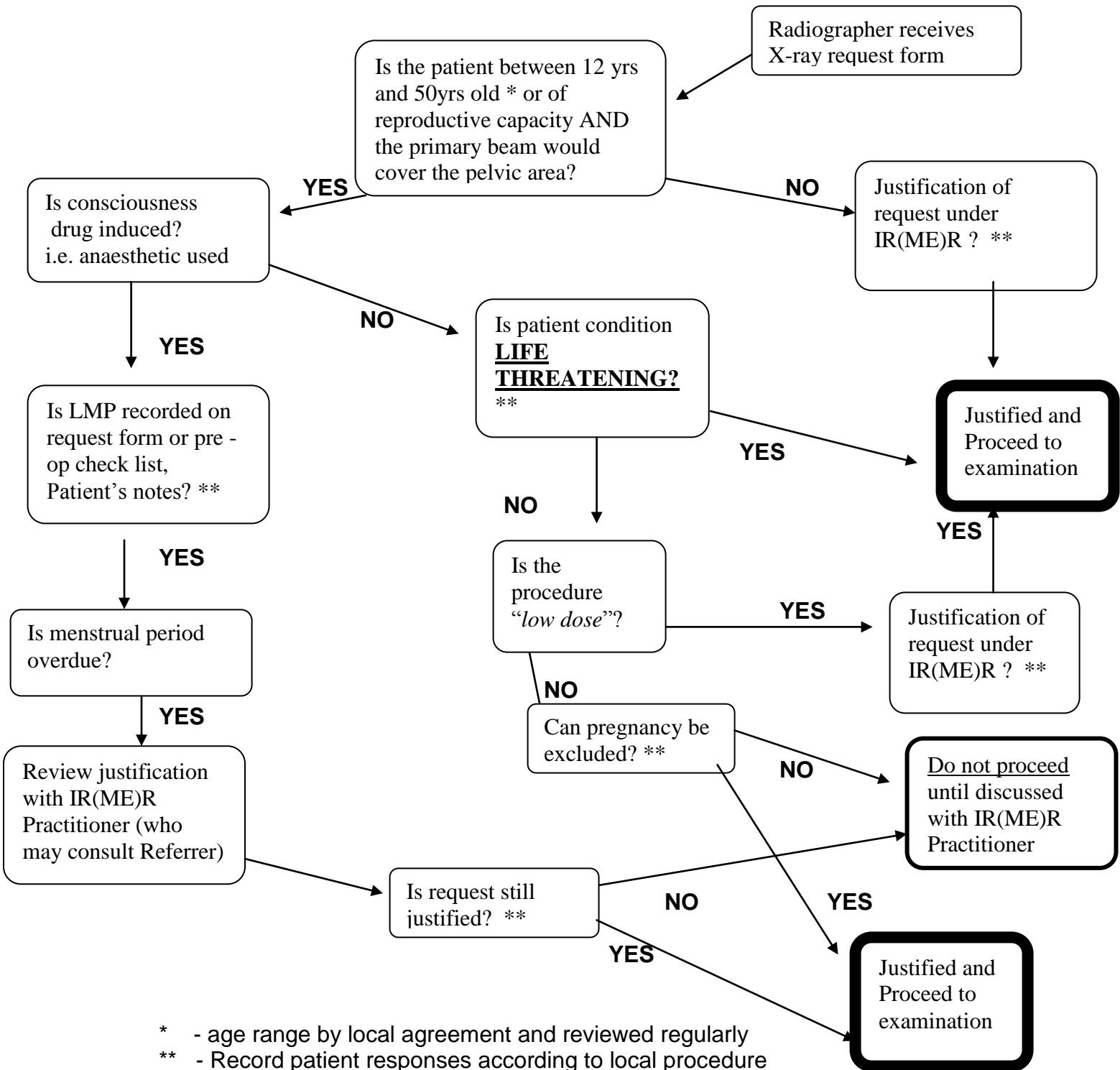
(i) Sample flow chart for checking pregnancy status in women of reproductive capacity who attend for diagnostic medical exposure to ionizing radiations (conscious patient).



* - age range by local agreement and reviewed regularly

** - Record patient responses according to local procedure

(ii) Sample flow chart for checking pregnancy status in women of reproductive capacity who attend for diagnostic medical exposure to ionizing radiations (unconscious patient).



* - age range by local agreement and reviewed regularly

** - Record patient responses according to local procedure