CONSULTATION PROCESS
Radiologists, Trevor Parker, Craig Moore, Operational Groups, RMT & RPSs

TARGET AUDIENCE
All Staff

PROCESS FOR MONITORING COMPLIANCE
Radiology Operational Groups and Radiology RMT Committee

REFERENCES
The Ionising Radiation (Medical Exposure) Regulations 2017

1 INTRODUCTION
This document is written to ensure that departmental process conforms with the Ionising Radiation (Medical Exposure) Regulations 2017 (IRMER 2017).

2 PURPOSE
This document ensures the Radiology Department is compliant with regulation 6(1) of the Ionising Radiation (Medical Exposure) Regulations 2017. Regulation 6(1) requires employers to write procedures associated with medical exposures. It is a legal requirement for all IRMER Practitioners and IRMER Operators to follow these procedures.

3 SCOPE
These procedures apply to all staff involved in radiographic (including interventional) medical exposures and associated practical aspects, such as image evaluation. These staff will normally include IRMER Operators such as radiologists, radiographers and assistant practitioners performing medical exposures. It also applies to IRMER Practitioners (Radiologists and Registrars) who justify individual exposures and evaluate images.

4 DUTIES
All IRMER Practitioners and IRMER Operators involved in radiographic (including interventional) medical exposures are legally obliged to follow these procedures.

1. Procedure to identify correctly the individual exposed to ionising radiation

1.1.1 Immediately prior to the start of the planned medical exposure, the Operator must verify the identity of the patient by asking them to state their name, date of birth and address and comparing these against the details on the referral. This ID process must be recorded by completing the 'ID checked by' field on the Radiology Information System (RIS).

1.1.2 Neonates and children under 1 year may not have identity bands/wristbands attached to their body - the details attached to the incubator (neonates) which must be checked against those details on the referral. If there is nothing on the incubator check with carer or healthcare professional to confirm identity. This ID process must recorded by completing the 'ID checked by' field on the Radiology Information System (RIS).

1.1.3 For any invasive procedure or any procedure requiring GA/sedation a Radiology Safety Checklist and/or WHO surgical checklist, the person performing the procedure must ensure it is completed. This can be a member of the clinical team in the room by asking the questions out loud and all staff in the room should stop and listen. The pregnancy status must also be asked by the nurse or member of the clinical team completing the checklist prior to entering the examination room.

1.1.4 If there is more than one Operator, such as in CT, it must be clear which Operator is responsible for identifying the patient. This must be agreed between the Operators prior to the exposure.

1.1.5 If an address is not available, then it is acceptable to verify the identity of the patient by checking name, date of birth and hospital number or NHS number against those on the referral.

1.1.6 Verbal communication may prove difficult and unreliable with certain patients and identification may be impossible to establish by the procedures detailed above. In such instances, the following procedure must be followed:

1.1.6.1 For inpatients, it is acceptable to rely on the patient's identity band/wristband alone.

1.1.6.2 If a patient is unable to speak but can write, this is an acceptable alternative.

1.1.6.3 For patients who cannot understand English, the wristband or photo identification are acceptable methods of identifying the patient. Furthermore, arrangements can be made for an interpreter to be available via the Trust's approved service. This must be done through the interpreter requesting system on Pattie or using an online language interpretation service

1.1.6.4 If a patient is not able to identify themselves, and is not wearing an identity band/wristband, a member of the patient's immediate family should be asked to supply name, date of birth and address on behalf of the patient. If this method is used, the identifying person and their relationship to the patient should be recorded on the Radiology Information System (RIS).

1.1.6.5 If an immediate family member is not available, the name, date of birth and address must be supplied by an escort with personal knowledge of the patient. If this method is used, the identifying person and their professional position or relationship to the patient must be recorded on the RIS.

1.1.6.6 If an unconscious patient, who cannot be identified, is admitted through the Emergency Department (ED) they will be identified via their 'unique' (ED) admission number. The Radiology Department is responsible for liaising with ED as regards obtaining the patient's true identity and demographic details.

1.1.6.7 If a patient attends the Radiology Department for a referral from the Sexual Health Clinic and will not divulge their personal details, then the unique identifying number issued by the clinic should be used.

1.1.6.8 If a patient is anaesthetised the Operator must verify the patient's ID with the Anaesthetist.

1.2 Procedure if details do not match those on the request

1.2.1 If the address is incorrect, the patient should be asked for previous addresses as this may be due to moving house. Details must be amended on both the RIS and the Hospital Information System by the relevant administration team

1.2.2 If any details are still incorrect, the Referrer should, where possible, be contacted. They must ensure that the patient is the correct patient, change the identification details on the referral to correct the errors before the investigation can proceed.

1.2.3 If the Referrer is not available, their secretary, or another member of their team, should be contacted to obtain the correct details. The correct details should be added to the RIS record by the member of staff who obtained them.

2. Procedure to identify individuals entitled to act as IRMER referrer, IRMER practitioner or IRMER operator within a specified scope or practice

All duty holders are made aware of their responsibilities under IR(ME)R through training (e.g. degree, FRCR theoretical training, local HEY247 training) and these procedures.

Entitlement of duty holders is authorised by the Clinical Director of Radiology through the Radiology Management Committee.

Training of duty holders will be signed off by the section managers and/or radiation protection supervisor (RPS). Training and entitlement will be assessed by the section managers and/or RPS every 1 - 3 years during the duty holder's appraisal. The appraisal template will be used for this process. Training records will be held by the section managers and/or RPS.

In most circumstances the referrer must supply the IRMER practitioner with:

- Sufficient medical data (such as previous diagnostic information, medical records and clinical indications) relevant to the medical exposure to enable the IRMER practitioner to justify the exposure, or an IRMER operator to authorise the exposure under justification guidelines written by the IRMER practitioner
- If applicable, information on the patient's menstrual status.
- Referrals can be electronic or written by hand on an appropriate referral template form/card. The referral source and the referrers name must be clearly indicated.

Verbal referrals: Theatre procedures
In circumstances where a written request is unavailable the referrer must be present with the operator during the radiographic procedure. In this situation, the referrer is physically identifying the patient and as such the operator may authorise the exposure.

Verbal referrals: Acute referrals in interventional procedures
In certain exceptional circumstances where loss of life is an acute risk, the referrer is permitted to verbally request the procedure directly with the radiologist. The radiologist will always justify and authorise subsequent exposures.

<u>Individuals entitled to act as IRMER Referrers</u>:

All referrals must be in line with referral protocols/guidelines.

MEDICAL STAFF	
Referrer	**Medical Exposure**
Consultants	All medical exposures
Specified Associate Specialist / Staff Grade Associate Specialist / Staff Grade Registrar	Plain Radiography Specified GI Fluoroscopic Exposures Image Intensifier CT Scanning Angiography and interventional

Senior House Officer House Officer	Plain Radiography GI Fluoroscopic Exposures CT Scanning Angiography and interventional
General Practitioner	Plain Radiography Specified GI Fluoroscopic Exposures CT Scanning

NON-MEDICAL STAFF		
Referrer	**Medical Exposure**	**Protocol**
Radiographers Specified Nurse Practitioners Specified Allied Health Professionals	Range of examinations for specified indications	As per appropriate protocol
Dentists	Extra Oral Radiography	

Individuals entitled to act as IRMER Practitioners:

The legal responsibility for justification always remains with the IRMER practitioner. However, authorising that the exposure has been justified is a separate function, the responsibility for which can rest with the IRMER practitioner or a suitably qualified operator (i.e. Registered Radiographer) who may authorise under justification guidelines produced by the relevant healthcare professional. The person responsible for authorisation may be someone other than the operator who subsequently carries out the exposure. For example, a senior radiographer may authorise but another radiographer may make the exposures. The method of authorisation should be stipulated by a signature on the request card (if appropriate) and by the naming the radiographer or radiologist in the relevant field in the Radiology Information System (RIS) (see below for specific authorisation methods).

IRMER Practitioner	**Medical Exposure**	**Training requirements**
Consultant Radiologists	Plain Radiography All Fluoroscopy (inc; angiography/interventional) CT scanning	FRCR qualified (IRMER schedule 3 training) GMC Registration 1 -3 yearly ongoing competency appraisal
Radiology Registrars who have successfully completed the relevant FRCR radiation safety & physics module	Plain Radiography All Fluoroscopy (inc; angiography/interventional) CT scanning	FRCR qualified (IRMER schedule 3 training) GMC Registration Competency appraisal initial sign-off 1 -3 yearly ongoing competency appraisal
Cardiologists who have received appropriate IR(ME)R training	CT cardiac scanning	IRMER schedule 3 training GMC Registration
Staff of outsourced company	Dependent on modality outsourced	Covered by a bespoke ‘cooperation of employers

		agreement'
Radiographers	Exposures relevant to speciality and training.	HCPC registered IR(ME)R schedule 3 training Competency appraisal initial sign-off 1 -3 yearly ongoing competency appraisal

Individuals entitled to act as IRMER operators:
Individuals entitled to act as IRMER operators are those personnel who have had theoretical training stipulated by IRMER Schedule 3, and practical training on the X-ray equipment they operate (with records demonstrating training); they must be from one of the following staff groups:

Operator	**Medical Exposure**	**Conditions/Training**
Radiologists & Registrars	Fluoroscopy, Angiography & Interventional	Working to schemes of work and who have received appropriate training
Main X-ray Radiographers	Plain Radiography, Fluoroscopy, Image Intensifier, Angiography & Interventional	Working to schemes of work and who have received appropriate training
Specified Barium Enema / GI Radiographers	Barium Enema and specified GI procedures	Working to schemes of work and who have received appropriate training
CT Radiographers	CT scanning	Working to schemes of work and who have received appropriate training
Assistant Practitioners	Plain Radiography, Fluoroscopy, Image Intensifier, Angiography & Interventional	Working to schemes of work and who have received adequate training
Clinical Imaging Support Workers (CISW)	Plain Radiography, Fluoroscopy, Image Intensifier,	Working in a support role NOT operating X-ray machines (note: CISW do not require theoretical training stipulated by IRMER Schedule 3 but do require training under the Ionising Radiation Regulation 2017 (IRR regulation 15))
Medical Physics staff	Quality assurance (QA) testing of any equipment if appropriately trained	Training records held by Consultant RPA/MPE
Staff of outsourced company	Dependent on modality outsourced	Covered by a bespoke 'cooperation of employers agreement'
Orthopaedic Surgeons	Image intensifier of simple trauma cases	Working to schemes of work and who have received adequate training

Duties of Operators:

The operator is any person who carries out a practical aspect of the medical exposure. The primary responsibility of the operator is to optimise the exposure. The operator must ensure that the patient is correctly identified, that the exposure has been justified and authorised, and for patients of childbearing age, status regarding their menstrual cycle is the same as that recorded on the request. The operator may then carry out the procedure. The original referrer (or radiologist) should be consulted where there is any doubt as to the appropriateness of any request.
Any additional information required to facilitate a retrospective estimation of the effective dose to the patient should be recorded. To undertake new techniques, and use new equipment, operators must be adequately trained, and this training must be documented.

Methods of authorisation:

General Radiography
The method of authorisation is carried out by naming the examining radiographer in the relevant field in the RIS.

Computed Tomography (CT)
Identification of the radiologist/registrar who justified the exposure is carried out by naming them in the relevant field in the RIS
The method of authorisation is carried out by naming the scanning radiographer in the relevant field in the RIS.

CT Brachytherapy patients
For Brachytherapy procedures, all concomitant CT exposures are justified and authorised by the clinical oncologist prior to treatment.
Radiographers may carry out the exposure without a specific written request from Oncology provided that the patient has had the relevant brachytherapy applicators inserted.

Screening Room 5 HRI, Screening Rooms 1 & 2 CHH and all mobile screening (HRI & CHH Theatres)
The method of authorisation is carried out by naming the operating radiographer or radiologist (i.e. whoever authorised the exposures) in the relevant field in the RIS.

Interventional Radiology
The method of authorisation is carried out by naming the operating radiologist in the relevant field in the RIS.

3. Procedure to be observed in the case of non-medical imaging exposures

3.1 Non-medical imaging exposures are those undertaken for insurance, administrative or legal purposes (such as suspected drug smugglers) where there is not expected to be any direct health benefit for the patient. In these cases, the IRMER Practitioner will take any non-medical benefits to the patient into account when justifying the procedure, and will take particular account of the risks in relation to those benefits.

3.2 Non-medical imaging exposures will only be undertaken with the consent of the patient (in the case of chest radiography for emigration purposes, the patient's signature on the relevant forms will be taken to imply consent). In all other cases, the request will be vetted by the appropriate radiologist (acting as IRMER Practitioner). Consent to the procedure will be sought before proceeding, if this has not already been obtained by the referrer (e.g. the Customs and Excise authorities in the case of suspected drug smugglers).

3.3 Any additional projections or investigations, which may be required as a result of the initial investigation, must be medically justified.

4. Procedure for making enquiries of individuals of childbearing age to establish whether the individual is or may be pregnant

4.1 In all individuals of reproductive capacity, the clinician requesting the examination should consider the possibility of pregnancy. National guidelines[1] acknowledge that there is no risk to the conceptus following irradiation during the first 10 days of the menstrual cycle. However, in the interval between 10 days and the date at which the next menstrual cycle is due there is a small risk for high dose procedures such as pelvic or abdominal CT and barium enemas.

4.2 If a foetus has been inadvertently exposed, the Medical Physics Expert (MPE) must be informed. He/she can then provide a dose and risk estimate.

4.3 At diagnostic dose levels, the only adverse effect of radiation on the conceptus is an increased risk of cancer induction. Dose levels are too low to induce death or malformations. Therefore, invasive foetal diagnostic procedures or termination of the pregnancy are not justified.

4.4 The accompanying flow diagram indicates the general procedure to be followed. Where necessary local rules will provide specific requirements for particular work areas.

4.5 The senior radiographer and/or Radiation Protection Supervisor (RPS) is responsible for ensuring that all staff are familiar with the correct procedure, and that normal good radiographic practice is carried out to ensure that radiation doses are kept as low as reasonably achievable.

4.6 In all individuals of reproductive capacity (age range 12 – 55 inclusive), if the primary beam is likely to irradiate the area between the diaphragm and femora, the individual must be asked whether they might be pregnant. If the answer is 'no' then the procedure can be carried out with no further enquiries. If the patient is unsure, the Operator must ask *"Is your last menstrual period overdue"?* especially if there is a long delay between request and exposure. This is to ensure that the examination is carried out within 10/28 days of the last menstrual period (LMP).

4.7 For any invasive procedure or any procedure requiring GA/sedation a Radiology Safety Checklist and/or WHO surgical checklist, the person performing the procedure must ensure it is completed. This can be a member of the clinical team in the room by asking the questions out loud and all staff in the room should stop and listen. The pregnancy status must also be asked by the nurse or member of the clinical team completing the checklist prior to entering the examination room.

4.8 For all pregnancy enquiries, the relevant fields in the RIS must be completed. This involves choosing 'Yes/No/Unknown' in the 'Pregnant?' field and adding the date of the LMP if appropriate.

4.9 Where a patient's first language is not English arrangements must be made for an interpreter to be available. This must be done through the interpreter requesting system on Pattie or using an online language interpretation service

4.10 For an unconscious patient, who cannot state whether they are pregnant or not, the procedure is to confirm with the clinician/radiologist that the clinical risk outweighs the risk from the exposure. The name of the clinician/radiologist must berecorded on the RIS.

4.11 Advisory notices should be prominently displayed in X-ray departments.

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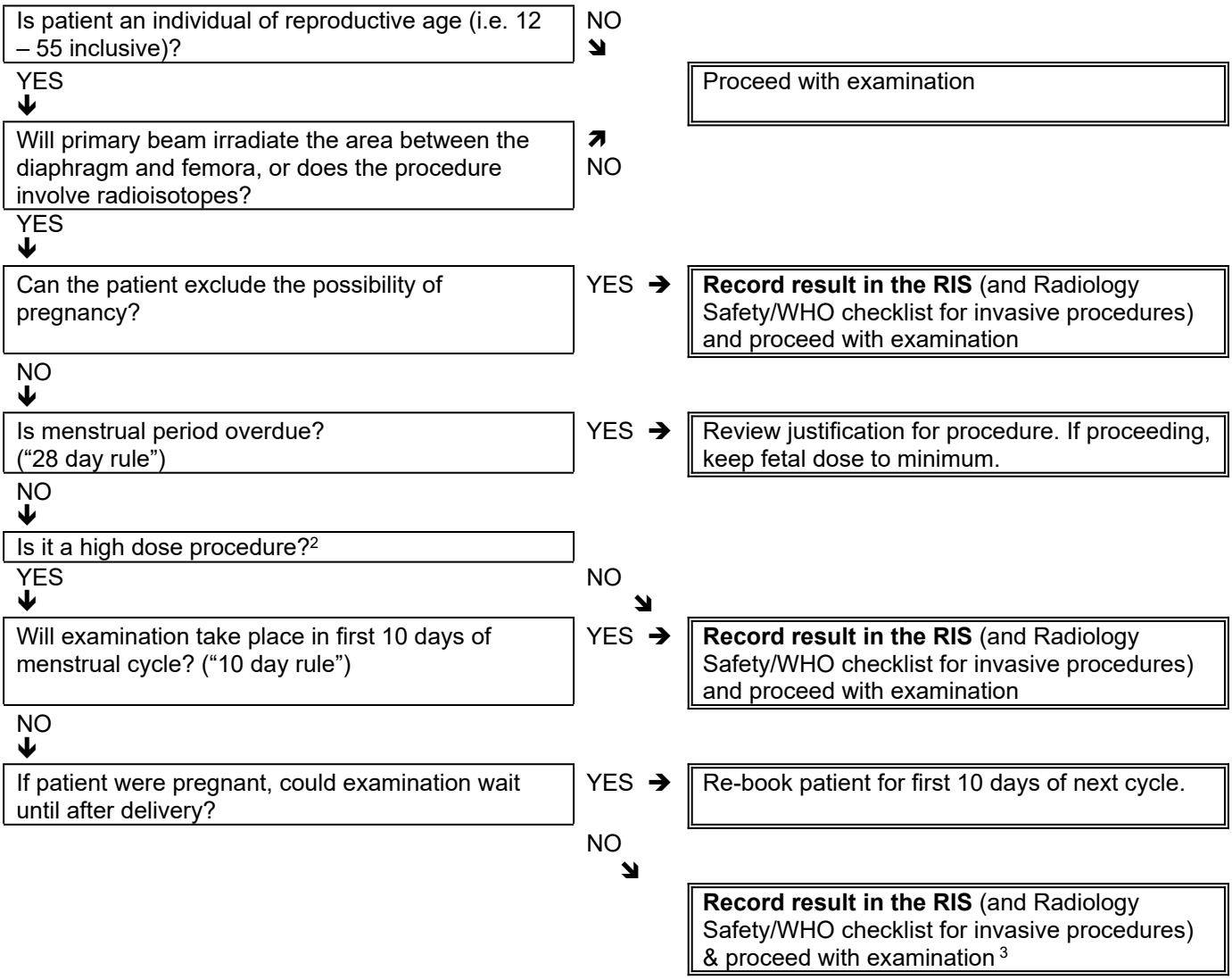
[1] Protection of Pregnant Patients during Diagnostic Medical Exposures to Ionising Radiation RCE 9, HPA, 2009 [http://www.hpa.org.uk/Publications/Radiation/DocumentsOfTheHPA/RCE09ProtectionPregnantPatientsduringDiagnosticRCE9/],

4.12 X-ray requests should have a space to allow for insertion of the LMP by the referring clinician.

4.13 If the operator does not obtain satisfactory assurance the request should be referred back to the requesting clinician or department, or to a radiologist.

4.14 This advice may be ignored in the following cases:-

- Individuals who have been on the contraceptive pill/implant/injection for three months or more, or have an IUD fitted.
- Individuals who have been sterilised.
- Nuns.
- Individuals who are outside the age range of 12 – 55 (inclusive) or are post menopausal.



[2] Fetal dose of tens of milligray. e.g. abdominal CT, pelvic CT, barium enema, (see www.hullrad.org.uk)

[3] The risk to fetus in first month of pregnancy is less than that in later months.

5. Procedure to ensure that quality assurance programmes in respect of written procedures, written protocols and equipment are followed

Written Procedures

5.1 All procedures and protocols must be subjected to periodic audit to ensure that they are current, effective and appropriate. Any necessary improvements or amendments should be identified

5.2 All radiation safety procedures/protocols will be reviewed every 2 - 3 years. The review will be carried out by the senior radiographer/RPS and an MPE.. All procedures will use the Trust's or RMT approved Document Control Headings

5.3 Ratification will be done through Ops Group and/or Radiology RMT Committee, where appropriate. An IR(ME)R Practitioner must be involved in the ratification process.

5.4 All written procedures will be made available to all relevant staff members via Q-Pulse Radiology's Electronic Document Management System.

5.5 Audits should be undertaken periodically. The RPA/MPE will audit the radiology department not less than every three years to assess compliance with IRR17 and IRMER. HUTH radiology management will audit the department for general 'radiographic' compliance on a more frequent basis.

5.6 Staff must report any instance when they are aware procedures and protocols are not being followed and are not working as expected.

5.7 A written log (electronic logs are permitted) must be kept of all reported incidents of procedural breakdown.

5.8 Written records of audits must be kept to demonstrate the quality assurance procedures being followed. A report to the Radiology Management Team should be submitted if there are persistent problems.

Equipment

5.9 The Radiology department's written user quality assurance (QA) procedures can be found via the QA software application available in the senior radiographer's office and most processing areas. This programme includes checks on all X-ray equipment including digital systems, as per the requirements of IPEM Report 91, as well as out of tolerance procedures.

5.10 The department's equipment and controlled area handover procedure and form can be found via the QA software application available in the senior radiographer's office and most processing areas

5.11 The Medical Physics Department will QA all X-ray equipment annually (or after equipment installation and maintenance where appropriate), as per the requirements of IPEM Report 91. The Physics department have their own written QA procedures.

6. Procedure for the assessment of patient dose

It is the responsibility of the operator (i.e. Radiographer) to ensure that patient dose is documented after every exposure. The dose area product (DAP) for general and screening/interventional procedures, and dose length product (DLP) for CT must be recorded in the RIS after the patient examination. Although not essential, the tube potential (kVp), tube current-time product (mAs) and focus to detector distance (FDD) should also be entered.

To identify multiple and abnormal exposures (i.e. large/obese patients), the appropriate 'Flag' should be set in the RIS..

For interventional and fluoroscopy procedures, the assessment of skin dose is documented in the department's skin dose procedure which can be found via the y-drive, Qpulse or document finder software application (if available), available in the senior radiographer's office and most processing areas

7. Procedure for the use of diagnostic reference levels (DRLs)

7.1 DRLs for standard procedures will be recommended by the Medical Physics Expert (MPE) and will be based on local dose audits, i.e. local DRLs will be established where these are consistently lower than national and/or European DRLs. The MPE will recommend new DRLs when necessary.

7.2 Where healthcare professionals believe that different DRLs are inappropriate, this should be discussed with the MPE, clinical lead, RPS and departmental manager. Any deviations agreed should be documented, with the reasons for the change. A copy should be given to the MPE.

7.3 The local DRL documentation must be approved by radiology management through a relevant committee (Ops Group and/or RMT). Local DRLs will be issued to operators by email and be available via the y-drive, document finder software application (if available) or Qpulse, available in the senior radiographer's office and most processing areas. Local DRLs will be reviewed every 3 years.

7.4 National and local DRLs "*are not expected to be exceeded for standard procedures when good and normal practice, regarding diagnostic and technical performance, is applied*." This will be checked using periodic patient dose assessments (*or "dose survey*") of a representative group of patients. If the median survey dose consistently exceeds the DRL the RPS should investigate the reason for this and in conjunction with MPE initiate an appropriate corrective action where appropriate.

7.5 Records of all survey results and investigations should be kept by the RPS.

7.6 The Radiation Physics Department will manage annual patient dose surveys. These should be performed for each X-ray unit for all standard radio-diagnostic examination performed. Normally this will be achieved by a member of the Radiation Physics Department collecting the appropriate data from the RIS. However, should a 'manual-paper' exercise be required, the following points will apply:

7.6.1 The frequency of surveys will be determined by the RPS or departmental manager, in consultation with the MPE. The frequency should not be less than three yearly.

7.6.2 Patient dose surveys should include at least ten patients, but preferably twenty.

7.6.3 Patients should be selected who individually weigh between 60 kg (9 st 6 lb) and 80 kg (12 st 8 lb). For less frequent examinations the range may be extended from 50 kg (7 st 12 lb) to 90 kg (14 st 2 lb). For greater than 20 patients in a survey, weight may not be required.

7.6.4 The assessed patient dose will then be compared to the national or local diagnostic reference level.

7.7 For dental exposures, the DRL for intra-oral examinations is the dose measured at the spacer (Patient Indicator Device) end. For panoramic examinations the DRL is taken as the Dose Area Product (DAP) in $mGy.cm^2$, at the beam receiving slot, for a full rotation. These are measured routinely as part of the regular routine radiation protection surveys. Values higher than the recommended DRLs are highlighted.

7.8 Up-to-date national DRLs can be found on Gov.uk website: https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls/ndrl

8. Procedure for the establishment of dose constraints and other matters for biomedical and research exposures

8.1 This procedure aims to cover all requirements for medical research exposures required by IRMER. It is the responsibility of the local Principal Investigator to ensure the latest Health Research Authority (HRA) guidelines are followed. They will identify a suitable IRMER Practitioner who will liaise with an appropriate local MPE.

8.2 All research programmes must have approval from the relevant Ethics Committee (EC) before commencing.

8.3 Each research project involving exposure to individuals for whom no direct benefit is expected from the exposure the IRMER practitioner will approve a dose constraint on the advice of a suitable MPE. This dose constraint must not be exceeded.

8.4 Each research project involving exposure to individuals for whom a direct benefit is expected from the exposure the IRMER practitioner will approve a target level of dose on the advice of a suitable MPE. This target level of dose should be set at a level which it is anticipated will not be exceeded, but may be exceeded if the clinical benefit of additional exposure outweighs the radiation detriment.

8.5 All volunteers must be screened to ensure suitability. Pregnant women and children should not normally be accepted as volunteers unless the project concerns their population group specifically. Adults who lack the capacity to consent must be excluded as volunteers.

8.6 The risks of the exposure must be communicated to the volunteers by the research proposer or team member and confirmed by the operator.

8.7 The IRMER Practitioner who authorises a research exposure must:

a) Satisfy themselves that the subjects participate voluntarily
b) Ensure that the subjects are informed in advance about the risks of exposure
c) Where no direct medical benefit for the individual is expected from the exposure, ensure that the employer's dose constraint is adhered to
d) Where there is a direct benefit, plan a target for the dose to an individual volunteer.

8.8 Just as for standard medical radiation exposures, there should be a record of the exposure factors, to enable an estimate of the effective dose to the individual and to ensure compliance with the dose constraint.

8.9 In the event that the research is part of a multi-centre trial being led by a Chief Investigator from another centre, the local IRMER Practitioner is responsible for reviewing the trial protocol and main REC application and confirm in writing to the local Principal Investigator and R&D office that the local site can adhere to the protocol, local patients are covered by the main REC (Ethical) submission and any additional exposure is justified having regard to IRMER. Similarly the local MPE is responsible for reviewing the trial protocol and main REC application to confirm to the local Principal Investigator that the estimated ranges of doses made by the Lead MPE for the research are reasonable. A local dose constraint or target dose should be established and this should be in line with the total research protocol dose estimated in the main REC application; concerns must be addressed with the Lead MPE for the research.

8.10 For local trials or studies which are not part of multi-centre research programmes, the procedure outlined above should be followed, where the local principal investigator and MPE have the additional responsibilities of the Chief Investigator and Lead MPE respectively.

9. Procedure for carrying out and recording of an evaluation for each medical exposure including, where appropriate, factors relevant to patient dose

General Radiology

The majority of images will be evaluated by a radiologist or reporting radiographer in the Radiology Department and a report entered on the RIS.

In specific circumstances images may be evaluated by specialist member of the medical staff of the department that requested the radiograph. These circumstances are subject to a written agreement between the clinical leads of the radiology department and the clinical department concerned. This agreement is reviewed at a 3 yearly interval. The outcome of this evaluation will be recorded in the patient notes.

CT

All CT images will be evaluated by a Radiologist, reporting radiographer or imaging cardiologist. The outcome of the evaluation will be entered in the RIS. A paper copy may be filed in the patient's case notes.

Interventional, Screening and Theatre Procedures

At the conclusion of the procedure, a summary will be written in the patient's case notes (when available) and a report will be entered on the RIS

Outsourced Reporting

Some images may be sent securely to an outsourced company for reporting. The department must produce a service level agreement (SLA) with the outsourced company that covers relevant IR(ME)R requirements.

10. Procedure to ensure that the probability and magnitude of accidental or unintended doses to patients from radiological practices are reduced so far as reasonably practicable

10.1 All staff are adequately trained and qualified, including agency/locum staff. Appropriate training takes place when new equipment is installed and records to this affect are completed. New staff undergo a period of induction.

10.2 Regular preventative maintenance and repairs are undertaken on each item of equipment involved in the imaging process

10.3 Handover procedures are in place.

10.4 Quality control procedures are in place, implemented and monitored.

10.5 It is the responsibility of all staff to identify equipment faults or procedural breakdowns which could lead to an accidental or unintended dose to a patient. These occurrences should be reported to their line manager to resolve. Lessons learnt will take place via staff meetings

10.6 Clinical audit as per regulation 7 of IRMER is carried out annually for each area of Radiology. Records of this are kept.

10.7 The following general approach is always taken:

10.6.1 Patient identity checked, prior to any radiation exposure, by the operator.

10.6.2 All equipment subject to regular preventative maintenance – to manufacturers and / or RPA/MPE advice.

10.6.3 Equipment quality assurance programme in place as outlined in IPEM 91 and advised by the RPA/MPE.

10.6.4 Local DRLs will be adhered to as far as practicable.

10.6.5 Equipment faults logged and reported to the Senior Radiographer.

10.6.6 Equipment with known faults likely to cause patient overexposure must be taken out of use until repair by a service engineer. Written confirmation must be obtained that the unit is safe for clinical use. Alterations affecting patient dose must be checked by the Radiation Physics Department and certified fit for clinical use.

10.6.7 All staff must undertake manufacturers or suitable in-house training before operating equipment for clinical use.

10.6.8 All incidents must be reported using the DATIX system, with correct investigation and follow up procedures. Any suspected accidental or unintended patient exposures must be reported to the RPA/MPE who will then decide whether the incident needs reporting to the HSE, CQC or EA as appropriate.

10.6.9 Incident investigation reports must be reviewed and appropriate action taken to minimise the risk of recurrence. Any learning from incidents will be shared amongst staff at relevant meetings.

10.6.10 When exposing patients to ionising radiation the most appropriate equipment available must be selected and operated in accordance with manufacturers' tolerances and Trust procedures.

11. Adequate information for the patient

It is a requirement under IR(ME)R to provide wherever practicable, prior to an exposure taking place, the individual or their representative information relating to the benefits and risks associated with the radiation dose from the exposure. Emergency Department, mobile examinations and theatre procedures are generally deemed not practicable.

For general radiology and CT, the information will be given to the patient verbally. Posters will also be displayed around the departments.

For interventional procedures, the information will be given to the patient by information leaflets with the invitation to the relevant procedure. Posters will also be displayed around the department.

All posters, where practicable, will be based on those developed by the Clinical Imaging Board (https://www.rcr.ac.uk/posts/new-patient-information-posters-benefits-and-risks-imaging).

12. Accidental and unintended exposures (AUE), significant accidental and unintended exposures (SAUE), and clinically significant accidental and unintended exposures (CSAUE)

In the event of any accidental or unintended exposure (AUE), the department senior radiographer and/or RPS must complete the radiation incident form in available on 'Pattie' or the Radiation Physics website (www.hullrad.org.uk) and send it to the RPA/MPE. A DATIX must also be completed. An investigation will then be undertaken by the MPE in collaboration with the department to determine the circumstances, and to perform and estimate of the dose received. In the event of any AUE, the MPE will provide an incident report. Remedial actions and shared learning will be carried out via staff meetings and email if appropriate. The MPE will log the incident on the Medical Physics y-drive and a thematic review will be carried out.

If the AUE is deemed a significant accidental or unintended exposure (SAUE) by the MPE, the MPE will seek permission from a Trust senior manager (usually the Clinical Support Health Group Clinical Director) prior to reporting the incident to the Care Quality Committee. If permission is granted the incident will be reported by an MPE.

If the AUE incident is deemed to be clinically significant accidental or unintended exposure (CSAUE) by the MPE (in conjunction with the practitioner), the patient, referrer and practitioner must be informed of the occurrence and the outcome of the analysis by the patient's consultant. This will be done verbally at clinic or in writing. The MPE will seek permission from a Trust senior manager (usually the Clinical Support Health Group Clinical Director) prior to reporting the incident to the Care Quality Committee. If permission is granted the incident will be reported by an MPE.

CSAUEs are defined as the following :

- An accidental or unintended exposure to ionising radiation that results in a 0.1% (1 in 1,000) or greater lifetime radiation-induced cancer risk.
- For foetal exposures where the pregnancy was not known about, a 0.1% (1 in 1,000) or greater risk or radiation-induced childhood cancer.
- Unjustified exposure to ionising radiation greater than:
  - 0.5 Gy to the lens of eye
  - 0.5 Gy to the heart or brain
  - 5 Gy to the skin
- If the patient suffers psychological harm or it affects the patient's quality of life.

The above definitions notwithstanding, in all situations, the patient's consultant must be consulted about what constitutes a CSAUE, especially if informing the patient may do more harm than good (e.g. end of life patient).

13. Dose constraints and guidance for the exposure of carers and comforters

Carers and Comforters (C&C) are individuals who knowingly and willingly incur an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of the individual undergoing the exposure. Pregnant persons are not usually permitted to be a C&C, unless in exceptional circumstances. An appropriate dose constraint for C&C is 0.3 mSv per year.

Justification & Authorisation of exposure:

Only IRMER Practitioners can justify exposures to C&Cs, but the operator is entitled to authorise an exposure of a C&C in the following circumstances:

- The C&C is required to comfort/reassure the patient during the exposure
- The patient will not have their x-ray taken unless C&C is present
- Safety & support – ie holding a child or difficult patient in the correct position

Where a C&C is to be present, the operator must inform them of the risk and benefit of the exposure by verbal instruction prior to the examination, and be assured that the C&C is knowingly and willingly incurring the exposure. Verbal instruction must include ensuring they remain outside the primary beam, stand as far back from the patient as possible and wear appropriate PPE. The name of the C&C and other details (such as dose) must be entered in the document finder software application (if available) or other suitable platform such as qpulse . This also signifies that the C&C was knowingly and willingly exposed.